Preventing pressure ulcers in nursing homes: the development and feasibility assessment of a theory and research-informed care bundle intervention

Volume I of II

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<th>Description</th>
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<tbody>
<tr>
<td>ACROBAT</td>
<td>A Cochrane Risk of Bias Assessment Tool: for Non-randomised studies of interventions</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>EPOC</td>
<td>Effective Practice and Organisation of Care</td>
</tr>
<tr>
<td>GRADE</td>
<td>Grading of recommendations, Assessment, Development and evaluations</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive care unit</td>
</tr>
<tr>
<td>MD</td>
<td>Mean difference</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>NIHR CLAHRC</td>
<td>National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care</td>
</tr>
<tr>
<td>PICOS</td>
<td>Population, intervention, comparison, outcome, study design</td>
</tr>
<tr>
<td>ROBINS-I</td>
<td>Risk of bias in non-randomised studies of interventions</td>
</tr>
<tr>
<td>RR</td>
<td>Risk ratio</td>
</tr>
<tr>
<td>SMD</td>
<td>Standardised mean difference</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
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Abstract

Background: Many nursing home residents are at risk of developing a pressure ulcer, which is an area of localised damage to the skin and/or underlying tissue due to immobility, increasing age and co-morbidities. Whilst guidelines for the prevention of pressure ulcers exist, their implementation can be sub-optimal. Care bundles are a set of research-informed practices used to facilitate the implementation of evidence into practice and incorporating psychological theory within their development may enhance their effectiveness. I aimed to co-design and assess the feasibility of implementing a theory and research-informed pressure ulcer prevention care bundle intervention in a nursing home setting.

Method: This thesis comprised four separate studies as part of an overall mixed methods research design. Firstly, I conducted a systematic review and meta-analysis to determine the effects of care bundles per se on patient outcomes. I then conducted theory-informed qualitative, semi-structured interviews with nursing home care staff and NHS community-based nurses to explore the context of, and the barriers and facilitators to, pressure ulcer prevention in nursing homes. Next I co-designed a pressure ulcer prevention care bundle with 13 healthcare workers during a four hour workshop and supplemental email consultation. Using the Nominal Group Technique, we reached a consensus about the content of the care bundle. Following the steps of the Behaviour Change Wheel, I finalised the care bundle intervention. The final study involved a before-after study design where one nursing home implemented the care bundle intervention. I collected and analysed quantitative and qualitative data to gain a more holistic understanding of the feasibility issues related to the implementation.

Findings: Findings from the systematic review suggested that care bundles may reduce the risk of negative outcomes in patients. These findings were based on very low quality evidence and the original study authors rarely reported adherence to the care bundle interventions. The theoretical understanding of the complexities in the prevention of pressure ulcers in nursing homes suggested there were four barriers and six facilitators, which my final care bundle intervention addressed. The co-designed care bundle intervention comprised three elements: support surfaces, skin inspection, repositioning; alongside three intervention functions and seven behaviour change techniques. In the final feasibility study, during the baseline period, there were 462 resident bed days and 5 new pressure ulcers recorded and in the intervention phase there were 1,181 resident bed days and no new pressure ulcers. The care bundle intervention appeared to be acceptable to the nursing home care staff and we have identified specific issues relating to the feasibility of implementing the care bundle intervention.

Conclusions: The current research evidence-base for care bundles is poor. However, it was possible to co-design and implement a pressure ulcer prevention care bundle intervention for a nursing home setting. Further feasibility research is necessary before we can assess whether the care bundle intervention is effective in preventing pressure ulcers in nursing homes.
Declaration
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I would also like to thank all of the research participants.

Thank you to all of my friends and family who have supported me over the last three years. In particular I would like to thank my sister Geraldine and my Musketeers Ruth, Helen and Laura who are ‘my cheerleaders when I need motivation!’ To my wonderful parents who have been an inspiration to me throughout my whole life. I am hugely grateful for everything you have done for me; for your unconditional love, kindness and support, and for always reminding me of the importance of ‘bounce back-ability’. Finally, thank you to my husband Paul for your unwavering patience, support and cooking! I could not have done this without any of you, thank you!

Dedication
I dedicate this thesis to my parents Steve and Janice Lavallée and to my husband Paul Lobaz.
Chapter 1: Thesis overview

1.1 Context

1.1.1 Background

My research is part of the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Greater Manchester, which aims to conduct high quality research and put the findings into practice to improve health. The NIHR CLAHRC Greater Manchester consists of a number of programmes and this research sits within the wound care programme. The objectives of the wound care programme are to:

- Build an active and collaborative network across Greater Manchester, focusing on wound care research.
- Support the implementation of evidence into clinical practice and service delivery.
- Develop community-wide research studies based on local wound care priorities and uncertainties.
- Understand the processes involved in the implementation of wound care research evidence.

This research was conceived as part of the NIHR CLAHRC Greater Manchester as pressure ulcer prevention was a high priority and nursing home residents were perceived as being at high risk of developing pressure ulcers.
1.2 Pressure ulcers

Pressure ulcers are also known as pressure injuries or pressure sores and are defined as an area of localised damage to the skin and/or underlying tissue (National Pressure Ulcer Advisory Panel, 2016; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). A pressure ulcer can develop as a result of a combination of extrinsic factors (e.g., pressure or pressure and shear) and intrinsic factors (e.g., tissue tolerance). Risk factors for developing a pressure ulcer include, but are not limited to, reduced mobility, restricted circulation of blood, existing or healed pressure ulcers and increased age (Coleman et al., 2013; Moore & Cowman, 2012). Thus, many of the individuals residing in a nursing home are at risk of developing a pressure ulcer.

Pressure ulcers are graded according to their severity and range from a Stage 1 (least severe; non-blanchable erythema of intact skin) to a Stage 4 (most severe; full-thickness skin and tissue loss). In some cases the severity may be unstageable and the deterioration of a pressure ulcer is not necessarily a linear process (National Pressure Ulcer Advisory Panel, 2016).

In March 2017, approximately 7,388 (4.5%) individuals across different healthcare settings in England had pressure ulcers during the 24 hour period when these data were reported (NHS Safety Thermometer, 2017). Developing a
pressure ulcer can impact on health-related quality of life with those affected having greater perceived pain and poorer physical functioning (Essex, Clark, Sims, Warriner, & Cullum, 2009). Individuals with pressure ulcers have also reported sleep disturbances and limited social tasks and activities of daily living (Gorecki et al., 2009). Caring for an individual with a pressure ulcer can decrease the aspects of quality of life relating to social and mental health among informal caregivers (Rodrigues, Ferreira, & Ferré-Grau, 2016). Pressure ulcers are a strain on the resources of the National Health Service (NHS) due to the additional care required with regard to both staff time and treatments and they are also costly in terms of litigation (Dealey, Posnett, & Walker, 2012). In the UK, the cost of treating pressure ulcers to healing is estimated to range from £1,214 (per Stage 1 pressure ulcer) to £14,108 (per Stage 4 pressure ulcer) (Dealey et al., 2012), with the estimated annual cost of treating a pressure ulcer previously estimated as £3 million (Dealey et al., 2012).

Clinical practice guidelines are available to assist with the prevention of pressure ulcers (e.g., National Institute for Health and Care Excellence: Pressure ulcers, 2014). However, the guidelines are constrained by the evidence which is generally of poor quality and based on randomised trials at a high risk of bias (National Institute for Health and Care Excellence: Pressure Ulcers, 2014). Whilst guidelines exist, the implementation of guidelines and research-informed practice can be sub-optimal (Barker et al., 2013). The context of
nursing homes may be particularly problematic for the prevention of pressure ulcers due to understaffing and high staff turnover (Demarré et al., 2012).

1.3 Care bundles

Care bundles are a set of three to five research-informed practices which are delivered collectively and reliably (Resar, Griffin, Haraden, & Nolan, 2012). Care bundles were developed to improve care processes and quality by encouraging adherence to clinical guidelines and are considered to be a “complex intervention”. Generally, complex interventions consist of several interconnecting parts which have a synergistic effect (Craig et al., 2008). An intervention may also be considered complex due to the number of components which interact in the experimental and control groups, the number and level of difficulty of the behaviours necessary to either deliver or receive the intervention, the number of those involved, the outcome measures and the degree of flexibility and/or tailoring of the intervention (Craig et al., 2008). Guidelines for the development and evaluation of complex interventions recommend using psychological theory to facilitate the understanding of the mechanisms of action within the complex intervention (Craig et al., 2008). However detailed guidance is not provided and many complex interventions do not explicitly report using theory as part of the intervention development (Prestwich, Webb, & Conner, 2015).
1.4 Wound care provision in nursing homes

Nursing homes are private organisations, independent of the NHS, which provide care for older adults who often have multi-morbidities (Steinman et al., 2012; van den Brink, Gerritsen, Voshaar, & Koopmans, 2013). Therefore, nursing homes provide a range of nursing care including respite, convalescent, dementia and palliative care. Nursing homes differ to care homes as registered nurses provide nursing care alongside healthcare assistants who also provide care; whereas healthcare assistants, on the whole, provide most of the care in care homes. Often within nursing homes, there is little or no input from NHS community nursing teams. NHS community wound care specialist nurses, known as tissue viability nurses, provide advice to the nursing home staff regarding pressure ulcer prevention practices. However, the NHS does not have any regulatory power over nursing homes to ensure that this advice is followed.

1.5 What this thesis adds

As stated pressure ulcers can cause pain and distress to individuals, which can reduce their quality of life (Gorecki et al., 2009). In addition, they can be costly to treat (e.g., £14,108 per Stage 4 pressure ulcer). Currently, approximately 7,388 individuals across England have at least one pressure ulcer. Due to the ageing population and the number of people living with at least one long-term condition, it is likely that more people will be at risk of developing pressure
ulcers in nursing homes. Therefore, it is vital to focus on developing a pressure ulcer prevention intervention such as a care bundle. However to date, the development, implementation and evaluation of pressure ulcer prevention care bundle interventions have been in hospital settings (Chaboyer et al., 2016; Tayyib & Coyer, 2017). This thesis makes three unique contributions to the literature.

1. I evaluated the evidence regarding the effectiveness of care bundle interventions using a systematic review and meta-analysis. This has improved the knowledge of care bundle interventions as a whole, highlighting the current deficits in the literature including the limited reporting of theory in the development of care bundle interventions.

2. I sought a theoretical understanding of the barriers and facilitators to pressure ulcer prevention in nursing home residents. This informed the development of a theory and research-informed pressure ulcer prevention care bundle intervention. To my knowledge, this approach has not been taken before and is the first step towards identifying the active ingredients involved in the prevention of pressure ulcers in nursing home residents. To support our knowledge of the care bundle elements themselves and the mechanisms of action important for eliciting behaviour change, I developed the care bundle intervention using transparent and systematic methods.

3. I conducted a rigorous feasibility study of the pressure ulcer prevention care bundle intervention in one nursing home which involved a process
evaluation, providing a deeper understanding of whether the care bundle intervention was feasible in practice within a nursing home context. The next steps following this research are: to explore the most efficacious methods to engage nursing home staff with research and how to maintain this engagement; to evaluate the effects of the pressure ulcer prevention care bundle intervention using a more robust study design (i.e. a cluster-randomised trial).

1.6 Overview of thesis structure

The thesis is presented in the journal format and each journal article is clearly labelled. Due to the nature of this research, it was logical to present the findings as individual research papers which address specific aspects of the overall aim of this research. Consequently, this thesis reports a series of four studies that focused on the co-design and feasibility testing of a theory and research-informed care bundle intervention for the prevention of pressure ulcers in nursing home residents. Each thesis chapter is outlined below.

Chapter One explains the context of this research and the significance of pressure ulcers. Chapter Two presents a topic review and an overview of the main research aims and objectives. Chapters Three to Five provide the rationale for and detailed descriptions and evaluations of the methods used within this research. Chapters Six to Nine detail the findings of the research in a format
appropriate for submission to a peer-reviewed journal and include the following studies:

- **Chapter Six** is a systematic review and meta-analysis of the effectiveness of care bundles.

- **Chapter Seven** presents the findings from a qualitative study which aimed to explore the context of pressure ulcer prevention in nursing home residents and the associated barriers and facilitators.

- **Chapter Eight** explains the development of the pressure ulcer prevention care bundle intervention.

- **Chapter Nine** is the final paper which presents the findings from the feasibility study which aimed to assess the feasibility of implementing the care bundle intervention in a nursing home context.

Finally, Chapter Ten summarises and discusses the overall findings of this body of research and their implications. Also provided within this chapter are the contributions of the thesis to the existing literature, the limitations of the research and recommendations for future research.

### 1.7 Candidate contributions to journal articles

As the candidate, I conceived and independently wrote all of the chapters in this thesis, including the journal articles in Chapters Six to Nine. This involved taking responsibility for developing, designing and co-ordinating the studies. I obtained ethics approvals, liaised with the research site organisations and
individuals, recruited participants and collected and analysed data.

Collaborating authors named on the journal articles presented in this thesis contributed to the studies through assisting with study conceptualisation and decision making throughout the study periods, as well as contributing to secondary analysis tasks (e.g., second coding datasets). Collaborating authors contributed to the commenting on manuscripts and provided approvals of the final version. Author contributions to the specific papers are presented at the end of each paper (Chapters Six to Nine).
Chapter 2. Background

This chapter presents the current and relevant literature relating to pressure ulcers and their prevention, including an overview of the potential causes, risk factors, classification of pressure ulcers and pressure ulcer prevention guidelines. I conclude this chapter with a discussion of research-informed practice and the theories of healthcare worker behaviour change.

2.1 Aetiology

Pressure ulcers develop when the skin and underlying tissue become damaged as a result of both intrinsic factors (e.g., cardiovascular disease, diabetes) and extrinsic factors (e.g., pressure, shear) (Coleman et al., 2013). The intrinsic factors are discussed in Chapter 2.2 (Risk Factors) and I discuss the extrinsic factors here.

The term ‘force’ is used to describe the effect of an external influence on an object and force has a direction and a magnitude. The application of external pressure to human tissue is a key cause of pressure ulceration (Coleman et al., 2013). Pressure is applied perpendicular to an area of the body and both the intensity and duration of this force impact on the development of tissue damage (Takahashi, Black, Dealey, & Gefen., 2010). Perpendicular forces can cause pressure, whereas parallel forces applied to the skin surface can cause
shear and are known as shear forces. For example when an individual is sat in bed, the underlying tissue and bone can move and shear stress occurs when the skin does not move with the underlying tissue and bone (Takahashi et al., 2010). Thus, shear forces can cause two connecting internal body parts to deform due to the stretching and tearing of small blood vessels (National Pressure Ulcer Advisory Panel, 2012).

When sufficient pressure or pressure and shear are applied to an area of the body that has little body fat (e.g., the elbow, sacrum), deformation of the skin and underlying tissue causes restricted blood flow and tissue ischaemia (Takahashi et al., 2010). In addition, lymphatic flow can become obstructed causing metabolic waste products, enzymes and proteins to accumulate in the affected tissue which can exacerbate tissue damage (Gray, Voegeli, & Bader, 2016). Patches of skin can become discoloured and if pressure is not relieved, cell death occurs resulting in an open wound, which at its most severe may expose underlying muscle or bone (National Pressure Ulcer Advisory Panel, 2016; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014).

Previously, in addition to pressure and shear, friction and moisture were considered to be factors which contributed to the development of pressure ulcers (see Antokal et al., 2012). Friction occurs when the skin is resistant to
motion when moving over another surface, for example sliding across the surface of a bed. Friction can cause the outer layer of the skin to break and if this is repeated, a deeper injury can occur (Reger, Ranganathan, Orsted, Ohura, & Gefen, 2010). In addition, excessive moisture on the surface of the skin can cause the skin to weaken, increasing an individual’s susceptibility to pressure and shear (Clark et al., 2010). However, the roles of friction and moisture in the development of pressure ulcers are less certain (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). Therefore, the common view is that the extrinsic factors affecting the development of pressure ulcers are pressure and shear (National Pressure Ulcer Advisory Panel, 2016; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014).

2.2 Risk factors

Pressure is the main extrinsic cause of pressure ulcers (see Chapter 2.1). However, exposure to pressure does not necessarily result in the development of a pressure ulcer because a person’s risk also depends on intrinsic factors (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). A systematic review of 54 studies (34 prospective cohort, nine retrospective record reviews, 11 randomised trials), with a total of 34,449 patients across hospital and
community settings, was conducted (Coleman et al., 2013). However, 47 of the 54 included studies had methodological limitations such as inadequate sample size and reporting limitations (e.g., not reporting baseline characteristics). Thus, Coleman et al. (2013) did not conduct a meta-analysis and the interpretation of the findings is limited. Nevertheless, the review highlights the complex interplay of factors which can contribute to the development of pressure ulcers and Coleman et al. (2013) reported three major risk factors for pressure ulceration:

1. *A person’s mobility* (i.e. impaired activity/immobility): individuals who remain in the same position are more susceptible to prolonged pressure and therefore tissue damage.

2. *Perfusion and oxygenation*: if the circulation of blood to a certain area of the body is restricted (i.e. limited perfusion) and the supply of oxygen to the cells and tissues is poor (i.e. no oxygenation), an individual’s tissue tolerance for pressure and/or shear will be less.

3. *Skin status*: a person’s skin is likely to be more vulnerable to tissue damage if they have an existing or healed pressure ulcer (Coleman et al., 2013; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014).
According to Coleman et al. (2013) other risk factors include:

- *Sensory perception*: sensory deficits can change a person’s ability to perceive discomfort and pain, which are symptoms associated with persistent local pressure and a reduced frequency of repositioning (Briggs et al., 2013).

- *Nutritional status*: the skin needs nutrients to remain healthy and minimise the risk of skin breakdown. In addition, poor nutrition can lead to weight loss and can increase the exposure of bony prominences which, coupled with reduced mobility, is likely to increase the risk of pressure injury.

- *General health status and underlying health conditions*: conditions which impair intravascular blood flow such as peripheral arterial disease, heart failure and chronic obstructive pulmonary disease can increase the likelihood of a pressure ulcer developing due to already compromised tissue perfusion. For example when peripheral arterial disease is present, the blood supply can become restricted due to a build-up of fatty substances within the arteries which disrupt the amount of normal blood flow through the body.

- *Body temperature*: a raised skin temperature increases the need for oxygen and energy within the body’s tissues. When an individual’s body temperature is elevated and they are exposed to pressure and shear, tissue damage can occur more quickly (Clark et al., 2010). However, the temperature of the skin can vary and is influenced by a number of external, physiological and pathological factors such as humidity and disease processes (Clark et al. 2010).
- **Skin moisture:** moisture may be present on the surface of the skin due to perspiration, incontinence or a wound and can weaken the skin, increasing the likelihood of skin damage from extrinsic factors such as shear. In contrast, excessively dry skin can increase a person’s risk of developing a pressure ulcer due to the reduced lipid levels and water content (Clark et al., 2010). Dry skin is less flexible and has decreased tensile strength and is at a greater risk of tissue damage in the presence of extrinsic factors (Dealey, 2009).

- **Advanced age:** especially those aged 80 years or older due to the problems associated with ageing such as reduced blood flow, a reduction in the amount of fat underneath the skin and a loss of skin elasticity (Chiari et al., 2017). Recently, a point prevalence survey of people with complex wounds (including pressure ulcers) in a northern UK city found that the point prevalence increased with age and was highest in people aged 90 years or above (22.88 per 1000 patients with complex wounds; 95% CI 19.08 to 27.42) (Hall et al., 2014). Consequently, many of those residing in nursing homes may be at risk of developing a pressure ulcer.

### 2.3 Classification of pressure ulcers

In 2016 the National Pressure Ulcer Advisory Panel revised the pressure ulcer classification system. The National Pressure Ulcer Advisory Panel (2016)
suggested the term ‘pressure injury’ more accurately reflects the current understanding of the aetiology of pressure ulcers:

- An injury can be described as the damage caused by the transfer or absence of energy (e.g., heat or pressure, respectively) (Langley & Brenner, 2004). Recently, the transfer and absence of energy have been highlighted in the aetiology of pressure ulcers in the form of tissue deformation, tissue tolerance, perfusion, microclimate and nutrition (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014).

- An ulcer occurs when there is a break in the skin or mucous membrane, surface tissue breaks down and epithelial tissue can become necrotic (Merriam-Webster’s Collegiate Dictionary, 2016).

However, there is disagreement regarding the most appropriate terminology (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014) and as pressure injury is not universally adopted across Europe, I will use the term ‘pressure ulcer’ throughout this thesis.

Pressure ulcers are graded according to their severity and range from a Stage 1 (least severe) to a Stage 4 (most severe), but the deterioration of a pressure ulcer is not necessarily a linear process. In some cases the severity may be unstageable (see Table 1 for the National Pressure Ulcer Advisory Panel
Pressure Injury Classification). The National Pressure Ulcer Advisory Panel pressure injury classification describes the various anatomical features present and absent at each stage of injury. According to the National Pressure Ulcer Advisory Panel (2016), when classifying a pressure ulcer, Arabic numbers are to be used instead of Roman numerals to categorise pressure ulcers. The change to Arabic numbers is to avoid misinterpretation with other terms used in healthcare settings, for example a Stage IV pressure ulcer/injury may be confused with intravenous (IV).
### National Pressure Ulcer Advisory Panel Pressure Injury Stages (2016)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Pressure injury: Non-blanchable erythema of intact skin</strong></td>
<td>Intact skin with a localised area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature or firmness may precede visual changes. Colour changes do not include purple or maroon discolouration; these may indicate deep tissue pressure injury.</td>
</tr>
<tr>
<td><strong>2. Pressure injury: Partial-thickness skin loss with exposed dermis</strong></td>
<td>Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture-associated skin damage including incontinence-associated dermatitis, intertriginous dermatitis, medical adhesive related skin injury or traumatic wounds (skin tears, burns, abrasions).</td>
</tr>
<tr>
<td><strong>3. Pressure injury: Full-thickness skin loss</strong></td>
<td>Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunnelling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.</td>
</tr>
<tr>
<td>Stage</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>4. Pressure injury: Full-thickness skin and tissue loss</td>
<td>Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunnelling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.</td>
</tr>
<tr>
<td>Unstageable pressure injury: Obscured full-thickness skin and tissue loss</td>
<td>Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar are removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.</td>
</tr>
</tbody>
</table>
Table 1

(Cont.)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Deep tissue pressure injury: Persistent non-blanchable deep red, maroon or purple discolouration</td>
<td>Intact or non-intact skin with localised area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin colour changes. Discolouration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Deep tissue pressure injury is not used to describe vascular, traumatic, neuropathic or dermatologic conditions.</td>
</tr>
</tbody>
</table>
2.4 Prevalence

Within the context of this thesis, prevalence is the number of people with a pressure ulcer at a given point in time divided by the population at risk of having a pressure ulcer at that time (Baharestani et al., 2009). There are two types of prevalence: point prevalence reflects a single point in time (e.g., one day); whereas period prevalence reflects a prolonged period of time (e.g., 12 months). Both types of prevalence measures include existing and newly developed pressure ulcers. In contrast, incidence is the number of people who have developed a new pressure ulcer within a specified timeframe (Baharestani et al., 2009). Thus, calculating prevalence provides a more detailed understanding of how many people are affected by pressure ulcers during a particular time period.

In England, the NHS Safety Thermometer is used by healthcare workers to record the number of harms to patients receiving NHS-funded care in hospitals, care homes (including nursing homes), community settings and their own homes. Harms include pressure ulcers, falls, catheter-associated urinary tract infections and venous thromboembolism (NHS Safety Thermometer, 2017). Healthcare workers record the number of harms present on one day per month, providing a point prevalence estimate. In March 2017, data for 164,194 patients were reported to the Safety Thermometer and 7,388 (4.5%) of the reported patients had pressure ulcers (NHS Safety Thermometer, 2017). Based on the
information reported to the Safety Thermometer, pressure ulcers were the most frequently reported harm in March 2017. Of the reported patients, 0.6% had catheter-associated urinary tract infections, 0.5% had falls and 0.4% had a new venous thromboembolism.

Estimating the true prevalence of pressure ulcers from the existing literature is difficult due to the different pressure ulcer classifications, as well as the differences in study populations, care settings, study methods, quality of care and prevention practices (Baharestani et al., 2009; McDermott-Scales, Cowman, & Gethin, 2009). For example, a systematic review of 48 individual cross-sectional studies was conducted to assess the measures taken to ensure the accuracy in the prevalence estimates in prevalence studies (Cullum et al., 2016). It was difficult to know with certainty how many people were affected by pressure ulcers and what proportion of the ‘at risk’ population had developed a pressure ulcer due to deficiencies in the design and reporting of the included studies (Cullum et al., 2016). Therefore, interpreting study results can be difficult, can limit generalisations and could result in the incorrect conclusions about the prevalence of pressure ulcers (Tubaishat, Papanikolaou, Anthony, & Habiballah, 2017; Vanderwee, Clark, Dealey, Gunningberg, & Defloor, 2007).

In an attempt to overcome the shortcomings of existing prevalence studies as identified by Cullum et al. (2016) and as part of the same stream of work, a
point prevalence survey of people with complex wounds (e.g., pressure ulcers, leg ulcers, surgical wounds) was conducted in a northern UK city (Hall et al., 2014) over a two week period. This was a survey of individuals being treated across multiple healthcare settings across the city (NHS community and primary care services, NHS mental health services, NHS acute services, independent hospitals, prisons, nursing homes, hospices). Hall et al. (2014) estimated the point prevalence of complex wounds to be 1.47 per 1000 population (95% CI 1.38 to 1.56). Pressure ulcers were the most prevalent complex wound reported as part of the survey (0.31 per 1000; 95% CI 0.28 to 0.36). The mean age of people with a complex wound was approximately 70 years of age and the number of complex wounds was highest in those aged 90 years and over (22.88 per 1000; 95% CI 19.08 to 27.42). Thus, it is reasonable to suggest that as we have an ageing population, there may be an increase in the number of people who develop a pressure ulcer (Riordan & Voegeli, 2009; Torpy, Lynm, & Glass, 2006). However, this survey did not include any information about the individuals who were not receiving care from any of the providers specified. Provider surveys are limited as they are likely to underestimate the true prevalence of pressure ulcers. Nevertheless, providing that prevalence studies have a low risk of bias and are adequately reported, they are useful for estimating the number of individuals affected by pressure ulcers during a certain period of time.
2.5 Prevention

2.5.1 Clinical practice guidelines

Experts in the clinical field, alongside methodologists, systematically develop clinical practice guidelines to integrate research evidence into decision making and to assist practitioners and patients in their decision making regarding care and treatment. In addition, clinical practice guidelines are devised to minimise the potential variations in care and improve patient outcomes and care costs (Effective Practice and Organisation of Care: Taxonomy, 2015).

In the UK, the National Institute for Health and Care Excellence (NICE) aims to improve health outcomes and provide research-informed guidance on many different health conditions. NICE regularly publish guidelines and their latest guidance on pressure ulcer prevention and management was released in 2014 (NICE: Pressure ulcers, 2014). A multidisciplinary team comprising professionals and consumer representatives developed these guidelines and the guidance is based on systematic reviews of the best available research evidence along with the consideration of expert knowledge and cost-effectiveness. In addition to the NICE guidance (2014), further national and international guidelines on pressure ulcer prevention draw on research and expert opinion including those of the National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance (2014).
The NICE (2014) guidelines recommend a range of activities and interventions for the prevention of pressure ulcers including risk assessment, skin assessment, repositioning, maintaining hydration and nourishment, the use of pressure redistributing devices and barrier creams, training for care staff, patient and carer information and care planning. The NICE (2014) guidelines recommend against skin massage (see Table 2). However, guideline recommendations are constrained by the availability of high quality research evidence and the NICE (2014) guidelines for the prevention and management of pressure ulcers are largely based on evidence of low quality. I will now discuss each of the guideline recommendations in more detail.
### Table 2

**Summary of the NICE (2014) Guidelines for Pressure Ulcer Prevention and Management [CG179]**

<table>
<thead>
<tr>
<th>Pressure ulcer prevention strategy</th>
<th>NICE (2014) guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pressure ulcer risk assessment</strong></td>
<td>1. Be aware of the potential risk for individuals to develop pressure ulcers.</td>
</tr>
<tr>
<td></td>
<td>2. Conduct and document a risk assessment for individuals who are at risk (e.g., for individuals who are unable to reposition themselves or are experiencing a significant loss of sensation).</td>
</tr>
<tr>
<td></td>
<td>3. Consider using a validated scale (e.g., Braden scale, Waterlow score, Norton scale) to assist with the risk assessment.</td>
</tr>
<tr>
<td></td>
<td>4. If there is a change in clinical status conduct a reassessment.</td>
</tr>
<tr>
<td><strong>Skin assessment</strong></td>
<td>1. Individuals at risk of developing a pressure ulcer should have a skin assessment by a trained healthcare professional.</td>
</tr>
<tr>
<td></td>
<td>2. Those conducting skin assessments should consider pain and discomfort as well as:</td>
</tr>
<tr>
<td></td>
<td>a. Skin integrity of the areas of the body that are most at risk of pressure damage.</td>
</tr>
<tr>
<td></td>
<td>b. Colour changes or discolouration.</td>
</tr>
<tr>
<td></td>
<td>c. Variations in heat, firmness and moisture.</td>
</tr>
<tr>
<td></td>
<td>3. Erythema or discolouration should be determined using finger palpitation or diascopy.</td>
</tr>
<tr>
<td></td>
<td>4. Take appropriate pressure ulcer prevention action in adults with non-blanchable erythema. It is desirable to continue skin assessments every two hours until resolved.</td>
</tr>
<tr>
<td>Pressure ulcer prevention strategy</td>
<td>NICE (2014) guideline recommendations</td>
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</tr>
</tbody>
</table>
| **Repositioning**                | 1. Encouraging/assisting those assessed as being at risk of developing a pressure ulcer to change position at least every six hours and document the frequency.  
2. Encouraging/assisting those assessed as being at high risk of developing a pressure ulcer to change position at least every four hours and document frequency. |
| **Nutrition and hydration**       | 1. If nutritional intake is adequate, do not offer nutritional supplements as a pressure ulcer prevention measure.  
2. If hydration status is adequate, do not provide subcutaneous/ intravenous fluids to prevent pressure ulcers. |
| **Pressure redistributing devices** | 1. Use a high-specification foam mattress for individuals at a higher risk of developing a pressure ulcer.  
2. Devise a care plan to offload heel pressure in those at a higher risk of developing heel pressure ulcers.  
3. Use a high-specification foam or equivalent pressure redistributing cushion for individuals who sit for prolonged periods (including people who use wheelchairs). |
<p>| <strong>Barrier creams</strong>                | 1. To prevent skin damage, use barrier creams in individuals who are at a higher risk of developing a moisture lesion or incontinence-associated dermatitis. |</p>
<table>
<thead>
<tr>
<th>Pressure ulcer prevention strategy</th>
<th>NICE (2014) guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin massage</td>
<td>1. Do not offer rubbing or skin massage.</td>
</tr>
<tr>
<td>Training for care staff</td>
<td>1. Provide training for healthcare professionals on pressure ulcer prevention (including who is most at risk, how to identify a pressure ulcer, how to prevent new or further pressure damage, who to contact for more information).</td>
</tr>
<tr>
<td></td>
<td>2. Provide further training to healthcare professionals who have contact with patients assessed as being at high risk. Training should include how to conduct risk and skin assessments, how to reposition patients, information about pressure redistributing devices, details of who to contact for advice and support, how to discuss pressure ulcer prevention with patients and carers.</td>
</tr>
<tr>
<td>Patient and carer information</td>
<td>1. Offer timely and tailored information to those assessed as being at high risk (and their carers). This should include information on the causes, early signs, prevention and implications of having a pressure ulcer and should be delivered by a trained/experienced healthcare professional. Where appropriate, provide a demonstration of the techniques and how to use the equipment.</td>
</tr>
<tr>
<td></td>
<td>2. When providing information, consider individual needs (e.g., neurological conditions, degenerative conditions).</td>
</tr>
</tbody>
</table>
Table 2

(Cont.)

<table>
<thead>
<tr>
<th>Pressure ulcer prevention strategy</th>
<th>NICE (2014) guideline recommendations</th>
</tr>
</thead>
</table>
| Care planning                     | 1. For each individual assessed as being at high risk of developing a pressure ulcer, develop and document care plans taking into account:  
- The outcome of the risk and skin assessment.  
- Other areas of the body which may be at risk and therefore require pressure relief.  
- The individual’s mobility.  
- Co-morbidities.  
- Individual preferences. |
2.5.1.1 Pressure ulcer risk assessment

Early recognition of those individuals who are at risk of developing a pressure ulcer is regarded as an essential aspect of pressure ulcer prevention (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). The NICE (2014) guidelines for the prevention and management of pressure ulcers in adults make four risk assessment recommendations (see Table 2). These recommendations are based on randomised trials, cluster-randomised trials and cohort studies. The included studies were assessed as being at a serious or very serious risk of bias (e.g., healthcare professionals not blinded, at risk of contamination from other instruments, inadequate or unclear allocation concealment) and the certainty of the evidence was rated as low or very low.

There are approximately 40 pressure ulcer risk assessment scales (Papanikolaou, Lyne, & Anthony, 2007; Thompson, 2005). The NICE (2014) guidelines do not stipulate which risk assessment tool to use, but recommend using either the Waterlow Scale (Waterlow, 1985), the Norton Scale (Norton, McLaren, & Exton-Smith, 1975) or the Braden Scale (Braden & Bergstrom, 1987). The content of these three scales is presented in Table 3. Whilst there are some similarities between the content of the scales (e.g., mobility, continence), there are also differences. These similarities and differences may reflect the limited certainty of the evidence from the prospective cohort studies examining the
potential prognostic factors associated with the development of pressure ulcers (Coleman et al., 2013). Prognostic research involves estimating the risk of future outcomes (e.g., pressure ulcers) in individuals based on their clinical and non-clinical characteristics (Moons, Royston, Vergouwe, Grobbee, & Altman, 2009). Causal pathways are not proven through prognostic research (Brotman, Walker, Lauer, & O’Brien, 2005; Moons & Grobbee, 2005), rather the aim is to make accurate predictions about the risk of future outcomes (Moons et al., 2009). Currently pressure ulcer risk cannot be explained by one factor and there are likely to be a number of factors which interact and increase the likelihood of developing a pressure ulcer (Coleman et al., 2013).
Table 3

*The Norton, Waterlow and Braden pressure ulcer risk assessment scales*

<table>
<thead>
<tr>
<th>The Norton Scale</th>
<th>The Waterlow Scale</th>
<th>The Braden Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consists of five categories:</td>
<td>Includes seven sections:</td>
<td>Comprises six subscales:</td>
</tr>
<tr>
<td>3. Activity</td>
<td>3. Visual assessment of the skin type (e.g., dry, healthy)</td>
<td>3. Activity</td>
</tr>
<tr>
<td>5. Incontinence</td>
<td>5. Mobility</td>
<td>5. Nutrition</td>
</tr>
<tr>
<td></td>
<td>6. A malnutrition screening tool</td>
<td>6. Friction and shear</td>
</tr>
<tr>
<td></td>
<td>7. Other risk factors including neurological deficit, medication, major surgery or trauma and tissue malnutrition</td>
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</tr>
</tbody>
</table>

Despite the guidelines recommending the use of a validated risk assessment tool, the evidence for the value of the risk assessment tools is limited. A Cochrane review evaluated whether the use of a structured risk assessment tool in any healthcare setting can reduce the incidence of pressure ulcers when compared with no structured risk assessment or clinical judgement (Moore & Cowman, 2014). The review identified and included only two studies.
conducted in hospital settings. One of the included studies was a large randomised trial (N = 1,231) classified as having a low risk of bias. The second study was a small cluster-randomised trial (N = 256) judged to be at a high risk of bias. Overall, Moore and Cowman (2014) found that there was no reliable evidence to suggest that using a structured risk assessment tool reduces pressure ulcer incidence rates.

In light of the current evidence and limited prognostic data, conducting a risk assessment is only one aspect of pressure ulcer prevention. A risk assessment can indicate whether a person is at risk, high risk or very high risk of developing a pressure ulcer and this is used to inform other aspects of pressure ulcer prevention. For example, if a person is identified as being at risk of developing a pressure ulcer, the NICE (2014) guidelines recommend conducting a skin assessment.

2.5.1.2 Skin assessment

The NICE (2014) guidance recommends conducting a thorough skin assessment (see Table 2). The skin assessment recommendations are based on randomised trials and prospective cohort studies at a serious or very serious risk of bias for methodological issues (e.g., the inclusion of unrepresentative samples) and the certainty of the evidence was assessed as moderate, low or very low.
Currently there is limited evidence to suggest that conducting a skin assessment prevents the development of pressure ulcers (NICE: Pressure ulcers, 2014). Nevertheless, the presence of non-blanchable erythema (i.e. a Stage 1 pressure ulcer) may indicate the risk of a more severe pressure ulcer developing (Nixon et al., 2006; Reed, Hepburn, Adelson, Center, & McKnight, 2003). In their systematic review of 54 studies (N = 34,449 patients), Coleman et al. (2013) found a strong correlation between a Stage 1 pressure ulcer and subsequent Stage 2 pressure ulcers and above. Thus, completing a skin assessment may enable the early identification of skin damage and subsequent prevention strategies.

2.5.1.3 Repositioning

The development of pressure ulcers is linked to the reduced blood flow to the skin in the affected area (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014) and immobility is considered to be a risk factor for developing pressure ulcers (Coleman et al., 2013). Consequently, repositioning is regarded as an essential component of pressure ulcer prevention. A systematic review of three randomised trials with a total of 502 participants across different healthcare settings was conducted (Gillespie, Chaboyer, Sykes, O’Brien, & Brandis, 2014). The studies included were classified as being at a high or unclear risk of bias and Gillespie et al. (2014) found that, whilst repositioning was important in the
prevention of pressure ulcers, there is insufficient evidence to conclude that repositioning at a greater frequency is more effective.

The lack of evidence to support higher frequency repositioning (Gillespie et al., 2014) is reflected within the current guidelines with the omission of the recommendation of repositioning individuals every two hours (NICE: Pressure ulcers, 2014; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). Consequently, the NICE (2014) guidance recommends repositioning every four or six hours depending on the individual’s risk. However, the certainty of the evidence behind these recommendations is low or very low and is based on randomised trials and one cluster-randomised trial. The included trials were classified as having a serious or very serious risk of bias (e.g., different mattresses used for the experimental groups, small sample size, high attrition).

2.5.1.4 Nutrition and hydration

Malnutrition may be an important risk factor in the development of pressure ulcers (Coleman et al., 2013). A systematic review of 23 randomised studies conducted in hospital settings, with a median sample size of 88 participants, compared the effects of nutritional supplements with a standard hospital diet (Langer & Fink, 2014). The data were at an unclear or a high risk of bias and there was no clear evidence of an effect of the supplements on the development
of pressure ulcers. Consequently, the NICE (2014) guidelines do not recommend nutritional supplements and subcutaneous or intravenous fluids as a means to prevent pressure ulcers in those who have an adequate nutritional intake and hydration status (see Table 2). However, the certainty of the evidence was assessed as low or very low and the recommendations are based on randomised trials at a serious risk of bias for methodological issues such as high attrition, baseline differences and high levels of missing data.

2.5.1.5 Pressure redistributing devices

Support surfaces are defined as specialised devices which aid the redistribution of pressure to spread tissue load and manage the person’s microclimate (National Pressure Ulcer Advisory Panel, 2007). Once an individual has been identified as being at risk of developing a pressure ulcer, using the correct support surfaces is regarded as an important aspect in the prevention of pressure ulcers. The type of support surface should be chosen based on individual needs (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). The certainty of the evidence for these recommendations was assessed as moderate or very low based on randomised trial evidence which was at a serious or a very serious risk of bias (e.g., inadequate sequence generation, incomplete outcome data not addressed).
According to a systematic review of 59 trials conducted across a variety of healthcare settings, with a median sample size of 98 participants (McInnes et al., 2015), there are three main types of pressure redistributing devices:

1. Lower technological specification with constant low pressure support surfaces (e.g., standard foam mattress).
2. Higher technological specification support surfaces (e.g., alternating-pressure mattress).
3. Other support surfaces (e.g., cushions, rotating beds, limb protectors).

McInnes et al. (2015) found that the higher-specification foam mattresses, when compared with the standard hospital foam mattresses, reduce pressure ulcer incidence in individuals at risk of developing a pressure ulcer. However, the benefits of using a higher-specification constant low pressure and an alternating-pressure support surface to prevent pressure ulcers are unclear. The certainty of these findings is tempered by poor methodological and reporting quality.

2.5.1.6 Barrier creams

Pressure ulcers differ from incontinence-related conditions such as incontinence-associated dermatitis which is the inflammation of the skin due to urine and/or faeces (Gray et al., 2011). However, moisture can cause the skin’s outer layer (the stratum corneum) to breakdown, making the skin more susceptible to pressure ulcers (Clark et al., 2010). A barrier cream can be applied
directly to the skin to protect against friction and is an example of a topical agent (Reddy, Gill, & Rochon, 2006). The NICE guidelines (2014) recommend using barrier creams in individuals who are at a higher risk of developing a moisture lesion or incontinence-associated dermatitis to prevent skin damage.

The recommendation to use barrier creams was based on research evidence that was assessed as being low or very low quality (randomised trials at a serious or very serious risk of bias). Methodological and reporting problems with the underpinning research included a risk of selection bias due to changes in the randomisation schedule, unclear information about blinding and a poorly reported study. Therefore, the certainty of the evidence is low. A systematic review of four randomised trials and one cluster-randomised trial with a total of 940 participants compared topical agents with a placebo (Moore & Webster, 2013). Overall this review did not find a beneficial effect of topical agents. However, when the cluster-randomised trial was removed from the analysis, there was a beneficial effect and pressure ulcer incidence reduced by 36%. The trials were at an unclear or a high risk of bias and the authors concluded that there is insufficient evidence regarding the effects of using topical agents to prevent pressure ulcers (Moore & Webster, 2013).
2.5.1.7 Skin massage

In the evidence review conducted as part of the NICE (2014) guideline development, one cross-over study with a sample size of 79 was identified (Duimel-Peeters et al., 2007). Participants who were at risk of developing a pressure ulcer were randomly assigned to one of three groups: repositioning only, massage with an ‘indifferent cream’, massage with a dimethyl sulfoxide cream. Dumiel-Peeters et al. (2007) found no differences between the groups. However the certainty of evidence was rated as very low due to the study design and reporting issues such as a lack of detail regarding the allocation concealment and it was unclear whether outcome assessors were blinded. Consequently, NICE (2014) do not recommend massaging or rubbing the skin as this may exert shearing stresses which can be particularly harmful for individuals who are at risk of developing pressure ulcers (Takahashi et al., 2010). However, the evidence to support or refute skin massage for the prevention of pressure ulcers is unclear and a recent Cochrane review did not find any studies eligible for inclusion (Zhang, Sun, & Yue, 2015).

2.5.1.8 Training for care staff

Based on two qualitative studies which included interviews, participant observations, group discussions, surveys and questionnaires, the NICE (2014) guidelines recommend providing training and education for healthcare professionals. However the effectiveness of training and education programmes
in relation to pressure ulcer prevention, including the programme content and mode of delivery, are yet to be established (Porter-Armstrong, Moore, Bradbury, & McDonough, 2015).

2.5.1.9 Patient and carer information

The NICE (2014) guidelines recommend providing patients and carers with information to facilitate pressure ulcer prevention. This recommendation is based on a review of 11 qualitative studies as part of the guideline development process. The 11 qualitative studies involved a variety of data collection methods including interviews, participant observations, questionnaires, surveys and group discussions. A thematic analysis of the qualitative data was conducted, resulting in three themes: perceived causation of pressure ulcers, patients’ and carers’ preferred mode of education on pressure ulcers, prevention of pressure ulcers. The certainty of the evidence was assessed as high. Nevertheless, the impact of patient and carer information and involvement on pressure ulcer prevention has not been systematically reviewed (O'Connor, Moore, Dumville, & Patton, 2015).

2.5.1.10 Care planning

Discussions between patients and healthcare professionals regarding treatment goals, options and preferences inform the development of personalised care plans which are anticipatory, agreed plans of action (Coulter et al., 2015).
inclusion of individualised care plans for people identified as being at a high risk of developing a pressure ulcer are recommended in the NICE (2014) guidelines (see Table 2). However, this recommendation was based on an informal consensus rather than research evidence.

I could not identify a systematic review assessing the effectiveness of care planning for individuals at risk of developing pressure ulcers. However, a systematic review of 19 randomised trials with a total of 10,856 participants compared the effect of personalised care plans for adults with long-term health conditions to usual forms of care (Coulter et al., 2015). The studies were conducted across primary care or community settings and hospital clinics, and the long-term health conditions included diabetes, mental health, renal disease, heart failure and asthma. This systematic review found moderate quality evidence that personalised care planning may lead to better health outcomes when compared with usual care (Coulter et al., 2015).

In summary, there is low certainty from the evidence based on randomised trials at a high risk of bias to support the guideline recommendations for the prevention of pressure ulcers. The limited reporting of study processes and findings restricts the extent to which research can usefully inform decision making and practice and ultimately lead to patient benefit (Chan et al., 2014). In the absence of certainty, the best available evidence, expert opinion and
evaluations of cost-effectiveness have informed the NICE (2014) guidelines (NICE, 2014). Consequently, whilst the NICE guidelines for the prevention and management of pressure ulcers recommend a number of practices, clinical judgement and patient preferences should not be undervalued (van Weel & Schellevis, 2006).

2.6 Research-informed practice

2.6.1 Evidence-informed practice

Evidence-informed practice involves clinical decision-making based on a combination of research evidence, clinical expertise, context and patient values and preferences with the aim of improving patient outcomes (Melnyk, Gallagher-Ford, Long, & Fineout-Overholt, 2014; Rycroft-Malone et al., 2004). Factors influencing clinical decision-making include the work environment, autonomy and how staff perceive themselves (i.e. active or passive in the decision-making process) (Thompson, Cullum, McCaughan, Sheldon, & Raynor, 2004). Recently Sundberg, Garvare and Nystrom (2017) distinguished between research evidence and non-research evidence (e.g., clinical experience). Non-research evidence can be gained during the day-to-day practice of preventing pressure ulcers, but it can be subjective in nature and may be derived from unstandardised observations (Thompson, McCaughan, Cullum, Sheldon, & Raynor, 2005). Consequently, such experiential evidence may be biased and unreliable (Adderley & Thompson, 2017) and research evidence
may be used to overcome this (Grobbee & Hoes, 2009). However as discussed, research evidence is not exempt from potential biases. As non-research evidence can be subjective and difficult to measure, I will now discuss research-informed practice.

2.6.2 Research-informed practice

The translation of research findings into practice is a slow process (Graham & Tetroe, 2009; Pentland et al., 2011). The delayed or limited translation of research into healthcare practice is sometimes referred to as the ‘research-practice gap’ (Woolf, 2008). Healthcare workers need to be able to access research findings (Chalmers & Glasziou, 2009). Thus, the identification of the barriers and facilitators to implementation is the first step towards reducing the research-practice gap before implementing and evaluating the interventions (Lau et al., 2014).

2.6.2.1 Barriers to research-informed practice

There has been a high volume of research published on the reported barriers to research-informed practice (e.g., Brown, Wickline, Ecoff, & Glaser, 2009; Daly, Elliott, Chang, & Usher, 2014; Kajermo et al., 2010; Leach, Hofmeyer, & Bobridge, 2016). For example, healthcare workers may not use some research findings to inform their practice if they feel that the research is not fit for purpose due to:
- The research not addressing the specific issue they require a solution to (Chalmers et al., 2014).
- The risk of bias introduced by study design and analysis (Ioannidis et al., 2014).
- The limited reporting of study methods and findings (Chan et al., 2014).

Low quality evidence limits the certainty we have in intervention effects and thus constrains the recommendations that can be made in the guidelines. This in turn can leave healthcare workers feeling uncertain about which practices are best to use (Hilton, Bedford, Calnan, & Hunt, 2009; Kitson et al., 2008). When faced with uncertainty or ambiguity, the accessibility of information is key (Thompson et al., 2004) and colleagues are preferred as sources of knowledge as they are easily accessed, highly regarded and often the primary source of information (Voldbjerg, Grønkjær, Sørensen, & Hall, 2016).

Another commonly reported barrier to research-informed practice is the lack of time to access and implement research findings (Kajermo et al., 2008). Thompson et al. (2008) performed a secondary data analysis of qualitative data to explore the relationship between insufficient time and research-informed practices, finding that limited time reflected the individuals' thinking time and energy required when searching for and appraising the evidence (Thompson et al., 2008). However, the findings reported by Thompson et al. (2008) are limited as the primary data which informed the secondary analysis were collected to
answer different research questions which may have limited the depth of the secondary data analysis.

2.7 Addressing the research-practice gap

2.7.1 Healthcare worker behaviour change

Improving research-informed practice has received much interest over the past decade (e.g., Jun, Kovner, & Stimpfel, 2016; McKee et al., 2017). Research-informed practice requires healthcare professionals to work and think differently (Baker et al., 2010) because providing the evidence is necessary but alone is not sufficient (McKee, Codd, Dempsey, Gallagher, & Comiskey, 2017; Paget, Lilischkis, Morrow, & Caldwell, 2014). So, more recently, research has looked at how we might change the behaviour of healthcare workers to facilitate the uptake of research-informed practice and the use of clinical practice guidelines in healthcare (Colquhoun, Squires, Kolehmainen, Fraser, & Grimshaw, 2017; French et al., 2012; Luker et al., 2017). Nevertheless, healthcare workers do not generally work in isolation; rather they work in a context with others where colleagues, organisational and cultural factors can all influence their practice (Harvey & Kitson, 2016; Kitson et al., 2008; Rycroft-Malone et al., 2004).

The delivery of research-informed practice can be sub-optimal in any healthcare setting and may be particularly challenging in nursing homes due to the limited
knowledge of, and training for, healthcare assistants (Kwong, Lee, & Yeung, 2016; Meesterberends, Wilborn, Lohrmann, Schols, & Halfens, 2014; Ousey, Kaye, McCormick, & Stephenson, 2016), high staff turnover and understaffing (Demarré et al., 2012; Donoghue, 2009) in addition to the aforementioned barriers. Therefore the barriers to research-informed practice may vary across healthcare contexts, highlighting the need for flexible and tailored approaches to reducing the research-practice gap.

Baker et al. (2010) conducted a systematic review to evaluate the impact of tailoring interventions to address the barriers to research-informed practice. This systematic review comprised 25 randomised trials which compared tailored interventions with either no intervention or interventions which were not tailored. The findings suggest that tailoring interventions to improve research-informed practice can facilitate changes in professional practice. The certainty of the evidence was assessed as moderate based on findings which were downgraded due to the high risk of bias in the studies. There was insufficient evidence to identify the most effective approach to tailoring interventions, including how best to identify the barriers to research-informed practice. Thus, one option is to use theory to guide intervention development and implementation (Eccles, Grimshaw, Walker, Johnston, & Pitts, 2005). Theory can broaden and deepen our understanding of why an intervention does or does not work (Moore et al., 2015). In addition, using standardised
language associated with theories can facilitate comparisons with other interventions, enhancing the generalisations made across the different healthcare settings and conditions.

Another systematic review of 235 studies compared interventions for guideline dissemination and implementation strategies (Davies, Walker, & Grimshaw, 2010). The review found that 53 studies reported using behaviour change or behavioural theories but the rationale for specific theories was often not stated (Davies et al., 2010). However, Davies et al. (2010) did not include studies published after 1998 and therefore their findings may not accurately reflect the studies published more recently.

A systematic review qualitatively synthesised the findings of 15 papers published between 2001 and 2014 to identify the methods used to develop interventions targeting the behaviours of healthcare workers (Colquhoun et al., 2017). The interventions targeted a range of behaviours related to the use of research-informed practices. All of these interventions were developed for use in a specific context and 13 of the papers reported using theory to inform the development of the intervention. The findings suggest that there are four steps generally involved in developing interventions targeting healthcare workers’ behaviours: identification of the barriers to knowledge translation interventions among healthcare workers; tailoring intervention components to address the
barriers; the use of theory and user engagement (Colquhoun et al., 2017).

However, this systematic review had some limitations. The search strategy involved three databases only and did not include the searching of grey literature and so there is likely to be a publication bias. Moreover, the inclusion criteria applied when screening the potential studies for inclusion in this systematic review may have limited the number of eligible papers, as the review only included studies reporting the development of an intervention, not the testing of the intervention.

2.7.1.1 Psychological theories of behaviour change

Within healthcare settings, a team of people usually implements behaviour change interventions and therefore focusing on individual behavioural processes may not be appropriate (Hernes, 2014; Thornton, Kuelbs, Zielinski, Liu, & Kurachek, 2012). Purely focusing on the individual’s characteristics likely to influence behaviour change may lead to a narrow focus and limit the real world application of interventions. Nursing homes, the setting for the work in this thesis, are viewed as complex healthcare systems due to the interaction of the different individuals (i.e. staff, residents and families) (Anderson, Issel, & McDaniel Jr, 2003; Leykum, Pugh, Lanham, Harmon, & McDaniel, 2009). Within the nursing home setting, complex interdependencies between healthcare staff and residents at the different levels of an organisation have been acknowledged and their behaviours are interconnected but not always
predictable. Psychological theories can be useful for providing a theoretical understanding of the behaviour, enabling the prediction of the behaviour in a variety of settings (Godin, Bélanger-Gravel, Eccles, & Grimshaw, 2008).

There is a plethora of theories of behaviour change, many of which include overlapping constructs (Michie et al., 2005). Consequently, there is uncertainty regarding which theories better predict behaviour change (Noar & Zimmerman, 2005) and which should underpin the implementation aspect of interventions (Grol, Bosch, Hulscher, Eccles, & Wensing, 2007; Lippke & Ziegelmann, 2008).

The evidence surrounding the effectiveness of theory-informed behaviour change interventions is equivocal. Some report that theory-informed behaviour change interventions are effective. For example, a stepped-wedge cluster-randomised trial of 60 hospital wards across England and Wales reported moderate improvements in healthcare workers’ adherence to hand-hygiene practices following the implementation of a theory-based intervention (Fuller et al., 2012). By contrast Prestwich et al. (2015) conducted a narrative review of the theory-based interventions that have been used to facilitate behaviour change and were more cautious in their conclusions about the effects of theory-based interventions. However, this review did not report its methods nor did it meta-analyse study findings making it difficult to ascertain the certainty of the evidence. Nevertheless, Prestwich et al. (2015) draw attention to the limited
reference to behaviour change theory in studies reporting the implementation of interventions. Below I discuss three psychological theories, a framework and a model to elaborate on the utility of developing a theory-informed behaviour change intervention.

2.7.1.1a Operant Learning Theory

Operant Learning Theory (Skinner, 1938; 1953) emphasises the importance of rewards and punishment in shaping behaviours. Examples used within the healthcare system include audit and feedback, financial incentives and regulatory sanctions (Scott et al., 2011; Tuti et al., 2017). Audit and feedback can involve a summary of clinical behaviours and outcomes over a period of time and are used widely with the aim of improving healthcare workers’ behaviours (Chauhan et al., 2017; Curti et al., 2015; Rourke, Oberholtzer, Chatterley, & Brassard, 2015). A systematic review of 70 studies assessed the effect of audit and feedback on healthcare professionals’ practice (Ivers et al., 2012). Evidence for the effects of audit and feedback was limited with small to moderate effects on actual behaviours and the certainty of this evidence was moderate (Ivers et al., 2012).

The use of audit and feedback as a behaviour change technique in interventions specifically aimed at changing healthcare workers’ pressure ulcer prevention practice is widely documented and associated with reduced pressure ulcer
incidence (e.g., Hiser et al., 2006; Horn et al., 2010; Jamtvedt, Young, Kristoffersen, O’Brien, & Oxman, 2006; LeMaster, 2007; Rosen et al., 2006). However, these studies which have evaluated audit and feedback in pressure area care are observational in nature and are unable to draw definite conclusions about effectiveness. A systematic review of 26 studies (Sullivan & Schoelles, 2013) found that audit and feedback are important aspects of the prevention of healthcare-acquired pressure ulcers. Whilst the review authors assessed the certainty of the evidence to be moderate, studies of any design were included in the review and a statistical analysis was not conducted. Thus, at this time there is no clear research evidence that audit and feedback improve healthcare workers’ pressure ulcer prevention behaviours or reduce the incidence of pressure ulcers.

2.7.1.1b Social Cognitive Theory

Social Cognitive Theory (Bandura, 1986) acknowledges the influence of and interaction between, the environment, personal cognitive factors and behaviours. Within the Social Cognitive Theory, learning can occur through observing and modelling others’ behaviours (Bandura, 1986). Modelling, epitomised by ‘skin champions’ (who aid the transfer of theoretical knowledge into practice) is another widely used technique for the prevention of pressure ulcers (Sullivan & Schoelles, 2013). Skin champions are healthcare workers selected from within the team, who build a rapport across disciplines and
advocate both patient safety and adherence to specified practices (Stockwell & Slonim, 2006). However according to the Social Cognitive Theory (Bandura, 1986), behaviour change will only be successful if the person observing and imitating the behaviour has a high perceived self-efficacy. Therefore, a person’s confidence and belief in their ability to successfully perform and accomplish a task will influence the extent to which they persevere with an action.

2.7.1.1c Theory of Planned Behaviour

The Theory of Planned Behaviour (Ajzen, 1988; 1991) evolved from the Theory of Reasoned Action (Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975) which postulated that attitudes and beliefs form intentions, and intentions are the best predictors of behaviour. Within the Theory of Reasoned Action, evaluations of the behaviour and expected outcomes are combined with the perceived social pressures to perform the behaviour. The Theory of Planned Behaviour added a third dimension, perceived behavioural control, which related to the individual’s beliefs about the factors which may impact on their performance of the behaviour. A meta-analysis of 161 published studies demonstrated that the Theory of Planned Behaviour has successfully predicted a wide range of health behaviours (Armitage & Conner, 2001). The Theory of Planned Behaviour was able to explain 27% of the variance in behaviour and 39% of the variance in intention (Armitage & Conner, 2001). Similarly, a more recent systematic review and meta-analysis of 206 studies containing a total of 237 prospective tests,
found that the Theory of Planned Behaviour accounted for 19% of the variance in behaviours and 44% of the variance in intentions (McEachan, Conner, Taylor, & Lawton, 2011).

The Theory of Planned Behaviour (Ajzen, 1988; 1991), however, does not account for the role of habit, associative learning (Sheeran, Gollwitzer, & Bargh, 2013) and emotional processing (Conner, Godin, Sheeran, & Germain, 2013). Habits are automatic responses to environmental cues which develop through the repeated response (i.e. the behaviour) in the presence of the cue (Lally, Van Jaarsveld, Potts, & Wardle, 2010). When an individual develops habitual behaviours, they are less likely to use the new information to change their behaviour (Verplanken & Wood, 2006). Clinical behaviours/interventions are health care practices that are directed to the patient (e.g., administering antibiotics, repositioning an individual) (Eldh et al., 2017). Clinical behaviours occur in relatively stable healthcare contexts and this can result in the formation of strong habits (Rochette, Korner-Bitensky, & Thomas, 2009). The implication of this research is that habitual behaviours may limit the effect of pressure ulcer prevention interventions which only focus on increasing knowledge and improving attitudes. Therefore, implementation interventions are used to promote and support the uptake of clinical interventions (Eldh et al., 2017).
To aid health services researchers in the identification of the appropriate psychological theory and to develop one unifying theory of behaviour change, Michie et al. (2005) developed the Theoretical Domains Framework. Michie et al. (2005) aimed to enhance the accessibility of behaviour change theories by simplifying and integrating 33 theories and 128 key theoretical constructs into one framework. Using a six-stage consensus approach, 18 psychological theorists, 16 health service researchers and 30 health psychologists developed the Theoretical Domains Framework. Firstly, the relevant behaviour change theories and theoretical constructs were identified. The theories and constructs were simplified into overarching theoretical domains which were made up of related theoretical constructs. The participants evaluated the importance of these theoretical domains by assessing the coherence, repetition and relevance of the constructs, followed by an interdisciplinary evaluation and synthesis of the domains. The domain list was validated to demonstrate the representativeness of the domains using a ‘backward validation’ exercise. The validation exercise involved the participants independently stating the theories and constructs relevant to each of the domains. Following this, the participants were asked to reach a consensus about which three constructs were the most important to each domain. Finally, interview questions relevant to the domains were piloted which resulted in 12 theoretical domains for the comprehensive
theoretical assessment of the potential challenges to the implementation of research-informed practices (Michie et al., 2005).

Since the original publication of the Theoretical Domains Framework, Cane, O’Connor and Michie (2012) undertook a three-step validation process. The validation process employed a ‘card sorting methodology’ whereby the 18 participants were assigned to a closed sort task and 19 participants to an open sort task. All of the participants had experience in using behaviour change theories through research, teaching or clinical practice. Participants assigned to the closed sort task assigned the 112 individual constructs to the relevant 12 domains from the Theoretical Domains Framework (Michie et al., 2005). The participants in the open sort task sorted the 112 constructs into semantically-related groups and assigned each of the groups a label. Both of the participating groups could allocate the constructs to multiple groups and provided confidence ratings for each of the grouped constructs. The validation process carried out by Cane et al. (2012) resulted in some minor changes to the Theoretical Domains Framework and the refined framework consists of 14 domains (see Table 4).
Table 4

The COM-B components (Michie, Atkins, & West, 2014, p. 92) and the Theoretical Domains Framework and definitions (Cane et al., 2012, p.13-14)

<table>
<thead>
<tr>
<th>COM-B components</th>
<th>Theoretical Domains</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capability</td>
<td>Framework domains</td>
<td></td>
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<td></td>
<td><strong>Psychological</strong></td>
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<td></td>
<td><strong>Knowledge</strong></td>
<td>An awareness of the existence of something [knowledge (including knowledge of condition/scientific rationale), procedural knowledge, knowledge of task environment]*.</td>
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<tr>
<td></td>
<td><strong>Skills (cognitive and interpersonal)</strong></td>
<td>An ability or proficiency acquired through practice [interpersonal skills]*.</td>
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<td></td>
<td><strong>Behavioural regulation</strong></td>
<td>Anything aimed at managing or changing objectively observed or measured actions [self-monitoring, breaking habit, action planning]*.</td>
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<td></td>
<td><strong>Memory, attention, and decision processes</strong></td>
<td>The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives [memory, attention, attention control, decision making, cognitive overload/tiredness]*.</td>
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<td></td>
<td><strong>Physical</strong></td>
<td></td>
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<tr>
<td></td>
<td><strong>Skills (Physical)</strong></td>
<td>An ability or proficiency acquired through practice [skills, skills development, competence, ability, practice, skill assessment]*.</td>
</tr>
<tr>
<td>COM-B components</td>
<td>Theoretical Domains</td>
<td>Definition</td>
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<td>-----------------</td>
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<tr>
<td>Opportunity</td>
<td></td>
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<tr>
<td>Physical</td>
<td>Environmental context and resources</td>
<td>Any circumstance of a person’s situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour [environmental stressors, resources/material resources, organisational culture/climate, salient events/critical incidents, person x environment interaction, barriers and facilitators]*.</td>
</tr>
<tr>
<td>Social</td>
<td>Social influences</td>
<td>Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours [social pressure, social norms, group conformity, social comparisons, groups norms, social support, power, intergroup conflict, alienation, group identity, modelling]*.</td>
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<tr>
<td>Motivation</td>
<td></td>
<td></td>
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<tr>
<td>Reflective</td>
<td>Social/professional role and identity</td>
<td>A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting [professional identity, professional role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment]*.</td>
</tr>
<tr>
<td>COM-B components</td>
<td>Theoretical Domains</td>
<td>Definition</td>
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<tr>
<td>Reflective</td>
<td>Beliefs about capabilities</td>
<td>Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use [self-confident, perceived competence, self-efficacy, perceived behavioural control, beliefs, self-esteem, empowerment, professional confidence]*.</td>
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<tr>
<td>motivation</td>
<td></td>
<td></td>
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<tr>
<td>(continued)</td>
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<tr>
<td>Optimism</td>
<td></td>
<td>The confidence that things will happen for the best or that desired goals will be attained [optimism, pessimism, unrealistic optimism, identity]*.</td>
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<tr>
<td>Intentions</td>
<td></td>
<td>A conscious decision to perform a behaviour or a resolve to act in a certain way [stability of intentions, stages of change model, transtheoretical model and stages of change]*.</td>
</tr>
<tr>
<td>Goals</td>
<td></td>
<td>Mental representations of outcomes or end states that an individual wants to achieve [goals (distal/proximal), goal priority, goal/target setting, goals (autonomous/controlled), action planning, implementation intention]*.</td>
</tr>
<tr>
<td>Beliefs about consequences</td>
<td></td>
<td>Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation [beliefs, outcome expectancies, characteristics of outcome expectancies, anticipated regret, consequents]*.</td>
</tr>
<tr>
<td>COM-B components</td>
<td>Theoretical Domains</td>
<td>Definition</td>
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<tr>
<td><strong>Automatic motivation</strong></td>
<td>Reinforcement</td>
<td>Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus [rewards (proximal/distal, valued/not valued, probable/improbable), incentives, punishment, consequents, reinforcement, contingencies, sanctions]*.</td>
</tr>
<tr>
<td>Emotion</td>
<td></td>
<td>A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event]*.</td>
</tr>
</tbody>
</table>

*Component constructs included within the square brackets.
There are advantages to using the Theoretical Domains Framework; firstly, the framework provides a comprehensive and precise account of the potential influences on behaviour. There are many examples from the literature where the Theoretical Domains Framework has been used to inform data collection and analysis to enable the identification of barriers and enablers to various different healthcare behaviours, including hand hygiene (Dyson, Lawton, Jackson, & Cheater, 2011), blood transfusion practices (Francis, Stockton, et al., 2009; Francis, Tinmouth, et al., 2009) and implementing guidelines relating to schizophrenia (Michie et al., 2007). Secondly, it is possible to apply the framework within either a qualitative or quantitative study design. Thirdly, there are clear links between behaviour change theories and behaviour change techniques enabling the development of theoretically informed interventions (Michie et al., 2014; Michie et al., 2011).

2.7.1.1e COM-B Model

The Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) can also be combined with the COM-B model (Michie et al., 2011) to enable a better understanding of the target behaviour and to aid the implementation of interventions (see Table 4). The COM-B model states that for a behaviour (B) to occur, an individual must have the capability (C), opportunity (O) and motivation (M). Within the COM-B model capability is defined as having the relevant knowledge and skills, as well as the capacity to engage in the thought
processes required to perform the behaviour (Michie et al., 2011). Thus, capability refers to the person’s psychological and physical capacity to engage in the target behaviour. The Theoretical Domains Framework domains represented within the capability component are: knowledge, memory, attention and decision processes, behavioural regulation and skills (skills are split into ‘cognitive and interpersonal’ or ‘physical’ and are mapped onto psychological or physical capability, respectively. Thus, Table 4 appears to contain 15 domains).

Opportunity refers to the factors that are external to the individual and influence the potential success of the behaviour. The physical environment (e.g., resources, time) or the social environment (e.g., cultural norms) can create an opportunity to perform the behaviour. Represented within the opportunity component of the COM-B model are the following Theoretical Domains Framework domains: environmental context and resources and social influences.

Motivation involves the psychological processes (including analytical decision-making, habitual processes and emotional responses) which can trigger and direct behaviour. Motivation is subdivided into reflective and automatic motivation. Automatic motivation involves quick and unconscious processes (e.g., emotions) which rely on the automatic reactions based on associative learning. In contrast, reflective motivation involves slower and more deliberate decision making and often relies on evaluations and plans. Represented within
the motivation component of the COM-B model are the following Theoretical Domains Framework domains: social/professional role and identity, reinforcement, beliefs about capability, beliefs about consequences, emotion, optimism, goals and intentions (see Table 4).

The arrows displayed in Figure 1 demonstrate how each of the COM-B components can influence one another, with capability and opportunity both influencing motivation. In addition, behaviour is both influenced by and influences a person’s capability, opportunity and motivation as demonstrated by the bidirectional arrows in Figure 1.

The Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) and COM-B model (Michie et al., 2011) can account for the individual, social and environmental factors involved in the behaviour change of healthcare workers. The Theoretical Domains Framework and the COM-B model have been applied within the context of improving research-informed practice in healthcare (Beenstock et al., 2012; Islam et al., 2012; Michie et al., 2007). Therefore, the Theoretical Domains Framework and COM-B model are likely to provide a comprehensive overview of the various constructs which could be involved in the prevention of pressure ulcers in nursing home settings.
2.7.2 Interventions to promote the uptake of research-informed practices

Research and guidelines can facilitate the standardisation of care, however without the use of implementation processes to support research and guideline utilisation in practice, their effect is likely to be limited (Zingg et al., 2015). Translating research into practice is widely reported and a variety of interventions are used including education, audit and feedback, reminders and multifaceted tailored interventions targeting a variety of barriers to change within a particular context (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012; Squires, Sullivan, Eccles, Worswick, & Grimshaw, 2014; Yamada, Shorkey, Barwick, Widger, & Stevens, 2015).

A theory-led overview of 67 systematic reviews found that the three main categories of healthcare worker behaviour change interventions were: persuasion, education and information and action and monitoring (Johnson & May, 2015). Nevertheless, there are inconsistent findings across the literature. For example, an overview of 25 reviews did not find any evidence to support the use of multifaceted interventions over single-component interventions (Squires et al., 2014). However, Squires et al. (2014) did not retrieve the primary data and relied only on the information reported within the reviews. Whereas, a systematic review of 88 studies reporting on multiple approaches to research-informed practice by healthcare teams found an overall improvement in knowledge and practice (Medves et al., 2010). However Medves et al. (2010)
included all study designs and did not conduct a meta-analysis, thus caution is needed when interpreting these results as the included studies may be at risk of bias, decreasing the certainty of the evidence.

2.7.2.1 Care bundles

The notion of ‘care bundles’ was first developed by the Institute for Healthcare Improvement in 2001 to improve the processes of care and the quality of care by encouraging healthcare workers to adhere to clinical guidelines (Resar et al., 2012). Care bundles are a set of three to five research-informed practices called ‘elements’. The Institute for Healthcare Improvement developed two care bundles to reorganise the care processes within intensive care units with the aim of preventing central line-associated bloodstream infections and ventilator-associated pneumonia in intensive care units (Resar et al., 2012). It is recommended that the elements are delivered collectively and reliably (Resar et al., 2012) as they are considered to be more effective than employing a single method (Baldelli & Paciella, 2008; Reddy et al., 2006).

The Institute for Healthcare Improvement recommend an ‘all-or-none’ approach to care bundle adherence when implementing care bundles. Within this approach the care bundle is considered to be complete only if all of the elements have been delivered. Thus, it is recommended that every eligible
patient should receive all of the elements included within the care bundle unless medically contraindicated (Resar et al., 2012).

Since the development of the first two care bundles, a number of care bundles have been developed and implemented across healthcare settings for a variety of health conditions. Examples include the prevention of surgical site infections in hospital settings (e.g., van der Slegt et al., 2013), of pressure ulcers in intensive care units (e.g., Tayyib & Coyer, 2017) and of sepsis (e.g., Levy et al., 2014). Condition-specific systematic reviews published since the work for this thesis began have demonstrated improved clinical outcomes following the implementation of care bundles (e.g., Ista et al., 2016; Ospina et al., 2017; Tanner et al., 2015). Ista et al. (2016) conducted a systematic review of 96 studies, which also included a meta-analysis of 79 studies, to assess the effectiveness of insertion and/or maintenance central line care bundles in preventing central line-associated bloodstream infections. The findings suggest that the central line care bundle may reduce the incidence of central line-associated bloodstream infections (Ista et al., 2016). Ospina et al. (2017) reviewed 14 studies to evaluate the effectiveness of discharge care bundles for patients with Chronic Obstructive Pulmonary Disease. Four randomised trials were included in a meta-analysis which found that the discharge care bundle leads to fewer readmissions amongst patients with Chronic Obstructive Pulmonary Disease.
(Ospina et al., 2017). However, the certainty of the evidence was assessed to be low.

Care bundles have been developed to assist healthcare workers with the prevention of pressure ulcers. An example is the SKIN bundle which was developed in the USA to eliminate hospital-acquired pressure ulcers (Gibbons, Shanks, Kleinhelter, & Jones, 2006). SKIN is an acronym for observations and activities that are believed to reduce the risk of pressure ulcer development: Support, Keep moving, Incontinence, Nutrition and hydration. Since the development of the SKIN bundle, the Institute for Healthcare Improvement Scotland added ‘skin’ as an additional element to promote regular skin checks and this bundle is known as the SSKIN bundle (Healthcare Improvement Scotland, 2011). However, there is little information available regarding the development, implementation and evaluation of either the SKIN or the SSKIN bundles.

Where a particular harm (e.g., pressure ulcers) occurs in more than one setting (e.g., hospitals, nursing homes), the Institute for Healthcare Improvement recommend developing specific care bundles for each location if necessary (Resar et al., 2012). For example pressure ulcers can occur in intensive care units, community settings and nursing homes. Therefore, separate care bundles may need to be developed for each healthcare setting. I have been unable, via
exhaustive searching, to identify an existing systematic review or meta-analysis evaluating the effectiveness of pressure ulcer prevention care bundles in any healthcare setting. Thus in line with the Institute for Healthcare Improvement’s recommendations (Resar et al., 2012) and in light of the limited evidence base for pressure ulcer prevention care bundles, it may be inappropriate to adapt care bundles developed for use in a particular healthcare setting due to the different characteristics of both patients and staff.

2.8 The Medical Research Council Guidance for the development and evaluation of complex interventions

Complex interventions which target the behaviour of healthcare workers are required to improve the quality of healthcare and patient outcomes (Bradley, Wiles, Kinmonth, Mant, & Gantley, 1999; Campbell et al., 2000). Care bundles are one example of a complex intervention as they contain several components which are thought to have a synergistic effect (Resar et al., 2012).

To aid the development and evaluation of complex interventions, the UK Medical Research Council (MRC) devised guidelines detailing a linear process (Campbell et al., 2000). However, the MRC guidance was criticised and some limitations were identified which led to the following recommendations:

- Greater attention to the development and piloting phases of complex interventions (Hardeman et al., 2005).
A more cyclical model of evaluation processes (Campbell et al., 2007).

An integration of process and outcome evaluations (Oakley et al., 2006).

The recognition of the potential need to tailor complex interventions to the local context (Campbell et al., 2007).

A greater use of theory (Shiell, Hawe, & Gold, 2008).

In 2008 an updated version of the MRC guidance for developing and evaluating complex interventions was published (see Figure 2) (Craig et al., 2008) which took into account some of these recommendations. The new MRC guidance involves four stages in the overall development and evaluation of complex interventions: development, feasibility and pilot testing, evaluation and implementation (Craig et al., 2008).

Having a theoretical understanding of how the intervention causes a behavioural change in the population of interest is crucial when developing and evaluating a complex intervention. The use of psychological and behaviour change theories were recommended by the NICE (2005) guidelines and the MRC guidance (Craig et al., 2008), but detailed guidance was not provided.
2.8.1 Developing a complex intervention

Before evaluating a complex intervention, the intervention should be at the stage where a worthwhile effect is expected. As Figure 2 demonstrates, there are three steps involved in the developmental phase:
1. **Identifying the evidence base:** involves identifying the existing evidence base surrounding the intervention and the methods used to evaluate it. During this step a systematic review can be conducted if an appropriate review does not already exist.

2. **Identifying and developing theory:** the existing evidence and theory are built on to further the theoretical understanding of the processes of change (e.g., the expected changes, how change will be achieved). If necessary, primary research can be conducted to enhance understanding of the target behaviour.

3. **Modelling processes and outcomes:** to assess the effectiveness of interventions, randomised trials are recognised as the ‘gold standard’. However, some trials demonstrate little or no effect and exploring the reasons why can highlight areas of improvement before conducting a more robust trial. For example, there are many aspects of an intervention which could influence the outcomes such as the skills and expertise of the person delivering the intervention or practitioner behaviour (Blackwood, O’halloran, & Porter, 2010) as well as implementation fidelity (Carroll et al., 2007). Consequently, prior to a larger trial, the modelling of the intervention can be beneficial for the refinement of the intervention and study design thus enabling any weaknesses to be identified and addressed.
2.8.1.1 The Behaviour Change Wheel

The Behaviour Change Wheel was designed to facilitate intervention developers in the transition from a behavioural analysis of the problem to intervention design (Michie et al., 2014; Michie et al., 2011). The Behaviour Change Wheel provides a systematic and transparent method for understanding the nature of the behaviour to be changed and for identifying the active ingredients of interventions that are likely to have an effect on changing the target behaviour (see Chapter 5.1.4). The Behaviour Change Wheel consists of three concentric circles whereby the inner circle contains the COM-B model (Michie et al., 2011). By using the COM-B model, the sources that maintain and/or prevent an individual from changing a behaviour can be identified. The middle circle is made up of nine intervention functions which can be used to address the problems identified using the COM-B model, and the outer circle has seven policy categories which are used to support the delivery of the intervention functions (see Figure 3).
The Behaviour Change Wheel (Michie et al., 2014; Michie et al., 2011) was developed from existing frameworks to incorporate important concepts and to overcome the limitations of the frameworks. A particular strength of the Behaviour Change Wheel is the recognition of the context within the ‘opportunity’ component of the COM-B model and its impact on behaviour. Understanding the context in which the target behaviour occurs can enhance the design and evaluation of the intervention. In addition, automatic processing
is included within the COM-B model which is an aspect missing from other models such as the Theory of Planned Behaviour (Ajzen, 1988; 1991). However, the Behaviour Change Wheel may not include all of the concepts important for all health-related behaviours and an element of judgement is required when choosing intervention functions and policy categories (Michie et al., 2014; Michie et al., 2011). This may result in different interventions for the same target behaviour depending on the intervention developers.

2.8.2 Feasibility and pilot testing

The second phase of the MRC guidance involves conducting a thorough feasibility or pilot study to overcome any problems of acceptability, implementation fidelity, recruitment and retention and smaller than expected effect sizes (Eldridge, Ashby, Feder, Rudnicka, & Ukoumunne, 2004). Contextual components which need to be understood include the characteristics of the population of interest, the extent of the problem (e.g., the incidence of the health condition) and those factors may which affect change (Campbell et al., 2007). A feasibility study does not need to be a full-scale study, but the testing of study aspects on a smaller scale is recommended when there is uncertainty about the potential viability of conducting a randomised trial (Eldridge et al., 2016). For example, undertaking process evaluations during a feasibility study enables the exploration of implementation fidelity. Process evaluations can provide valuable insights into why the intervention has been successful, has
failed or has produced unexpected consequences and how to maximise the intervention effects.

2.9 Chapter summary

In summary, pressure ulcers develop due to a combination of extrinsic (e.g., pressure, shear) and intrinsic (e.g., tissue tolerance) factors. Many people residing in nursing homes are at risk of developing a pressure ulcer. Whilst the precise proportion of avoidable pressure ulcers is unknown, it is widely believed that most pressure ulcers are avoidable and the elimination of pressure ulcers is a priority across all healthcare settings. There are national and international guidelines available to assist healthcare workers with the prevention of pressure ulcers, but the certainty of the evidence is low and this limits the recommendations in the guidelines. When research evidence is not fit for purpose, healthcare workers can feel uncertain about which practices to use resulting in their reliance upon experiential evidence. Moreover healthcare workers often report having a lack of time and resources as barriers to research-informed practice, as well as limited knowledge in accessing research findings.

Care bundles are complex interventions and were initially designed to improve the use of guidelines within intensive care units in hospital settings. Care bundles comprise of three to five research-informed practice elements, however defining and understanding how to implement these elements is key to
achieving intervention success. To facilitate understanding, the use of psychological and behaviour change theories are recommended. However there are a number of theories to choose from, many of which have overlapping constructs. The Behaviour Change Wheel was developed to aid the design of interventions and provides a systematic, theory-informed process for developing interventions. Therefore the Behaviour Change Wheel processes have guided the approaches taken within this thesis.

The Theoretical Domains Framework enables a thorough understanding of the barriers and facilitators of the target behaviour. The Theoretical Domains Framework can be mapped onto the COM-B model to facilitate our understanding of healthcare workers’ behaviours within a particular context. The Theoretical Domains Framework and the COM-B model underpin the Behaviour Change Wheel and may provide a useful framework for understanding the context of pressure ulcer prevention in nursing home settings. Whilst the Theoretical Domains Framework, COM-B model and Behaviour Change Wheel have been applied successfully across many healthcare contexts, to my knowledge they have not been used to aid the prevention of pressure ulcers in a nursing home setting.
2.9.1 The current thesis

It is widely believed, by community nursing teams and by others contributing to the pressure ulcer literature, that there is scope to improve the pressure ulcer prevention practices in nursing homes. Therefore, I set out to implement the aspects of best practice in the form of a research-based and theory-informed care bundle intervention which was co-designed with its intended users. In addition, I assessed the feasibility of using the care bundle intervention in practice. Within this thesis I present the developmental work needed prior to conducting a definitive trial of the effectiveness of the care bundle, which was beyond the scope of this research.

2.10 Aims and objectives of the research

2.10.1 Aims

To co-design, with tissue viability specialists and nursing home staff, a pressure ulcer prevention care bundle intervention and assess the feasibility of implementing it within nursing home settings.

2.10.2 Objectives

Guided by the MRC guidance for the development and evaluation of complex interventions (Craig et al., 2008), I have addressed eight key objectives:
Study 1 objectives

(1) To evaluate the effects of care bundles on patient outcomes and healthcare delivery by synthesising the current best research evidence.

(2) To identify effective approaches to care bundle implementation and to explore the factors that could plausibly modify the effects of care bundles (e.g., healthcare settings, fidelity with the care bundle, the number of care bundle elements, different implementation techniques) using evidence synthesis.

Study 2 objectives

(1) To understand the context of pressure ulcer prevention in nursing homes within Greater Manchester.

(2) To explore the potential barriers and facilitators to research-informed practices in nursing homes.

Study 3 objectives

(1) To develop the first theory and research-informed pressure ulcer prevention care bundle intervention specifically for use in nursing home settings.

Study 4 objectives

(1) To implement a care bundle intervention within a nursing home setting.

(2) To determine the feasibility of the care bundle intervention in relation to implementation fidelity and acceptability to staff.
(3) To determine the potential impact of the care bundle on the incidence of pressure ulcers.
Chapter 3. Research design

A paradigm is a set of beliefs and practices that influence a researcher’s selection of research questions and their choice of methods to answer the research questions (Kuhn, 1962; Morgan, 2007). This chapter presents the strengths and limitations of quantitative, qualitative and mixed methods research approaches, followed by the rationale for my choice in research design. This chapter finishes with a critique of my methodological decisions surrounding sampling, data collection, data analysis and rigour.

3.1 Qualitative research

Qualitative research methods stem from constructivist/phenomenological paradigms where time- and context-free generalisations are deemed neither possible nor desirable. Rather, knowledge is viewed as being embedded within, and as a product of, the individuals and their culture (Yardley & Bishop, 2015). Qualitative approaches focus on gaining a deeper and more subjective understanding of the social world and can produce rich detail about people’s experiences, which cannot be fully understood using closed-ended questionnaires (Corbin & Strauss, 2008; Plano Clark, Huddleston-Casas, Churchill, O’Neil Green, & Garrett, 2008).
Qualitative approaches can be used throughout the different stages of the research depending on the research questions (Craig et al., 2008; O’Cathain & Thomas, 2006). For example, qualitative research enables complementary insights into why an intervention may be effective or ineffective, allowing the identification of the aspects of the intervention that may need to be altered (e.g., Bradbury, Dennison, Little, & Yardley, 2015). Whilst qualitative research is sometimes criticised for small sample sizes and low generalisability (Castro, Kellison, Boyd, & Kopak, 2010), authors such as Denzin and Lincoln (1994) have argued strongly that issues such as statistical generalisability, reliability and validity are not relevant to qualitative research. Rather, qualitative research has the aims of gaining an understanding of individual experiences (e.g., Janson et al., 2017; Ritchie et al., 2016) and developing theory (Glaser, 2017).

3.2 Quantitative research

Quantitative research methods are associated with the positivist/empiricist or realist paradigms in which it is argued that knowledge is systematically observed and measured in a value-free and abstract manner (Guba, 1990; Roberts & Priest, 2010). Conclusions based on quantitative data are considered to be generalisable when the research has been conducted using a robust study design (e.g., randomised trial) to minimise the risk of bias (Eccles, Grimshaw, Campbell, & Ramsay, 2003). Thus quantitative researchers assume that there is a truth that can be measured and presented using numbers, often in the form of
statistics, to summarise and make inferences from samples to populations (Guba, 1990).

The aim when using quantitative research methods is often to collect data in tightly controlled experimental conditions using reliable measures (Yardley & Bishop, 2008). Castro et al. (2010) describes quantitative methods as being advantageous, as the targeted construct can be accurately measured and replicated; the strength of the associations between the variables can be evaluated; hypotheses can be tested and the groups can be compared. Quantitative researchers commonly test theories by stating specific hypotheses and collecting and analysing numerical data which may support or refute the hypotheses (Creswell, 2003). Moreover, quantitative research can enable the identification of causal relationships between variables and facilitate understanding in areas where there is uncertainty (Denzin & Lincoln, 1994).

Quantitative research has been accused of de-contextualisation as this approach is often associated with being detached from the real world context due to the belief in an objective reality (Moghaddam, Walker, & Harre, 2003). However, Kuhn (1970) argued that all research (including quantitative research) is conducted within a paradigm and human beliefs and perceptions contribute to all scientific inquiries. In choosing methods for data collection researchers make judgements and as a consequence the foundations of positivism have been
questioned (e.g., Feyerabend, 1978; Kuhn, 1970; Popper, 1959). Some have rejected positivism and moved towards a post-positivist stance (e.g., Phillips, 1990). Post-positivists acknowledge the value of using multiple research methods to provide an in-depth understanding of a phenomenon (Silverman, 2010; Thomas, 2003).

3.3 Mixed methods research

In the past, the selection of a research paradigm was considered a choice of two alternatives with researchers aligning with either quantitative or qualitative approaches (Creswell, 2003; Lincoln, Lynham, & Guba, 2011; Tashakkori & Teddlie, 1998). The epistemological origins of quantitative and qualitative paradigms have differences and relate to how the two approaches produce valid knowledge. The two paradigms were viewed as incompatible and this led to the ‘paradigm wars’ (Teddlie & Tashakkori, 1998). The ‘paradigm wars’ centred on the different philosophical assumptions and the view that the two paradigms could not be mixed due to their distinct underlying assumptions (Teddlie & Tashakkori, 2003). More recently it has become much less contentious to combine the two approaches (Creswell, 2015). Mixed methods research involves integrating the data collection, analysis and interpretation of quantitative and qualitative data within a study or programme of inquiry (Creswell, 2015; Johnson & Onwuegbuzie, 2004; Tashakkori & Teddlie, 2010).
Over time, both quantitative and qualitative approaches have been recognised as being important in the production of knowledge and a focus on taking a pragmatic approach to answering the research question involving a qualitative interpretation and a quantitative evaluation may be necessary (Yardley & Bishop, 2008). For example, a programme of research may aim to evaluate an intervention and therefore a quantitative approach is the most suitable to address issues such as bias and confounding. Depending on the quantitative study design (e.g., randomised trial), causal inferences may be possible. However to assess whether the intervention was relevant and acceptable to those using it, a qualitative approach would enable an in-depth exploration of any pertinent issues which may impact on the success of the intervention. Thus, integrating quantitative and qualitative data can greatly increase the value of mixed methods research (Bryman, 2006; Creswell & Plano Clark, 2011).

In recognising the advantages of using both quantitative and qualitative approaches, mixed methods research has become recognised in its own right (Johnson & Onwugebuzie, 2004; Tashakkori & Teddlie, 1998). Nevertheless, mixed methods research presents the challenge of how researchers can usefully employ and integrate both quantitative and qualitative research in a coherent manner that acknowledges the differences between the approaches.
3.3.1 Philosophical paradigms

The four paradigms typically discussed in relation to mixed methods research are pragmatism, transformative-emancipation, critical realism and dialectic (Creswell & Plano Clark, 2011; Freshwater & Cahill, 2013; Hesse-Biber & Johnson, 2013). Pragmatism acknowledges that there are a number of ways to interpret the world and the research methods used to collect and analyse data depend on the research question (Biesta, 2010; Bishop, 2015; Hesse-Bieber, 2015; Johnson & Onwuegebuzie, 2004; Sandelowski, 2014). Qualitative and quantitative research methods are viewed as complementary, as knowledge is produced by both approaches (Yardley & Bishop, 2015), disrupting the dichotomy of being either completely objective or completely subjective (Morgan, 2007; Shannon-Baker, 2016).

The transformative-emancipation approach focuses more on adopting specific value-based goals for research (Shannon-Baker, 2016). This approach emphasises the role of power, oppression and privilege through the research process (Mertens, 2003). Transformative-emancipation is commonly used with minority or marginalised groups to enact positive social change (see Mertens, 2010) and is not relevant within the context of this research.

The dialectic paradigm proposes the use of two or more paradigms together throughout the research process (Greene & Hall, 2010; Shannon-Baker, 2016).
The dialectic paradigm focuses on the different perspectives of each paradigm and can be used to address dissonant data (Mathison, 1988). Within this paradigm there are no hierarchies between the paradigms used, supporting the binding of potentially opposing perspectives (Burke Johnson & Stefurak, 2013). The dialectic paradigm is particularly suited to mixed methods research where the aim is to identify and legitimise differences in perspectives in order to provide a greater understanding and acceptance of the variations (Greene & Hall, 2010). Moreover, the dialectic paradigm is particularly suited to diverse research teams, as it promotes a continuous reflection and dialogue providing a framework within which teams can work together. The aim of this research was to gain a detailed understanding of the research-informed pressure ulcer prevention practices in a nursing home setting rather than to focus on the differences and contradictions between the data from different methods. Therefore, I felt that the dialectic paradigm with its focus on fragmentation and polarisation was not relevant here.

Within a critical realist view, quantitative research data can be used to overcome the limitations of qualitative research data and vice versa (Shannon-Baker, 2016). Both approaches can be used to gain a greater understanding of the study context (Maxwell & Mittapalli, 2010). Critical realism assumes a ‘post-positivist’ position (Trochim, 2006) and can bridge the gap between dichotomised quantitative and qualitative approaches. Within this paradigm a
realist ontology is accepted whereby a single external reality is assumed rather than multiple realities, but a constructivist epistemology is favoured (i.e. we access and understand reality from our own perspectives which will be incomplete, imperfect and influenced by our own assumptions) (Maxwell, 2012). Thus, an important feature of critical realism is the detachment of epistemology from ontology (Maxwell, 2012). Finally, critical realism allows process-based causal inferences, emphasising the perspective taking and individual views whilst also recognising that these are only partial representations of an objective reality (Maxwell & Mittapalli, 2010). This is not possible with the other three perspectives detailed (Shannon-Baker, 2016), thus I have adopted a critical realist position.

3.3.2 Strengths and limitations of mixed methods research

Data can be collected and analysed concurrently or sequentially and integrated, enabling inferences to be drawn (Creswell et al., 2003; Tashokkori & Creswell, 2007). Some authors have argued that a greater and more nuanced understanding of a field is derived from the combination of quantitative and qualitative findings (Creswell et al., 2003; Johnson & Onwuegbuzie, 2004; Morgan, 2007). For example, Evans, Snooks, Howson and Davies (2013) conducted a mixed methods study to facilitate their understanding of the role of research in the decision-making of commissioners and service managers when implementing and evaluating policy. The mixed methods approach involved
collecting quantitative data using a questionnaire which provided an overview of the participants’ views and their experiences of decision-making within local health boards. Following the analysis of the quantitative data, Evans et al. (2013) conducted qualitative, in-depth interviews to explore the important issues further. The study authors explained that the mixed methods approach enhanced their interpretation of the findings due to the greater exploration of the topic using the qualitative approach (Evans et al., 2013).

Convergent, complementary or dissonant quantitative and qualitative data can provide greater insights into a phenomenon (Moffatt, White, Mackintosh, & Howel, 2006; Tonkin-Crine et al., 2016). For example, if the findings derived from different data collection methods, including quantitative and qualitative methods, are convergent (i.e. they agree), there is strong evidence for a single conclusion. If discrepancies exist (i.e. data are dissonant), the researcher will have gained a greater knowledge about the phenomenon facilitating the appropriate conclusions (Farmer, Robinson, Elliott, & Eyles, 2006; Miles & Huberman, 1994). A recent example within the literature is provided by Tonkin-Crine et al. (2016) who conducted a process evaluation of a cluster-randomised trial to evaluate the effectiveness of two interventions which aimed to decrease the number of antibiotic prescriptions for an acute cough given by general practitioners (Little et al., 2013). The process evaluation involved the sequential collection of quantitative and qualitative data relating to the views of
the general practitioners and patients about the interventions (Tonkin-Crine et al., 2016). The findings demonstrated dissonance between the views of the general practitioners and patients. The general practitioners reported that explaining the blood test result was useful and important in persuading the patient that a non-antibiotic approach to treatment was appropriate; whereas the patients reported that this was unnecessary if the general practitioner explained what the acute cough was, as well as what the non-antibiotic approach entailed. Thus, these two opposing views provided greater insight and a more holistic understanding of antibiotic prescriptions for an acute cough in general practice (Tonkin-Crine et al., 2016).

3.3.3 Rationale for the mixed methods approach taken

An explicit rationale for the use of mixed methods research is believed to be vital (Creswell, 2015). Greene, Caracelli and Graham (1989) analysed 57 empirical mixed methods studies and identified five main reasons for employing a mixed methods research design, including:

1. **Triangulation**: seeking to combine the quantitative and qualitative findings to strengthen the validity of the findings.

2. **Complementarity**: seeking elaboration and clarification of the findings from one method (e.g., quantitative) using the results from another (e.g., qualitative).
3. *Development:* using the findings from one method to develop/inform another.

4. *Initiation:* seeking to support or refute findings from one method by using another method.

5. *Expansion:* expanding the range of inquiry through the use of different methods.

Within this thesis I report on the development of a pressure ulcer prevention care bundle intervention which I co-designed with key stakeholders prior to assessing the feasibility of implementing the care bundle intervention in a nursing home setting. I had a number of research questions and consequently a wide range of methods were required and a mixed methods approach was the most appropriate research design.

### 3.3.4 Integration

Within mixed methods research, integration involves combining the quantitative and qualitative components of a study (O’Cathain, Murphy, & Nicholl, 2010). Researchers can integrate the two approaches in a number of ways and the approach taken will depend on the research question. According to Fetters, Curry and Creswell (2013), integration should occur throughout the whole research process. Therefore, Fetters et al. (2013) recommend integrating the qualitative and quantitative approaches during the design of the study, the
data collection and analysis and throughout the reporting of the research. Thus, I will now discuss the suitability of the mixed methods research designs for this research and explain how I planned to integrate the two approaches during the various phases of the research.

3.3.5 Mixed methods designs

A plethora of mixed methods designs is available for researchers to choose from but selecting the design can be challenging and depends upon the aim of the research. According to Creswell (2003) once the research question has been developed, choices regarding the integration of the data will impact on the choice of study design and how the data are collected. When choosing the strategy for data collection in mixed methods research, Creswell (2003) describes four considerations:

1. *Implementation* refers to whether data will be collected concurrently or sequentially. Within concurrent data collection both methods are implemented simultaneously, whereas researchers using sequential methods choose which is collected first depending on the aim of the research. For example, where the aim is to explain a topic, a quantitative questionnaire may be conducted followed by qualitative data collection to expand on the quantitative findings.

2. *Priority* is given to the qualitative or quantitative strategies depending on the aim of the research and sometimes both may be given equal weighting.
3. *Integration* refers to how the researcher combines the data. Integration can occur during the data collection, analysis or interpretation phases and is influenced by whether concurrent or sequential data collection methods are used. When concurrent methods are used, findings are integrated during the interpretation of the findings. In contrast, when using sequential data collection methods quantitative findings may inform the qualitative aspects of the research study or vice versa.

4. The *theoretical perspective* guides the research design and may be explicit and independent of the three aforementioned considerations.

To summarise, there are two main considerations when designing mixed methods studies. Firstly, quantitative or qualitative data can be given priority or receive equal weighting; and secondly whether the methods will be employed sequentially or concurrently. Below I present and discuss three basic mixed methods designs (convergent, explanatory sequential and exploratory sequential) and two advanced designs (multistage evaluation, embedded intervention) based on those provided by Creswell (2015) and Creswell and Plano Clark (2011).
3.3.5.1 Basic mixed methods designs

The convergent design

The convergent design, also known as convergent parallel or concurrent triangulation (Creswell & Plano Clark, 2011; Creswell et al., 2003), addresses an overarching research question which aims to give a greater understanding of the study topic (Doyle, 2015). Qualitative and quantitative data are assigned equal weighting and are collected concurrently before integration occurs in the analysis phase. Simultaneous data collection enables the two approaches to complement each other (Tashakkori & Teddlie, 1998) and is advantageous as the influence of time on the data will be limited (Doyle, Brady, & Byrne, 2016).

The explanatory sequential design

In this design, data collection and analysis occur sequentially and priority is given to the quantitative data. This study design usually begins with the collection and analysis of the quantitative data which informs the subsequent qualitative phase. Data collection can be time-consuming and participants may not be accessible in the next phase. The final study included within this thesis, which assessed the feasibility of implementing a pressure ulcer prevention care bundle intervention in a nursing home setting, employed an explanatory sequential design (Chapter Nine). The quantitative data informed the collection of qualitative data and increased my understanding of how feasible it was to implement a care bundle intervention.
The exploratory sequential design

The exploratory sequential design begins with the collection and analysis of the qualitative data followed by a quantitative phase (Onwuegbuzie, Leech, & Collins, 2010). This design is often used to explore a phenomenon as the quantitative data assist with the interpretation of the qualitative data. For example, quantitative findings from a questionnaire can be used to increase the generalisability of the data from the qualitative interviews. Priority can be given to either the qualitative or quantitative phases depending on the purpose of the study.

3.3.5.2 Advanced mixed methods designs

Advanced mixed methods designs involve adding one of the three basic designs to a larger framework. For example, when designing and evaluating an intervention, the research may involve a number of stages which contribute to a larger body of evidence. As this thesis presents a wider programme of research, the basic mixed methods designs did not suffice for the overall data integration. A more advanced mixed methods design was required for this research overall. Currently there are four advanced mixed methods designs. However two of these mixed methods designs are more appropriate for case studies and participatory research and are not relevant to this research, therefore I will discuss only two designs.
The embedded intervention design

The embedded intervention design is also known as the experimental intervention design (Creswell, 2015). A qualitative phase is embedded within an intervention study and can be used to overcome some of the challenges associated with conducting experimental research. For example, process evaluations can be conducted to gain an understanding of how and why an intervention may be successful (e.g., Roberts et al., 2016; Tonkin-Crine et al., 2016). Qualitative data collection and analysis can occur before, during and/or after the intervention (see Figure 4) (Creswell, 2015).

Multistage evaluation design

Within a multistage mixed methods design, researchers use multiple stages of data collection, which can include a combination of explanatory sequential, exploratory sequential and convergent approaches (Nastasi et al., 2007). Where there is a sequential component, there must be three or more stages and two or more stages if there is a convergent component. Thus, this design is particularly suited to longitudinal research (Fetters et al., 2013).

This thesis contains four sequential studies which have contributed to the overall understanding of preventing pressure ulcers in nursing home settings. Thus, as Figure 5 demonstrates, the multistage evaluation design appears to be the most appropriate for the needs of this work.
Figure 4. An example of the embedded intervention mixed design.

Figure 5. An example of the multistage evaluation design used within this research.
3.3.6 Phases of the research

Tashakkori and Creswell (2007) proposed that mixed methods research studies can utilise and integrate quantitative and qualitative approaches in the following ways:

- By developing two types of research questions which require different methodological approaches.
- By employing two types of sampling procedures such as purposive sampling for qualitative approaches and probability sampling for quantitative methods.
- By using two types of data collection procedures, for example focus groups and questionnaires.
- By having two types of data (e.g., numerical and non-numerical).
- By conducting two types of data analysis such as statistical and thematic analysis.
- By having two types of conclusions, for example objective and subjective, a greater understanding of the phenomenon is possible.

I will now discuss the various stages involved in the processes of this research and where appropriate, consider how I integrated both the qualitative and quantitative approaches.
3.3.6.1 Sampling

Sampling is the process by which participants are selected to take part in research because they represent the population of interest (Burns & Grove, 2005). Usually inclusion and exclusion criteria are applied and the sample will be a subset of the population of interest. The strategies used for sampling often depend on whether qualitative or quantitative methods are being used.

Probability sampling can be used for quantitative research whereby a random selection of participants is used to draw a sample that is representative of the wider population. If the sample is not representative, Type I and Type II errors may occur. A Type I error occurs when a true null hypothesis is rejected; whereas a Type II error is the failure to reject the null hypothesis when it is false (Bowling, 2009).

Within qualitative research, non-probability sampling is conducted whereby the participants are chosen deliberately on the basis of their characteristics (e.g., the presence of a particular health condition, their area of professional expertise). Thus, the participants are not representative statistically of the population of interest (Ritchie, Spencer, & O’Connor, 2003). There are a number of non-probability sampling techniques which can be used including:

- *Purposive sampling*: involves selecting individuals with particular characteristics from a population of interest enabling the research questions to be answered (Coyne, 1997; Creswell, 2007).
- **Variation sampling**: covers a broad range of perspectives.

- **Criterion sampling**: includes participants or settings which meet specified criteria.

- **Theoretical sampling**: a technique usually used with grounded theory (Charmaz, 2006) as certain participants are sought to explore new concepts emerging from the data (Corbin & Strauss, 2008; Marshall, 1996). Theoretical sampling can also be used to test a particular theory.

- **Snowball sampling**: a technique that can be used when a target group is difficult to reach (Howitt & Cramer, 2005). Existing participants help the researcher to identify new participants (Coyne, 1997; Maxwell, 2012), although this can limit the breadth of the views and experiences accessed (King & Horrocks, 2010).

- **Convenience sampling**: the least resource-intensive sampling technique as those individuals most accessible to the researcher are selected. However, this sampling technique has been criticised for a lack of rigour and the production of poor quality data (Marshall, 1996).

As I have taken a mixed methods approach with an exploratory focus, I have used qualitative sampling techniques. I have conducted purposive sampling as I wished to include the individuals who regularly provided pressure ulcer prevention care in nursing homes. However for pragmatic reasons, namely location and a willingness to participate, only the individuals who worked in particular nursing homes or the affiliated NHS trust were eligible to participate.
As I did not aim to produce generalisable findings from the mixed methods research and I provided clear and explicit inclusion and exclusion criteria, I believe that my deliberate sampling choices were appropriate (Ritchie et al., 2003). For the systematic review I aimed to have a comprehensive sample and included all eligible studies (see Chapter Four).

3.3.6.2 Data collection

Depending on the research question and the subsequent choice of research design, a mixed methods study may have many points of integration. Integration can occur through linking the methods of data collection and analysis by:

- **Connecting**: sampling links one type of data with another (e.g., participants are invited to participate in a research interview because they completed a research survey).

- **Building**: findings from one data collection method inform subsequent data collection approaches.

- **Merging**: findings from each method are brought together and compared.

- **Embedding**: data collection and analysis are linked at multiple points and may involve connecting, building and/or merging.

Data integration occurred throughout the projects described in this thesis using connecting, building and merging processes. For example, I collected and merged both the quantitative and qualitative data in the feasibility study.
reported in Chapter Nine to gain a greater understanding of how the care
bundle intervention was used in practice. I will now discuss the important
issues relating to data collection.

3.3.6.2a Sample sizes and data saturation

Traditionally, qualitative studies have smaller sample sizes when compared
with quantitative studies (Creswell, 2009). Within quantitative research a larger
sample size can reduce the risk of a sampling error which can arise from an
unrepresentative sample and may lead to a Type I or Type II error. Therefore,
power calculations are conducted prior to recruitment to determine the sample
size required to answer the research question and avoid making a Type I or
Type II error (Jones, Carley, & Harrison, 2003). Within this programme of
research I conducted two quantitative research studies. The first study aimed to
reach a consensus about the content of the care bundle via voting (Chapter
Eight) and the second study was a feasibility study which assessed
implementation fidelity and adherence to the care bundle intervention (Chapter
Nine). Thus, I did not require a sample size large enough to reach statistical
significance.

Within qualitative research, data saturation is used to determine sample size
(Francis et al., 2010; Mason, 2010). Data saturation refers to the point when the
data collected do not contribute any new information to the existing or
emerging themes, findings or concepts (Francis et al., 2010; Glaser & Strauss, 1967). Thus, additional participants would result in data repetition (Ritchie et al., 2003). If researchers do not make full use of the data, this becomes an ethics issue relating to wasting a participant’s time and research funds (Francis et al., 2010). Equally, small samples sizes can result in findings that are non-transferable and not representative of the population they are taken from (Francis et al., 2010). However, a number of factors including the heterogeneity of the population (Ritchie et al., 2003) and the phenomenon under investigation (Morse, 2000) can influence data saturation. Thus the size of the sample is an important issue in qualitative data, yet there is limited practical guidance advising researchers when data saturation has been achieved (O’Reilly & Parker, 2013).

Francis et al. (2010) developed four principles to guide data saturation decisions in theory-based interview studies. As the Theoretical Domains Framework guides a large part of work described in this thesis, I applied these principles to the data analyses described in the qualitative studies (Chapters Seven and Nine). Within the research protocols I predefined both the ‘initial analysis sample’, which is the minimum number of participants required for the initial analysis, and the ‘stopping criteria’ (i.e. the number of additional interviews that needed to be conducted without new data emerging before confirming that data saturation had been achieved). Francis et al. (2010) suggest an initial
sample size of 10 and a stopping criterion of 3 (the 10 + 3 criterion). Guest, Bunce and Johnson (2006) conducted 60 interviews across two African countries and documented their theme identification progress. Guest et al. (2006) reported that 97% of the important codes had emerged within the first 12 interviews and concluded that 12 interviews were sufficient for data saturation. Thus, the 10 + 3 criterion based on Francis et al. (2010) appeared appropriate for the theory-based analysis within this research. However, the 10 + 3 criterion was developed based on studies exploring three theoretical constructs (attitudes, subjective norms, perceived behavioural control). As the Theoretical Domains Framework contains 84 constructs across the 14 domains (compared with three constructs), I was aware that data saturation may take longer and a larger sample size may be necessary. Additional factors may also drive data saturation including study design, the study population (i.e. if the study participants are heterogeneous) and the problem under investigation (Atkins et al., 2017). These differences in data saturation may be reflected in the various sample sizes of similar studies also informed by the Theoretical Domains Framework (e.g., Alexander, Brijnath, & Mazza, 2014; Birken, Presseau, Ellis, Gerstel, & Mayer, 2014; Patey, Islam, Francis, Bryson, & Grimshaw, 2012; Tavender et al., 2014).
3.3.6.2b Qualitative data collection

Data collection can include a range of different methods including interviews, focus groups and observations. Conducting observations enables data to be collected and generated within the naturally occurring environment (Silverman, 2005). Therefore, observations can be useful in exploring and understanding day-to-day practices in a variety of settings (Guest, Namey, & Mitchell, 2013). However, observers may misinterpret the actions of the participants (Corbin & Strauss, 2008). In addition, being observed can influence the behaviour of the participants resulting in the ‘Hawthorne’ effect, whereby participants alter their behaviour due to being observed (Mays & Pope, 1995; McCambridge, Witton, & Elbourne, 2014). Whilst observations can increase our understanding of behaviours, I did not deem observations appropriate in the context of this research. I wished to gain an in-depth understanding of pressure ulcer prevention in nursing homes, the barriers and facilitators to research-informed practice and the perspectives of those using the care bundle intervention.

Focus groups are group discussions organised and facilitated to explore specific topics under investigation (Kitzinger, 1994). The emphasis on the dynamics of the group is a distinctive feature of focus groups and can be useful for gathering large volumes of data from multiple participants, as well as capturing convergent and divergent views in real time (Rabiee, 2004). The group element can be advantageous as the participants discuss their experiences and others are
able to comment and build on these descriptions (Kitzinger, 1994; Liamputtong, 2011). Moreover, through the participants’ interactions, it is possible to identify the areas of agreement or disagreement among the participants (Kitzinger, 1994). However, focus groups can be influenced by dominant participants and it is not always possible to gain an in-depth understanding of a particular topic or specific sub-elements (Carlsen & Glenton, 2011; Krueger, 1994; Mansell, Bennett, Northway, Mead, & Moseley, 2004). As I wished to explore, in-depth, individual views on specific topics I conducted one-to-one interviews with participants. Typically, interviews fall under one of three categories: structured, semi-structured or unstructured, and the philosophical approach taken by the researcher can guide decisions regarding the most appropriate interview to conduct (Edwards & Holland, 2013).

Within a structured interview the questions are pre-set and the interviewer does not deviate from the interview schedule. However, such an inflexible approach may result in data which lacks detail. In contrast, the unstructured interview is highly flexible and the questions can be adapted depending on the participant’s response. Due to the in-depth nature of unstructured interviews, the interviewer can probe for further details and clarification (Low, 2013).

Semi-structured interviews involve a flexible and open-ended approach, enabling a focus on individual experiences (King & Horrocks, 2010). Topic
guides can be used to prompt and explore the perspectives of interviewees but a non-judgemental stance is required to allow the participants to elaborate in a manner that is not influenced by the researcher (King & Horrocks, 2010). In line with the critical realist perspective the interviewer can use theory to guide the questions but judges which questions are likely to be appropriate in the context of the interview and can probe for depth and clarification (Maxwell, 2012). Due to the structured but flexible approach, and in line with the aims and objectives of this research, I conducted semi-structured interviews to explore the barriers and facilitators to pressure ulcer prevention in nursing homes (Chapter Seven) and the qualitative findings informed the development of the intervention (Chapter Eight). I also conducted semi-structured interviews with the nursing home care staff to gain an understanding of their experiences of using the care bundle intervention (Chapter Nine).

3.3.6.2c Quantitative data collection

Quantitative data collection usually involves the collection of data that can be measured and quantified using numbers or values. Quantitative data can be collected prospectively or retrospectively (e.g., Gaal et al., 2011; Middleton et al., 2016; Wallin, Gustavsson, Ehrenberg, & Rudman, 2012). Prospective studies take place over time (e.g., longitudinal studies). In contrast, retrospective studies involve the collection of data about an event that occurred in the past.
Consequently retrospective studies are at risk of recall bias and error; thus, prospective studies are preferable (Vandenbroucke, 2008).

Throughout this research I used a number of quantitative data collection methods. Questionnaires and surveys are commonly used to collect quantitative data (Baker et al., 2015; Krause et al., 2014) and are advantageous as they can be an inexpensive tool for gaining data from a large and diverse sample. I used questionnaires to collect the demographic information from the participants (e.g., age and qualifications). The demographic questionnaires allowed me to quickly and easily capture this brief descriptive data where in-depth and specific contextual information were not necessary. During the workshop where I co-designed the care bundle intervention (Chapter Eight), I collected the quantitative data using a consensus method that is outlined in more detail in Chapter Five. Finally, in the feasibility study (Chapter Nine), I conducted an uncontrolled before-after study and collected data detailing the pressure ulcer incidence rates and the behaviours of the healthcare workers in relation to the care bundle intervention. Uncontrolled before-after studies are subject to several potential biases such as selection bias (i.e. there may be differences between the baseline characteristics of each of the comparison groups) and performance bias (i.e. the comparison groups may be exposed to additional factors that are not part of the intervention) (Portela, Pronovost, Woodcock, Carter, & Dixon-Woods, 2015; Trochim, 2006). Thus, it is not
possible to draw firm conclusions about cause and effect from uncontrolled before-after studies (Effective Practice and Organisation of Care, 2014). Nevertheless, an uncontrolled before-after study is practical and a suitable approach for assessing the feasibility of using the care bundle intervention within the context of this research.

3.3.6.3 Data analysis

In general, qualitative research is typically more aligned with inductive data analysis whereby ideas emerge from the data (Pope, Ziebland, & Mays, 2000). In contrast quantitative research is usually associated with deductive data analysis which can involve the testing of hypotheses to support or refute an idea (Creswell, 2013). However, qualitative and quantitative research can employ both inductive and deductive data analysis procedures (Pope et al., 2000; Rashidian, Eccles, & Russell, 2008).

3.3.6.3a Qualitative data analysis

When analysing qualitative data, different approaches can be used and the most suitable method depends on the aim of the study. For example, those concerned with social interaction and language may use discourse analysis (Fairclough, 2010) or ethnomethodology (Garfinkel, 1996). Researchers aiming to develop a theory derived from the data may apply grounded theory (Charmaz, 2006; Glaser & Strauss, 1967). Interpretative phenomenological analysis (Smith,
Flowers, & Larkin, 2009) aims to explore and understand people’s experience of a particular phenomenon (e.g., preventing pressure ulcers in nursing home residents) with a focus on how they ascribe meaning to their experiences (Smith et al., 2009). However, Interpretative Phenomenological Analysis focuses on an individual’s unique experience and I did not deem this to be appropriate for achieving the aim and objectives of this research. Moreover, specific epistemological, philosophical or theoretical approaches underpin these analysis methods (Crotty, 1998) which may make the integration of the various data more difficult. Another approach to data analysis is the framework method which is not aligned with such specific underpinnings; rather it is viewed as an adaptable and flexible method that can be used with qualitative data (Gale, Heath, Cameron, Rashid, & Redwood, 2013). In addition, the framework method does not have an allegiance to either inductive or deductive thematic analysis and the approach taken depends on the research question (Gale et al., 2013).

Framework analysis was developed as a pragmatic approach to exploring real-world phenomena (Ward, Furber, Tierney, & Swallow, 2013). It is considered to be an explicit approach to data analysis (Ram, Campling, Grocott, & Weir, 2008) with transparent results and conclusions that are true to the original data (Johnston et al., 2011). It is a rigorous and transparent method for the charting of coded data using analytical matrices (Ritchie et al., 2003). Similarities and
differences in the data are identified and descriptive and/or explanatory conclusions are assembled around the themes. The defining feature of framework analysis is the matrix output which includes the participants as rows, the codes as columns and the cells of summarised data (Dixon-Woods, 2011). The matrix also provides a structure to the data, assisting the researcher to systematically reduce the data and analyse the data by participant and code. It is also a flexible process facilitating the ease of data retrieval (Swallow, Lambert, Santacroce, & MacFadyen, 2011). However, the framework method has been criticised for not having a theoretical basis (Smith, Bekker, & Cheater, 2011) and is not suitable for highly heterogeneous data (Gale et al., 2013).

Using thematic analysis to describe the themes (Braun & Clarke, 2006), the framework method facilitates comparisons between and within the data whilst retaining context and individual perspectives. Thus, throughout the qualitative aspects of this research I used the framework method and followed the guidance provided by Gale et al. (2013) as they provide clear illustrations of how to apply the method in practice. The method involves the following seven iterative steps:

**Stage 1: Transcription**

The interviews were audio recorded and notes were taken after the interview. Verbatim transcription was conducted to capture the content of each interview
word for word (Poland, 1995). When applying the framework method all of the conventions of dialogue (e.g., pauses) do not always need to be included within the transcript as the content of the interview is the focus (Gale et al., 2013).

When the researcher transcribes the data from focus groups and interviews, transcription is often regarded as the first step in the qualitative data analysis (Easton, McComish, & Greenberg, 2000). The researcher becomes immersed in the data (Wray, Markovic, & Manderson, 2007) which increases their familiarity with the data (Bailey, 2008) and this is important for the next stage. However, mistakes during the transcription stage, including transcription errors or incorrect punctuation, can alter the meaning of the data (Easton et al., 2000) and lead to misinterpretations. Such mistakes can be minimised if the person transcribing the interviews also conducted them (Gale et al., 2013). Thus, I decided to transcribe all of the interviews conducted as part of this research. In line with the guidance provided by Gale et al. (2013), I included wide margins and good line spacing to allow for the coding and note taking. It is advisable for two people to transcribe the interviews independently and compare agreement (Kvale, 1996). However, this was not feasible due to the resources that this would require (e.g., time). Instead I checked the accuracy of the transcription against the original recorded interview.
Stage 2: Familiarisation with the interview

During this stage the researchers immerse themselves in the data (Srivastava & Thomson, 2009). Data include the interview data (audio recordings and transcriptions) and any contextual or reflective notes. Familiarisation with the data was facilitated by conducting all of the interviews and transcriptions myself. I read and re-read the transcripts and notes, and also listened to the audio recordings multiple times. This was an iterative process and I noted any emerging ideas and recurrent themes. One margin was used to document any thoughts and analytical notes (Gale et al., 2013).

Stage 3: Coding

I read each of the transcripts line-by-line and applied a ‘code’ (label) to describe the salient aspects of each passage and/or sentence. This classification of data allowed me to systematically compare the whole dataset and the line-by-line coding enabled a deeper analysis of the data as it facilitated the identification of any anomalies. Within qualitative research, researchers must decide whether to manually code the data or use computer-assisted methods and a combination of approaches may be used depending on the project size and the time available (Basit, 2003). Computer assisted qualitative data analysis software can be a useful way to keep track of new codes (see Chapter 3.3.4.3b). However, during the early stages I coded with a pen and paper and used the computer assisted
qualitative data analysis software in stage 5. During this stage I maintained a reflexive journal to record my decisions regarding the data.

The approach described above is known as inductive coding, which is ‘open-ended’ and exploratory by nature. To allow theories to emerge from the raw data, a code that the researcher feels may be relevant or may become relevant is applied to all of the data (Saldana, 2009). As recommended by Gale et al. (2013), I took an inductive approach to enable the exploration of unexpected codes and themes within the data. I then repeated the process using the more structured approach of deductive analysis whereby I coded the data using the predetermined codes from the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005).

Stage 4: Developing a working analytical framework

After coding the first five transcripts I developed a working analytical framework to structure the process using the Theoretical Domains Framework. As qualitative data can have multiple meanings which can be interpreted in a variety of ways, having a second coder can enhance the reproducibility of the study findings if they also independently code the data and report similar findings (Campbell, Quincy, Osserman, & Pedersen, 2013). I met with a second coder (a research colleague), who coded all of the transcripts, to discuss and compare the codes assigned and we agreed a set of codes to apply to all of the
subsequent transcripts. Developing the analytical framework was an iterative
process. As the data collection progressed, the codes continued to be grouped
into clearly defined categories until no new codes emerged and the coding of
the final transcript was complete (Gale et al., 2013).

Stage 5: Applying the analytical framework

During this stage I applied the categories and codes developed during the
working analytical framework to all of the transcripts. Computer assisted
qualitative data analysis software facilitates the management of large data sets
through the use of nodes and coding trees (Saldana, 2009). This is particularly
useful when taking a deductive approach to data analysis as the software can
help to reduce the complications associated with organising data into
hierarchies (Saldana, 2009). The researcher is able to sort and manage the data
easily and quickly locate any materials. However the software does not conduct
data analysis or interpretation, and the responsibility of the analysis remains
with the researcher who is crucial in the analytic process (Silverman, 2005;
Thorne, 2000).

Historically there have been concerns that computer assisted qualitative data
analysis that can count the frequencies of the codes in the data might encourage
a more quantitative analysis of the qualitative data (Kelle, 1995; Lee & Fielding,
1991; Weaver & Atkinson, 1994). The more recent discourse has been related to
the appropriate and effective use of the software which requires methodological knowledge and analytic skills (Silver & Woolf, 2015). Transparency is regarded as essential for the conduct and analysis of qualitative research (Lincoln & Guba, 1985). Some have argued that rigour can be improved through the use of software (Richards & Richards, 1991). Computer assisted qualitative data analysis software packages enable researchers to closely examine the data (Creswell, 2007) using a transparent data analysis process, generating a reliable review of the data (Morison & Moir, 1998; Richards & Richards, 1991). However, using software to improve the reliability and provide robust methodology is very user-dependent.

I used NVivo 10 (QSR International, Australia) (Chapter Seven) and NVivo 11 (QSR International, Australia) (Chapter Nine) during this stage. NVivo can be used for complex searches of the data and theory testing and supports a non-linear approach to qualitative research (Sinkovics & Alfoldi, 2012) which facilitated the easy retrieval of data within this research.

Stage 6: Charting data into the framework matrix

This stage involved managing and reducing the data by producing a summary in the form of a matrix (i.e. a spreadsheet) enabling a better understanding of the data. The data were summarised by category and ‘charted’ into the matrix. However, retaining the true meaning of the data can be challenging whilst
trying to reduce the data. The matrix involved illustrative quotes from the participants and the framework method facilitated a clear audit trail where decisions at each stage of the analysis could be followed clearly.

Stage 7: Interpreting the data

During this stage I interpreted the key themes by comparing and contrasting the data and this led to the findings presented in Chapters Seven and Nine.

3.3.6.3b Quantitative data analysis

Strategies of inquiry within quantitative research include descriptive, causal and correlational analyses (Parahoo, 2006; Burns & Grove, 2005). Descriptive statistics present accurate accounts of the situations as they naturally occur (e.g., individual characteristics, frequencies of events) (Burns & Grove, 2005). Causal analyses aim to identify whether causal relationships exist by examining the differences between exposed and unexposed individuals for pre-determined dependent variables (Cochrane Community, 2017). In contrast, correlational research is interested in the potential relationships between variables and within the analysis the strength of the association can be measured.

Usually descriptive statistics precede inferential statistics, but as I was not concerned with inferring cause and effect or identifying relationships, I have presented descriptive statistics when discussing the outcomes of the voting in
Chapter Eight and the implementation fidelity in Chapter Nine. To provide a simple summary of the findings I have used percentages, interquartile ranges and incidence rates. As part of the systematic review I conducted a meta-analysis and I have discussed the specific aspects of this data analysis in Chapter Four.

The integration of data can occur during the interpretation level whereby meta-themes are presented using findings from both qualitative and quantitative methods (O’Cathain et al., 2010). According to Fetters et al. (2013) integration during this phase can occur through three approaches:

1. *Integrating through a narrative*: qualitative and quantitative findings are presented in a single or series of reports using one of the following approaches:
   - *Weaving*: themes or concepts are used to discuss both the quantitative and qualitative findings.
   - *Contiguous*: the qualitative and quantitative findings are presented in different sections of a single report.
   - *Staged*: the results of each phase are reported and published separately.
   
   Thus, this approach suits the multistage evaluation mixed methods research design.

2. *Integrating through data transformation*: if data are integrated using data transformation, qualitative data are converted into quantitative data (or
vice versa) and integrated. For example, the frequency of codes within qualitative data can be presented in the quantitative database.

3. **Integrating through joint displays:** researchers can use joint displays to integrate findings whereby data are presented together visually (e.g., using a graph).

Within the results chapters of this thesis (Chapters Six to Nine), the data are integrated through a narrative using a *staged approach* as the analyses were conducted separately (Fetters et al., 2013). However during Chapter Ten, I integrated the overall findings from the research using a *weaving approach*.

### 3.3.7 Rigour within mixed methods research

Rigour can be said to be related to the extent to which a study demonstrates integrity and competence (Tobin & Begley, 2004). The philosophical position underpinning the research influences the assessment of rigour. For example, reliability and validity are regarded as the key features of quantitative research (Noble & Smith, 2015; Rolfe, 2006). Reliability refers to whether the findings can be replicated and validity refers to the extent to which the findings are likely to be true (Cochrane Community, 2017) (see Table 5). However, some question how appropriate the terms reliability and validity are within qualitative research due to the epistemology and ontology of the paradigms being semantically incompatible (Hamberg & Johansson, 1999). This debate has led to the development and adoption of new criteria to determine the reliability and
validity of qualitative research which include rigour and trustworthiness (Lincoln & Guba, 1985). Lincoln and Guba (1985) proposed four ‘trustworthiness’ criteria for the assessment of rigour within qualitative research (see Table 5). Central to assessing the rigour of both quantitative and qualitative research are procedural fidelity and the quality of the methods employed (Maxwell, 2012). Thus, I will use the term ‘rigour’ from now on.
Table 5

*Rigour criteria for quantitative and qualitative research (adapted from Lincoln & Guba (1985) and the Cochrane Community (2017))*

<table>
<thead>
<tr>
<th>Quantitative research studies</th>
<th>Qualitative research studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal validity:</strong></td>
<td><strong>Credibility:</strong></td>
</tr>
<tr>
<td>- How likely the results are to be true for the people within the study.</td>
<td>- Authentic representations and accounts of the data.</td>
</tr>
<tr>
<td><strong>External validity:</strong></td>
<td><strong>Transferability:</strong></td>
</tr>
<tr>
<td>- How likely the results are to hold true for people not in the study.</td>
<td>- Sufficient detail is provided for the reader to determine the applicability of findings.</td>
</tr>
<tr>
<td><strong>Reliability:</strong></td>
<td><strong>Dependability:</strong></td>
</tr>
<tr>
<td>- How likely it is that repeated studies would give the same results.</td>
<td>- Explicit and systematic information regarding the methodological decisions.</td>
</tr>
<tr>
<td><strong>Objectivity:</strong></td>
<td><strong>Confirmability:</strong></td>
</tr>
<tr>
<td>- Freedom from bias.</td>
<td>- Results are linked to the data.</td>
</tr>
</tbody>
</table>

There is some disagreement within the literature regarding whether the rigour of the qualitative and quantitative components of mixed methods research should be appraised separately (O'Cathain, 2010). However, there is agreement on the importance of transparent descriptions of the research processes.
including data collection, data analysis, interpretation and integration (Bryman et al., 2008; O’Cathain, 2010; Wisdom, Cavaleri, Onwuegbuzie, & Green, 2012). Thus, establishing rigour in mixed methods research can be complex and challenging and requires careful consideration.

According to Giddings and Grant (2009), the assessment of rigour in mixed methods research depends on whether the qualitative or quantitative approaches are given priority. When the quantitative approach is given a higher weighting the processes of reliability, validity and generalisability are applied. Whereas, when the qualitative approach is weighted more highly the strategies of trustworthiness are applied. Thus, the rigour of the processes used within mixed methods research vary and due to the exploratory nature of this research, I will apply the processes more strongly associated with qualitative research methods (i.e. credibility, transferability, confirmability, dependability).

*Credibility*

As credibility refers to the value and believability of the findings (Lincoln & Guba, 1985; Polit-O’Hara & Beck, 2006), I aimed to increase the credibility of this research by developing good relationships with the participants and conducting iterative questioning (Shenton, 2004). ‘Member checking’ can enhance credibility. However, this was not possible due to the erratic shift patterns of the participants, sickness within the nursing homes and NHS
community nursing teams and the high turnover of staff. In addition, I aimed to enhance the credibility of this research through the explicit and systematic integration of methods throughout the research process (including the design, methods and interpretation phases). Finally, I was aware that I needed to acknowledge my role as a researcher within the production of the themes. As the researcher I have had an active role within all of the processes and have included a reflexive account describing my experiences, prior assumptions and theoretical and methodological approaches which may have shaped the data (see Chapter 3.3.8.1). I also maintained records detailing my personal reactions to various research events and the content of the research processes and communications.

Transferability

Transferability relates to the applicability of the findings in different settings (Rodwell, 1998). I aimed to achieve transferability through the use of purposive sampling and ‘thick’ (i.e. detailed) descriptions of the study content including the context and participant’s demographic information.

Dependability

Dependability is similar to reliability as it is concerned with the plausibility of accounts (Silverman, 2009). However, qualitative research often emphasises the importance of experiences and these may change over time. Thus, aiming to
achieve reliability in the quantitative sense (i.e. attaining similar results if the study was conducted again) was not appropriate. However ‘methodological coherence’ can improve dependability by demonstrating the rationale for, and appropriateness of, the chosen methods. I have clearly articulated the research questions as well as the methods for integration, data collection and data analysis to establish auditability. I constantly reflected on the research strategies employed throughout the research process, and discussions with my supervisory team facilitated this reflection and subsequent interpretation. I aimed to report the processes in a transparent manner and have stated the limitations of this research.

**Confirmability**

Confirmability refers to the findings being a product of the inquiry, not of the researcher’s biases. Due to the subjective nature of qualitative research, to achieve confirmability, interpretations need to be rooted in the data (i.e. based on the participants’ experiences). Audit trails of the research processes detail the transparent steps taken within the research and can facilitate confirmability as the decisions about the data can be tracked and data traced to its source (Koch, 2006). Thus, I aimed to achieve confirmability within this thesis by keeping a research diary, documenting the processes and any decisions, maintaining a reflexive account and continually being critical of the processes and findings.
3.3.8 Reflexivity

Reflexivity can help to enhance integrity and trustworthiness within qualitative research (Finlay, 2002; Guillemin & Gillam, 2004). Reflexivity relates to the researcher’s self-awareness regarding how they may influence the participants and/or the data (including data collection, analysis and interpretation) (Maxwell, 2012; Mays & Pope, 2000). Researchers observe, acknowledge and examine the extent to which their experiences, values and biases may influence their inquiry (Charmaz, 2006). Consequently, reflexivity is vital at every stage of the research process.

Reflexivity is important when taking a critical realist approach as both the researchers and the participants are active agents within the research process, and not merely passive perceivers of an objective reality. Having clearly stated the methodological, theoretical and philosophical positions I have taken throughout this research, I will now present my personal characteristics and experiences which may have influenced my research processes.

3.3.8.1 Reflexive Account

I am a White British female in my late-20s from the North West of England. None of my family members reside in a nursing home, nor have they ever developed a pressure ulcer. Consequently, I do not have any personal experience of pressure ulcers. In a professional capacity, I have worked as a
nursing assistant for the last four years on psychiatric units with adolescents, adults and those aged over 65 years with severe psychological and behavioural difficulties. Some of these patients have been at risk of developing a pressure ulcer for a number of reasons (e.g., immobility, malnutrition, catheterised with a urethral catheter). Therefore, I have had some experience of caring for those at risk of developing a pressure ulcer and I have had to deliver some prevention strategies, namely repositioning. However, I have not worked in a nursing home.

I am a postgraduate research student with experience in conducting both qualitative and quantitative research. I have an undergraduate degree in Psychology, a Master’s degree in Health Psychology and currently I am undertaking training to become a qualified Health Psychologist alongside the completion of this PhD. I have always had an interest in health and improving health outcomes and following the completion of my Master’s degree, I accepted a job as a psychiatric nursing assistant with a view to becoming a Clinical Psychologist. With experience, I realised that my passion was more aligned with health psychology and physical health conditions. I developed a particular interest in behaviour change, psychological theory and the implementation of health-related behaviour change interventions. Therefore, my interests, experience and areas of expertise are likely to have guided the direction of this thesis in terms of its theoretical underpinnings, the research
design and my approach to designing and evaluating the care bundle intervention.

### 3.9 Chapter summary

Within this chapter I have addressed the ontological, epistemological and methodological approaches taken within this thesis. To summarise:

- I have taken a critical realist approach with the view that knowledge exists independent of humans but scientific inquiry is socially embedded and imperfect.

- I have provided the justifications for the methods used in Chapters Six to Nine and presented a clear rationale for the mixed methods approach taken. Mixed methods research designs can be advantageous and appealing due to the increased ability to gain a broader and deeper understanding of complex circumstances and healthcare settings (Morse, 2015).

- Mixed methods research is an appropriate choice of design to meet the overall aim of this research. In particular, I employed a multistage evaluation mixed methods design. Within this design, qualitative and quantitative data were collected sequentially, analysed separately and then integrated.

- I have discussed the importance of rigour and reflexivity within mixed methods research. I have explicitly stated my personal characteristics and
prior experiences detailing my assumptions and preconceptions which may have influenced the research processes and outcomes.

Having provided clarity regarding the focus and direction of this thesis, and examined the appropriateness of mixed methods research when conducting empirical studies, the next chapter will focus on the appropriate methodologies for reviewing the evidence.
Chapter 4. Research methods: reviewing the evidence

4.1 Types of literature reviews

There are different types of literature reviews and the extent to which they employ systematic procedures in the identification and evaluation of the evidence varies (Booth, Sutton, & Papaioannou, 2016). The terminology used to describe the reviews reflects this. Grant and Booth (2009) conducted scoping searches of the review literature in health care and health information and explored the vocabulary associated with reviewing and synthesising the literature, before developing an analytic framework to examine the main types of reviews. They do not provide specific details describing the methodological quality of the reviews but report on the identification and content the of 14 review types (Grant & Booth, 2009). There are many overlapping characteristics within these 14 review types, thus most reviews within the field of health can be categorised as one of four broad types: narrative reviews, scoping reviews, rapid reviews and systematic reviews (Smith & Noble, 2016). According to Gough, Thomas and Oliver (2012) the review types differ along three dimensions including the:

1. Aims and approaches.
2. Structure and components.
Thus, I will now consider each of the four types of reviews and their relevance to this thesis.

4.1.1 Narrative reviews

Experts in the subject area review a selection of studies to summarise and consolidate primary evidence (Gough, 2013). Narrative reviews can include both quantitative and qualitative data (Dixon-Woods, Agarwal, Jones, Young, & Sutton, 2005). Reviewers examine an issue, interpret data and create an overarching summary of the separate findings (Wong et al., 2013). This involves iterative explorations of the data rather than an exhaustive search of the literature. Narrative reviews can be informative but there may be an element of bias in the selection and reporting of studies (Grant & Booth, 2009). They are often criticised for the unsystematic methods used in the searching and interpretation of the data which limits the reproducibility (Dixon-Woods et al., 2005; Grant & Booth, 2009; Mays, Pope, & Popay, 2005). Nevertheless, narrative reviews are useful when an overview of, or an introduction to, a topic is required (Arksey & O'Malley, 2005).

4.1.2 Scoping reviews

Scoping reviews include a comprehensive search strategy to assess the existing evidence across a range of study designs. They are exploratory in nature and can be used to identify the key concepts, evidence and gaps in the research.
Thus, they can inform reviewers and policy makers about the value of conducting a full systematic review (Arksey & O’Malley, 2005; Tricco et al., 2016). However within scoping reviews, the risk of bias in the included studies is not usually assessed (Davis, Drey, & Gould, 2009; Grant & Booth, 2009) and the reporting of the methodological detail is often limited, which restricts our understanding of how the authors analysed and appraised the data (Davis et al., 2009).

4.1.3 Rapid reviews

Rapid reviews enable research findings to be summarised and synthesised within specific time and resource constraints (Grant & Booth, 2009). Whilst the methods are rigorous, explicit and systematic, they are usually less extensive when compared with systematic reviews (Centre for Reviews and Dissemination, 2009). Due to the time-constraints placed on rapid reviews, they are at increased risk of a publication bias due to the restricted amount of grey literature that can be identified. Moreover, the reviewer may introduce bias due to the limited critical appraisal and quality assessments which may limit the conclusions or result in incorrect conclusions (Grant & Booth, 2009).

4.1.4 Systematic reviews

A systematic review is defined as a scientific inquiry that enables the identification, assessment, analysis and synthesis of the research findings
through explicit and predefined methods (Higgins & Green, 2011). A systematic review systematically assesses how study design, conduct and the consequent risks of bias may affect the conclusions from individual studies and from the body of research as a whole. In addition, the process of conducting a systematic review can identify relevant studies that can be combined in a meta-analysis where feasible. The research question should be focused and address the salient aspects of the research question. Identifying the specific aspects of the review question can be facilitated by using the participants, intervention, comparison, outcomes and study designs (PICOS) (Higgins & Green, 2011). Using the PICOS elements determines study eligibility, data extraction, analysis and interpretation and ensures that the decisions are transparent. The systematic review protocol will state the explicit and transparent strategies that the authors will employ during the identification, critical appraisal and synthesis of the evidence to produce reliable findings with minimal bias (Higgins & Green, 2011). Thus if the authors deviate from the protocol and the reasons why are not stated, the authors could introduce bias.

Systematic reviews are themselves a form of research and are time-consuming and resource intensive, but are an efficient and reliable method used to synthesise research findings (Gough et al., 2012) and are essential for avoiding research waste (Chalmers et al., 2014). Presenting all of the relevant research findings is especially important in healthcare, as the conclusions regarding the
effectiveness of a healthcare intervention can be drawn from the results of a systematic review to inform practice, policy and guidelines (Oliver, Innvar, Lorenc, Woodman, & Thomas, 2014).

4.1.4.1 Meta-analyses

Systematic reviews may include the statistical pooling of data from separate studies that address the same or similar research questions and this is referred to as a meta-analysis. A meta-analysis is a set of statistical procedures where the data from multiple studies are combined to estimate the strength of effect (Glass, 1977; Petticrew & Roberts, 2006). A key assumption of meta-analyses is that the aggregation of the results across studies provides greater statistical power to detect any effects and a better estimate of the true effect (fixed effect model) or an average of the effect (random-effect model) is possible (Higgins, Thompson, & Spiegelhalter, 2009). The application of meta-regression within a meta-analysis can enable the identification of moderating and mediating variables to provide an explanation for the inconsistencies within the research findings (Deeks, Higgins, & Altman, 2011). However, erroneous inferences can be caused by the studies included, as well as a publication bias, the sample size and methodological heterogeneity (Murphy, 2017). Consequently, caution must be taken when conducting and interpreting meta-analyses.
4.1.5 Review type summary

My review aimed to evaluate the magnitude of the effect of care bundles on patient outcomes and therefore aggregative methods were necessary. The review conducted as part of this programme of research (Chapter Six) had a broad scope and there was high heterogeneity among the included studies (e.g., health condition, setting). The specific methods used for the systematic review and meta-analysis are reported in Chapter Six, however the justifications for the methods are discussed below and full details are provided in the systematic review protocol in Appendix 1.

4.2 Review methodology considerations

The importance of minimising research waste and improving research usability has received much attention in recent years (Chalmers et al., 2014; Chan et al., 2014; Ioannidis et al., 2014; Nasser et al., 2017). One imperative emerging from these discussions is the importance of authors reporting any interventions studied in adequate detail. This is a necessity for the interpretation of the studies of complex interventions (Hoffman et al, 2017). Complete descriptions of the interventions are relevant not only for the empirical studies, but also in the planning, conducting and reporting of systematic reviews as without this, the reproducibility and usability become limited (Hoffman et al., 2017). Consequently, the systematic review presented in Chapter Six used the
definition of a care bundle formulated by the Institute for Healthcare Improvement (Resar et al., 2012) (see Chapter Six).

Cochrane reviews are peer-reviewed systematic reviews of primary research in health care and health policy (The Cochrane Collaboration, 2018). Whilst I did not undertake a Cochrane systematic review, I followed the guidance provided in the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1 (Higgins & Green, 2011) with the following stages:

- Review protocol.
- Defining the review question and developing criteria for including studies.
- Developing and running a search strategy.
- Selecting studies and data extraction.
- Assessing the risk of bias in included studies.
- Analysing data and undertaking meta-analysis.
- Addressing reporting bias.
- Presenting results.
- Interpreting results and drawing conclusions informed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) (Guyatt et al., 2008).

The justifications for the methodological decisions made in advance of undertaking the review are provided in the review protocol (see Appendix 1). The specific methodological details are presented in Chapter Six thus, I will
now focus on some of the important methodological considerations which informed the review protocol and methods.

4.2.1 Review protocol

There are concerns regarding the potential existence of a publication bias within systematic reviews where there is a bias towards including studies with positive findings (Kirkham, Altman, & Williamson, 2010; Silagy, Middleton, & Hopewell, 2002; Tricco et al., 2009). One way to reduce the potential of a publication bias is to publish a systematic review protocol in advance of conducting the review (Booth et al., 2011). It is recommended that a systematic review protocol should provide a clear justification for conducting the review, including a discussion of the existing literature and the aims and objectives of the review (Silagy et al., 2002). In addition, the protocol should include a clear description of the review methods including the approaches to the data collection, analysis and interpretation (Green & Higgins, 2011). Any modifications to the review methods should be clearly stated (Silagy et al., 2002) enabling any discrepancies between the planned and actual methods to be identified more easily (Silagy et al., 2002).

Currently, there is an international Prospective Register of Ongoing Systematic Reviews (PROSPERO) where systematic review protocols can be published. Each of the protocols is given a unique identifying number and it is
recommended that the authors of the reviews report this number in any publication arising from the review protocol (Green & Higgins, 2011). Databases such as PROSPERO enable the identification of similar planned reviews and this may help to reduce research waste as potential review authors may plan to collaborate with other authors or they may choose not to pursue that particular review (Booth et al., 2011). I searched the PROSPERO register as well as the existing systematic reviews and did not identify a systematic review that answered my review questions. Therefore, I developed a protocol for the systematic review reported in Chapter Six and published this protocol in the PROSPERO register (CRD42016033175) (see Appendix 1).

4.2.2 Defining the review question

To design the review question O’Connor, Green and Higgins (2011) suggest specifying the types of population, intervention(s), comparator(s), outcome(s) and study design(s) (PICOS) that will be included in the review. These five aspects inform the review question, determine the focus of the review and guide the review processes (Anderson et al., 2013; Squires, Valentine, & Grimshaw, 2013).

Reviews may be broad or narrow in scope and this depends on multiple factors including the purpose of the review and how it is intended to be used and by whom (O’Connor et al., 2011; Viswanathan et al., 2017). There are advantages
and disadvantages to conducting reviews with either a broad or narrow scope (Table 6). I aimed to answer a broad question relating to whether there are particular circumstances when care bundles seem to be effective. Therefore I deemed a broad review, which included a large number of heterogeneous studies, to be appropriate.
Table 6  
*Advantages and disadvantages of broad versus narrow review questions*

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Broad scope</strong></td>
<td><strong>Disadvantages</strong></td>
</tr>
<tr>
<td>- Generalisability across populations and settings.</td>
<td>- Risk of heterogeneity which can make interpretation more difficult.</td>
</tr>
<tr>
<td>- Increases the number of eligible studies.</td>
<td>- An overview of reviews may be more appropriate.</td>
</tr>
<tr>
<td>- Opportunity to explore the sources of heterogeneity and effect modification.</td>
<td></td>
</tr>
<tr>
<td><strong>Narrow scope</strong></td>
<td><strong>Disadvantages</strong></td>
</tr>
<tr>
<td>- Objectives can be more focused.</td>
<td>- Evidence may be sparse due to the smaller number of eligible studies.</td>
</tr>
<tr>
<td>- Intervention may be relevant to a specific population or setting.</td>
<td>- Potentially misleading conclusions due to the sparse evidence.</td>
</tr>
<tr>
<td>- Assessment and summary of the evidence remains manageable and can be more clear.</td>
<td>- Generalisations to other settings and populations may be limited.</td>
</tr>
<tr>
<td></td>
<td>- The findings may have limited value.</td>
</tr>
<tr>
<td></td>
<td>- The scope of the review may reflect the authors’ desires to produce certain results.</td>
</tr>
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</table>
4.2.3 Search strategy

The development of an appropriate search strategy is an essential component of any systematic review and if sufficiently comprehensive, objective and reproducible, the potential for bias should be minimised (Lefebvre, Manheimer, & Glanville., 2011). The search terms are informed by the eligibility criteria for the studies to be included in the review. For example, using the PICOS, certain terms would be included in the search strategy (e.g., randomised trial). Searching a number of sources to identify relevant studies is recommended (Lefebvre et al., 2011) and should include published and unpublished studies, as well as the trials registers and the reference lists of included studies to minimise any unintentional publication bias.

The use of a smaller number of search concepts (e.g., study design, population) and a wide variety of related terms combined with ‘OR’ (e.g., randomised trial OR cluster-randomised trial OR controlled before-after study) are advised (Lefebvre et al., 2011). The different concepts can then be combined using ‘AND’. For example, the study design concept can be combined with the intervention concept:

(randomised trial OR cluster-randomised trial OR controlled before-after study) AND (care bundle OR prevention bundle OR clinical bundle).
I developed the search strategy for the systematic review presented in Chapter Six by conducting a scoping search in MEDLINE and CINAHL to enable the identification of relevant words and index terms (see Chapter Six and Appendix 2 for the full search strategy).

**4.2.4 Study selection and data extraction**

It is recommended that at least two people independently assess studies for eligibility and extract the data from the included studies in order to minimise bias and errors (Higgins & Deeks, 2011). I stored the results of the searches in Covidence, an online review manager (Covidence, 2013). Within Covidence I was able to import references and conduct the screening, study selection and full-text review. Towards the end of the review process I repeated the searches to ensure the most up-to-date research was included.

Data collection forms can be used to assist with extracting data from the included studies and multiple reports from the same study can be linked together. It is possible to extract data using Covidence. However, in line with the recommendations made by Higgins and Deeks (2011), I developed the data collection sheet to meet the needs of the review questions (see Appendix 3) and piloted the form with five studies; no changes to the form were necessary.
4.2.5 Risk of bias

Bias refers to a systematic error or a variation from the truth which can cause either an over- or under-estimation of the intervention effect (Higgins & Green, 2011). According to Higgins and Green (2011), there are six main sources of bias in studies assessing the effectiveness of healthcare interventions:

1. Selection bias: systematic differences in the baseline characteristics between the comparison groups.

2. Performance bias: systematic differences in the exposure to the factors within, or in addition to, the intervention.

3. Detection bias: systematic differences between the comparison groups in the measuring or verifying of outcomes.

4. Attrition bias: systematic differences between comparison groups in the number of withdrawals from the study.

5. Reporting bias: systematic differences between the reported and unreported findings (e.g., statistical significance).

6. ‘Other sources’: includes those that cannot be categorised specifically including trial design and specific clinical settings.

The validity of the results of the individual studies included in a systematic review, and therefore of the overall review itself, depends on the extent to which the potential sources of bias have been avoided. The study design can introduce bias and can influence the study’s internal validity (i.e. how likely the
results are to be true for the people in the study) and external validity (i.e. how likely the results are to hold true for people not in the study) (Cochrane Community, 2017). Study design is therefore an important consideration for reviewers as it can impact on the reliability and validity of the estimate of the intervention effects (Centre for Reviews and Dissemination, 2009) via effects on the risk of bias. Since writing the systematic review protocol (see Appendix 1) and conducting the systematic review in Chapter Six, The Effective Practice and Organisation of Care have published new guidance on the range of study designs (The Effective Practice and Organisation of Care, 2017). The guidance suggests:

1. Avoiding the use of abbreviations.

2. The term randomised controlled trial should be replaced by randomised trial as the word ‘controlled’ is regarded as ambiguous and redundant within this term.

3. Non-randomised trials should replace the term quasi-randomised controlled trials.

4. Controlled before-and-after studies should be known as controlled before-after studies.

5. Replacing ‘design’ or ‘analysis’ with ‘study’ in an interrupted time series study.

Thus, throughout this thesis I will use the newly revised terminology.
The candidate study designs for the systematic review in Chapter Six are at varying levels of risk of bias (The Effective Practice and Organisation of Care, 2017):

- **Randomised trials**: participants are randomly assigned to the comparison groups with the only difference between groups being the exposure to the intervention. That is, the process of random allocation means that other factors that might affect the outcome should be distributed equally. Where it is not appropriate to randomise individuals (e.g., the intervention is targeting healthcare professionals), groups (i.e. clusters) of people can be randomised and these trials are known as cluster-randomised trials. Within cluster-randomised trials, the lack of independence between the participants in a cluster means that the assumption of independence, which underpins frequentist statistical analysis, is violated. Thus, to adjust for the clustering effect, larger sample sizes are required and the analysis is undertaken at the level of the cluster. If there are not enough clusters other factors which might affect the outcome may not be distributed equally.

- **Non-randomised trials**: participants are allocated to the comparison groups using methods that are not random which increases the risk of bias when compared with randomised trials, especially selection bias.

- **Controlled before-after studies**: the outcomes of interest are measured in at least one control group and at least one intervention group during a controlled period before the intervention and then a later period where an
intervention is received. The researcher does not control the allocation of the participants to any group and there may be differences between the groups that could impact on the outcomes being measured. Thus, these studies are at a high risk of bias.

- *Interrupted time series studies:* when randomisation or control groups are impractical, interrupted time series studies can be used to measure the effect of an intervention. At least three data points are collected before and after the intervention and comparisons are made between the pre- and post-intervention data. However, interrupted time series studies are at a high risk of bias due to the impact of temporal changes or concurrent events on the outcomes of interest (The Effective Practice and Organisation of Care, 2017).

Randomised trials are often viewed as the gold standard study design for evaluating the effectiveness of interventions because the random allocation to the groups limits the potential bias from the uneven distribution of the known and unknown prognostic factors at baseline. However, it is not always possible or ethical to conduct a randomised trial and sometimes non-randomised studies are necessary (Higgins & Green, 2011). For example, it is not ethical to provide barriers to interventions which are thought to promote benefits such as breastfeeding. In addition, conducting a randomised trial to evaluate a complex intervention within a service can be particularly challenging, as participants in
the control group may learn about the intervention and adopt the intervention practices, thus contamination between the individuals is likely to occur (Craig et al., 2008; Ukoumunne et al., 1999). Cluster-randomised trials are more likely than randomised trials for complex interventions targeting healthcare workers. In addition, I expected that many of the studies reporting on the effectiveness of care bundles would be controlled before-after studies or interrupted time series studies due to financial and time constraints (Eccles et al., 2003). Finally, non-randomised studies can provide evidence in addition to that gained from randomised trials surrounding the long-term outcomes, adverse effects and rare events within real world practice (Sterne et al., 2016). Consequently non-randomised studies were considered for inclusion within the review in Chapter Six.

As non-randomised studies are at a greater risk of selection bias due to the lack of the random allocation of the participants to the study groups, I chose to use a risk of bias tool for non-randomised studies in addition to a tool for randomised trials. Whilst many tools were available (Deeks et al., 2003), to my knowledge, there was not a widespread adoption of one tool for the systematic reviews of non-randomised studies. Recently, the Cochrane Bias Methods Group and the Cochrane Non-Randomised Studies Methods Group developed a tool to evaluate the risk of bias in non-randomised studies and is known as the Risk Of Bias In Non-randomised Studies – of Interventions (ROBINS-I; Sterne et al.,
At the time of developing my review protocol and conducting the systematic review, the ROBINS-I tool was known as ACROBAT (A Cochrane Risk of Bias Assessment Tool for Non-Randomised Studies) (Sterne, Higgins, & Reeves, 2014). I chose to use ACROBAT to assess the risk of bias in the included non-randomised studies (see Appendix 4). For the included randomised trials, I assessed the risk of bias using the Cochrane collaboration tool for assessing risk of bias (Higgins et al., 2011) (see Appendix 5).

4.2.6 Data analysis and synthesis

It may not always be possible or appropriate to conduct a meta-analysis within a systematic review (Schroll, Moustgaard, & Gøtzsche, 2011). Considering the measures of treatment effect, unit of analysis issues and dealing with missing data are important as they can impact on whether it is possible to conduct a meta-analysis. For example there may be insufficient data to reanalyse the results or important data may be missing. I pre-specified plans for addressing these issues in the review protocol. I planned to conduct a meta-analysis if there were sufficient information and data once the pre-analysis issues had been addressed. I will now discuss the meta-analysis issues particularly salient for the meta-analysis presented in Chapter Six including heterogeneity and the appraisal of quality.
4.2.6.1 **Heterogeneity**

Homogeneity suggests that each study included within the meta-analysis is estimating a single, true intervention effect and any differences are due to sampling errors (Nikolakopoulou, Mavridis, & Salanti, 2014). However, any clinical variation may result in statistical heterogeneity and this is of particular importance to the systematic review in Chapter Six due to the ‘lumping’ nature of the review. It was likely that the data would be highly heterogeneous and consequently it would be inappropriate to estimate an intervention effect across all of the studies (Deeks et al., 2011). In this case, ‘vote counting’ is not advocated (Borenstein, Hedges, Higgins, & Rithstein, 2009; Deeks et al., 2011; Hedges & Olkin, 1980). Vote counting can be a simple way to assess whether there is evidence of an effect as the number of positive studies is compared with the number of negative studies. However, studies may be defined as positive or negative based on statistical significance or subjective decisions. Vote counting is problematic because the sample size and the size of the effect are not taken into account and the conclusions may be misleading or incorrect (Borenstein et al., 2009; Hedges & Olkin, 1980).

When heterogeneity cannot be explained, a random-effect meta-analysis can consider the heterogeneity across the studies but does not explain the heterogeneity. A random-effect meta-analysis assumes that the true intervention effect differs from study to study and that the included studies are
a random sample of all of the studies and their results follow a distribution (Deeks et al., 2011). The average of the effects is demonstrated in the centre of the distribution and heterogeneity is shown through the width of the distribution.

If there is a sufficient number of studies, it is important to explore the possible causes of heterogeneity (Deeks et al., 2011). The confidence interval reflects the uncertainty surrounding the findings. For example 95% confidence intervals mean that if a study was repeated 100 times with different participants from within the population of interest, 95% of the confidence intervals from those repeated studies would contain the true population parameter (Cochrane Community, 2017). When confidence intervals are wide, there is more uncertainty surrounding the value of the true population parameter being measured.

4.2.6.2 Subgroup analysis

Where high levels of heterogeneity are observed, explorations in the form of subgroup analyses can be conducted (Deeks et al., 2011). However, subgroup analyses are observational and are therefore at risk of bias through confounding by other study-level characteristics (Sun, Briel, Walter, & Guyatt, 2010). Explanatory factors are aspects of studies which could potentially explain any differences in the results (e.g., characteristics of the population, study design).
Explanatory factors can be used to explore heterogeneity in subgroup analyses and meta-regression (Deeks et al., 2011). For example, within a meta-regression the effects of explanatory variables (also known as ‘potential effect modifiers’) on the study outcome can be explored (Cochrane Community, 2017; Deeks et al., 2011). Generally it is recommended that there are at least 10 studies per explanatory variable to enable a plausible exploration of heterogeneity using a meta-regression (Deeks et al., 2011).

I specified the potential explanatory factors in my review protocol to reduce the risk of spurious findings which can occur when findings are data driven (i.e. post hoc) and this is known as ‘data dredging’ (Cochrane Community, 2017). I was uncertain whether the search of the literature would yield enough eligible studies to conduct a meta-regression. Therefore, I planned to conduct a subgroup analysis using pre-specified hypotheses (see Appendix 1 for review protocol).

4.2.6.3 Quality appraisal

The quality of the evidence which informs the findings of systematic reviews directly impacts on the confidence in the conclusions drawn (Guyatt, Oxman, Visit et al., 2008). GRADE (Guyatt et al., 2008) is a tool used to assess the quality of the evidence based on five factors:
1. Limitations in the design and implementation which suggests a high level of bias is likely.

2. Indirectness of evidence.

3. Unexplained heterogeneity or inconsistent results.

4. Imprecise results.

5. A high chance of publication bias.

A body of evidence may be weaker in one or more of these five factors (Guyatt et al., 2008). The quality of the evidence can be rated as being at one of four levels (high, moderate, low, very low) and the greater the problems the lower the evidence rating. Therefore, the quality of the evidence impacts on the certainty of the conclusions (Guyatt, Oxman, Kunz, et al., 2008).

4.3 Chapter summary

When developing a complex intervention, reviewing the evidence to identify what is already known about similar interventions and the associated methods for evaluation is strongly recommended. Craig et al. (2008) advise conducting a systematic review if one does not already exist to identify any gaps in the literature and to avoid research waste. Thus, within this chapter I have discussed the various types of reviews, providing a rationale for the methods in the systematic review I conducted (Chapter Six). I have outlined some of the important methodological considerations which are relevant to Chapter Six, including the broad scope of the review question, the risk of bias assessment for
non-randomised trials and the subgroup analysis. Finally, systematic reviews can inform knowledge surrounding the effectiveness of interventions and whether specific intervention components are more effective than others.
Chapter 5. Research methods: developing and testing the care bundle intervention

As discussed in the Background Chapter of this thesis, ideally the elements of a care bundle should be informed by the research-based recommendations within well-constructed clinical practice guidelines. In addition, it is advisable that the intended users of the care bundle are in agreement about the elements included within the bundle in relation to their applicability to the local context and the population of interest. Moreover, where a particular harm (e.g., pressure ulcers) occurs in more than one setting (e.g., hospitals, nursing homes), specific care bundles for each location might be needed (Resar et al., 2012). Thus, within this chapter I will outline the existing guidelines for developing care bundles, consider the relevance of co-design and consensus methods for reaching agreement among participants and provide greater details about the methodology used during the development of the bundle intervention (i.e. the Behaviour Change Wheel). I also present the components involved in the evaluation of the care bundle intervention including a discussion of feasibility studies and implementation fidelity assessments.

5.1 Developing the care bundle intervention

The MRC guidance for developing and evaluating complex interventions (Craig et al., 2008) informed the developmental stages of the care bundle intervention.
The development phase comprised of three steps (see Figure 2 and Chapter 2.8).

The first step involved ‘identifying the evidence base’. I conducted a systematic review and meta-analysis and have stated the methodology in Chapter Four. Thus I will now focus on the second and third steps: identifying/developing theory and modelling processes and outcomes.

5.1.1 Guidelines for developing care bundles

Guidelines for developing care bundles are provided by Resar et al. (2012) and de Wet, McKay and Bowie (2012). These guidelines have similarities and recommend that care bundles:

- are developed by a multidisciplinary team (Resar et al., 2012);
- relate to a specific clinical condition (de Wet et al., 2012);
- specify the target population and care setting (Resar et al., 2012);
- have at least three elements (de Wet et al., 2012) and a maximum of five research-based elements (Resar et al., 2012);
- have elements that are relatively independent to ensure that implementation is not impeded due to the absence of another (de Wet et al., 2012; Resar et al., 2012);
- have elements which are specific, measurable and reproducible (de Wet et al., 2012);
- consider clinical judgement and the customisation of the elements (Resar et al., 2012).
Whilst this guidance is useful it does not provide a standardised method for developing care bundles. For example, there is no guidance for developers explaining how the care bundle elements should be chosen or how to choose between two competing elements. Detailed guidance would aid the development processes as the choice of the elements will ultimately impact on how the healthcare workers use the care bundle, as well as patient outcomes.

To develop the care bundle intervention I generally followed the guidance provided by Resar et al. (2012) and de Wet et al. (2012), ensuring that the care bundle intervention content was based on up-to-date and evidence-based clinical guidelines, stakeholder involvement and agreement and included all of the above aspects. However, as specific details about how to develop a care bundle are not provided I will now consider the value of co-designing interventions and using consensus methods to reach agreement among research participants.

5.1.2 Collaboration and co-design

Collaborative approaches to the design of healthcare interventions involve the active contribution of all stakeholders to the development and provision of services, with effective information exchange and shared decision making at the forefront of addressing the needs of users (Bettencourt, Ostrom, Brown, & Roundtree, 2002; Bovaird, 2007). Service developers and service users are both
active agents within the intervention design processes (Ostrom, 1996) and the knowledge and experiences of all those involved in a service are valued equally (Boyle et al., 2010; Osborne, Radnor, & Strokosch, 2016). However, the extent to which knowledge is translated between the different ‘communities’ depends upon whether they share similar approaches to the production, sharing and application of knowledge (Oborn, Barrett, & Racko, 2013).

Co-design more specifically involves the key stakeholders in the design processes (Sanders & Stappers, 2008) where research, knowledge and practice are combined and service users actively design interventions rather than being passive receivers (Blackwell, Lowton, Robert, Grudzen, & Grocott, 2017). As I wished to develop a care bundle intervention that was contextually relevant, I decided to co-design the care bundle intervention with the nursing home care staff (healthcare assistants, nurses, managers) and NHS community-based tissue viability nurses. Thus, I contributed my academic expertise in terms of developing and interpreting the research evidence; and the healthcare workers provided their expertise in clinical practice and the nursing home context. Service users can also be involved in the co-design of healthcare interventions (Blackwell et al., 2017; Lwembe, Green, Chigwende, Ojwang, & Dennis, 2017). However, my priority was to ensure that the healthcare workers felt able and confident to speak openly about some of the difficulties they faced when trying to complete certain pressure ulcer prevention practices. Therefore, I chose to
include healthcare workers rather than residents. In order to reach agreement about the content of the care bundle intervention, I used a consensus method which I will now discuss.

### 5.1.3 Consensus methods

As discussed in Chapter Four, systematic reviews and meta-analyses can be used to summarise and explore any inconsistencies in the literature. However consensus methods can also be used as they provide additional information such as the opinions of appropriate experts, which can facilitate decision-making (Jones & Hunter, 1995). Thus, consensus methods aim to determine the extent to which people agree about a particular topic; that is to assess the extent of agreement or to resolve disagreement.

Consensus methods are advantageous for two main reasons. Firstly, better decisions can often be made by a group of people compared with individuals, as the group will possess at least as much knowledge as the most knowledgeable member and interactions may facilitate the production of new knowledge (Hutchings, Raine, Sanderson, & Black, 2006). Secondly, a facilitator is usually present which limits the extent to which certain participants can dominate discussions (Rankin et al., 2016). However consensus methods in general, have some limitations. Bias can be introduced through the selection of the participants and the panel members may affect the findings (Pagliari,
In addition, the findings will reflect current opinion and can limit the applicability of the findings to other contexts (Raine et al., 2004).

Two commonly used consensus methods are the Delphi technique and the Nominal Group Technique and these are discussed below.

5.1.3.1 Delphi technique

The Delphi technique involves iterative and systematic processes that are repeated in rounds of voting with expert panellists to determine a group consensus where there is limited evidence and/or opinion about a defined problem (Linstone & Turoff, 1975). The Delphi technique is usually conducted via means other than face-to-face exchanges (Linstone & Turoff, 1975). Therefore, the Delphi technique enables large numbers of participants to be involved and limits the effects of dominant participants (Sinha, Smyth, & Williamson, 2011).

There are many variations of the Delphi technique but, in general, they all share a similar core format. A questionnaire/interview schedule is presented to the group of experts who are asked for their opinion about a particular topic. Responses are summarised and a new questionnaire/interview schedule is developed. The experts are asked to consider their initial opinion as well as the
opinion of the other members in the group and then provide a response. Thus opinions may converge, or disagreements may continue, and this process is repeated until a consensus is reached (Linstone & Turoff, 1975).

The Delphi technique has been used widely across many areas of healthcare as a reliable technique for determining a consensus about a defined clinical problem (e.g., Chang, Chen, Wu, & Liao, 2017; Eubank et al., 2016; Foth et al., 2016; Rodgers, Booth, Norman, & Sowden, 2016). There are many advantages to using a Delphi technique such as, large groups of experts can collaborate in the decision-making process without physically attending the meetings (Linstone & Turoff, 1975). Thus, even though experts may be placed in different geographic locations, they are all able to contribute. Considering each person’s viewpoint is encouraged within the Delphi technique whilst maintaining anonymity and this is an advantage of the Delphi technique when compared with other consensus techniques. However, the communication process can be limited by the lack of face-to-face contact and non-verbal cues (Donohoe, Stellefson, & Tennant, 2012).

The Delphi technique can be beneficial when the group is likely to have wide-ranging and potentially opposing views as group decision-making is possible but without any of the negative aspects of the group interaction (Rowe & Wright, 2011). For example, it can be an efficient use of time as the conversations will not drift off-topic and participants are not usually influenced
by social desirability. Finally, the occurrence of premature decision-making is reduced due to the multiple iterations involved and this is facilitated by the separating of the processes involved in the formulation and evaluation of ideas (Whitman, 1990).

There are some limitations to consider when using the Delphi technique. Due to the methods used, Delphi studies require a competent facilitator as their role can influence outcomes. Linstone and Turoff (1975) state that researchers should avoid: over-specifying the problem; providing feedback that is of poor quality and not exploring the reasons for disagreement. In addition, the expertise of the group members may not be accessed fully as the group do not meet, response rates are often poor and there is a lack of accountability. An important limitation of the Delphi technique is the potentially different interpretations of the data by both the participants and the researcher. Without the opportunity for verbal clarification there is no guarantee that the final agreement represents the best solution (Courtney, Crossdell, & Paradice, 2007).

5.1.3.2 Nominal Group Technique

Initially the Nominal Group Technique was developed within social psychology to facilitate the decision making of groups (Van de Ven & Delbecq, 1972) and has subsequently been employed across a wide range of disciplines including health (e.g., McSharry, Fredrix, Hynes, & Byrne, 2016; Urquhart-
Secord et al., 2016; Wortley, Tong, & Howard, 2016). The Nominal Group Technique can be used to identify a problem and generate research questions, develop solutions and establish priorities for action.

The Nominal Group Technique is utilised to gain information from 5-8 experts about a particular topic (Van de Ven & Delbecq, 1972). It is a highly structured technique, usually delivered face-to-face, consisting of three distinct phases where ideas are generated, items or questions are rated, then discussed and re-rated by the expert panellists (see Table 7). The Nominal Group Technique enables the grouping of individual judgements and can be used in areas where there is uncertainty regarding the problem of interest and the potential solutions (e.g., Buckley, Grant, Tincello, Wagg, & Firkins, 2010; Wortley et al., 2016). To minimise the effects of any dominant participants, all of the group members are provided with an equal opportunity to contribute to the overall decision making through their individual votes (Harvey & Holmes, 2012; Van de Ven & Delbecq, 1972). The Nominal Group Technique is useful as the moderator/facilitator does not attempt to reduce diversity and create an artificial consensus; rather the clarification of the important issues is vital in capturing, exploring and understanding the opinions of and any diversity within, the group. Therefore, the facilitator does not interpret the findings (Cantrill, Sibbald, & Buetow, 1996).
Table 7
The Nominal Group Technique (adapted from Van de Ven and Delbecq, 1972)

<table>
<thead>
<tr>
<th>Round</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Preliminary round | 1. Participants spend time noting their views on the topic.  
2. The facilitator asks each participant to provide one idea, and this is written on a flip chart.  
3. Where appropriate, similar suggestions are grouped together and discussions are held to clarify and evaluate each idea. |
| Round 1 | 4. The participants privately rank each idea.  
5. This ranking is calculated and presented to the participants. |
| Round 2 | 6. Overall ranking is discussed and re-ranked.  
7. The final rankings are calculated and the participants are informed. |

The Nominal Group Technique is a beneficial technique as it is usually conducted face-to-face with participants during one, facilitated event (Van de Ven and Delbecq, 1972). The Nominal Group Technique can facilitate the production of large amounts of data in a relatively short period of time and the results are instantaneous (Potter, Gordon, & Hamer, 2004). Moreover, prior to the event, little preparation from the participants is needed. This is advantageous when working with nursing home care staff and community-
based nurses (e.g., tissue viability nurses) as they have limited availability which may impact on their decision to participate.

For this project there were a number of reasons why the Nominal Group Technique was the most appropriate consensus method. Having face-to-face structured meetings with the nursing home care staff and the NHS experts involved in wound care enabled rich and detailed first-hand information to be collected. Moreover, face-to-face meetings provided me with the opportunity to build a rapport with the potential participants (Creswell, 2007; Novick, 2008; Shuy, 2003). I deemed these two aspects to be more important to this research than the anonymity permitted by the Delphi technique.

5.1.4 The Behaviour Change Wheel

The Behaviour Change Wheel is a framework for designing behaviour change interventions such as care bundles which aim to improve or change the behaviours of healthcare workers and increase the uptake of research-informed practice (Resar et al., 2012). The Behaviour Change Wheel was developed through the synthesis of 19 existing behaviour change frameworks (Michie et al., 2014; Michie et al., 2011). The Behaviour Change Wheel outlines a systematic and transparent approach to identify the appropriate theory-based intervention content which may bring about change in the population of interest. The Behaviour Change Wheel comprises of three concentric circles (see Figure 3 in
Chapter 2.8.1.1) which relate to the three stages involved in designing the behaviour change intervention. The Behaviour Change Wheel (Michie et al., 2014; Michie et al., 2011) has also been linked to the MRC guidance for the development of complex interventions and can be applied to suit different behaviours and contexts (e.g., Barker, de Lusignan, & Cooke, 2016; Craig et al., 2008; Sinnott et al., 2015).

I chose to follow the steps outlined by the Behaviour Change Wheel to guide the development of the care bundle intervention (Chapter Eight). The COM-B model is at the centre of the Behaviour Change Wheel and is used to understand the target behaviour in context. Understanding the behaviour in context can facilitate the development of interventions by targeting the barriers to changing that behaviour. Tailoring interventions to overcome context-specific barriers can improve the delivery of care and patient outcomes (Baker et al., 2010). The Behaviour Change Wheel links the COM-B components to nine intervention functions (the middle section of the wheel) and seven policy categories (the outer section of the wheel) (see Figure 3 in Chapter 2.8.1.1). The Behaviour Change Wheel also links the intervention functions to the behaviour change techniques stated in the Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013) (see Appendix 6 for the Behaviour Change Technique Taxonomy Version 1) and the modes of delivery (e.g., face-to-face).

Within Phases 2 and 3 of the Behaviour Change Wheel, the APEASE criteria for
designing and evaluating interventions are used to guide the decisions on the
intervention content and how to implement the intervention within a particular
setting (Michie et al., 2014; Michie et al., 2011). These criteria involve an
assessment of:

1. Affordability (cost considerations).
2. Practicability (the intervention should be able to be delivered as planned).
3. Effectiveness and cost-effectiveness (the effect size of the intervention
   within a real world context and the ratio of effect to cost).
4. Acceptability (the extent to which relevant stakeholders judge the
   intervention to be appropriate).
5. Side-effects/safety (unwanted side-effects or unintended consequences).
6. Equity (the extent to which disparities in well-being or health between
   different sectors of society may be increased or decreased).

Chapter Eight details the specific application of the Behaviour Change Wheel in
the context of this research. Therefore to avoid repetition, below I have
described the broad Behaviour Change Wheel approach taken throughout this
research.
**Phase 1: Understanding the behaviours**

This phase involved four steps which facilitated my understanding of the target behaviours in terms of what behaviour(s) needed to change, how and to what extent they could change and who needed to change these behaviours.

**Step 1: Defining the problem in behavioural terms**

The problem of interest was described as a behaviour, and the population of interest was specified.

**Step 2: Selecting the target behaviours**

All of the potential behaviours relevant to the problem of interest were listed and I considered the following:

- The potential impact if the behaviour was changed.
- The likelihood of the behaviour change.
- Any positive ‘spillover’ effects of the behaviour onto other behaviours.
- How easy it would be to measure the behaviour.

**Step 3: Specifying the target behaviour**

Using the appropriate and relevant detail, I selected the target behaviour and the context. I used the following questions to assist this process:

- What needs to be done differently to achieve the change in the selected behaviour?
- Who performs the behaviour?
- When and where do they perform the behaviour?
- How often will they perform the behaviour and with whom?

Step 4: Identifying what needs to change

During this step I spent time understanding the target behaviour. More specifically, what needed to change in order to achieve the desired behaviour. A range of sources were used to strengthen my understanding of the target behaviour (e.g., interviews, service protocols, expert opinion). The Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) and COM-B model (Michie et al., 2011) underpin the Behaviour Change Wheel and were used in this first phase. Analysing the qualitative data using the Theoretical Domains Framework enabled a more granular understanding of the behaviours (Chapters Seven and Nine), but using the Theoretical Domains Framework in addition to the COM-B model is not always necessary. The salient domains from the Theoretical Domains Framework can be mapped onto the COM-B components (see Table 4; Chapter 2.7.1.1d). Using the Theoretical Domains Framework and the COM-B model as the framework to analyse the qualitative data assisted with the identification of the facilitating or competing behaviours (i.e. the barriers and facilitators). Identifying the barriers and facilitators enabled the intervention to include the aspects which were believed to enhance
the behaviour and inhibit any actions which might compete with the behaviour (Chapter Eight).

**Phase 2: Identifying the intervention options**

This phase involved two steps which guided the selection of the intervention options (i.e. components), including the:

- Nine *intervention functions* (i.e. “broad categories of means by which an intervention can change behaviour”) (Michie et al. 2014, p. 109).
- Seven *policy categories* that “support the delivery of the intervention functions” (Michie et al., 2014, p. 134).

**Step 5: Identifying the intervention functions**

There are nine intervention functions:

- *Education*: increasing knowledge or understanding.
- *Incentivisation*: creating an expectation of reward.
- *Persuasion*: using communication to induce positive/negative feelings or stimulate action.
- *Coercion*: creating an expectation of punishment or cost.
- *Training*: imparting skills.
- *Restriction*: using rules to reduce the opportunity to engage in the target behaviour (e.g., if the target behaviour is negative such as smoking) or to
increase the target behaviour by reducing the opportunity to engage in competing behaviours.

- *Environmental restructuring:* changing the physical or social context.

- *Modelling:* providing an example for people to aspire to or imitate.

- *Enablement:* increasing the facilitators or reducing the barriers to increase capability or opportunity.

The Behaviour Change Wheel provides a matrix that enabled me to identify which of the nine intervention functions were appropriate for the COM-B components identified during Phase 1 (see Figure 6). Following this, the relevant intervention functions were judged in line with the APEASE criteria.
### Relevant intervention function for each of the COM-B components.

![Intervention functions matrix of the links between the COM-B model and the intervention functions](image)

**Figure 6.** Intervention functions matrix of the links between the COM-B model and the intervention functions (From “The behaviour change wheel: a new method for characterising and designing behaviour change interventions”, by S. Michie, M. M. van Stralen, and R. West, 2011, *Implementation Science, 6*, p.42. Open access, 2017 by BioMed Central).

### Step 6: Identifying the policy categories

This step involved considering which of the policy categories would best support the delivery of the intervention functions identified in step 5. There are seven policy categories:

- **Communication/marketing**: using print or electronic media.
- **Guidelines:** creating documents that recommend or stipulate practice
  (including all of the changes to the provision of services).
- **Fiscal measures:** using the tax system to reduce or increase the financial cost.
- **Regulation:** establishing rules of behaviour or practice.
- **Legislation:** making or changing laws.
- **Environmental/social planning:** designing and/or controlling the physical or social environment.
- **Service provision:** delivering a service.

Using the matrix, the Behaviour Change Wheel states which policy categories are appropriate for each of the intervention functions (Figure 7). Again the policy categories were judged against the APEASE criteria to identify the most appropriate.
<table>
<thead>
<tr>
<th>Policy categories</th>
<th>Intervention functions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Education</td>
</tr>
<tr>
<td>Communication/marketing</td>
<td></td>
</tr>
<tr>
<td>Guidelines</td>
<td></td>
</tr>
<tr>
<td>Fiscal measures</td>
<td></td>
</tr>
<tr>
<td>Regulation</td>
<td></td>
</tr>
<tr>
<td>Legislation</td>
<td></td>
</tr>
<tr>
<td>Environmental/social planning</td>
<td></td>
</tr>
<tr>
<td>Service provision</td>
<td></td>
</tr>
</tbody>
</table>

- Relevant intervention function for each policy category.

*Figure 7. Policy categories matrix of the links between the intervention functions and the policy categories (From “From “The behaviour change wheel: a new method for characterising and designing behaviour change interventions”, by S. Michie, M. M. van Stralen, and R. West, 2011, *Implementation Science, 6*, p.42. Open access, 2017 by BioMed Central).*

**Phase 3: Identifying the content and implementation options**

There were two steps within this phase which enabled a more detailed specification of the content of the care bundle intervention.
**Step 7: Identifying the behaviour change techniques**

Behaviour change techniques are the active components of the intervention designed to change the target behaviour. Behaviour change techniques are observable, replicable and irreducible. Through the intervention functions, the Behaviour Change Wheel is linked with The Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013). The Behaviour Change Technique Taxonomy is a list of 93 techniques which can be incorporated into interventions to bring about behaviour change (Michie et al., 2013) (see Appendix 6).

The Behaviour Change Wheel includes a list of which behaviour change techniques are the most suitable for each of the intervention functions. Moreover, the list of behaviour change techniques includes those which are most frequently and less frequently used (Abraham et al., 2015). The potentially appropriate behaviour change techniques were considered against the APEASE criteria to assess their suitability to the context of nursing homes.

**Step 8: Identifying the mode of delivery**

*Modes of delivery* refer to how the intervention will be delivered (see Table 8) and I considered who, what, how and where each aspect of intervention would be delivered. The APEASE criteria were used to judge the suitability of the various modes of delivery.
Table 8

*Modes of delivery matrix (adapted from Michie et al. (2014) p. 178)*

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Individual-level</th>
<th>Individual</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Distance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population-level</td>
<td>Broadcast media</td>
<td>Television</td>
<td>Radio</td>
</tr>
<tr>
<td>Outdoor media</td>
<td>Billboard</td>
<td>Poster</td>
<td></td>
</tr>
<tr>
<td>Print media</td>
<td>Newspaper</td>
<td>Leaflet</td>
<td></td>
</tr>
<tr>
<td>Digital media</td>
<td>Internet</td>
<td>Mobile phone app</td>
<td></td>
</tr>
<tr>
<td>Individual-level</td>
<td>Phone</td>
<td>Phone helpline</td>
<td>Mobile phone text</td>
</tr>
<tr>
<td></td>
<td>Individually accessed computer program</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.2 Assessing the feasibility of implementing the care bundle intervention in a nursing home context

Care bundles are more commonly implemented in hospital settings thus, a novel aspect of my research was to assess whether it was feasible to implement a pressure ulcer prevention care bundle intervention in a nursing home setting (Chapter Nine). As discussed, the use of the Behaviour Change Wheel guided the development of the care bundle intervention. This led to the development of a behavioural specification for the implementation (e.g., mode of delivery) of
the care bundle intervention (Chapter Eight) and the implementation processes are described in detail in Chapter Nine. Thus, I will now discuss the approaches I took in order to evaluate the care bundle intervention. The *feasibility and piloting phase* within the MRC guidance for developing and evaluating complex interventions (Craig et al., 2008) informed the evaluation of the care bundle intervention. This phase involved the *testing of the procedures, estimating recruitment and retention* and *determining the sample size*. I have discussed the sample size considerations in Chapter 3 and the recruitment and retention issues are discussed in Chapter Ten. Thus, I will now explain the *testing of the procedures*.

5.2.1 *Feasibility and piloting*

The MRC guidance for developing and evaluating complex interventions explicitly recommends conducting feasibility and pilot studies before running a randomised trial (Craig et al., 2008). However, the guidelines do not provide any formal definitions of feasibility and pilot studies. Rather, guidance is provided regarding the content of such studies (e.g., the testing of the procedures).

Within the literature there is a lack of clarity with various and conflicting definitions of feasibility and pilot studies (e.g., National Institute for Health Research: Glossary, 2015; Thabane et al., 2010). This led to the re-evaluation of
the definitions by Eldridge et al. (2016) which involved a Delphi study and an international expert consensus meeting that aimed to develop and extend the 2010 CONSORT statement for randomised trials (Schulz, Altman, & Moher, 2010). Following the re-evaluation and validation, Eldridge et al. (2016) stated that it is appropriate to conduct a feasibility study when there is uncertainty about the potential viability of conducting a randomised trial. Eldridge et al. (2016) further explained that ‘feasibility’ is an overarching term for three distinct types of studies:

1. **Randomised pilot studies**: aspects of the planned randomised trial (e.g., randomisation of the participants) are conducted on a smaller scale to assess the feasibility. Consequently, randomised pilot studies often incorporate the same design as the future trial, but may involve different strategies due to uncertainty.

2. **Non-randomised pilot studies**: this term covers many different types of studies. Non-randomised pilot studies may involve all of the aspects of the future trial except the randomisation of the participants, or studies may only conduct the intervention aspects to assess feasibility.

3. **Feasibility studies that are not pilot studies**: the intervention and other study aspects are not implemented, rather researchers attempt to answer questions relating to specific aspects of the future trial. For example, a researcher may conduct a focus group to discuss the likely acceptability of
the intervention. Thus, this type of feasibility study differs from the first two as no aspect of the future trial is conducted.

Under the definitions provided by Eldridge et al. (2016), the study reported in Chapter Nine is a non-randomised pilot study as I implemented the care bundle intervention using the procedures I would expect to use in a future trial. However, throughout this thesis, I have chosen to use the term ‘feasibility’ in the broad sense, as I aimed to explore the viability of conducting a future trial. This exploration included assessing whether the care bundle intervention could be implemented within a nursing home context and whether it was acceptable to key stakeholders (e.g., healthcare workers, patients).

5.2.1.1 Testing procedures

The MRC guidance suggests conducting process evaluations when evaluating complex interventions (Craig et al., 2008). Within the context of this research, process evaluations were used to assess the degree to which the care bundle intervention was implemented as planned (i.e. implementation fidelity) and to identify any barriers or facilitators to implementation. Thus, process evaluations can facilitate understanding regarding the feasibility of the intervention and this is likely to maximise the potential for success in future trials (Moore et al., 2015). As the MRC guidance (Craig et al., 2008) provides very little guidance, I will outline the rationale for the specific feasibility testing procedures that I conducted and have reported in Chapter Nine.
5.2.1.1a Implementation fidelity

The extent to which an intervention actually delivers the intended outcome is partly moderated by the extent to which it is delivered as intended, (i.e. implementation fidelity) (Carroll et al., 2007; Damschroder et al., 2009; Mihalic, 2004). Moreover, assessing implementation fidelity may help to avoid false conclusions being drawn regarding the effectiveness of an intervention.

During my research project exploring the feasibility of implementing the pressure ulcer prevention care bundle intervention in a nursing home context (Chapter Nine), I examined the aspects of implementation fidelity outlined by Carroll et al. (2007). Carroll et al. (2007) developed a conceptual framework for understanding and evaluating implementation fidelity. Within the framework, implementation fidelity is measured through adherence (i.e. the extent to which those delivering the intervention implemented it as outlined by the designers of the intervention). Adherence includes four sub-categories: content, frequency, coverage and duration and there are four other variables (i.e. moderator variables) that can influence the level of adherence:

1. Intervention complexity: comprehensiveness of the intervention description.

   Detailed and specific interventions are more likely to be implemented with high fidelity (Dusenbury, Brannigan, Falco, & Hansen, 2003; Hasson, Blomberg, & Dunér, 2012). Whilst I have developed a detailed specification (see Chapter Eight), more complex interventions are at a greater risk of
lower fidelity rates when compared with more simple interventions because of the number of components involved and the variations in their delivery (Arai, Roen, Roberts, & Popay, 2005; Hasson et al., 2012; Roen, Arai, Roberts, & Popay, 2006).

2. *Facilitation strategies*: strategies can be used to standardise and optimise implementation fidelity (e.g., training, monitoring and feedback). The more implementation is supported through the use of such strategies, the higher the implementation fidelity is likely to be. However, this does not mean that implementation fidelity will be higher if more facilitation strategies are used.

3. *Quality of delivery*: how appropriate the intervention is for achieving the intended outcomes.

4. *Participant responsiveness*: the level of engagement with the intervention by the study participants. Implementation fidelity can be influenced by whether those delivering and receiving the intervention find it acceptable (Diepeveen, Ling, Suhrcke, Roland, & Marteau, 2013; Stok et al., 2016).

Thus, acceptability has been included as part of the feasibility assessment and participant responsiveness is usually measured via self-reports.

These four moderators may be discrete components or they may influence each other (Carroll et al., 2007). The final component of the implementation fidelity framework (Carroll et al., 2007) is the analysis of the outcomes to enable the identification of the components essential to the intervention.
5.2.1.1b Barriers and facilitators to implementation

To explore the barriers and facilitators to the implementation of the care bundle intervention (Chapter Nine) and to assess whether the initial barriers and facilitators identified (Chapter Seven) had been addressed successfully, I chose to analyse the qualitative data using the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005). I believed this would increase the consistency throughout the research and avoid overcomplicating the procedures because the same domains were applied. All of the qualitative data were analysed sequentially using an inductive approach followed by a deductive approach (see Chapter Three) thus, it is unlikely that I overlooked any important themes relating to the implementation of the care bundle intervention.

5.3 Ethics

I endeavoured to meet the highest research standards throughout this thesis which included the following principles of research ethics:

- **Autonomy:** participants were free to participate in the research without coercion or penalty, and they were free to withdraw at any point without giving a reason.

- **Beneficence:** the research was worthwhile and the benefits of conducting the research outweighed the risks.

- **Non-maleficence:** robust precautions were in place to avoid or mitigate harm.

- **Confidentiality:** the participants had the right to remain unknown.
- **Integrity:** I was open about the potential gains I would make from the research (e.g., gaining a PhD qualification).

I will now discuss how I sought to achieve these key principles throughout this research.

I obtained ethics approval for the studies reported in Chapters Seven to Nine from the University of Manchester. For the studies reported in Chapters Seven and Eight, I also obtained approval from the NHS Research and Development department; this additional approval was not required for the research conducted in Chapter Nine.

I discussed the research in detail with the nursing home managers and care staff, as well as the NHS community-based nursing teams. It was important that the participants did not feel coerced into engaging in the research and I provided a Participant Information Sheet for each of the studies (see Appendix 7). The Participant Information Sheet was used to enhance the participants’ understanding of the study and highlight the implications of participating, as well as to provoke any questions they may have had about the research. The Participant Information Sheet enabled the potential participants to make an informed decision about whether or not they wished to participate.
The Participant Information Sheet explained that the data collected were confidential and I reiterated this verbally and explained to the potential participants what exactly this term meant. I also explained that participation was voluntary and that I would anonymise all of the data following the transcription of the interviews. I gave the potential participants the opportunity to ask for clarification of anything they were unsure about. I provided further information as required before asking those who agreed to participate to sign a consent form (see Appendix 8) and complete a demographic questionnaire (see Appendix 9).

Whilst I transcribed the qualitative data, the audio recordings and electronic data were stored on the University of Manchester’s shared network drive, within my personal network area which was secure and password protected. Once I had completed the transcription process I destroyed all of the digital recordings of the interviews and anonymised all of the transcripts, removing all identifying descriptions and providing participants with pseudonyms. Identifiable information (e.g., signed consent forms) were kept in a locked cabinet within a locked room at the University of Manchester and only I had access to this cabinet. This data will be stored in line with the University’s storage of personal data policy which states that personal data must be stored for a minimum of five years after the research has been completed. Finally, I
5.4 Chapter summary

Within this chapter I have outlined the MRC guidance for developing and evaluating complex interventions, highlighting the recommendations for the use of theory as well as the lack of standardised procedures. Thus, when deciding how best to develop a care bundle intervention, developers are left to find the method they feel is the most suitable.

I have outlined a two-fold method for the development of the care bundle intervention. Firstly, I discussed the importance of involving the key stakeholders in the process of designing the care bundle intervention. All of the stakeholders had relevant knowledge and expertise and contributed to the overall design of the care bundle intervention. Thus, I viewed a consensus method as the most appropriate means to gain agreement regarding the care bundle content. More specifically, due to the limited time of the nursing home care staff and the NHS community-based nurses, a Nominal Group Technique was viewed to be the most suitable method to gain consensus. Secondly, in line with the recommendations (e.g., the MRC guidance; Craig et al., 2008), the intervention design was informed by psychological and behaviour change theories. The Theoretical Domains Framework enabled the identification and
specification of what needed to change, which informed the intervention options and content. The matrices and the APEASE criteria used as part of the Behaviour Change Wheel provided a framework for the explicit reporting of the rationale for the decisions regarding the inclusion and exclusion of certain components. Finally, I have explained the evaluation methodology employed within this research. I have clearly defined feasibility studies and explained how I applied a conceptual framework for implementation fidelity and the Theoretical Domains Framework during the analysis in the feasibility study.
Chapter 6

The effects of care bundles on patient outcomes: a systematic review and meta-analysis.

(Journal article)

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Prepared for submission
6.1 Abstract

**Background:** Care bundles are a set of three to five research-informed practices performed collectively and reliably to improve the quality of care. Care bundles are used across healthcare settings with the aim of preventing and managing different health conditions. This is the first systematic review designed to determine the effects of care bundles on patient outcomes and the behaviour of healthcare workers in relation to fidelity with care bundles.

**Methods:** This systematic review is reported in line with the PRISMA Statement for reporting systematic reviews and meta-analyses. A total of 5796 abstracts were retrieved through a systematic search for articles published between January 1, 2001 to February 4, 2017 in the Cochrane Central Register for Controlled Trials, MEDLINE, EMBASE, British Nursing Index, CINAHL, PsychInfo, British Library, Conference Proceeding Citation Index, OpenGrey. Randomised trials (including cluster-randomised trials) and non-randomised studies (comprising controlled before-after studies, interrupted time series, cohort studies) of care bundles for any health condition and any healthcare setting were considered. Following the removal of duplicated studies, two reviewers independently screened 3134 records. Three authors performed data extraction independently. We compared the care bundles with usual care to evaluate the effects of care bundles on the rates of negative patient outcomes. Random-effect models were used to further explore the effects of subgroups.
Results: In total, 37 studies (6 randomised trials, 31 controlled before-after studies) were eligible for inclusion. The effect of care bundles on patient outcomes is uncertain. For randomised trial data, the pooled relative risk of negative effects between care bundle and control groups was 0.97 [95% CI 0.71 to 1.34; 2,049 participants]. The relative risk of negative patient outcomes from controlled before-after studies favoured the care bundle treated groups (0.66 [95% CI 0.59 to 0.75; n = 119,178]). However, using GRADE, we assessed the certainty of all of the evidence to be very low (downgraded for risk of bias, inconsistency, indirectness).

Conclusions: Very low quality evidence from controlled before-after studies suggests that care bundles may reduce the risk of negative outcomes when compared with usual care. By contrast the better quality evidence from the six randomised trials is more uncertain.

Registration: The systematic review protocol was registered a priori in PROSPERO (CRD42016033175).

Keywords: Care bundle, effectiveness, implementation fidelity, behaviour change.
6.2 Introduction

According to Eccles and Mittman (2006) “implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care” (p.1). However, most research evidence is not implemented into practice (Deedwania, 2015; Runciman et al., 2012). Recently, Sundberg et al., (2017) distinguished between research evidence and non-research evidence (e.g., clinical expertise, context, patient values and preferences). Non-research evidence can be at risk of bias in terms of individuals favouring certain practices (Raine et al., 2004). Nevertheless, research evidence and non-research evidence contribute to clinical decision making about which clinical practices to conduct. Thus, a goal of health research is to identify effective ways of translating research findings into practice whilst considering the other forms of evidence used by healthcare workers (Eccles & Mittman, 2006).

To improve the quality of care and reduce the variations in care within intensive care units (ICUs), the Institute for Healthcare Improvement introduced the notion of care bundles (Resar et al., 2012; Resar et al., 2005). Care bundles contain three to five research-informed practices, which need to be delivered collectively and consistently with the aim of improving patient outcomes (Resar et al., 2012). The Institute for Healthcare Improvement
recommend that every eligible patient should receive all of the elements included within the care bundle unless medically contraindicated (Resar et al., 2012). Care bundles are used within healthcare for many different conditions (e.g., to prevent: ventilator-associated pneumonia, pressure ulcers). Whilst care bundles formalise care, their success will be influenced by the implementation processes used to support care bundle use in practice (e.g., the shaping of knowledge, monitoring and feedback). Consequently, the behaviours of healthcare workers need to be targeted as part of the intervention (Zingg et al., 2015).

Interventions aimed at changing health behaviours are often complex and comprise of several components which have a synergistic effect (Craig et al., 2008). Thus, care bundles are sometimes regarded as “complex interventions” due to the number of components which interact within the care bundle; the number and variability of outcomes; the extent to which the care bundle can be tailored and how difficult it is to perform the care bundle tasks. The Medical Research Council’s guidance for developing and evaluating complex interventions recommends grounding complex interventions in theory to increase the likelihood of effectiveness (Craig et al., 2008). Capitalising on behaviour change theory is important as the factors which influence the target behaviour, the active components of the intervention and the delivery of the intervention can be identified and selected (French et al., 2012).
Behaviour change techniques are the observable and replicable components of behaviour change interventions, often referred to as the ‘active ingredients’ (Michie et al., 2013; Michie et al., 2011). Previously studies reporting the use of behaviour change interventions have employed a number of different behaviour change techniques, but they have been defined differently or unclearly which limits the evaluation and replication of these interventions (Stavri & Michie, 2009). To address this issue, a taxonomy of 93 behaviour change techniques (Michie et al., 2013) was developed and can be used to identify intervention components, enabling the standardisation of terms as well as the comparison of behaviour change techniques across studies. Feedback on outcomes of behaviour, prompts/cues and instruction on how to perform a behaviour are examples of behaviour change techniques commonly used to facilitate a behaviour change in healthcare workers (e.g., Presseau et al., 2015; Steinmo et al., 2016). Identifying the specific behaviour change techniques employed during the implementation of care bundles could enable researchers and healthcare workers to understand which components were key when a care bundle was successful. Moreover, by using standardised behaviour change language, comparisons with other care bundles will be possible. Such standardised language and comparisons will increase our knowledge of the most suitable methods for implementing care bundles and facilitate the prediction and explanation of any subsequent behaviour change (Michie, Johnston, Francis, Hardeman, & Eccles, 2008).
To date, systematic reviews of care bundles have been condition (Aboelela, Stone, & Larson, 2007; Chamberlain, Willis, & Bersten, 2011; Damiani et al., 2015; Ferrer & Artigas, 2011; Ista et al., 2016; Ospina et al., 2017; Payne, Johnson, Smith, & Hall, 2016; Schweizer et al., 2013; Schweizer et al., 2014; Tanner et al., 2015) or setting-specific (Bannan & Tully, 2016; Borgert, Goossens, & Dongelmans, 2015; Marwick & Davey, 2009). Very few systematic reviews have explored the common behaviour change techniques employed to facilitate the implementation of care bundles (Borgert et al., 2015) and it is unknown which factors may impact on the success of care bundles. Therefore, the objectives of this review were to: evaluate the effects of care bundles as tools for improving patient outcomes; to identify potentially effective approaches to the implementation of care bundles by exploring whether there are plausible factors that modify the effects of care bundles (e.g., healthcare settings, fidelity with the bundle, the number of care bundle elements, different implementation techniques).

6.3 Methods

To maximise clarity and transparency, we have reported our review in line with the PRISMA statement for the reporting of systematic reviews and the meta-analyses of studies evaluating healthcare interventions (Moher, Liberati, Tetzlaff, Altman, & Group, 2009).
6.3.1 Eligibility criteria

We applied the following eligibility criteria:

- **Study design:** Randomised trials (including cluster-randomised trials) and non-randomised trials (comprising controlled before-after studies, interrupted time series studies and cohort studies) were eligible for inclusion. Additionally interrupted time series studies were required to have at least three data points both before and after the intervention. Conference abstracts were eligible if we were able to contact the authors and they provided sufficient information to allow a decision to be made regarding inclusion based on our eligibility criteria. We were only able to include English language articles due to resource constraints.

- **Participants:** Evaluations of the impact of care bundles on patients of any age, in any setting and with any condition were eligible for inclusion.

- **Intervention:** Studies were eligible for inclusion if they evaluated a care bundle. Our operational definition of a care bundle was informed by the Institute for Healthcare Improvement:
  - to have a maximum of five research-informed elements agreed by the multidisciplinary team; include elements that are relatively independent; have elements that are descriptive rather than prescriptive to allow for clinical judgment and customisation; be specific to a particular population and care setting (Resar et al., 2012).
- **Outcome measures**: Studies were eligible for inclusion if one of the primary outcomes for this review was reported: clinical outcomes, implementation fidelity (i.e. adherence to the care bundle).

Where study eligibility was in doubt due to a lack of information in the publication (e.g., conference abstracts) we attempted to contact the authors. After contacting the study authors all papers with doubtful eligibility were excluded.

### 6.3.2 Search strategy

The search strategy was developed using the terms based on the intervention and outcomes (see Appendix 2 for search terms). To maximise retrieval we searched the following databases: British Nursing Index, CINAHL, MEDLINE, EMBASE, CENTRAL, PsycINFO, British Library, Conference Proceedings Citation Index and OpenGrey. As the Institute for Healthcare Improvement developed the notion of care bundles in 2001, searches were restricted to the studies conducted during or after 2001 until 4th February 2017. The reference lists of the included articles were also checked.

### 6.3.3 Data collection and analysis

#### 6.3.3.1 Selection of studies

References were managed in EndNote, which assisted with the identification and removal of duplicate studies, and then imported into Covidence Systematic
Review Software. Two reviewers (JL, WR), who were not blinded to study authors, screened the titles and abstracts before conducting a full-text review of the remaining studies. Where discrepancies occurred, we reached agreement through discussion.

6.3.3.2 Data extraction

Three reviewers independently performed data extraction using a pre-defined extraction sheet (JL [n = 37], WR [n = 6], TG [n = 31]). We extracted the following data:

- Title.
- Aims/objectives.
- Study design.
- Country of study.
- Patient population (inclusion and exclusion criteria, age, co-morbidities, sex).
- Healthcare settings.
- Care bundle content: the number and nature of the care bundle elements; the characteristics of those delivering and receiving the care bundle; the frequency with which the components were delivered and for how long.
- Intervention content: we considered a care bundle to have been informed by theory if the authors explicitly stated using a relevant theory when describing either the development or implementation of the care bundle.
- Behaviour change techniques: a post-hoc approach was taken where we retrospectively assigned the reported implementation techniques (e.g., training session) to one of the 16 behaviour change technique categories according to the Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013). Where several behaviour change techniques within the same category were used, this was counted as one (e.g., if ‘monitoring of behaviour’ and ‘feedback on behaviour’ were used, according to the taxonomy, these would be classed as “feedback and monitoring”).

- Fidelity data relating to adherence to the care bundles were extracted from the data provided in the papers.

- Duration of follow-up.

- Outcome measures.

- Outcome data.

- Funding source.

6.3.3.3 Risk of bias assessment

Three reviewers independently assessed the included studies for their risk of bias (JL [n = 37], WR [n = 28], TG [n = 9]) and we resolved disagreements through discussion. Interrater reliability was calculated using Cohen’s Kappa (Cohen, 1960). The Cochrane Collaboration tool for assessing risk of bias (Higgins et al., 2011) was used for randomised trials. The Cochrane Risk of Bias Assessment Tool: for Non-Randomised Studies of Interventions (Sterne et al.,
2014) was used to assess the risk of bias for non-randomised studies. We assessed the inter-rater reliability for the risk of bias judgements of the randomised trials (K = 0.82) and non-randomised studies (K = 0.70).

6.3.3.4 Measures of treatment effect

For dichotomous outcomes (e.g., the presence/absence of a clinical condition) we calculated the risk ratio (RR) with 95% confidence intervals (CI). A RR value of < 1 favoured the use of the care bundle (i.e. indicated a lower risk of the negative events with care bundles) and a value > 1 indicated more favourable outcomes when usual care was applied (i.e. there was a higher risk of the negative events with care bundles). Fidelity with the care bundle was recorded as a percentage indicating the extent to which the patient received either a particular care bundle element or the whole care bundle. For continuous data using the same scale, we used the difference in means (MD) with 95% CIs; and when different scales were used we calculated the standardised difference in means (SMD) with 95% CIs.

6.3.3.5 Assessment of heterogeneity

We considered clinical and methodological heterogeneity; that is how participants, outcomes and characteristics (e.g., number of care bundle elements) varied between studies. This assessment was complemented by an assessment of statistical heterogeneity using the Chi² test (statistically
significant heterogeneity was indicated by a significance level of $P < 0.1$). In addition, $I^2$ (Higgins, Thompson, Deeks, & Altman, 2003) was also calculated, which is the percentage of the total variation across studies due to heterogeneity. We followed the rubric that an $I^2$ of 0% - 40% indicated low heterogeneity (Higgins et al., 2003) whilst 75% to 100% indicated very high heterogeneity (Deeks et al., 2011). A fixed effect analysis was planned when minimal clinical heterogeneity was supported by 0% statistical heterogeneity (Kontopantelis, Springate, & Reeves, 2013). In cases where statistical heterogeneity was greater than 0%, we planned to use a random effect model.

### 6.3.3.6 Assessment of reporting biases

We planned to present funnel plots for meta-analyses comprising 10 randomised trials or more to detect a possible publication bias (Higgins et al., 2011).

### 6.3.3.7 Dealing with missing data

We conducted a complete case analysis and dealt with the issues relating to missing data during the risk of bias assessment.

### 6.3.3.8 Data synthesis

A narrative summary of the characteristics of the included studies and a forest plot of study findings are presented. We planned to pool data across studies
where possible but we anticipated high levels of clinical and methodological heterogeneity due to the broad review question. Thus, we planned to explore the heterogeneity by conducting considered subgroup analyses using Comprehensive Meta-Analysis software ("Comprehensive Meta Analysis," 2006-2017). We pre-specified that the following study features may potentially explain some of the heterogeneity: study design, health condition, healthcare setting, the number of care bundle elements, the number of behaviour change techniques and the levels of fidelity with the care bundles. We pooled the data from each of the subgroups using a random-effect model and reported the principle measures of effect using 95% CIs with risk ratios. As we present data from a random effect model, the reported results are the average effect for each subgroup. We used this approach to explore whether there was an underlying effect of care bundles and to guide future research (Kraemer, Wilson, Fairburn, & Agras, 2002; Pincus et al., 2011).

6.3.3.9 Sensitivity analysis

We planned to perform sensitivity analyses to explore the effect of the risk of bias by conducting a meta-analysis both with and without the studies assessed as being at a high or unclear risk of bias. However, this was not possible due to the limited number of studies assessed as being at a low risk of bias.
6.4 Results

The initial search generated 5796 records and a total of 37 met the criteria for inclusion in the review (Figure 8). The reasons for excluding records are stated in Figure 8.
Figure 8. PRISMA flow diagram to identify eligible studies (Moher et al., 2009).
6.4.1 Study characteristics

The characteristics of each study are presented in detail in Appendix 10. We identified four individually randomised trials (Anthony et al., 2011; Chipps et al., 2016; Jennings et al., 2015; Loftus et al., 2012), two cluster-randomised trials (Chaboyer et al., 2016; Power et al., 2014) and 31 controlled before-after studies (Al-Tawfiq & Abed, 2010; Anderson et al., 2015; Antworth et al., 2013; Battersby et al., 2014; Berenholtz et al., 2011; Boesch et al., 2012; Düzkaya, Bozkurt, Uysal, & Yakut, 2016; El Azab et al., 2013; Eom et al., 2014; Hakko et al., 2015; Hocking & Pirret, 2013; Jeong, Park, Lee, Song, & Lee, 2013; Lawrence & Fulbrook, 2012; Levy et al., 2014; Lim et al., 2015; Lindsay et al., 2013; Morris et al., 2011; Muszynski et al., 2013; Pena-Lopez et al., 2016; Resende, Brito, Abdallah, & Gontijo Filho, 2011; Salama, Jamal, Al Mousa, & Rotimi, 2016; Schindler, 2010; Schweizer et al., 2015; Smith, 2017; Stano, Avolio, De Rosa, Modolo, & Camporese, 2013; Steiner et al., 2015; Stolbrink et al., 2014; Subramanian, Choy, Gobal, Mansor, & Ng, 2013). All of the included studies reported on care bundles within inpatient settings. A variety of health conditions were targeted with ventilator-associated pneumonia being the most common (seven studies: Al-Tawfiq & Abed, 2010; Berenholtz et al., 2011; El Azab et al., 2013; Eom et al., 2014; Morris et al., 2011; Pena-Lopez et al., 2016; Subramanian et al., 2013). Two studies reported the implementation of two bundles (Levy et al., 2014; Power et al., 2014) and one study reported on the implementation of three care bundles (Hocking & Pirret, 2013). Descriptions of the people delivering the care bundles
were limited. The duration of the intervention varied from 3 months to 7.5 years (the median length of time was 31.5 months).

A variety of behaviour change techniques were used to facilitate the implementation and the potential success of the care bundles (see Appendix 10). However, a theoretical basis for choosing the various behaviour change techniques was not stated in any of the studies. ‘Feedback and monitoring’ was the most commonly reported behaviour change technique used to support the implementation of the care bundles and was reported in 22 studies (see Appendix 10). Eight studies reported using an implementation framework or psychological theory to inform the implementation of the care bundles (Battersby et al., 2014; Berenholtz et al., 2011; Boesch et al., 2012; Conway-Morris et al., 2011; El Azab et al., 2013; Huddart et al., 2014; Power et al., 2014; Smith, 2017) (see Appendix 10).

6.4.2 Risk of bias

Summaries of the risk of bias assessments for the included randomised trials and non-randomised trials are presented in Appendix 11. The cluster-randomised trial (Power et al., 2014), which aimed to improve the consistency of stroke care through the implementation of a care bundle, was assessed as being at a low risk of bias. Three randomised trials and one cluster-randomised trial were at a high risk of bias (Anthony et al., 2011; Chaboyer et al., 2016;
Chipps et al., 2016; Loftus et al., 2012) and one study had an unclear risk of bias due to poor reporting (Jennings et al., 2015). Two of the controlled before-after studies were assessed as having a low risk of bias (Battersby et al., 2014; Huddart et al., 2014), eight were assessed to be at moderate risk of bias (Antworth et al., 2013; Boesch et al., 2012; Lawrence & Fulbrook, 2012; Morris et al., 2011; Roquilly et al., 2013; Schindler, 2010; Stolbrink et al., 2014), 15 were assessed to be at serious risk of bias (Al-Tawfiq & Abed, 2010; Anderson et al., 2015; Berenholtz et al., 2011; Düzkaya et al., 2016; El Azab et al., 2013; Eom et al., 2014; Hakko et al., 2015; Hocking & Pirret, 2013; Jeong et al., 2013; Lindsay et al., 2013; Muszynski et al., 2013; Resende et al., 2011; Rinke et al., 2013; Schweizer et al., 2015; Subramanian et al., 2013) and seven studies were assessed to be at critical risk of bias (Conway-Morris et al., 2011; Levy et al., 2014; Pena-Lopez et al., 2016; Salama et al., 2016; Smith, 2017; Stano et al., 2013; Steiner et al., 2015).

6.4.3 Effects of care bundles

There was a substantial variation in the effect of the care bundles across the individual studies, ranging from a RR of 0.08 (the care bundle decreased the risk of ventilator-associated pneumonia (Berenholtz et al., 2011) to a RR of 1.88 (the care bundle increased the risk of surgical site infections (Anthony et al., 2011) (see Figure 9) (Chi² = P < .1; I² = 86%). As a consequence of this heterogeneity we did not pool all data into one analysis. Rather, we used
subgroup analysis to explore cautiously whether specific methodological features and intervention aspects of the care bundles might impact on their relative effects (see Figure 10). One randomised trial (Power et al., 2014) and one controlled before-after study (Lawrence & Fulbrook, 2012) did not report any patient outcomes, only fidelity with the care bundles, and it was not possible to re-analyse the findings from Smith (2017) due to insufficient information. Thus, these three studies are not included within this section of the analysis. Due to the limited number of studies we could not conduct meta-regression.
Figure 9. A forest plot of the risk ratios for each of the included studies demonstrating the effects of care bundles on patient outcomes.

Key:
*: Randomised trial
VAP/1000: ventilator-associated pneumonia per 1000 ventilator days;
MBM: maternal breast milk;
VAP: ventilator-associated pneumonia;
CLABSI: central line-associated bloodstream infections;
BP: blood pressure;
VAT: ventilator-associate tracheobronchitis;
SSIs: surgical site infections;
CABI: catheter-associated bloodstream infections;
HAP: hospital-acquired pneumonia;
SSIs: surgical site infections;
CAP: community-acquired pneumonia;
CAUTI: catheter-associated urinary tract infections;
HAPU: hospital-acquired pressure ulcer;
COPD: chronic obstructive pulmonary disease.
<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Health condition</th>
<th>Risk ratio</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Risk and 95% CI</th>
<th>Overall differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAP (n = 3,531)</td>
<td></td>
<td>0.38</td>
<td>0.26</td>
<td>0.57</td>
<td>Favours usual care</td>
<td>$I^2 = 86%$ $P = 0.03$</td>
</tr>
<tr>
<td>CLABSI (n=1,587)</td>
<td></td>
<td>0.46</td>
<td>0.26</td>
<td>0.8</td>
<td></td>
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<tr>
<td>Pressure ulcers (n = 3,157)</td>
<td></td>
<td>0.33</td>
<td>0.21</td>
<td>0.52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (n = 113,032)</td>
<td></td>
<td>0.79</td>
<td>0.71</td>
<td>0.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU (n = 42,314)</td>
<td></td>
<td>0.59</td>
<td>0.49</td>
<td>0.72</td>
<td>Favours usual care</td>
<td>$I^2 = 86%$ $P = 0.04$</td>
</tr>
<tr>
<td>Level 1 trauma centre (n = 925)</td>
<td></td>
<td>0.5</td>
<td>0.31</td>
<td>0.82</td>
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<tr>
<td>Other (n = 78,078)</td>
<td></td>
<td>0.78</td>
<td>0.67</td>
<td>0.91</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 (n = unclear)</td>
<td></td>
<td>0.78</td>
<td>0.37</td>
<td>1.67</td>
<td>Favours usual care</td>
<td>$I^2 = 86%$ $P = 0.93$</td>
</tr>
<tr>
<td>3 (n = 8,175)</td>
<td></td>
<td>0.64</td>
<td>0.48</td>
<td>0.85</td>
<td></td>
<td></td>
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<tr>
<td>4 (n = 77,062)</td>
<td></td>
<td>0.71</td>
<td>0.57</td>
<td>0.89</td>
<td></td>
<td></td>
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<tr>
<td>5 (n = 40,872)</td>
<td></td>
<td>0.67</td>
<td>0.57</td>
<td>0.79</td>
<td></td>
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<tr>
<td>0 (n = 3,877)</td>
<td></td>
<td>0.7</td>
<td>0.53</td>
<td>0.92</td>
<td>Favours usual care</td>
<td>$I^2 = 86%$ $P &lt; 0.05$</td>
</tr>
<tr>
<td>1 (n = 4,937)</td>
<td></td>
<td>0.67</td>
<td>0.48</td>
<td>0.93</td>
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<tr>
<td>2 (n = 4,490)</td>
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<td>0.49</td>
<td>0.33</td>
<td>0.75</td>
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<tr>
<td>3 (n = 2,721)</td>
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<td>0.44</td>
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<td>0.65</td>
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<tr>
<td>4 (n = 399)</td>
<td></td>
<td>0.6</td>
<td>0.43</td>
<td>0.84</td>
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</tr>
<tr>
<td>5 (n = 36,062)</td>
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<td>0.85</td>
<td>0.66</td>
<td>1.1</td>
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<tr>
<td>6 (n = 35,263)</td>
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<td>0.84</td>
<td>0.66</td>
<td>1.1</td>
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<tr>
<td>7 (n = unclear)</td>
<td></td>
<td>0.29</td>
<td>0.53</td>
<td>1.53</td>
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<tr>
<td>8 (n = 520)</td>
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<td>0.23</td>
<td>0.03</td>
<td>1.52</td>
<td></td>
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</tr>
<tr>
<td>Inadequate (&lt;95%)</td>
<td></td>
<td>0.79</td>
<td>0.65</td>
<td>0.96</td>
<td>Favours usual care</td>
<td>$I^2 = 86%$ $P = 0.03$</td>
</tr>
<tr>
<td>Adequate (&gt;95%)</td>
<td></td>
<td>0.37</td>
<td>0.21</td>
<td>0.66</td>
<td></td>
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</tr>
</tbody>
</table>

**Key**
- VAP: ventilator-associated pneumonia
- CLABSI: central line-associated bloodstream infection

*Figure 10. Subgroup analysis of included studies.*
6.4.4 Impact of study features on effect sizes

There were insufficient comparisons involving patient outcomes to enable a meta-regression of study features and the magnitude of the effects (Figure 10). Below we report on the findings of the subgroup analysis.

6.4.4.1 Study design

Given that observational studies are generally at a higher risk of bias than randomised studies, we compared the results of randomised and non-randomised studies. The pooled treatment effect for the randomised trials (n = 2,049) was on average, RR = 0.97 [95% CI 0.71 to 1.34]. There were five randomised trials included in the analysis and it is likely that the findings were driven by one randomised trial which found an increase in the number of negative events and the study was stopped early (Anthony et al., 2011). The difference in the between subgroup effects for the randomised trials and controlled before-after studies was statistically significant. The controlled before-after studies generated a greater average treatment effect in favour of care bundles than the randomised trials (n = 119,178; RR = 0.66 [95% CI 0.59 to 0.75]). However, the quality of the evidence was very low (downgraded for risk of bias, inconsistency and indirectness).
6.4.4.2 Health condition

We assessed whether the health condition impacted on the effectiveness of care bundles (Figure 10). The care bundles appeared to be potentially effective in all of the conditions we evaluated (including a heterogeneous ‘other’ group). The test for differences between the subgroups was statistically significant ($P < 0.001$) suggesting that there were differences in effects between the subgroups. The studies assessing the effects of care bundles on the incidence of pressure ulcers, central line-associated bloodstream infections and ventilator-associated pneumonia may have the largest reductions in the risk of negative patient outcomes. A small reduction was observed for the heterogeneous ‘other’ category. However, we considered all of these data to be of very low quality due to their risk of bias, inconsistency and indirectness.

6.4.4.3 Healthcare setting

The data also suggested that the care bundles were potentially effective across all of the settings in which they were evaluated (Figure 10). Care bundles may be more effective in trauma centres and ICUs compared with the heterogeneous ‘other’ group. The use of care bundles in trauma centres may be associated with the lowest risk of negative patient outcomes (e.g., ventilator-associated pneumonia) followed by ICUs and ‘other’ settings. However, this is very low quality evidence (downgraded for risk of bias, inconsistency and indirectness).
6.4.4.4 Care bundle elements

We assessed whether the number of care bundle elements impacted on patient outcomes (Figure 10). Whilst all of the care bundles (regardless of the number of elements) reduced the risk of the negative patient outcomes, the test for differences between the subgroups was not statistically significant ($P = 0.93$). The RR was similar irrespective of the number of elements. For example, for three elements the RR was 0.64 [95% CI 0.48 to 0.85] and for five elements the RR was 0.67 [95% CI 0.57 to 0.79]. However, the quality of the evidence within this subgroup was very low (downgraded for risk of bias, inconsistency and indirectness).

6.4.4.5 Behaviour change techniques

The frequency with which the behaviour change techniques were delivered was often not reported, nor were the levels of engagement with the behaviour change techniques. We assessed the impact of the number of behaviour change techniques on the effectiveness of care bundles. There were significant variations between the subgroups and the lowest risk for the negative patient outcomes was in the subgroup with ‘eight behaviour change techniques’ (RR = 0.23 [95% CI 0.03 to 1.52]) (Figure 10). The apparent effect of the care bundles appeared to reduce as the number of elements increased (the care bundles with five elements had an RR of 0.85 [95% CI 0.66 to 1.1]). However, we considered
these data to be of very low quality due to the risk of bias, inconsistency and indirectness.

6.4.4.6 Fidelity with the care bundle

Fidelity with the care bundle content was regarded as adequate at 95% or above. As hypothesised, adequate fidelity (3 studies) may be associated with a larger effect on patient outcomes (RR = 0.37 [95% CI 0.21 to 0.66]) when compared with the care bundles implemented with inadequate fidelity (RR = 0.82 [95% CI 0.66 to 1.0]). However, the evidence was of very low quality which was downgraded for the risk of bias, inconsistency and indirectness.

6.5 Discussion

This is the first systematic review to examine the current best evidence for the effects of care bundles with a maximum of five care bundle elements. We have identified a large, heterogeneous body of research which shows that the implementation of care bundles may be effective in improving patient outcomes in acute settings (e.g., preventing ventilator-associated pneumonia in ICUs). However, the certainty of our conclusion is greatly tempered by the low or very low quality of the evidence (with most of the evidence coming from controlled before-after studies). We have shown that the care bundles evaluated using the non-randomised study designs are more likely to report greater patient benefits. This is likely to be due, at least in part, to the biases in the
study design and conduct. Unfortunately, the evidence from the randomised trials was uncertain (five studies with a total sample size of N = 2,049).

It was difficult to assess the effect of fidelity on the patient outcomes. Thirteen studies reported the levels of fidelity in terms of adherence with the care bundle. Levels of adherence varied between the studies suggesting that the full implementation of the care bundles was rare. This is an important issue as three studies demonstrated fewer occurrences of the negative events (central line-associated bloodstream infections (Hakko et al., 2015), mortality (Levy et al., 2014) and surgical site infections (Schweizer et al., 2015)) when fidelity with the associated care bundle was high. However, within the analysis we were generally working with uncertain data, and the review findings must be considered in line with the observational nature of subgroup analyses. As noted previously, the quality of the evidence is very low and therefore we are uncertain whether there was an underlying effect of care bundles that is independent of these study characteristics.

The lack of theory reported in the development and implementation of the care bundles was evident throughout the systematic review. Eight studies reported using an implementation framework or a psychological theory to guide their implementation (Battersby et al., 2014; Berenholtz et al., 2011; Boesch et al., 2012; Conway-Morris et al., 2011; El Azab et al., 2013; Huddart et al., 2014;
Power et al., 2014; Smith, 2017). When encouraging healthcare workers to use research-based strategies, taking a theory-informed approach is recommended (Craig et al., 2008; NICE: Pressure ulcers, 2014). However, often a pragmatic approach is taken, and this lack of explicit psychological theory during the design and implementation phases of the care bundles may impact on the effectiveness of such interventions (Davies et al., 2010; Michie et al., 2005).

Mechanisms of action are the theoretical constructs through which behaviour change techniques have their effect. Explicitly stating the potential mechanisms of action (e.g., restructuring the environment, training) can facilitate the generalisations of the care bundle findings to other healthcare settings. The most commonly used behaviour change techniques were ‘feedback and monitoring’ and ‘shaping knowledge’. This is in line with previous findings on implementation strategies (Borgert et al., 2015; Dijkstra et al., 2016; Sinuff et al., 2013). However, the frequency of these behaviour change techniques was often not reported, and neither were the levels of engagement with the behaviour change techniques (e.g., attendance at training sessions) or the mechanisms of action. Thus, conclusions regarding the effectiveness of using the behaviour change techniques to facilitate a change in the behaviours of healthcare workers was not possible.
6.5.1 Limitations

Our systematic review had some limitations. Firstly, we did not explore the strength of the evidence underpinning the care bundles. It is possible that the elements themselves have contributed to the heterogeneity, but it was not within the scope of the current review to assess the content of the care elements. Secondly, the behaviour change techniques used in each study were coded retrospectively according to the Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013). Thus, we are unsure whether these behaviour change techniques were intentionally used to increase the uptake of the care bundles. Finally the data are heterogeneous with high variability between the health conditions, settings, care bundle elements and outcomes, thus the comparisons are limited.

6.5.2 Future research

This systematic review has highlighted interesting but very low quality data. The need for clear and unambiguous reporting has been highlighted during this review especially with regards to who is delivering the care bundle and the content of the implementation intervention. The TIDieR checklist for interventions (Hoffmann et al., 2014) needs to be followed more rigorously.
6.5.3 Conclusions

Very low quality evidence from controlled before-after studies (downgraded due to the risk of bias, inconsistencies and potential indirectness of outcomes) suggests that a care bundle may be an effective strategy to improve patient outcomes when compared with usual care. By contrast the low quality evidence from five randomised trials (downgraded due to the risk of bias, inconsistencies and potential indirectness of outcomes) is highly uncertain. Future research should focus on the explicit and transparent reporting of the implementation of the care bundle including issues relating to implementation fidelity such as the frequency with which the behaviour change techniques were used. The higher quality reporting of the research findings will enable stronger conclusions to be drawn about the effectiveness of care bundles.

Authors’ contributions

JL developed, designed and coordinated the review; performed the screening process, extracted the data, conducted the quality assessment, analysed and interpreted the data, performed the statistical analysis and completed the drafting and revisions of the review. JD contributed to the statistical analysis and interpretation of data and assisted with the revising of the review. TG performed the data extraction, conducted the quality assessment, contributed to the interpretation of the data and assisted with the revising of the review. WR performed the screening process, extracted the data and conducted
the quality assessment. **NC** contributed to the conception and design of the review, contributed to the statistical analysis and the interpretation of the data and assisted with the revising of the review.
Barriers and facilitators to preventing pressure ulcers in nursing home residents: an analysis informed by the Theoretical Domains Framework

(Journal article)

Lavallée, J. F., Gray, T. A., Dumville, J., Cullum, N.

Prepared for submission
7.1 Abstract

**Background:** Pressure ulcers are areas of localised damage to the skin and underlying tissue; and can cause pain, immobility, infections and delay recovery, impacting on health-related quality of life. The individuals who are most at risk of developing a pressure ulcer are those who are seriously ill, elderly, have impaired mobility and/or poor nutrition; thus, many nursing home residents are at risk.

**Objectives:** To understand the context of pressure ulcer prevention in nursing homes and to explore the potential barriers and facilitators to research-informed practices.

**Methods:** Semi-structured interviews were conducted with nursing home nurses, healthcare assistants and managers, National Health Service community-based wound specialist nurses (known in the UK as tissue viability nurses) and a nurse manager in the North West of England. The interview guide was developed using the Theoretical Domains Framework to explore the barriers and facilitators to pressure ulcer prevention for nursing home residents. Data were analysed using a framework analysis and the domains were identified as salient based on their frequency and the potential strength of their impact.

**Findings:** 25 participants (nursing home: 2 managers, 7 healthcare assistants, 11 registered nurses; National Health Service community services: 4 tissue viability nurses, 1 manager) were interviewed. Depending upon the behaviours
reported and the context, the same domain could be classified as both a barrier and a facilitator. We identified seven domains that are perceived as relevant in the prevention of pressure ulcers in nursing home residents mapping to four ‘barrier’ domains and six ‘facilitator’ domains. The four ‘barrier’ domains were knowledge, physical skills, social influences, environmental context and resources and the six ‘facilitator’ domains were interpersonal skills, environmental context and resources, beliefs about capabilities, beliefs about consequences, social influences, social/professional role and identity.

Knowledge and insight into these barriers and facilitators provide a theoretical understanding of the complexities in preventing pressure ulcers with reference to staff capabilities, opportunities and motivation related to pressure ulcer prevention.

**Conclusion:** Pressure ulcer prevention in nursing home residents is complex and is influenced by several factors. The findings will inform a theory and research-informed intervention to aid the prevention of pressure ulcers in nursing home settings.

**Keywords:** research-informed practice; nursing homes; pressure ulcer prevention; semi-structured interviews; Theoretical Domains Framework.
7.2 Background

Pressure ulcers are defined as an area of localised damage to the skin and/or underlying tissue as a result of pressure or pressure and shear (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Injury Alliance, 2014). Risk factors for pressure ulcers include, but are not limited to, increasing age, poor mobility, poor nutrition and multimorbidity; putting many nursing home residents with multiple risk factors at the higher end of the risk continuum (Coleman et al., 2013; Moore & Cowman, 2012). In England, approximately 106,675 (4.5%) of 2,458,317 of individuals across all healthcare settings have a pressure ulcer (NHS Safety Thermometer, 2017). The prevalence of pressure ulcers among nursing home residents in the UK is unknown. Nevertheless, Hall et al. (2014) conducted a point prevalence survey of people with complex wounds (including pressure ulcers) across a northern city in the UK. Hall et al. (2014) found that pressure ulcers were the most commonly reported complex wound and the point prevalence increased with age and was highest in people aged 90 years or above (22.88 per 1000 patients with complex wounds; 95% CI 19.08 to 27.42).

Pressure ulcers can be a major burden for patients and can cause pain (Pieper, Langemo, & Cuddigan, 2009), distress and a loss of independence (Keen, 2009; National Institute for Health and Care Excellence: Pressure ulcers, 2014). Pressure ulcers are believed to negatively impact on patient’s health and health-
related quality of life (Hopkins, Dealey, Bale, Defloor, & Worboys, 2006; Spilsbury et al., 2007). When a pressure ulcer develops, additional care is required causing a significant strain on National Health Service (NHS) resources. The estimated treatment costs have been previously estimated to range from £1,214 for a Stage 1 pressure ulcer to £14,108 for a Stage 4 pressure ulcer (Dealey et al., 2012). Moreover, serious complications can occur, for example cellulitis or gangrene, which can lead to amputation and in some cases death (Allman, 1997).

The National Patient Safety Agency (2010) regards pressure ulcers as either avoidable or unavoidable with most being avoidable when the correct preventative measures are used. There are currently national and international clinical guidelines for the prevention of pressure ulcers (e.g., National Institute for Health and Care Excellence: Pressure ulcers, 2014; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). These guidelines draw on research findings and expert opinion, and recommend a range of activities and interventions to promote pressure ulcer prevention including risk assessment, skin assessment, repositioning, good hydration and nutrition, pressure redistributing devices and barrier creams.
In England, nursing homes are private organisations and are not obliged to follow national guidance such as the National Institute for Health and Care Excellence guidance on the prevention and management of pressure ulcers (National Institute for Health and Care Excellence: Pressure ulcers, 2014). As a consequence, the NHS does not have any legislative power over the care provided in nursing homes. However, the Care Quality Commission, an independent regulator of health and social care in England, requires all care provider organisations (including nursing homes) to report the development of Stage 3 pressure ulcers and above (Care Quality Commission Regulation 18: Notification of other incidents, 2009). If appropriate, the Care Quality Commission can refer a case to the police or local council concerning the safeguarding of individuals (Care Quality Commission, 2017).

A range of staff including healthcare assistants and Nursing and Midwifery Council registered nurses provide care in nursing homes. As nursing homes are largely independent organisations there is often little or no input from NHS community nurses. Nursing home staff are able to refer residents with a pressure ulcer to a NHS tissue viability nurse. The role of a tissue viability nurse is to provide advice about clinical practices, such as pressure ulcer prevention, rather than stipulate care and how it should be conducted. Thus, it is critical for the nursing home care staff to have the knowledge of pressure ulcer prevention and assessment guidelines. However, translating guidelines
into practice is often a slow and disorganised process (Eccles et al., 2009; Grimshaw et al., 2012); and guidelines themselves are generally an insufficient method for the implementation of best practices (Grimshaw et al., 2012). Moreover, the Care Quality Commission have raised concerns about the quality of the care some nursing homes provide (Care Quality Commission, 2014).

Several explanations are offered as to why guideline implementation is unpredictable and frequently sub-optimal (Flodgren et al., 2012; Grimshaw et al., 2012). Understaffing, high staff turnover and limited staff knowledge are the barriers often reported for the limited adherence to guidelines (Demarré et al., 2012; Donoghue, 2009); whereas communication and positive attitudes towards pressure ulcer prevention have been described as facilitators (Dellefield & Magnabosco, 2014; Hartmann, Solomon, Palmer, & Lukas, 2016; Worsley, Smith, Schoonhoven, & Bader, 2016). To facilitate the uptake of research-informed guidelines in healthcare, care staff can become the potential target for behaviour change interventions. Having a theoretical understanding of the behaviours, attitudes and beliefs of care staff can increase the likelihood of behaviour change in care staff (Baker et al., 2010).

Theory can be used to assist the interpretation and prediction of behaviours, enabling targeted interventions to be developed and evaluated (Corace et al., 2016; Michie et al., 2005). There are several behaviour change theories, many of
which include similar constructs, making it difficult to decipher which are the most appropriate. Moreover, many theories include only a small number of constructs (e.g., Theory of Planned Behaviour, Health Belief Model) and it is possible that the key determinants of the target behaviour are not represented.

The Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) was developed in an attempt to improve healthcare researchers’ access to psychological theory. The framework was developed by taking a systematic consensus approach to simplify behaviour change-related theories. The Theoretical Domains Framework consists of 14 theoretical domains taken from 33 theories and 128 constructs. The Theoretical Domains Framework can be used to explore the determinants of professional behaviour change and inform intervention designs. Each of the Theoretical Domains Framework 14 domains can be mapped onto the COM-B model (Table 9) (Michie et al., 2014; Michie et al., 2011). The COM-B model suggests that human behaviour (B) is the result of physical and psychological capabilities (C), social and physical opportunity (O) and reflective and automatic motivation (M). The Theoretical Domains Framework provides a more detailed understanding of the important determinants of behaviour and subsequently the COM-B is useful for developing an intervention that targets the issues identified.
Table 9

The COM-B components (Michie et al., 2014, p. 92) and the Theoretical Domains Framework and definitions (Cane et al., 2012, p. 13-14)

<table>
<thead>
<tr>
<th>COM-B components</th>
<th>Theoretical Domains Framework domains</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Capability</strong></td>
<td></td>
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</tr>
<tr>
<td>Psychological</td>
<td>Knowledge</td>
<td>An awareness of the existence of something [knowledge (including knowledge of condition/scientific rationale), procedural knowledge, knowledge of task environment]*.</td>
</tr>
<tr>
<td></td>
<td>Skills (cognitive and interpersonal)**</td>
<td>An ability of or proficiency acquired through practice [interpersonal skills]*.</td>
</tr>
<tr>
<td></td>
<td>Behavioural regulation</td>
<td>Anything aimed at managing or changing objectively observed or measured actions [self-monitoring, breaking habit, action planning]*.</td>
</tr>
<tr>
<td></td>
<td>Memory, attention, and decision processes</td>
<td>The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives [memory, attention, attention control, decision making, cognitive overload/tiredness]*.</td>
</tr>
<tr>
<td></td>
<td>Physical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Skills (physical)*</td>
<td>An ability or proficiency acquired through practice [skills, skills development, competence, ability, practice, skill assessment]*.</td>
</tr>
<tr>
<td><strong>Opportunity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>Environmental context and resources</td>
<td>Any circumstance of a person’s situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour [environmental stressors, resources/material resources, organisational culture/climate, salient events/critical incidents, person x environment interaction, barriers and facilitators]*.</td>
</tr>
<tr>
<td>COM-B components</td>
<td>Theoretical Domains</td>
<td>Definition</td>
</tr>
<tr>
<td>------------------</td>
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</tr>
<tr>
<td><strong>Opportunity</strong> (cont.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Social</strong></td>
<td>Social influences</td>
<td>Those interpersonal processes that can cause individuals to change their thoughts, feeling, or behaviours [social pressure, social norms, group conformity, social comparisons, groups norms, social support, power, intergroup conflict, alienation, group identity, modelling]*.</td>
</tr>
<tr>
<td><strong>Motivation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reflective</strong></td>
<td>Social/professional role and identity</td>
<td>A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting [professional identity, professional role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment]*.</td>
</tr>
<tr>
<td>Beliefs about capabilities</td>
<td></td>
<td>Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use [self-confident, perceived competence, self-efficacy, perceived behavioural control, beliefs, self-esteem, empowerment, professional confidence]*.</td>
</tr>
<tr>
<td>Optimism</td>
<td></td>
<td>The confidence that things will happen for the best or that desired goals will be attained [optimism, pessimism, unrealistic optimism, identity]*.</td>
</tr>
<tr>
<td>Intentions</td>
<td></td>
<td>A conscious decision to perform a behaviour or a resolve to act in a certain way [stability of intentions, stages of change model, transtheoretical model and stages of change]*.</td>
</tr>
</tbody>
</table>
### Table 9 (Cont.)

<table>
<thead>
<tr>
<th>COM-B components</th>
<th>Theoretical Domains Framework domains</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Motivation (cont.)</strong></td>
<td>Goals</td>
<td>Mental representations of outcomes or end states that an individual wants to achieve [goals (distal/proximal), goal priority, goal/target setting, goals (autonomous/controlled), action planning, implementation intention]*.</td>
</tr>
<tr>
<td>Reflective</td>
<td>Beliefs about consequences</td>
<td>Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation [beliefs, outcome expectancies, characteristics of outcome expectancies, anticipated regret, consequents]*.</td>
</tr>
<tr>
<td><strong>Motivation</strong></td>
<td>Automatic</td>
<td>Reinforcement</td>
</tr>
<tr>
<td></td>
<td>Emotion</td>
<td>A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event]*.</td>
</tr>
</tbody>
</table>

* Component constructs included within the square brackets.

** Skills are split into ‘cognitive and interpersonal’ or ‘physical’ and are mapped onto psychological or physical capability, respectively.
Using the Theoretical Domains Framework, we aimed to explore staff perceptions of the barriers and facilitators to pressure ulcer prevention practices within nursing home settings across the North West of England. This study expands current knowledge by embedding the data collection and analysis within behaviour change theory to help inform the future development of a tailored pressure ulcer prevention intervention based on both theory and research evidence.

7.3 Methods

7.3.1 Study design

We conducted a qualitative study using individual semi-structured interviews. The Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) informed both the data collection and data analysis.

7.3.2 Participants

Purposive sampling was conducted to recruit registered nurses and healthcare assistants working in nursing homes and specialist nurses who regularly provide wound care advice and training to nursing home care staff in the North West of England (e.g., tissue viability nurses). A local NHS Trust providing community nursing services expressed interest in participating. Thus, the nursing homes that received specialist input from the Trust were identified through an online search. This process identified 57 nursing homes, as well as
the NHS Trust, as the potential recruitment sites. The managers (nursing home and NHS) and tissue viability nurses were contacted via an invitation letter and a follow-up phone call. Six nursing home managers, one NHS manager and four tissue viability nurses expressed an interest in participating and they were asked to circulate the participant information sheet on behalf of the research team. Those who were interested in participating were asked to contact the researcher, and an appointment for the researcher to visit the nursing home was made. Interview participants were all asked to complete a consent form if they agreed to take part. Sample size was based on data saturation which was assessed using the criteria proposed by Francis et al. (2010) whereby data collection can cease when no additional codes emerge within three consecutive interviews following the analysis of at least ten interviews.

7.3.3 Data collection

The topic guide was developed based on the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) which contains 14 domains related to practitioner behaviours (see Table 9). Consequently, the topic guide consisted of open-ended questions for each of the 14 theoretical domains and a number of prompts to enable a deeper exploration of the domain. Each question focused on the outcome of the behaviour (i.e. pressure ulcer prevention in a nursing home context). When developing the topic guide we used simple language relevant to the target population (i.e. nurses, healthcare assistants, managers).
The topic guide was piloted with two participants and no further changes were necessary, thus the pilot data were also included in the main analysis.

We collected demographic information relating to the participants’ experiences of working with individuals who are at risk of developing pressure ulcers (i.e. how long they have cared for those at risk, how long they had been in their current role, wound care qualifications specific to pressure ulcers). We explained to the participants that we were exploring pressure ulcer prevention (i.e. the outcome of behaviours) and we allowed the participants to explore the behaviours most likely to result in pressure ulcer prevention. This is a novel approach to applying the Theoretical Domains Framework and therefore, represents an innovative methodological process. Face-to-face interviews were conducted at the participant’s place of work. Each interview was conducted by the same researcher [JL] to ensure consistency and was approximately 50 minutes in length depending on the work commitments of the participants. The interviews were audio-recorded, transcribed verbatim and proof-read. Names and organisations were removed from all of the transcripts to enable anonymity to be maintained and pseudonyms were provided.

7.3.4 Data analysis

Data were managed in NVivo 10. Using the framework method outlined by Gale et al. (2013) the transcripts were read and initially coded inductively and
then deductively using the Theoretical Domains Framework, where specific themes and codes were categorised according to the related domain. If data were relevant to different domains, they were incorporated into the most relevant code. Data were analysed inductively to ensure important themes were not lost through the deductive data analysis and no new themes were identified during the inductive analysis. All transcripts were analysed by one author [JL] and independently reviewed by another author [TG] to ensure the reliability of the coding. Any discrepancies were reviewed and resolved and the content of each code was discussed with all of the authors.

We used the following criteria concurrently to identify the importance of the domains (Francis et al., 2009; Patey et al., 2012):

- the *frequency* of the domains across all of the participants;

- *elaboration*: the presence of conflicting beliefs or inconsistencies across all of the participants;

- the *expressed importance* of the domain and the perceived strength of the belief that the domain impacts on the behaviour.

Seven of the Theoretical Domains Framework domains were considered to be important within the current context and the extent to which the domains were viewed as barriers or facilitators to pressure ulcer prevention in nursing home residents lies along a continuum. Thus we present the domains as either
barriers or facilitators in the discussion only, to ensure important data is not lost during the presentation of the findings.

7.3.5 Reflexive account

Some of the authors have previously worked as a healthcare assistant [JL] or a nurse [TG, NC] and all have experience in conducting wound care research and qualitative research. This study forms part of the first author’s PhD project and all of the other authors work within academia and research, and have previously gained their PhD. As the authors have experience in the delivery of care and conducting research into wound care, we continuously reflected on the interview process and analysis to ensure the analysis was always a true reflection of the data.

7.3.6 Ethics

This study was given approval by The University of Manchester (ref: 15409; 15446), together with approval from the Research and Development department at the participating NHS site (ref: 100324).

7.4 Results

A total of 25 participants took part in semi-structured, face-to-face interviews from three nursing home sites which provide a range of care services including nursing, dementia, residential, respite, palliative and convalescent care for 70-
125 residents each in the North West of England. The remaining 54 nursing homes either did not respond to the researcher or declined due to understaffing, sickness within the management team or having recently participated in research activities.

The age of the participants ranged from 26 to 55 years and two participants were male. The care staff included healthcare assistants (n = 7), registered nurses (referred to from now on as nurses; n = 11) and nurse managers (n = 2). Five NHS staff were also included: community-based tissue viability nurses (n = 4) and a community nurse manager (n = 1). The median years of experience in caring for those at risk of developing a pressure ulcer was 14 years (interquartile range: 8.5 to 23 years), and eight stated that they had attended pressure ulcer prevention training.

Knowledge

The views of the nursing home care staff collectively and the tissue viability nurses differed. The care staff believed they had a good understanding of pressure ulcers, the various causes and prevention procedures (e.g., repositioning). However, many of the nursing home care staff were unable to specify any particular pressure ulcer prevention protocols endorsed by the home (e.g., National Institute for Health and Care Excellence guidelines) and
the tissue viability nurses discussed their concerns regarding the pressure ulcer prevention knowledge of the care staff.

“I don’t believe people are managed individually on their individual risk factors. Everybody seems to get the same care in terms of people will do 2 hourly turns” [Tissue viability nurse, 1].

“we do, like, a prevention plan, which everyone pretty much has one for prevention anyway. We put them on 4 to 2 hourly turns depending on how bad, usually it’s 2 hourly turns” [Nurse, 10].

Skills (skills development, interpersonal skills)

Nursing home staff spoke enthusiastically about training and the importance of keeping up-to-date with practices. Some explained that the guidelines may have changed since they last attended training. The participants reported attending regular training for pressure ulcer prevention, but were uncertain about the content of the training, who provided it and when they last attended. The training of the nursing home care staff was a concern for the tissue viability nurses. In particular, the tissue viability nurses wished to correct any wrong or biased information given by outside agencies including pharmaceutical companies. Thus, the tissue viability nurses provided training sessions for the nursing homes, but they explained that attendance was usually poor; perceived reasons for this included a curfew on training due to poor staffing levels and financial reasons.
The importance of good interpersonal skills (e.g., good communication and teamwork) was raised throughout all of the interviews. Communication was identified as occurring through several sources, namely handover and documentation. Documentation was used to communicate the care a person needed in the future but also the care that they had received, with the nurses relying on the healthcare assistants to inform them of any changes to the residents.

“if it’s not been written down, it’s not happened!” [Healthcare assistant, 2].

“communication is vital! You know, if they don’t report to us, obviously we don’t always know what’s going on” [Nurse, 7].

Social influences

All of the participants spoke about collaborating with the multidisciplinary team when preventing pressure ulcers. The nursing home care staff explained how they welcomed the input of the tissue viability nurses, dieticians and podiatrists. Four nursing home care staff participants highlighted the importance of working together as a multidisciplinary team by speaking about the negative impact on them when their relationship with the tissue viability nurse had previously broken down. These four participants also reported a lack of confidence to seek assistance with pressure ulcer prevention as they explained that there was little support available and they did not want to be blamed for the development of a pressure ulcer.
“staff need to be treated not like they’re incompetent children, because they’re trained nurses.” [Nurse, 13].

Environmental context and resources

The nursing home staff saw the context of the nursing home as a facilitator to pressure ulcer prevention due to the long length of stay of the residents. Consequently, the nursing home care staff become familiar with their residents’ needs and report feeling able to recognise even minor deteriorations in their health. Thus, the nursing home care staff develop tacit knowledge about managing pressure ulcer risk in the nursing home environment.

“you can kind of tell when someone’s a bit off because you know them, er, or you can kind of tell when somebody’s mobility’s not as good as it was or they’re not eating as well as they should. So I think because I know them, that helps.” [Nurse, 6].

The environmental context was also discussed as being problematic as a nursing home becomes a resident’s home, making it difficult to maintain residents’ adherence to pressure ulcer prevention practices in the long-term. This was particularly problematic when the participants spoke about the adherence to pressure ulcer prevention practices throughout the night. The participants explained that the residents did not wish to be disturbed by staff trying to reposition them every two to four hours. Whilst repositioning was the
main practice reportedly affected by resident “non-compliance” the participants explained that the residents sometimes refused food, fluids and creams (e.g., barrier cream). When discussing poor adherence, a resident’s mental capacity was often mentioned (e.g., dementia). Nevertheless, the staff recognised that some of the residents who have the mental capacity to understand why the procedures need to be conducted will still refuse; highlighting the complexity of the care required within nursing home environments.

“you’ve got other people that feel that they do know better and are just not compliant” [Nurse, 1].

“it doesn’t matter what, how much you sit down and tell them, they’re, they’re just gonna do what they want anyway” [Nurse, 12].

Consequently, many of the participants reported that the support of other staff was vital for their own health and job satisfaction:

“you need support in this role. You’d get, you’d probably get depressed if you didn’t. You know so you need people talk to as well” [Healthcare assistant, 4].

The nursing home care staff did not report having any problems in sourcing the appropriate equipment required for preventing pressure ulcers (e.g., mattresses, cushions). Understaffing was highlighted as a barrier by the majority of participants as they explained that pressure ulcer prevention requires a team of people and was time and resource intensive (e.g., repositioning). The tissue viability nurses explained that the transient nature of
the workforce within nursing homes impacted on the continuity of care, as important information may not be handed over especially if the member of staff they have spoken with is not a permanent employee. For example, the tissue viability nurses explained how they normally demonstrate a clinical technique to whoever has accompanied him/her to see the resident, yet they were concerned that this demonstration may not be passed on to colleagues especially if the staff member was temporary (i.e. worked for an agency). In addition, the tissue viability nurses explained that whilst the nurses and healthcare assistants were keen to accompany them during consultations, they were often prevented from doing so due to other work commitments (e.g., medication rounds). Neither the tissue viability nurses nor nursing home care staff were able to provide a solution to these problems.

“When I go, ideally, it’s better if you can get someone to come with you erm especially the nurse that’s on duty there. Erm, it’s hard to be honest with you, because sometimes they’ve just got agency staff. Last few times I’ve been in to the homes they’ve been agency, and some like to come with you because they just want to absorb so much” [Tissue viability nurse, 4].

Beliefs about consequences

The tissue viability nurses explained that they did not feel that the care was standardised across the homes because each nursing home was a different private organisation, making quality assurance more difficult. They compared
this to working within the NHS, where Trusts use standardised care protocols. The tissue viability nurses also explained how they would only go into a nursing home to provide advice if the home had referred a resident, which resulted in regular contact with some homes but minimal contact with others. However, the tissue viability nurses did not perceive the number of referrals to be a true indication of the quality of pressure ulcer prevention within the nursing homes, as they were uncertain whether the limited contact reflected a lack of pressure ulcers or a lack of referrals for residents warranting specialist support. Thus, in an attempt to regulate the pressure ulcer prevention behaviours of the nursing home care staff, the tissue viability nurses reported continually highlighting to the staff the serious consequences that can arise following the development of a pressure ulcer (e.g., safeguarding issues).

“There’s never anything severe is there? Nothing! They’ve never left it until it’s got really severe before they’ve called us in which is really good! Quite promising really. … unless they’re not reporting them and then they’re not letting us know then that’s and that’s the thing we don’t know.” [Tissue viability nurse, 4].

Each participant reported several consequences if a resident developed a pressure ulcer and this reinforced the importance of pressure ulcer prevention. Firstly, they were aware of how painful pressure ulcers can be for a resident and wished to avoid the health risks associated with pressure ulcers.
“them not having sores is fantastic. They have enough to deal with being at older life without having anything added to it” [Nurse, 11].

Secondly, some spoke about how people may associate the number of pressure ulcers with the quality of care provided by nursing home care staff. The participants described the development of a pressure ulcer as being a form of “abuse” and “neglect”. Thirdly, the nursing home care staff were aware of the potential consequences for themselves if a resident in their care developed a pressure ulcer. One unit lead was very clear that her staff knew what to expect should a pressure ulcer develop and they knew that there would be serious consequences in the form of “final warnings” (i.e. there are a finite number of warnings staff can receive and if they breach this number they will lose their job). Finally, the fear of being reported to the Care Quality Commission if a pressure ulcer reaches a Stage 3 or above was discussed by most of the participants.

“I don’t want getting, y’know, get into trouble for getting people with pressure sores” [Healthcare assistant, 4].

Social/professional role and identity

All of the participants saw pressure ulcer prevention as part of their daily role and some reported it as the most important aspect in their caring role. However, the participants’ beliefs surrounding who was responsible for the
prevention of pressure ulcers were role dependent. Most of the healthcare assistants stated that it was everyone’s responsibility, whereas the nurses and tissue viability nurses perceived it to be a nurse’s job. Nevertheless, all of the participants agreed that it was the healthcare assistants who provided much of the hands-on care.

Professional role and professional boundaries were reported in similar instances as a participant’s role appeared to dictate the boundaries within which they worked. For example, the healthcare assistants explained that they report any tissue viability concerns (e.g., skin redness) to the nurses and, if a nurse deems it necessary, they refer to the tissue viability nurse. All of the participants were very clear about what is expected of them within their role in pressure ulcer prevention.

“I’d let them [the nurses] know and then they would have to act on it and let us [the healthcare assistants] know what to do about it” [Healthcare assistant, 5]. The NHS community-based participants believed that many of the referrals they received were “inappropriate” (i.e. pressure ulcer below a Stage 3) and that the nursing home care staff viewed any change in the condition of a resident to warrant specialist support. Thus, the community-based participants were concerned that the nursing home care staff did not have a strategy for managing pressure ulcers up to Stage 2 in-house.
“Yeah we get tissue viability involved with all pressure ulcers. When, if somebody comes in with a pressure ulcer, they’re referred to the tissue viability nurse straight away” [Nurse, 4].

Moreover, the community-based NHS participants were concerned that sometimes this was a way of passing responsibility:

“at the minute it comes to us for everything, so they hold no responsibility with regards to any dressings, any form of assessment, or anything like that” [Nurse, 14].

Whereas the nursing home care staff viewed sending a referral to a tissue viability nurse to assess a Stage 1 or Stage 2 pressure ulcer as being pro-active.

Beliefs about capabilities

The nursing home care staff reported a high perceived competence in pressure ulcer prevention, as most of the nurses explained that the healthcare assistants were very good at identifying and reporting changes in the condition of a resident’s skin. Most of the nursing home care staff reported feeling confident in preventing pressure ulcers but they explained that this could be influenced by the health status of the residents, how well the residents adhere to pressure ulcer interventions and the perceived views of outside agencies. For example the blame culture that is associated with pressure ulcers and the local tissue viability nurses’ lack of confidence in the ability of nursing home care staff to prevent or manage pressure ulcers effectively negatively impacted on their
confidence. In some cases the nursing home care staff explained that pressure ulcers were inevitable regardless of how hard they tried to prevent them.

“if I rang up [the tissue viability nurse] today and said there’s been a further deterioration, she’s not going to think “Oh I need to change the treatment plan then”, she’s gonna think “well they’re doing something wrong!”” [Nurse, 7].

One tissue viability nurse acknowledged that sometimes pressure ulcers were unavoidable; however, she stated that:

“99.9% of the time there’s a case to answer because there will be a problem with their piece of equipment, there will be a problem with decontamination, there will be a problem with the way a person’s sitting or lying” [Tissue viability nurse, 1].

7.5 Discussion

This study explored the context of pressure ulcer prevention within nursing home settings. Drawing on the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005), the barriers and facilitators to research-informed pressure ulcer prevention were identified. Seven domains appeared to be consistently relevant. Whether the domains were barriers or facilitators varied and some of the domains appeared to influence others, therefore we have grouped them broadly into barriers or facilitators in line with the results presented.
Barriers

Knowledge, physical skills, social influences, environmental context and resources

The knowledge and skills reported by the nursing home care staff in this study appeared to be limited and these are known to be barriers to the prevention of pressure ulcers (e.g., Demarré et al., 2012; Sharkey et al., 2013). However, we identified a high level of enthusiasm towards pressure ulcer prevention in the nursing home care staff who were very keen to improve their knowledge and skills.

The differences between the views of the nursing home care staff (registered and unregistered) and the tissue viability nurses, with regards to the quality of the pressure ulcer prevention care provided within nursing homes, may reflect the specialist knowledge of the tissue viability nurses. The tissue viability nurses were keen to help the nursing home care staff improve their skills, expressing a concern that the clinical techniques they demonstrated to a member of the nursing home care staff during a visit to a resident may not be passed on to colleagues unless at least one of the following circumstances exist:

- Nursing home care staff are motivated to share the information and newly acquired skills with their colleagues.
- Nursing home care staff remain on duty immediately after the tissue viability nurse visit and have the time to discuss the consultation with other staff.
- Nursing home managers allocate time for the sharing of practice and transference of skills.
- The tissue viability nurse returns to provide regular training sessions.

The tissue viability nurses appeared to be very frustrated by the lack of attendance at the training sessions from the nursing home care staff. This is where the collaborative approach discussed by the nursing home participants would be useful. The tissue viability nurses explained that they have a programme of education on pressure ulcer prevention, but they thought that the training may not be accessible to the nursing home care staff due to understaffing and limited funding. Limited access to training was also reported by Cooper et al. (2017) who conducted a modified Delphi survey to reach a consensus on the continuing professional development needs of registered nurses working in nursing homes in the UK. Cooper et al. (2017) received a total of 352 responses and the participants ranked staffing levels as the most frequent barrier to accessing training courses. Another barrier reported by Cooper et al. (2017) was the lack of support provided to the nurses by the nursing home organisation, as the nurses were often not allocated the time or funds to attend training sessions. Thus, the nursing home organisation has become a recognised barrier to the prevention of pressure ulcers due to the limited opportunities given to staff to improve their knowledge and skills (Shekelle et al., 2011; Soban, Finley, & Miltner, 2016). However, changing the behaviour of healthcare
workers by increasing pressure ulcer prevention knowledge is often ineffective when conducted in isolation (LaRocca, Yost, Dobbins, Ciliska, & Butt, 2012).

Instead, a multifaceted approach is recommended which also takes into account any barriers from the organisational context (Baker et al., 2010; Coleman et al., 2013; Colquhoun et al., 2017; Michie et al., 2014; Michie et al., 2011).

Currently, there are concerns regarding the inconsistent pressure ulcer categorisation and measurement accuracy (Dealey et al., 2012; Hall et al., 2014; Moore & Cowman, 2014; Stevenson et al., 2013) and the number of inappropriate referrals to the tissue viability nurses. The number of inappropriate referrals by the nursing home care staff may have been due to a lack of confidence and limited skills to assess and manage pressure ulcers effectively, which may have resulted from a limited access to skills development training and support. Cross, Hindley and Carey (2017) demonstrated the value of knowledge in a study which found that an education intervention aimed at community-based formal caregivers increased their confidence in their ability to identify signs of skin changes. Consequently, developing a method of education and support that will be feasible and sustainable may be beneficial to both nursing home care staff and tissue viability nurses.
The nursing home environment can be a barrier due to understaffing and the transient workforce. Understaffing in nursing homes is widely recognised within the literature as a problem and has been found to impact on the quality of care (Azermai et al., 2017; Carthon, Rearden, Pancir, Gamble, & Rothwell, 2016; Lawrence, Fossey, Ballard, Ferreira, & Murray, 2016). Castle and Engberg (2007) found that the increased use of agency staff and low stability (i.e. staff who have not worked in the home for a long period of time) were associated with a lower quality of care. Moreover Brannon et al. (2005) found that nursing homes with high stability had fewer pressure ulcer incidences, highlighting the importance of reducing the staff turnover rates in nursing homes.

Our findings also highlight the additional demands the nursing home care staff faced when providing care for their residents with limited capacity, (e.g., residents diagnosed with dementia). The neuropsychiatric symptoms common to dementia (e.g., aggression, psychosis, depression) have been found to pose serious challenges to care staff (Davison et al., 2016; Hazelhof, Schoonhoven, van Gaal, Koopmans, & Gerritsen, 2016) and impact on staff turnover rates (Pitfield, Shahriyarmolki, & Livingston, 2011; Testad, Mikkelsen, Ballard, & Aarsland, 2010). In addition, some residents with dementia may lack the ability to communicate their feelings of pain with the nursing home care staff, potentially compromising the effective and timely prevention of pressure ulcers as pain can indicate the development of a pressure ulcer (McGinnis et al., 2014).
Facilitators

Interpersonal skills, social influences, environmental context and resources, beliefs about capabilities, beliefs about consequences, social/professional role and identity

Teamwork and effective communication channels are consistently reported as facilitators in the prevention of pressure ulcers (e.g., Dellefield & Magnabosco, 2014; Hartmann et al., 2016) and pressure ulcer prevalence has been found to be associated with staff cohesion (Temkin-Greener, Cai, Zheng, Zhao, & Mukamel, 2012). Leadership and supportive team structures enable staff to feel that they are working towards achieving their goal and facilitate the integration of the various staff roles (Hartmann et al., 2016). This study complements these findings and extends our knowledge by explaining the types of communication and teamwork that nursing home care staff use. There appears to be two types of communication: formal and informal. The latter generally occurs between staff during a shift and will not be planned; whereas formal communication occurs in several forms such as handover, care plans and documentation. Many of the participants talked about how the care delivered is reflected in the case notes of the residents and if something is not recorded, it cannot be believed to have happened. This is important when considering the safety of the residents and reducing the risk of litigation. Despite participants reiterating the importance of accurate documentation, studies examining the quality of pressure ulcer prevention documentation continue to report inadequate record keeping (e.g., Li, 2016; O’Brien & Cowman, 2011; Webster et al., 2017).
Effective teamwork within the multidisciplinary team was an important factor as indicated by the value the nursing home care staff placed on the input from the tissue viability nurses. It is unfortunate therefore, that due to work-load pressures, support from the tissue viability nurses is often transient. Recently, the difficulties faced by nursing homes when trying to access specialist services has been highlighted in the literature and access appears to depend on the speciality, with some being more difficult than others (Iliffe et al., 2016). Despite the British Geriatric Society stating the need to clarify the NHS obligations to nursing home residents, disparities between the services provided by the NHS and the needs of the staff working in long-term care facilities (e.g., nursing homes) remain (Carter, 2015; Goodman et al., 2013).

Skin champions or link nurses have been introduced within some services (including nursing homes) and they are members of the team who are trained by specialist nurses to disseminate, facilitate and promote the use of research-informed wound care practices (Flodgren et al., 2012). Findings from a systematic review of 26 pressure ulcer prevention implementation studies in hospital settings suggest that having a designated skin champion can facilitate the success of pressure ulcer prevention interventions (Sullivan & Schoelles, 2013). However, little is known about their roles and responsibilities in the nursing home setting in relation to pressure ulcer prevention, and very few participants mentioned skin champions or link nurses. Nevertheless, improving
leadership through the use of skin champions may be an effective approach for pressure ulcer prevention initiatives (Sharkey et al., 2013).

According to the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005), a person’s behaviour can be affected by their beliefs about the consequences of a particular action. The domain ‘beliefs about consequences’ encompasses five constructs and includes a person’s outcome expectancy (i.e. the belief that a particular behaviour will lead to a certain outcome (Bandura, 1977). All of the participants within this study reported feeling that within society pressure ulcers are associated with a lower quality of care. The participants explained that their beliefs about what might happen if a resident developed a pressure ulcer motivated them to ensure they conducted the appropriate pressure ulcer prevention practices. Moreover, all of the participants repeatedly reported having a positive attitude towards pressure ulcer prevention.

The literature regarding staff attitudes towards pressure ulcer prevention is equivocal. Some studies report that staff have a lack of interest in pressure ulcer prevention and low motivation (Beeckman, Defloor, Schoonhoven, & Vanderwee, 2011; Kaddourah, et al., 2016). Whereas others report positive staff attitudes towards pressure ulcer prevention (Aslan & van Giersbergen, 2016; Moore & Price, 2004; Tubaishat, Aljezawi, & Al Qadire, 2013). Our findings
suggest that the “fear of adverse consequences” may be facilitating the positive attitudes of the nursing home care staff and motivating them to prevent pressure ulcers. This is a facilitator which has not been identified previously. Within the UK, the prevention of avoidable pressure ulcers is part of a national agenda (Department of Health: NHS Outcomes Framework, 2014/2015) and the participants in this study highlighted the fear of being associated with the poor quality of care and/or being reported to the Care Quality Commission. Fear may be regarded as a barrier or facilitator and where present it may impact on staff attitudes. A positive behaviour change can be induced by a perceived threat but behaviour change will only occur if the threat is severe; the individual is susceptible to the threat; there is an effective response and the person feels able to execute the response (De Hoog, Stroebe, & de Wit, 2007). Most of the participants reported high levels of perceived competence, thus despite their potentially limited knowledge and skills, they reported that their ability to respond to the threat of being reported to the Care Quality Commission by using the appropriate practices was high.

7.5.1 Strengths and limitations
This study has several strengths. Firstly, the findings from our study support those of previous studies exploring the barriers and facilitators of pressure ulcer prevention. In addition we provide a more detailed and theory-based understanding of the context and behaviours involved in the prevention of
pressure ulcers in nursing home residents. Additionally, this work adds to the literature through its focus on nursing home settings and staff rather than more general nursing. Secondly, this study captured multiple viewpoints including the views of specialist nurses who are independent of the nursing home. Gaining the views of the wider team facilitated a more detailed understanding of the context of pressure ulcer prevention, rather than one specific aspect (i.e. immediate nursing care).

Thirdly, the Theoretical Domains Framework guided the design of the interview schedule and was a lens through which we analysed the data, enabling the exploration of the behavioural aspects of pressure ulcer prevention. Taking such a deductive approach to data analysis assisted with the identification of the new barriers and facilitators which previous studies have not identified (e.g., fear of being reported to the Care Quality Commissioners). However in taking a deductive approach, the data could have been viewed as being relevant within multiple theoretical domains and this is a common problem with deductive data analyses (Phillips et al., 2015). Moreover, there is a lack of clear guidance on how the findings obtained using the Theoretical Domains Framework should be reported. In our case some of the domains were both barriers and facilitators thus, the domains within the Theoretical Domains Framework appear to lie along a continuum. Through discussion and reflection we felt that the data were assigned to the most salient theme, and this is a novel
approach within the pressure ulcer literature. Additionally, presenting the findings as barriers or facilitators within the results section could have led to the repetition of some themes or the data may have been reduced too soon.

Finally, the findings from this study will inform a theory and research-informed intervention to facilitate the implementation of pressure ulcer prevention guidelines. Based on the current findings it is likely that the intervention will include a pressure ulcer prevention care bundle with an accessible education and training component. The categorisation of data using the Theoretical Domains Framework is a strength of the current research. The findings from this study can be mapped on to the COM-B model to aid the identification of the target behaviours for future pressure ulcer prevention interventions. Within nursing homes, both psychological and physical capability are current barriers to pressure ulcer prevention, alongside some aspects of physical opportunity (e.g., staffing levels) and social opportunity (e.g., the perceived negative views of the tissue viability nurses). Reflective motivation was a facilitator of pressure ulcer prevention (e.g., perceived competence) as well as the social opportunity (e.g., social support) and physical opportunities (e.g., availability of resources). The COM-B model has been applied successfully in a number of contexts including audiology (Barker, Atkins, & de Lusignan, 2016), medication adherence (Jackson, Eliasson, Barber, & Weinman, 2014) and health assessments of preschool children (Alexander et al., 2014).
There are some limitations to the current study. Many participants reported a lack of pressure ulcers among their residents. Thus, the participating nursing home care staff may not have come from nursing homes that are representative, either in terms of the health of the residents or the quality of the care provided. Nevertheless, the nursing homes were all situated in different areas of North West England and different levels of staffing grades were recruited; therefore we believe the participants, and consequently our findings, are representative. The small number of participating nursing homes was a limitation of the current research and this is similar to other studies (e.g., Tilden, Thompson, Gajewski, Buescher, & Bott, 2013). The barriers to nursing homes participating in research has been reported (Buckwalter et al., 2009; Maas, Kelley, Park, & Specht, 2002; Mentes, Tripp-Reimer, & West, 2002); although much of the research currently focuses on engaging nursing home residents in research. Thus, the lack of interest in research from nursing home managers is a finding in itself.

7.5.2 Conclusion

The prevention of pressure ulcers is a high priority in all areas of healthcare in the UK. This study has highlighted the barriers and facilitators to pressure ulcer prevention in nursing home settings using the Theoretical Domains Framework. We used this framework to inform the data collection and analysis and to explore how pressure ulcer prevention behaviours in nursing homes
could be optimised. There appears to be a complex interplay between nursing home care staff, residents and outside agencies such as NHS staff and the Care Quality Commission. The findings confirm the need for an intervention to support nursing home care staff in their pressure ulcer prevention practices, with a particular focus on increasing knowledge, improving skills and providing a supportive environment using the appropriate behaviour change techniques. Using the COM-B model will facilitate the design of a targeted intervention which should facilitate the prevention of pressure ulcers in nursing homes.

Authors’ contributions

All of the authors conceived the study and contributed to its design. JL coordinated the study, interviewed all of the participants and transcribed the data, analysed and interpreted the data and completed the drafting of the paper. TG independently coded the data. All authors contributed to the interpretation of the data and assisted with the revisions of the paper.
Chapter 8

Preventing pressure ulcers in nursing homes: Developing a care bundle intervention using the Behaviour Change Wheel

(John article)

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8.1 Abstract

**Background:** Pressure ulcers are areas of localised damage to the skin and underlying tissue; which can lead to life-threatening complications. Guidelines for the prevention of pressure ulcers are available. However, the implementation of guidelines can be sub-optimal in any care setting and may be particularly challenging in nursing homes. Care bundles are used in hospital settings to facilitate the adherence to research-informed guidelines. Incorporating psychological theory into the development of complex interventions is recommended. By using a theoretical approach to behaviour change, the Behaviour Change Wheel can facilitate the development and implementation of a care bundle intervention.

**Objective:** To co-design, with nurse specialists and nursing home care staff, a theory and research-informed pressure ulcer prevention care bundle intervention for use in nursing home settings.

**Methods:** Following the steps of the Behaviour Change Wheel, we conducted face-to-face qualitative interviews with 25 participants who regularly deliver pressure ulcer prevention care in nursing homes and the COM-B model informed the data analysis. We used clinical practice guidelines to identify the effective research-based pressure ulcer prevention practices. Subsequently, during a four hour workshop with 13 healthcare workers and supplemental email consultation, we co-designed the key research-informed elements for the pressure ulcer prevention care bundle. In line with the Behaviour Change
Wheel, the care bundle intervention was finalised with a clear theory-informed rationale for the intervention functions, policy categories, behaviour change techniques and the modes of delivery likely to influence the prevention of pressure ulcers in nursing home settings.

**Results:** The analysis of the interview data using the COM-B model suggested that capability, opportunity and reflective motivation were the potential drivers of pressure ulcer prevention behaviours in nursing home settings. The target behaviour was the use of pressure ulcer prevention guidelines in the form of a care bundle intervention consisting of three elements: support surfaces, skin inspection, repositioning. The intervention functions (education, training, modelling) and the behaviour change techniques (information about social, environmental, and health consequences; feedback on behaviour and outcomes; prompts/cues; instructions on how to perform the behaviour; demonstration of behaviour) were incorporated into the care bundle intervention.

**Conclusions:** This is the first study to state explicitly the development of a pressure ulcer prevention care bundle intervention using the Behaviour Change Wheel. Key stakeholders identified and prioritised the appropriate elements of care for a pressure ulcer prevention care bundle intervention designed specifically for nursing home settings.
Keywords

Pressure ulcer prevention; nursing homes; care bundle; nominal group technique; behaviour change wheel; intervention development; complex intervention.
8.2 Background

Pressure ulcers are areas of localised damage to the skin and underlying tissue (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). They are caused by prolonged (or short but intense) periods of pressure or pressure and shear. The time taken for a pressure ulcer to develop when exposed to pressure and shear varies and is affected by intrinsic factors such as tissue tolerance, perfusion and co-morbidities (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). The severity of pressure ulcers ranges from Stage 1 (defined as intact skin with a localised area of non-blanchable erythema) to Stage 4 (defined as full-thickness skin and tissue loss), although sometimes the pressure ulcer may be unstageable (National Pressure Ulcer Advisory Panel, 2016). Recently, a survey of people with complex wounds (e.g., pressure ulcers, leg ulcers, foot ulcers, open surgical wounds) conducted in a northern UK city estimated the point prevalence of complex wounds to be 1.47 per 1000 population (95% CI 1.38 to 1.56). Pressure ulcers were the most prevalent complex wound reported as part of the survey (0.31 per 1000; 95% CI 0.28 to 0.36) (Hall et al., 2014). Pressure ulcers have been identified by the Department of Health’s Quality, Innovation, Productivity and Prevention programme as one of the top four ‘harms’ within the National Health Service (NHS), and they have been prioritised for reduction or elimination across all care settings (Department of Health, 2013).
Individuals at the greatest risk of developing a pressure ulcer include the seriously ill, elderly people and people with impaired mobility (Coleman et al., 2013; Moore & Cowman, 2012). Thus, many of those at risk of developing a pressure ulcer may reside in nursing homes. Pressure ulcers can lead to severe pain and distress, poor health-related quality of life and serious complications (e.g., gangrene, mortality) (Allman, 1997; Essex et al., 2009; Keen, 2009). In addition to the personal cost of having a pressure ulcer, there is also a financial cost. In the UK the cost of treating a pressure ulcer to a healed state has been estimated to range from £1,214 for a Stage 1 pressure ulcer to £14,108 for a Stage 4 pressure ulcer (Dealey et al., 2012). The estimated annual cost of treating a pressure ulcer has previously been estimated as £3.36 million (Dealey et al., 2012).

In the UK, nursing homes are private health care providers where care is provided mainly by healthcare assistants, supervised by smaller numbers of registered nurses but with little or no input from NHS community nurses. NHS community wound care specialist nurses, known in the UK as tissue viability nurses, provide advice to the nursing home care staff regarding the prevention of pressure ulcers. However, the NHS does not have any regulatory power over nursing homes to ensure that this advice is followed. Moreover, the Care Quality Commission, an independent regulator of health and social care in
England, have raised concerns about the quality of the care in nursing homes (Care Quality Commission, 2014).

National and international guidelines have been developed for the prevention of pressure ulcers (e.g., National Institute for Health and Care Excellence: Pressure ulcers, 2014; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). These guidelines draw on empirical studies, systematic reviews of the research and expert opinion. The guidelines recommend a range of activities and interventions to aid pressure ulcer prevention including: risk assessment, skin assessment, repositioning, maintaining hydration and nourishment, the use of pressure redistributing devices and barrier creams, training for care staff and accurate monitoring and documentation. Whilst adherence to guidelines can improve the quality of patient care (Resar et al., 2012; Sciarra, 2012), alternative sources of information, especially from colleagues, have been reported as being more accessible, clinically relevant, context-specific and time efficient (Thompson et al., 2004). Thus, in order to be accessed, disseminated and implemented, guidelines need to be perceived as important and more informative than personal and peer knowledge (Sciarra, 2012).

Translating guidelines into practice is often a slow and disorganised process (Eccles et al., 2009; Grimshaw et al., 2012) and can be further impeded by
understaffing, high staff turnover and a lack of monitoring of the clinical practices which can result in limited staff knowledge and inconsistent clinical care (Demarré et al., 2012; Donoghue, 2009). Including the intended users of research (e.g., nurses) in the design and dissemination of resources and materials may encourage staff to use such information sources to inform their clinical decision making (Thompson et al., 2004).

Care bundles were first introduced by the Institute for Healthcare Improvement with the aim of improving the quality of, and reducing the variations in care (Resar et al., 2012). Care bundles comprise of three to five research-informed practices that have the potential to improve patient outcomes when performed collectively and reliably. The Institute for Healthcare Improvement suggest that every eligible patient should receive all of the bundle elements unless medically contraindicated (Resar et al., 2012). Whilst the Institute for Healthcare Improvement provides information regarding the definition of a care bundle, there is very little detail about how to develop and implement a care bundle (Resar et al., 2012).

Collaborating and co-designing healthcare interventions involves the active contribution of all stakeholders to the development and provision of services, with effective information exchange and shared decision making at the forefront of addressing the needs of users (Bettencourt, Ostrom, Brown, &
Including the intended users of research (e.g., nurses) in the design and dissemination of resources and materials may encourage staff to use such information sources to inform their clinical decision making (Thompson et al., 2004). Resar et al. (2012) recommend a multidisciplinary approach to the development of care bundles, but it is not always clear how a care bundle was developed (Lavallée, Gray, Dumville, Russell, & Cullum., 2017). The Nominal Group Technique (Van de Ven & Delbecq, 1972) is a method commonly used to reach a consensus about a particular topic (e.g., Rankin et al., 2016; Tuffrey-Wijne et al., 2016). The Nominal Group Technique enables the grouping of individual judgements and can be used in areas where there are uncertainties regarding the problem and the potential solutions (Moore, 1987). Therefore, the Nominal Group Technique may be an appropriate method for the co-designing of care bundles with key stakeholders.

The risk of developing a pressure ulcer increases with age (Coleman et al., 2013; Hall et al., 2014) and nursing home residents are often at a high risk of developing pressure ulcers. Despite this, there is a lack of pressure ulcer prevention care bundles designed for, and implemented in, nursing home settings. Most of the published pressure ulcer prevention care bundles focus on acute hospital settings such as intensive care units and critical care units (e.g., Anderson et al., 2015; Baldelli & Paciella, 2008; Boesch et al., 2012; Chaboyer et
al., 2016; Gray-Siracusa & Schrier, 2011; Schindler, 2010). An example is the SKIN bundle which was developed in the USA to eliminate hospital-acquired pressure ulcers (Gibbons et al., 2006). SKIN is an acronym for the observations and activities thought to reduce the risk of pressure ulcer development: 

*Surfaces, Keep the patients turning, Incontinence management, Nutrition.* However, there is little information available regarding the development of the SKIN bundle and no clear guidance regarding its implementation. Moreover, the Institute for Healthcare Improvement recommend developing separate care bundles for each location where a particular harm occurs (e.g., pressure ulcers can occur in intensive care units, community settings, nursing homes) (Resar et al., 2012). Thus, it may not be appropriate to implement care bundles in a variety of settings when they have been developed for use in a particular healthcare context.

Many care bundles are implemented with the aim of changing the behaviour of healthcare workers but they often lack any theoretical basis, especially within the developmental stages (Lavallée, Dumville, Gray, Russell, & Cullum, unpublished manuscript (Chapter Six)). Consequently such interventions are at risk of having a sub-optimal effect on the target behaviour, limiting clinical effectiveness (Michie et al., 2005). Taking a theoretical approach to developing and evaluating complex interventions can provide a more transparent understanding of the mechanisms of action and the active ‘ingredients’ of the
intervention. In turn, the theoretical understanding should provide insight into how and why the intervention does (or does not) work (Craig et al., 2008).

There are multiple theories and frameworks for behaviour change, many with overlapping constructs (Michie et al., 2005). The Behaviour Change Wheel (Michie et al., 2014; Michie et al., 2011) was developed to facilitate the integration of behaviour change theory and intervention development through a series of three key stages which can be subdivided into eight steps (see Figure 11). The COM-B model (Michie et al., 2011) forms the centre of the Behaviour Change Wheel (Michie et al., 2014; Michie et al., 2011) and assists with understanding the behaviour in context (stage 1 of intervention development). The COM-B model hypothesises that capability (C), opportunity (O) and motivation (M) all interact and can explain behaviour (B) and can become the focus for the behaviour change intervention. The COM-B components can be subdivided into the following:

- Capability: physical (e.g., physical skills, physical health);
- Capability: psychological (e.g., knowledge, capacity to participate in mental processes);
- Opportunity: physical (e.g., environmental opportunity including resources, time etc.);
- Opportunity: social (e.g., cultural norms, social cues);
- Motivation: reflective (e.g., plans, self-evaluations);
- Motivation: automatic (e.g., impulses, inhibitions).

![Stage 1: Understand the behaviour](image1)

1. Define the problem in behavioural terms
2. Select target behaviour
3. Specify the target behaviour
4. Identify what needs to change

![Stage 2: Identify intervention options](image2)

5. Identify intervention functions
6. Identify policy categories

![Stage 3: Identify content and implementation options](image3)

7. Identify behaviour change techniques
8. Identify mode of delivery


Previously, as part of the first stage of the Behaviour change wheel we:

- searched the literature for the potential causes of pressure ulcers in nursing home residents (outcome), the link to pressure ulcer prevention practices (behaviours of residents and staff) and the effective pressure ulcer prevention interventions that could be used in nursing home settings.

Following this, we conducted a more detailed systematic review as we focused on our pressure ulcer prevention intervention (review method and findings reported in Lavallée et al., unpublished manuscript (Chapter Six)).

In addition, we searched for the relevant literature to aid the understanding of the barriers and facilitators to pressure ulcer prevention in nursing home...
residents (e.g., Dellefield & Magnabosco, 2014; Hartmann et al., 2016; Li, 2016; Sharkey et al., 2013; Webster et al., 2017).

- Conducted qualitative semi-structured interviews with nursing home care staff and managers and NHS tissue viability nurses and managers (Lavallée, Gray, Dumville, & Cullum, unpublished manuscript (Chapter Seven)) to understand from multiple perspectives, the barriers and facilitators to pressure ulcer prevention in nursing home residents. We were able to identify the potential targets of the intervention using the COM-B model. The findings from the qualitative interviews informed stages 2 and 3 of the Behaviour Change Wheel processes which involved identifying the intervention content and implementation options (see Figure 12).

To facilitate a change in the target behaviour(s), the second and third stages of the Behaviour Change Wheel recommend that intervention developers choose from a range of:

- **Intervention functions:** broad categories of interventions which can change the behaviour through the general function they serve. For example, *education* increases knowledge or understanding, *incentivisation* creates an expectation of punishment or cost.

- **Policy categories:** represent the different decisions made by the authorities to support and approve the interventions (e.g., *legislation* involves the making
or changing of laws; *communication/marketing* is defined as the use of print, electronic, broadcast or telephonic media).

- *Behaviour change techniques:* are the active ingredients designed to change behaviour within the intervention (e.g., *goal setting* involves setting or agreeing a goal defined in terms of the behaviour to be achieved). The behaviour change techniques are observable, replicable and irreducible and have been synthesised and refined within the Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013) which includes 93 behaviour change techniques.

- *Modes of delivery:* how the intervention will be delivered (e.g., *face-to-face*, *print media*) and must be appropriate for changing the target behaviours, population of interest and setting.

Once the relevant intervention functions, policy categories, behaviour change techniques and modes of delivery have been identified, the APEASE criteria for designing and evaluating the interventions (Michie et al., 2014) can be used to guide decisions about which are the most appropriate. The APEASE criteria involve an assessment of:

1. **Affordability** (cost considerations);
2. **Practicability** (the intervention should be able to be delivered as planned);
3. **Effectiveness** and cost-effectiveness (the effect size of the intervention within a real world context and the ratio of effect to cost);
4. **Acceptability** (the extent to which the relevant stakeholders judge the intervention to be appropriate);

5. **Side-effects/safety** (unwanted side-effects or unintended consequences);

6. **Equity** (the extent to which disparities in the well-being or health between the different sectors of society may be increased or decreased).

However, there are only a few published examples of how behaviour change models have been applied within the development of healthcare interventions (e.g., Barker et al., 2016; Fulton, Brown, Kwah, & Wild, 2016; Sinnott et al., 2015).

This paper describes the development of the first reported pressure ulcer prevention care bundle intervention, developed specifically for use in a nursing home setting, which was co-designed with nurse specialists and nursing home care staff. We have provided a clear and practical description of how the Behaviour Change Wheel was used to support the theory-driven processes in the design of the care bundle intervention.

### 8.3 Methods

Figure 12 presents a diagrammatical outline of how we applied the Behaviour Change Wheel processes within the current context.
Figure 12. The Behaviour Change Wheel stages: the processes involved in developing the pressure ulcer prevention care bundle intervention.

Behaviour Change Wheel stage 1: Understanding the behaviours

In the first stage we aimed to produce a detailed understanding of the target behaviours and the barriers and facilitators to implementing research-informed pressure ulcer prevention practices. Central to the implementation of strategies to reduce pressure ulcers is the belief that the actions of healthcare workers (e.g., repositioning) directly influence the development of pressure ulcers (Black et al., 2011).
Workshop: care bundle development

Having identified the target behaviours, this phase involved defining the pressure ulcer prevention measures relevant to the nursing home context during a four hour interactive workshop. This workshop used a Nominal Group Technique (Van de Ven & Delbecq, 1972) approach to gain consensus regarding the most important pressure ulcer prevention strategies to form the care bundle elements. The Nominal Group Technique is a method commonly used to reach a consensus about a particular topic (e.g., Rankin et al., 2016; Tuffrey-Wijne et al., 2016). It is a highly structured technique consisting of multiple rounds where items or questions are rated, discussed and re-rated by the expert panellists (e.g., nurses). The Nominal Group Technique enables the grouping of individual judgements and can be used in areas where there are uncertainties regarding the problem and the potential solutions (Moore, 1987). This method also minimises the effects of any dominant participants as all group members are provided with equal opportunities for voting.

In order to recruit the participants with the relevant clinical and management experience and expertise, we conducted purposive sampling in the North West of England. Participants were eligible to participate if they were a:

- Nursing home based: registered nurse (referred to from now on as a nurse), manager or healthcare assistant;
- Community based tissue viability nurse.
We extracted and presented an overview of the relevant research-based international and national pressure ulcer prevention guidelines to the participants attending the workshop (National Institute for Health and Care Excellence: Pressure ulcers, 2014; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). Following this, we discussed the guideline recommendations focusing in particular on their applicability to the nursing home context. Before the participants began voting for the pressure ulcer prevention practices they believed were the most suitable for use in nursing home settings, all of the participants had the opportunity to add any practices they thought were missing from the guidelines. For the three tissue viability nurses who were unable to attend the workshop, we conducted face-to-face and email discussions following the same format.

The Nominal Group Technique procedure was explained and for the purpose of voting, the participants were split into two groups; one group for the healthcare assistants and the second group for the registered nurses. Within these groups, participants individually voted for their top three to five pressure ulcer prevention activities using colour-coded stickers. We used coloured stickers to ascertain whether certain practices were more popular amongst the participants in the different care roles (i.e. healthcare assistants versus tissue viability nurses). We counted the votes in real time and presented the results to the
participants to facilitate a discussion prior to the second round of voting. In the
case of a tie, we offered the participants an extra vote for one of the two tied
practices. We invited the participants to express their opinions on the
prevention activities and whether they believed clarification was required.
Again, colour-coded stickers were used to cast votes in the second round. This
round was used to finalise the agreement between the participants (Van de Ven & Delbecq, 1972). Following a discussion of the activities which received the
highest number of votes, the care bundle elements were agreed.

Having selected the care bundle elements, we asked the workshop participants
to consider a more detailed specification of:

- What the elements should involve.
- The frequency with which they should be delivered.
- Where and when each element should be conducted and by whom.

A member of the research team (TG) facilitated an open discussion regarding
each element. We then asked the participants to score the steps out of 10 (0 = not
important, 10 = extremely important). After the workshop and the email voting
with the remaining tissue viability nurses, both the care bundle elements and
specific steps were reviewed in line with existing research evidence; and the
tissue viability nurses were consulted regarding the validity of the chosen care
bundle elements.
Behaviour Change Wheel stages 2 + 3: Identifying the intervention, content and implementation options

During stage 1 we identified the target behaviours for change (i.e. implementing the pressure ulcer prevention care bundle which included the regular checking of support surfaces, skin inspection and repositioning). During stages 2 and 3 choices regarding how best to implement the care bundle intervention were made by the research team and guided by the Behaviour Change Wheel (Michie et al., 2014; Michie et al., 2011). We first identified the relevant intervention functions. Then, drawing on the findings from our systematic review and using the links between the Behaviour Change Wheel and the Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013), we identified the behaviour change techniques most appropriate for the intervention functions; enabling the active ingredients of the intervention to be embedded within theory (i.e. via the COM-B and Behaviour Change Wheel). Following this, we identified which policy categories, behaviour change techniques and modes of delivery were likely to support the successful implementation of the care bundle intervention. We applied the APEASE criteria (Michie et al., 2014) for designing and evaluating interventions to each of the relevant implementation aspects to guide our judgements in selecting the most appropriate policy categories, behaviour change techniques and modes of delivery.
To ensure the intervention was suitable, we held discussions individually with the nursing home care staff, tissue viability nurses and academic researchers before we finalised the care bundle intervention. These discussions were based on the ‘modelling’ guidance provided in the UK Medical Research Council’s guidance for developing and evaluating complex interventions (Craig et al., 2008) which includes: who should receive the intervention; how changes to practice are usually introduced; what the barriers to change might be and how delivery can be documented. Finally, we developed a logic model for the implementation and evaluation of the care bundle intervention (see Figure 13).

8.3.1 Ethics

This study was given approval by The University of Manchester (ref: 15451), together with approval from the Research and Development department at the participating NHS site (ref: 100321).
Figure 13. Logic model for the pressure ulcer prevention care bundle intervention.

Note. PU is the abbreviation of pressure ulcer; TVN is the abbreviation for tissue viability nurse.
8.4 Results

*Behaviour Change Wheel stage 1: Understanding the behaviours*

The analysis of the interview data using the COM-B model identified: psychological and physical capability; physical and social opportunity; and reflective motivation as the factors that might influence the prevention of pressure ulcers in nursing home settings. In particular the following are required:

- **Improved pressure ulcer prevention knowledge and skills**: the tissue viability nurses need to provide information about, and training on, pressure ulcers and how to prevent them within a nursing home context. The nursing home care staff also need to be permitted to attend this training.

- **Increased use and documentation of research-informed pressure ulcer prevention activities**: pressure ulcer prevention measures need to be conducted in line with the resident’s risk of developing a pressure ulcer. If it is not possible to complete an aspect of care, this must be documented.

*Identification of care bundle elements of care*

In total, 13 participants including nine registered nurses (four tissue viability nurses and five nurses) and four nursing home healthcare assistants contributed to specifying the elements of care that were the focus for pressure ulcer prevention. The participants ages ranged from 26 to 55 years, one
participant was male and one had previously attended wound care training. The median years of experience in working with people at risk of developing pressure ulcers were 7 years (interquartile range: 2 years to 14 years). The participating nursing home had also participated in the study exploring the barriers and facilitators to pressure ulcer prevention in nursing homes (see Chapter 7) prior to taking part in the workshop.

During the discussion prior to round one, it was agreed that ‘pain management’ should be added as an activity, and nutrition and hydration should be separated into two. The activities voted for in round one by each group differed (Table 10). For example none of the healthcare assistants voted for skin assessment to be part of the care bundle, whereas 80% of the nurses and 75% tissue viability nurses did. Similarly, 75% of the healthcare assistants and half of the tissue viability nurses voted for support surfaces to be included but the nurses did not. During the discussion the nurses explained that they did not select support surfaces as one of the key activities as they reported that the pressure redistributing devices covered this (although this only received one vote from the nurses group). Further discussion resulted in the reuniting of nutrition and hydration as all of the nursing home care staff explained that they offer nutrition and hydration together. Consequently, six activities went through to the second round of voting (skin care, continence care, skin assessment, repositioning, nutrition and hydration and support surfaces).
Table 10

*Votes from rounds one and two from each healthcare staff group*

<table>
<thead>
<tr>
<th>Care element</th>
<th>Healthcare assistants (n = 4)</th>
<th>Nurses (n = 5)</th>
<th>Tissue viability nurses (n = 4)</th>
<th>Overall percentage of votes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Voting round 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutrition</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>69%</td>
</tr>
<tr>
<td>Hydration</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>31%</td>
</tr>
<tr>
<td>Skin care</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>38%</td>
</tr>
<tr>
<td>Support surfaces</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>46%</td>
</tr>
<tr>
<td>Repositioning</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>92%</td>
</tr>
<tr>
<td>Continence care</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td>Pressure redistributing devices</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>31%</td>
</tr>
<tr>
<td>Skin assessment</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>54%</td>
</tr>
<tr>
<td>Pain</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Barrier cream</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Voting round 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin care</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>45%</td>
</tr>
<tr>
<td>Continence care</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>92%</td>
</tr>
<tr>
<td>Skin assessment</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>46%</td>
</tr>
<tr>
<td>Repositioning</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td>Nutrition and hydration</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td>Support surfaces</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>31%</td>
</tr>
</tbody>
</table>

The pressure ulcer prevention activities that were voted into the top five during round two were *repositioning, skin assessment, skin care, continence care* and *nutritional and hydration strategies* (see Table 10). Every tissue viability nurse
voted for support surfaces; however, the healthcare assistants considered support surfaces to be important but embedded within repositioning and this was reflected in their voting. Through discussion the participants agreed that including support surfaces as an element separate to repositioning was important and support surfaces should incorporate pressure redistributing devices too. Whilst the participants deemed nutrition and hydration and continence care to be important, they decided that providing and monitoring such practices are part of basic care and should not be included in a specific pressure ulcer prevention care bundle. The skin care and skin assessment activities were merged. Consequently, three elements made up the care bundle: skin inspection, support surfaces and repositioning. All of the participants agreed that each individual resident should receive a formal pressure ulcer risk assessment before using the care bundle; with a monthly reassessment of individual risk unless a resident’s clinical condition warranted more frequent assessments.

The participants ranked, in order of perceived importance the steps required to ensure the accurate and consistent completion of each of the care bundle elements of care (see Appendix 13). The support surfaces element involves checking that all of the support surfaces are free from creases, tubing and personal equipment, as well as ensuring the equipment is working correctly. The skin inspection element includes checking for any changes to the resident’s skin with a particular focus on all of the pressure areas. Whilst none of the
participants voted for *pain management* as an element of the care bundle, they explained that it was an important aspect of the *skin inspection* element. Finally, within the *repositioning* element, the type of repositioning should be specified (e.g., when a resident is assisted with changing position from their left side to their right side). It was agreed that the nursing home care staff should complete and document every element of the care bundle for all residents deemed to be at risk of developing a pressure ulcer, and where an element cannot be completed a reason must be provided (e.g., where a resident has refused assistance with their repositioning). The frequency with which the elements of care are to be delivered will be informed by a risk assessment conducted monthly unless there is a change to a resident’s health status.

*Behaviour Change Wheel stages 2 + 3: Identifying the intervention, content and implementation options*

Based on the findings from the qualitative data analysis, we used the Behaviour Change Wheel to define the key intervention functions and policy categories that could be used to meet the objectives identified in stage 1. The three most suitable intervention functions were *education, training* and *modelling* (i.e. providing a role model). Increasing the knowledge of the nursing home care staff through education and improving their skills through training is a crucial aspect to facilitating the prevention of pressure ulcers in nursing home residents. The policy categories most suitable for achieving the behaviour
change included communication/marketing (e.g., posters), guidelines, regulation and service provision. Using the APEASE criteria (Michie et al., 2014) we suggest that establishing a reliable and research-informed protocol (i.e. a care bundle intervention composed of the elements of care and components that support behaviour change to maximise the implementation of these elements) for staff to use may be affordable, practical and effective.

Using the Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013) and the findings from our systematic review we selected the seven techniques we believed were most suitable to facilitate behaviour change and support prevention practices (information about social and environmental consequences, information on health consequences, feedback on behaviour, feedback on the outcome of the behaviour, prompts/cues, instruction on how to perform the behaviour, demonstration of behaviour). We then formulated a plan regarding how, and by whom, the care bundle intervention would be implemented in practice and this was based on the discussions held with key stakeholders. The delivery of the care bundle intervention will involve different people at specific stages and the key modes of delivery are specified in Table 11 (e.g., the tissue viability nurses will deliver the face-to-face group training to address the limited capability of nursing home care staff as identified through the COM-B model in stage 1).
Table 11

**Behavioural specifications for pressure ulcer prevention care bundle intervention**

<table>
<thead>
<tr>
<th>What</th>
<th>Why</th>
<th>Who</th>
<th>How/frequency</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training and education:</td>
<td>Access to training was identified as a barrier to pressure ulcer prevention in nursing homes. To improve pressure ulcer prevention knowledge and skills in nursing home care staff (registered and unregistered).</td>
<td>Provided by a tissue viability nurse to nursing home care staff (registered and unregistered).</td>
<td>Training will be provided one week prior to the implementation of the care bundle and will be a one-off face-to-face, three hour interactive group session. Presentation using PowerPoint and printed materials will be provided to staff who attend and also to the nursing home for staff who are unable to attend (see Appendix 14 for intervention manual). Additional training sessions will be offered to the nursing home care staff to maximise attendance.</td>
<td>Due to practical reasons, training will be held off-site. Written training materials will be available in the nursing home.</td>
</tr>
<tr>
<td>- on risk factors, pressure ulcer prevention, equipment, outcomes, protocols.</td>
<td>To increase the uptake of the care bundle, to familiarise staff with the processes involved.</td>
<td>Provided by a researcher with expertise in behaviour change to nursing home care staff (registered and unregistered).</td>
<td>Face-to-face one hour interactive group session. PowerPoint and printed materials will be provided to staff who attend and also to the nursing home for staff who are unable to attend.</td>
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Table 11

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<thead>
<tr>
<th>What</th>
<th>Why</th>
<th>Who</th>
<th>How/frequency</th>
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<tbody>
<tr>
<td><strong>Modelling:</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- skin champions</td>
<td>The skin champion is available during a shift and staff can speak with them if they have any concerns or queries. Skin champions are also able to demonstrate pressure ulcer prevention techniques and provide examples of good record keeping (i.e. documentation).</td>
<td>Nursing home care staff (likely to be a registered nurse).</td>
<td>This is available face-to-face and is likely to be on an individual basis. This will be available as required. The researcher will meet with the skin champion at least bi-weekly to discuss any issues or concerns.</td>
<td>Nursing home.</td>
</tr>
<tr>
<td><strong>Implementation of the care bundle:</strong></td>
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<tr>
<td>- risk assessment</td>
<td>To identify any risk factors for the development of a pressure ulcer and indicate the frequency with which the care bundle needs to be delivered.</td>
<td>Registered nurse and/or nursing home manager.</td>
<td>Using a validated risk assessment tool, the risk assessment will be completed at least monthly. If there is a change to a resident’s clinical status, the risk assessment should be conducted again.</td>
<td>Nursing home.</td>
</tr>
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Table 11
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<table>
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<tr>
<th>What</th>
<th>Why</th>
<th>Who</th>
<th>How/frequency</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation of the care bundle:</td>
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<tr>
<td>- complete care bundle for each eligible resident (support surfaces, skin inspection, repositioning).</td>
<td>To improve the reliability of care and to prevent pressure ulcers using elements identified locally as being important within a nursing home context. To improve the documentation of pressure ulcer prevention practices.</td>
<td>Nursing home care staff (registered and unregistered).</td>
<td>Nursing home care staff will complete each element of care included within the care bundle. If it is not possible to conduct all of the elements of care (support surfaces, skin inspection, repositioning) within the care bundle, this must be documented on the overleaf section of the care bundle documentation sheet. The frequency with which this needs to be conducted will depend on each individual resident. However, for those at risk of developing a pressure ulcer it should be at least every 6 hours, at least every 4 hours for those at a high risk, and at least every 2 hours for those at a very high risk. The frequency should be amended in line with a resident’s needs and risk. Staff are required to ensure the appropriate pressure relieving equipment is being used and is functioning.</td>
<td>Nursing home.</td>
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Table 11
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<th>Why</th>
<th>Who</th>
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<tbody>
<tr>
<td><strong>Prompts and cues</strong></td>
<td>An aide memoire was reported as a facilitator of pressure ulcer prevention in nursing homes. Thus, posters will be placed in staff communal areas (e.g., nursing office) to remind staff of the steps involved within the care bundle. The care bundle itself also acts as a checklist as staff are required to document the provision of care on the care bundle sheets.</td>
<td>The research team will provide posters and care bundle documentation.</td>
<td>The unit manager will decide the positioning of the posters on the unit (see Appendix 15). The nursing home staff are responsible for the completion of the care bundle and associated documents. These will be available daily for three months (during the study period).</td>
<td>Nursing home (including nursing office, resident’s bedrooms, resident files).</td>
</tr>
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Table 11
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<th>What</th>
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<th>Where</th>
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</table>
| Feedback:  | To maintain motivation and engagement with the intervention.       | Researcher    | The research team will provide verbal feedback to the unit manager on a monthly basis during the study period. This will include the number of pressure ulcers acquired and adherence to the care bundle. Feedback will be provided in the form of percentages on the following:  
- All-or-none compliance (when all aspects of the care bundle were delivered, including times when it was not possible to complete the care bundle but reasons have been documented);  
- Overall adherence with each individual element: support surfaces, skin inspection, repositioning. | Nursing home. |
| - on behaviours and outcomes. | To highlight areas of care where staff are maintaining high levels of care and also areas which could be improved. |               | Following the completion of the study, the above information will be collated and the findings from the whole study period will be presented verbally to the unit manager and nursing home care staff. |
8.5 Discussion

This is the first explicit behaviour change theory-driven pressure ulcer prevention care bundle intervention that we have been able to identify. We held qualitative interviews with tissue viability nurses and nursing home care staff to identify the areas for improvement in the prevention of pressure ulcers in nursing home residents, and used the COM-B model as a framework to support the process. Using the steps outlined by the Behaviour Change Wheel we were able to develop a pressure ulcer prevention care bundle intervention targeting the delivery of three specific elements of care (the checking of support surfaces, skin inspection and repositioning). The broad functions of the intervention (education, training, modelling) will be achieved using seven theoretically-based behaviour change techniques (information about social and environmental consequences, information on health consequences, feedback on behaviour, feedback on the outcome of the behaviour, prompts/cues, instructions on how to perform the behaviour, demonstration of behaviour).

We expected that our care bundle would differ from existing pressure ulcer prevention care bundles since the nursing home context is different to a hospital setting. However, our pressure ulcer prevention care bundle intervention shares similarities with some of the other pressure ulcer prevention care bundles. For example repositioning, skin assessment and the use of support surfaces appear to be common elements included within pressure ulcer
prevention care bundles for acute care settings (e.g., Anderson et al., 2015; Baldelli & Paciella, 2008; Boesch et al., 2012; Gibbons et al., 2006). However, we did not incorporate incontinence or nutrition and hydration within our care bundle intervention. Nevertheless, the three main aspects of pressure ulcer prevention which consistently feature in care bundles were included within our nursing home care bundle, though operationalised differently.

There are clear recommendations for using psychological theory to inform behaviour change interventions (e.g., Craig et al., 2008; National Institute for Health and Care Excellence: Behaviour change: general approaches, 2007). Despite this, the behaviour change interventions informed by psychological theory have demonstrated small effects (Abraham, Kelly, West, & Michie, 2009); and there appears to be a weak relationship between the use of theory and the effectiveness of an intervention (Prestwich et al., 2014). This may be due to the inconsistency in the implementation literature describing the optimal methods to apply theory to practice. Within the literature there is often a lack of explicit detail explaining the link between the mechanisms of action and the chosen theoretical constructs (Michie & Prestwich, 2010; Prestwich et al., 2014). Consequently, through the transparent reporting of the mechanisms of action, modes of delivery and the theoretical constructs, future evaluations of the effectiveness of this care bundle intervention will be possible.
8.5.1 Strengths and limitations

The theoretical basis and systematic presentation of the development of the care bundle intervention is a strength of the current study. Through the empirical work conducted, more detailed accounts of the context of the prevention of pressure ulcers within nursing home settings and the associated barriers and facilitators were gained. Consequently, the target behaviours (i.e. delivering the pressure ulcer prevention care bundle intervention in nursing home settings) became apparent, and using the Behaviour Change Wheel it was possible to clarify the aims of the care bundle intervention. Previous studies detailing pressure ulcer prevention care bundles (e.g., Anderson et al., 2015; Boesch et al., 2012) have not provided such explicit and transparent methods, which may limit the understanding of the mechanisms of action and causal relationships within the interventions (Soban et al., 2011). Thus, the present study addresses these concerns and will facilitate subsequent evaluations and future replications. Moreover, our findings support those of Niederhauser et al. (2012) and Sullivan and Schoelles (2013) who found those implementing a variety of pressure ulcer prevention interventions in hospitals prioritised audit and feedback, skin champions and staff education.

Employing a Nominal Group Technique process to develop the care bundle was beneficial for many reasons. The participation of the nursing home care staff and the NHS tissue viability nurses was vital in the current workshop to
ensure the inclusion of both specialist and practical knowledge. As the nursing home care staff will use the care bundle intervention, it was important that they co-designed the care bundle and felt able to take ownership of it to increase their commitment to the next stage (i.e. testing the feasibility in practice). The Nominal Group Technique approach enabled each participant to express their view (via individual votes) which minimised the effects of any potentially dominant participants. Using the Nominal Group Technique during the workshop was advantageous as it yielded extensive and rich data in a relatively short period of time and the results were instantaneous.

A limitation of the current study was the inclusion of only one nursing home who had participated in the research interviews that preceded the current study and the relatively small number of tissue viability nurse workshop participants. Therefore, it is possible that care bundle intervention may reflect the priorities of that particular nursing home. Although, the target behaviours identified are in line with international and national guidelines for the prevention of pressure ulcers (e.g., National Institute for Health and Care Excellence: Pressure ulcers, 2014; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). Expert opinion is a fundamental aspect of the Nominal Group Technique, and whilst the majority of the participants who did attend had a range of expertise in caring for individuals residing in nursing homes, specialist nurse input was crucial.
Initially all of the local tissue viability nurses agreed to attend however, due to unforeseen circumstances, some could not. Consequently, the process was repeated with the tissue viability nurses via face-to-face meetings or online consultations to ensure their specialist knowledge of the prevention of pressure ulcers could be combined with the results. We believe that taking such a systematic and structured approach to designing the intervention will result in a more efficacious intervention and will aid subsequent evaluations and improvements.

8.5.2 Future research

The next phase of this research is to test the feasibility of implementing the care bundle intervention in a nursing home context. If the care bundle intervention is feasible and acceptable to nursing home care staff, further evaluation will be necessary to assess the clinical and cost-effectiveness. The explicit theoretical links provided through the use of the Behaviour Change Wheel (Michie et al., 2014; Michie et al., 2011) and Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013) will facilitate future replications and data synthesis.

8.5.3 Conclusion

Care bundles have received much attention within inpatient settings over the past decade due to the potentially synergistic effect of incorporating several care elements within one larger package. The structure of care bundles can be
used to facilitate reliable and sustainable changes in the work habits of staff.

However, there is a lack of theory-informed care bundle interventions reported within the literature. This paper describes how a pressure ulcer prevention care bundle intervention was developed for use in a UK nursing home context, and how the Behaviour Change Wheel guided the development of the intervention. Key stakeholders from the nursing homes and the NHS co-designed the care bundle, forging the first step towards standardising wound care practices within nursing home settings. Whilst preventing pressure ulcers in nursing home residents is complex and multifaceted, this structured and transparent approach will enable a thorough evaluation of the intervention. The next step is to assess the feasibility of implementing this care bundle intervention within the nursing home environment to ensure that it is acceptable for wider circulation across nursing home settings.

Authors’ contributions

All of the authors conceived the study and contributed to its design. JL co-ordinated the study, developed the standard operating procedures for the workshop, held the email/face-to-face consultations with the tissue viability nurses, analysed and interpreted the data and completed the drafting of the paper. TG facilitated the workshop. All of the authors contributed to the interpretation of the data.
Chapter 9

Preventing pressure ulcers in nursing homes using a care bundle intervention: A feasibility study

(Journal article)

Lavallée, J. F., Gray, T. A., Dumville, J., Cullum, N.

Prepared for submission
9.1 Abstract

**Background:** Pressure ulcers can cause pain and infections, impacting on health-related quality of life. Many individuals residing in nursing homes are at risk of developing a pressure ulcer. To assist nursing home care staff with the prevention of pressure ulcers, we developed the first theory and research-informed care bundle intervention specifically for use in nursing home settings.

The care bundle intervention consisted of three prevention practices (*skin inspection, support surfaces, repositioning*) and a range of behaviour change techniques. We aimed to assess the feasibility of implementing the pressure ulcer prevention care bundle intervention in a nursing home setting.

**Method:** We conducted a mixed methods feasibility study in one nursing home in the North West of England. Assessing the feasibility of the care bundle intervention involved conducting a before-after study design. We collected quantitative data on the pressure ulcer prevention behaviours conducted by the nursing home care staff and the pressure ulcer incidence rates for five weeks before the care bundle intervention was implemented. We continued to collect the same data for a further nine weeks after the care bundle was introduced. We explored participants’ experiences of using the care bundle intervention and we conducted semi-structured interviews informed by a conceptual framework for implementation fidelity and the Theoretical Domains Framework.

Acceptability was assessed as part of the feasibility evaluation. Quantitative
and qualitative data were analysed using descriptive statistics and a deductive framework analysis, respectively.

Results: Prior to implementing the care bundle intervention, we collected data for 462 resident bed days. Five new pressure ulcers were reported and repositioning was the only pressure ulcer prevention behaviour documented. We collected data for 1181 resident bed days during the intervention period; no new pressure ulcers developed and the documented prevention behaviours included repositioning, skin inspection and support surfaces. Participants accepted the care bundle intervention, described how they felt it enhanced the delivery of their nursing care and offered suggestions for future improvements.

Conclusion:

A pressure ulcer prevention care bundle intervention specifically designed for use in nursing home settings was acceptable to nursing home staff. Further evaluative work is necessary to gain a deeper understanding of the feasibility of implementing in a nursing home context.

Keywords: pressure ulcer prevention; nursing homes; healthcare workers; care bundle; implementation, implementation fidelity, acceptability.
9.2 Background

Pressure ulcers are areas of localised damage to the skin and underlying tissue. Pressure ulcers are caused by a combination of extrinsic factors (e.g., pressure or pressure and shear) and intrinsic factors such as tissue tolerance and comorbidities (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). The severity of pressure ulcers ranges from Stage 1 (non-blanchable erythema of intact skin) to Stage 4 (full-thickness skin and tissue loss), but sometimes the pressure ulcer may be unstageable (National Pressure Ulcer Advisory Panel, 2016). Pressure ulcers can lead to pain and infection, and the presence of a pressure ulcer may be associated with an increased length of stay in hospital and a poor prognosis overall (Smith et al., 2017). In addition to the considerable personal implications associated with pressure ulcers there are financial consequences too. In the UK previous estimates for the annual cost of treating a pressure ulcer to a healed state was £3.36 million with the estimated costs ranging from £1,214 to treat a Stage 1 pressure ulcer to £14,108 for a Stage 4 pressure ulcer (Dealey et al., 2012). All of these implications highlight the importance of delivering timely and appropriate prevention measures.

The number of pressure ulcers are viewed as an important indicator of the quality of care provided by an organisation (Amir, Lohrmann, Halfens, & Schols, 2017) as they are regarded as largely preventable (Black et al., 2011).
However, in England, approximately 4.5% of individuals across all healthcare settings have a pressure ulcer (NHS Safety Thermometer, 2017). Moreover, a point prevalence survey of complex wounds (e.g., pressure ulcers, leg ulcers, surgical wounds) was conducted in a northern city in the UK and found that pressure ulcers were the most prevalent complex wound reported (0.31 per 1000 people with a complex wound; 95% CI 0.28 to 0.36) (Hall et al., 2014). Hall et al. (2014) also found that point prevalence was highest among the individuals aged 90 years or above (22.88 per 1000 patients with complex wounds; 95% CI 19.08 to 27.42). Increasing age, immobility and illness are some of the risk factors associated with developing pressure ulcers (Chiari et al., 2017). Thus, many nursing home residents will be at a high risk of developing a pressure ulcer and prevention in this setting is a priority.

In the UK, NHS wound care specialist nurses who are known as tissue viability nurses can provide advice regarding the prevention and management of pressure ulcers to registered nurses and healthcare assistants who are employed to deliver care in nursing homes. Whilst the NHS does not have any regulatory power over the provision of care in nursing homes as they are private organisations, the reporting of Stage 3 pressure ulcers (defined as full-thickness loss of skin) to the Care Quality Commission (an independent regulator of health and social care) is mandatory for all registered providers of care (Care Quality Commission Regulation 18, 2009).
A range of activities are recommended to facilitate the prevention of pressure ulcers in all care facilities (National Institute for Health and Care Excellence: Pressure ulcers, 2014; National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014). The recommendations include a risk assessment, frequent skin assessment, repositioning, maintenance of hydration and nourishment, the use of pressure redistributing devices and barrier creams, training for care staff and accurate monitoring and documentation. However, the inconsistent use of research findings and guidelines by healthcare workers continues to be reported (Eccles et al., 2009; Grimshaw et al., 2012).

To facilitate the implementation of guidelines and research-informed practices, the Institute for Healthcare Improvement developed the notion of care bundles in 2001 (Resar et al., 2012). Care bundles are a set of three to five research-informed practices that have the potential to improve patient outcomes when performed collectively and consistently. The Institute for Healthcare Improvement recommend that every eligible recipient should receive all of the elements unless medically contraindicated (Resar et al., 2012).

Since 2001, care bundles have been widely applied across many healthcare conditions (Lavallée et al., unpublished manuscript (Chapter Six)). A systematic review which synthesised the evidence from 37 care bundles and conducted a
meta-analysis found that care bundles may be effective in reducing negative patient outcomes (Lavallée et al., unpublished manuscript (Chapter Six)). The SKIN bundle (Gibbons et al., 2006) can be used to aid pressure ulcer prevention in hospital settings and is an acronym for activities believed to reduce the risk of pressure ulcers: *Surfaces, Keep moving, Incontinence, Nutrition and hydration*. However, the Institute for Healthcare Improvement recommend developing a separate care bundle for each location (Resar et al., 2012). Moreover, many care bundles are developed and implemented with the aim of changing the behaviour of healthcare professionals, yet explicit theory-driven approaches to behaviour change are not reported (Lavallée et al., unpublished manuscript (Chapter Six)). Using theory to inform the intervention development and evaluation is recommended to provide a framework to monitor and explain the process (Craig et al., 2008; Michie et al., 2005; Michie & Prestwich, 2010). Thus, we developed a theory-driven pressure ulcer prevention care bundle intervention specifically for use in nursing home settings (Lavallée, Gray, Dumville, & Cullum, unpublished manuscript (Chapter Eight)).

Feasibility studies can be conducted prior to a randomised trial to gain a greater understanding of the issues relating to the success of a trial such as recruitment and retention, sample size and ease of follow up (Craig et al., 2008; Kistin & Silverstein, 2015). Whilst feasibility studies are not usually powered to enable statistical testing, process evaluations such as implementation fidelity and
acceptability can be conducted to gain a greater understanding of the contribution of an intervention to the outcomes (Moore et al., 2015). Without process evaluations, it may be unclear whether a lack of effect is due to inadequacies within the intervention or poor implementation.

The assessment of the feasibility of complex interventions can include implementation fidelity and acceptability, yet there is some debate about how to conduct these assessments. Carroll et al. (2007) developed a conceptual framework for implementation fidelity, measuring adherence using four dimensions (content, coverage, frequency, duration). The framework also includes four moderators which can influence adherence to the intervention (intervention complexity, facilitation strategies, quality of delivery, participant responsiveness). Carroll et al. (2007) viewed acceptability as integral to implementation fidelity, as an intervention with low acceptability may result in a limited delivery and effectiveness (Borrelli et al., 2005; Proctor et al., 2009). Within the conceptual framework for implementation fidelity, acceptability is part of the ‘participant responsiveness’ component (Carroll et al., 2007) as shown in Table 12.
Table 12

*Feasibility assessment framework (Carroll et al. (2007))*

<table>
<thead>
<tr>
<th>Conceptual framework for implementation fidelity</th>
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<tr>
<td><strong>Adherence</strong></td>
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<td>- Content</td>
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<td><strong>Moderators</strong></td>
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<td>- Intervention complexity</td>
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<td>- Facilitation strategies</td>
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<td>- Quality of delivery</td>
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<td>- Participant responsiveness</td>
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The Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) is an integrative framework of behaviour change theories and is made up of 14 domains which enable a comprehensive and precise account of the potential influences on behaviour (see Table 4 (Chapter 2.7.1.1d) for full definitions). Thus, the Theoretical Domains Framework may also aid our understanding of the barriers and facilitators to the implementation of an intervention (e.g., Steinmo et al., 2016).

We conducted a study to assess whether it was feasible to implement a pressure ulcer prevention care bundle intervention in a nursing home setting. The objectives of this study were to explore the feasibility issues such as recruitment
and retention, implementation fidelity and the acceptability to those using the care bundle intervention (i.e. nursing home care staff). In addition, we sought to determine whether the care bundle intervention had the potential to be effective in preventing pressure ulcers in future trials.

9.3 Methods

9.3.1 Design

We conducted a sequential explanatory mixed methods study design (Creswell, 2015) comprising a quantitative before-after study of the pressure ulcer prevention behaviours and incidence rates; followed by qualitative semi-structured face-to-face interviews informed by the implementation fidelity framework (Carroll et al., 2007) and the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005).

9.3.2 Participating sites

The care bundle intervention was implemented at the level of the nursing home and we used purposive sampling to recruit the participating sites (i.e. nursing homes) in the North West of England. We contacted five nursing home managers via an invitation letter and follow-up phone call. Two nursing home managers expressed an interest in participating; one had been involved in the previous aspects of the project (e.g., care bundle intervention design) and one had not. One researcher [JL] met with the nursing home managers and agreed a
date to begin baseline data collection. As this was a feasibility study we did not pre-define the sample size.

9.3.3 Pressure ulcer prevention care bundle intervention

The pressure ulcer prevention care bundle intervention was developed for use in nursing home settings to assist with the prevention of pressure ulcers in the residents at risk of developing a pressure ulcer. Tissue viability nurses and nursing home care staff co-designed the care bundle with the research team. A full description of the development of the pressure ulcer prevention care bundle intervention is reported elsewhere (Lavallée et al., unpublished manuscript (Chapter Eight)).

The care bundle comprised of three elements of care (support surfaces, skin inspection, repositioning). Each element involved completing a number of steps each time the care bundle was delivered (see Figure 14). The frequency with which the care bundle needed to be completed by the nursing home staff depended on the resident’s risk of developing a pressure ulcer. For example, those at a high risk required a minimum frequency of every four hours (see Appendix 15). In addition to the care bundle elements of care, the intervention also involved:

- A one-off training and education session: a tissue viability nurse (who focused on how to prevent pressure ulcers) and one of the research team with expertise in implementation science (who discussed how to implement the
care bundle), provided an education and training session face-to-face. The session included the following behaviour change techniques to increase the likelihood of a successful implementation: *information about social and environmental consequences, information on health consequences, and instructions on how to perform the behaviour.*

- **Skin champions:** nursing home care staff could speak with the skin champions (who came from within the nursing home team) if they had any concerns or queries. The skin champions were also able to demonstrate the pressure ulcer prevention techniques and provide examples of good record keeping (i.e. documentation).

- **Prompts/cues:** posters were displayed in the nursing office to remind the care staff to use the care bundle (see Appendix 15). The care bundle itself also acted as a checklist (see Figure 14) as staff were required to document care on the bundle sheets.

- **Monthly feedback on behaviours and outcomes:** provided by the researcher to maintain the motivation and engagement of the care staff with the care bundle intervention.
Figure 14. Pressure ulcer prevention care bundle elements and documentation sheet.

9.3.4 Procedure and data collection

9.3.4.1 Care bundle intervention

The study ran from October 2016 to February 2017. The pre-intervention period ran for five weeks (October to November 2016) and consisted of ‘usual care’ with the care staff continuing to complete their standard pressure ulcer prevention practices including:

- Repositioning the residents.
- Documenting on the charts the minimum frequency with which repositioning should have been conducted based on the resident’s risk of developing a pressure ulcer (informed by the Waterlow risk assessment tool which was conducted monthly or more frequently if there was a change to
the resident’s clinical status). For example, those identified as being at risk of developing a pressure ulcer should have been assisted with their repositioning at least every six hours (National Institute for Health and Care Excellence: Pressure ulcers, 2014).

- Documenting the actual frequencies of the repositioning and the position the resident has been assisted to. For example ‘L’ indicated the resident had been assisted on to their left side.

- Data were recorded per bedroom rather than per resident.

Baseline data were collected weekly and also included the pressure ulcer incidence rates (i.e. newly acquired pressure ulcers) and details regarding the pressure ulcer severity and location. There was a two week gap following the baseline data collection to enable the provision of the pressure ulcer prevention training and education session before the nursing home care staff began to implement the care bundle elements of care. We offered repeated training sessions to the nursing home care staff to maximise attendance and provided spare printed materials for the staff who could not attend due to their shift patterns. The participants evaluated the training using a feedback form which included open-ended questions (e.g., ‘give three examples of something new you have learnt’) and closed questions (e.g., ‘I understood most of the content [1: strongly disagree through to 5: strongly agree]’).
The care bundle intervention implementation period continued for nine weeks (November 2016 to January, 2017). The nursing homes already had designated skin champions. We asked the unit manager to place the posters and the training materials detailing how to use the care bundle elements of care in communal staffing areas. We provided the posters to prompt and remind the care staff of the steps involved in the care bundle. Care staff were required to complete the care bundle elements of care every day for each resident at risk of developing a pressure ulcer, including those with existing pressure ulcers. In order to complete these elements, each one needed to be completed every time pressure ulcer prevention care was delivered (see Figure 14). Documenting when it was not possible to complete an element was required, for example due to refusal by a resident. The frequency with which the care staff completed the care bundle elements within a 24-hour period depended upon the resident’s risk which was determined by the risk assessment score. The risk assessment score and the date of the next scheduled risk assessment was documented on the care bundle schedule; although this was not a mandatory part of the bundle. Data were collected and recorded weekly and included how the care staff used the care bundle (i.e. the extent to which they completed each element of the care bundle as a whole throughout a 24-hour period). We also collected weekly pressure ulcer incidence rates.
9.3.4.2 Healthcare workers’ experiences of using the care bundle intervention

Once the quantitative data collection period was complete and we had assessed the implementation fidelity, we conducted face-to-face semi-structured interviews with the nursing home care staff (approximately 45-60 minutes per interview). The topic guide was informed by the implementation fidelity framework (Carroll et al., 2007) and the Theoretical Domains Framework (Cane et al., 2012; Michie et al., 2005) (see Appendix 16 for topic guide). To ensure consistency, the same researcher [JL] conducted each interview. The interviews were audio-recorded, transcribed verbatim, anonymised and proof-read. We collected the demographic information relating to the participants’ experience of working with people at risk of developing pressure ulcers. We were not able to collect any demographic information about the residents in the nursing homes due to ethics constraints.

9.3.5 Data analysis

We managed and analysed the quantitative data using SPSS Statistics 22. We performed a descriptive analysis to provide an overview of the baseline pressure ulcer prevention behaviours and how the care staff used the care bundle. Adherence was based on the self-reported documentation of the care delivered. We calculated the all-or-none adherence using the number of residents per bed day receiving the care bundle per week as the denominator and the number of residents per bed day who received the complete care
bundle within 24 hours as the numerator (Nolan & Berwick, 2006). Adherence
to the individual elements was calculated using an item-by-item measurement
whereby the numerator is the number of residents per bed day who received
the element fully within the 24-hour period, and the denominator was the total
number of residents per bed day included (Nolan & Berwick, 2006). Pressure
ulcer incidence rates were calculated as the number of newly acquired pressure
ulcers within the specified time period.

We managed the qualitative data in NVivo 11. Using the framework method
outlined by Gale et al. (2013) the transcripts were read and initially coded
inductively and then deductively using the implementation fidelity framework
(Carroll et al., 2007) and the 14 domains from the Theoretical Domains
Framework (Cane et al., 2012; Michie et al., 2005). Data were analysed
inductively to ensure no important themes were lost through the deductive
data analysis. If data were relevant to different themes and sub-themes, we
incorporated them into the most relevant. All transcripts were analysed by two
authors [JL, TG] to ensure the reliability of the coding, and we resolved any
discrepancies through discussion.

9.3.6 Reflexive account

This study forms the final part of the first authors PhD project. All of the
authors work within research and have experience in conducting wound care
research and using mixed methods research designs. Some of the authors have previously worked as a healthcare assistant [JL] or a nurse [NC, TG]. JL maintained a research diary and as a team we discussed and reflected on the interview process and analysis ensuring that the analysis and findings were a true reflection of the data.

9.3.7 Ethics

This study was given approval by the University of Manchester (ref: 16284).

9.4 Results

Two nursing homes which provide a range of care services including nursing, residential, respite, dementia and palliative care for 70-125 residents each initially agreed to participate. One nursing home was unable to continue with the study following the baseline data collection due to staff shortages and resident illness which resulted in the home being closed to the public. Consequently, one nursing unit within one nursing home (which had not participated in any other aspects of the research) completed this study (n = 21 nurses and healthcare assistants; n = 29 residents). Of the 21 members of care staff who participated, 12 attended the training session (nurses (n = 3); healthcare assistants (n = 8); manager (n = 1)) and nine participated in the face-to-face interviews (nurses (n = 4); healthcare assistants (n = 5)). The median
years of experience in caring for those at risk of developing a pressure ulcer was 12 years (interquartile range: 8 to 15 years).

We have presented the baseline data first followed by the post-care bundle intervention data. Both the quantitative and qualitative data are presented together to provide a more in-depth understanding of how the participants used the care bundle intervention. The data are reported in line with the implementation fidelity framework (Carroll et al., 2007). There were two salient themes each with sub-themes: adherence (content, frequency, duration and coverage) and potential moderators (participant responsiveness, knowledge, behavioural regulation, beliefs about consequences).

**Baseline**

Pressure ulcer incidence rates and repositioning charts were provided for a total of 462 resident bed days. Overall, adherence with the repositioning charts was completed 74% of the time. The number of repositions offered matched the minimum number expected 95% of the time, and the remaining 5% required at least one additional reposition within the 24-hour period. Five individuals developed one new pressure ulcer during baseline (2x Stage 1 [hip, back], 1x Stage 2 [sacrum], 1x Stage 3 [sacrum], 1x not staged [hip]).
Care bundle intervention

Following the introduction of the care bundle, data for a total of 1181 resident bed days were collected and no new pressure ulcers developed.

Theme 1. Adherence with the care bundle intervention

Content

Not all of the nursing home care staff attended the training and education session, but the materials were available on the nursing unit. The nursing home unit had two skin champions and I maintained regular contact with one skin champion; the second was a member of the night staffing team with whom regular contact was more difficult. I did not provide feedback on the behaviour of the care staff and on the outcomes of their behaviour on a monthly basis as planned due to staff shift patterns and difficulties collecting the data weekly. Prompts/cues were used in the form of posters in the nursing office which all care staff had access to and the participants reported that the care bundle documentation sheet was a prompt in itself.

“It’s a prompt yeah. We know that we should check it, but sometimes you just think ‘pad changed, swap sides, yeah we’re done’. But with them you’re like, ‘oh actually we’ll just check the skin while we’re here, just a quick look’ ... so yeah it probably just prompted me a bit more to check people.” [Healthcare assistant, 3].
**Frequency**

The risk assessment score was provided 65 times (6%) and only once was the date of the next risk assessment documented on the care bundle sheet. Of those 65, a Waterlow risk assessment score of 19 (17%) was most common, followed by 28 (12%) and 30 (12%), suggesting that the residents had a high to very high risk of developing a pressure ulcer. Due to the large volume of missing data, we had limited information regarding whether the care bundle elements were delivered with adequate frequency based on an individual’s risk. Where a risk assessment score was recorded, the frequency with which the care bundle was delivered was appropriate 63% of the time (41 times) and should have been delivered more frequently on 24 occasions (37%).

All of the participants reported that the inclusion of the risk assessment score and the date of the individual’s next assessment on a daily basis were unnecessary. They explained how they felt that they knew which frequencies were required for each resident and if there was a change in a resident and subsequent care, this was communicated during handover. Reasons for not completing the risk assessment section included a lack of time, limited understanding of the risk assessment score and copying how others had completed the care bundle. The care staff did not acknowledge a link between a person’s risk assessment score and the frequency of care during the interviews.
“I don’t think it was needed. I think to be honest the actual Waterlow is more in their [resident] files.” [Nurse, 3].

“I don’t think it means anything to us as carers. I don’t think, whether it was on there or not, it wouldn’t affect the care that they were receiving.” [Healthcare assistant, 3].

Overall, the care bundle was delivered every:

- Four hours 62% of the time (733/1181).
- Two hours 26% of the time (310/1181).
- Every six hours, 12 hours or ‘other’ 10% of the time (118/1181).

The frequency was not documented 2% of the time (20/1181). Where the frequency was documented, the number of times the care bundle was delivered matched the stated minimum frequency 81% of the time (940/1161), and 19% (221/1161) of residents should have received the care bundle at least one more time within the 24-hour period.

**Duration and coverage**

Overall, the all-or-none adherence to the care bundle elements was 16% but this varied throughout the nine weeks and was highest during week three (33%) (see Figure 15). The reported adherence to the individual elements also varied:
- The adherence to the repositioning and support surfaces elements was 75% (887/1181) and 22% (260/1181), respectively. When these elements were not completed, reasons were rarely documented.

- The support surfaces element involved checking the support surfaces for creases and tubing, and ensuring the equipment was functioning correctly. The equipment check was completed 24% of the time (281/1181) and the surface checks were completed 30% of the time (355/1181).

- The adherence to each aspect of the skin inspection element was 21% (248/1181). This element involved checking all of the resident’s pressure areas and recording any skin redness and pain. Pressure areas were checked 24% of the time (280/1181). ‘No redness’ was reported 55% of the time (646/1181). Redness was reported 8% of the time (98/1181) and, where redness was reported, details were documented 63% of the time (62/98). ‘No pain’ was reported 57% of the time (675/1181). Pain was rarely reported (2%; 19/1181) and, where pain was reported, the details were recorded 37% of the time (7/19).

The participants were surprised and disappointed with the varied use of each of the elements because they understood the ‘all-or-none’ approach taken when using a care bundle.

“It’s disappointing that some of the figures don’t tally, because I would have liked them to all come out and mirrored each other” [Nurse, 2].
Figure 15. Weekly reported adherence with the care bundle.
Some of the participants thought that the priorities of the staff may explain some of the differences, as repositioning had always been a priority and the care staff were used to concentrating on this aspect of pressure ulcer prevention. Another participant explained how most of the care staff would prioritise reporting any pressure issues to the nurse-in-charge before documenting the care provided and consequently, they may have forgotten to complete the care bundle documentation sheet.

“If there’s something slightly amiss do you think it might be that there is something and then your priority has been to come and tell one of us [instead of documenting the issue]” [Nurse, 2].

Other reasons provided for the variations in the adherence rates to the individual care bundle elements included a lack of time to complete the checks; the belief that the skin inspections only needed to be conducted once or twice daily and confusion in how to document the completion of some of the elements. For example, both the skin redness and pain components required either a ‘Y’ or ‘N’ response. The participants thought that these responses could have caused some confusion among the staff members, impacting on how they documented their check and how the documentation was interpreted by the researchers. The participants highlighted this response as an aspect of the care bundle which could be improved.

“The cross is most probably a ‘no’ because a lot of them will put a tick for ‘yes there is a change’ and a cross for ‘no’. So that’s probably where the overlooks
come because they probably have done it. I’ve picked up a few myself now you mention it and they have put crosses on it and I’ve said straight away to who I’ve been working with and they’ve actually said ‘No they’ve no change in their skin, that’s a no.’” [Healthcare assistant, 1].

Theme 2: Potential moderators

Participant responsiveness

Acceptability and accessibility

The training session received good feedback from the participants and there appeared to be high levels of satisfaction:

- 88% reported that the workshop met their expectations.
- 100% reported that they understood the content and that sufficient examples were provided enabling them to build on their existing knowledge.
- 67% enjoyed the content.

The participants reported that they had learnt about the care bundle and how to use it, as well as increasing their knowledge of pressure ulcer prevention and the staging of pressure ulcers. One participant reported that they would have liked more information about skin integrity, but provided no further details on the feedback form. The participants who attended the training session and participated in the interviews, reported to have enjoyed the training and found it useful and informative, but did not believe that the training impacted on how
they used the care bundle in practice. Similarly, all of the interviewees acknowledged the importance of training and keeping up-to-date with the prevention practices. However, none believed that it was necessary to attend training on how to use the care bundle.

“I remember seeing them in that training, and it didn’t, when I come back here and started using them I didn’t think ‘Ooh yeah I remember that’, I just thought ‘yeah that was them papers’. But yeah I don’t think there’s anything in that training that could make you use them more effectively, you just live and learn. You’ve just got to get used to them I think.” [Healthcare assistant, 3].

Initially, the care staff found the care bundle to be time-consuming as they had to familiarise themselves with it. With practice, the time required decreased and the participants found the care bundle straight forward to use. One participant reported having more time with the residents as a consequence of using the care bundle.

Good communication and teamwork aided the accessibility of the care bundle. The care bundles were discussed during handover as well as any other important information (e.g., frequency, redness in pressure areas). If the care staff had any problems or concerns they were able to speak to the nurse-in-charge or the unit manager.
“If they’re doing handover you get updated and also because sometimes you can have one day off or two day off and people who have annual leave have a week off, so those who’ve had a week off will get updated by the manager or nurse in charge. And then obviously we get a lot of handover by the night staff and the day staff are updated.” [Healthcare assistant, 2].

The participants often compared the care bundle elements with their previous turning charts, reporting that their care became more comprehensive as they were required to address several issues relating to the prevention of pressure ulcers not just repositioning. The space to document information on the reverse side of the care bundle documentation sheet was also something which their previous charts did not have. The participants found it useful to have this additional space on the care bundle documentation sheet to record other aspects of care (e.g., urine output, bowel movements). Consequently, the participants reported an increase in the continuity of care as they found it easier to communicate the provision of care and any changes to a resident’s clinical status during their shift.

“no matter what you pick up, you’re making your colleague aware that you’ve seen something because what [Healthcare assistant, 2] sees, I might not have seen that day. So then I’d pick it up and go “Ooh crikey, x has got a mark on their right leg. I didn’t know about that, I’ll just go and check”” [Healthcare assistant, 1].
The documentation sheet was particularly important when they considered how they evidenced the care they delivered. They thought that a more in-depth description of the care they had provided was something that the Care Quality Commissioning regulators and Clinical Commissioning Groups would find useful and more constructive.

“sometimes you can’t explain it and sometimes if someone comes at you and says “My mum’s had a red mark for 2 days and you’ve not done anything about it!” You can go and find this [the bundle] you can tick are they red? Yeah tick such a body is red and we know about it and we’ve been actively doing something about it. So I think we do need that on the back.” [Healthcare assistant, 5].

The participants recommended three revisions to the care bundle. Firstly, the addition of a continence care element as they believed this to be an important aspect of the prevention of pressure ulcers. The care staff reported continence issues on a separate document, but felt that including continence care within the care bundle would be useful. Secondly, the participants stated that the wording for the repositioning element did not accurately describe how they used the hoist to assist a resident to reposition. For example, they explained that the wording indicated they only used the hoist when the resident was in bed. Thirdly, one participant reported that some of the elements were too broad and she was not always sure what they meant.
“I think if it was simplified, people are more likely to pay a bit more attention to what they’re ticking! Because I bet they think ‘I’m not reading all of that, I’ll just tick it’” [Healthcare assistant, 5].

Knowledge

All of the participants reported changing their practice as a result of using the care bundle due to an increased awareness of the different aspects involved in the prevention of pressure ulcers. The participants explained that this greater awareness also resulted in their care becoming more comprehensive and helped the care staff to recognise the early signs of skin deterioration in their residents.

“I think it’s better at highlighting a problem than it is using this our traditional turn charts that we’ve got because you can clearly see that, you can plot if there is starting to be a problem and then obviously it gets picked up a lot quicker I think. I think that’s with that if there is any pressure problems it gets picked up quicker with these [bundle] than it does with our traditional charts.” [Nurse, 2].

However, there were some limitations in their knowledge regarding some of the specific aspects of pressure ulcer prevention, which may have impacted on how the care bundle was used.

“I think that pressure thing [referring to the skin inspection element of the bundle], the skin, the pressure areas checked, as long as we do it once a day or
twice a day, that we’ve seen with our own eyes that they’re OK” [Healthcare assistant, 3].

Behavioural regulation

Staff were required to provide their signature when they had or had not delivered the care bundle, and the participants reported that this impacted on how they used the care bundle. Some of the participants reported the possibility of the care bundle becoming a ‘tick-box’ exercise but, due to the accountability of their signatures, they did not feel that this was an issue. All of the participants explained how they made sure every element was completed and accurately reflected the care they had provided before signing, as legally they would be held accountable if there were any problems. In turn, the care staff reported an increased awareness of the care they were conducting as they paid greater attention to whether the residents had any pressure area redness.

“I think we probably checked the pressure areas a little bit more actually. Because you’ve got to tick whether you’ve done it, you have got to physically look. It’s a bit easier, because we don’t have the element of ‘have you checked this person’s skin?’ So sometimes we don’t do it and it is because of time, and it’s not a good enough excuse. Sometimes we would just go in and turn people, but then because it’s there on the thing [the bundle] you think ‘Oh do you know what, I’ll just have a quick look’, and you do, you do just have a quick look! So
yeah it did make me look personally. I did check people more with them, 
definitely!” [Healthcare assistant, 3].

In addition, the participants reported that if a staff member had not completed
the care bundle, they may have left some of the elements blank because they
were aware that their colleagues were able to see whether or not they had
completed the care bundle. The participants explained that this motivated some
staff to ensure it was completed.

“someone else is gonna go in and say “Look well they’ve not done it, they’ve
not checked this person’s skin” [Healthcare assistant, 5].

Beliefs about consequences

All of the participants spoke enthusiastically about preventing pressure ulcers
and using the care bundle and were prepared to deliver all of the elements if
they believed they would be of benefit to their residents. Initially, the staff
agreed to participate in the study as they believed it would help to reduce the
incidence of pressure ulcers on their nursing unit. Following the
implementation of the care bundle the participants reported a reduction in the
number of pressure ulcers which helped to maintain motivation throughout the
implementation period.

“I do think the incidences of pressure problems had reduced using them
[bundles].” [Nurse, 2].
9.5 Discussion

This study provided evidence that using a pressure ulcer prevention care bundle intervention may be an acceptable approach to pressure ulcer prevention in nursing homes. The participants reported that the care bundle was easy to follow, facilitated the continuity of care and led to the provision of comprehensive pressure ulcer prevention care for the nursing home residents. However, the findings have also highlighted a number of feasibility issues that need to be addressed including: the recruitment and retention of nursing home sites; collecting outcome data; and improving staff adherence to the care bundle intervention.

According to Rogers’ Diffusion of Innovations Theory (1995), people are more likely to adopt and implement certain practices if they perceive it to be advantageous with visible benefits, easy to use and compatible with their values. The current findings reflect this as the participants explained that they used the care bundle as they believed it would help to reduce the incidence of pressure ulcers in the nursing home residents. In addition, the care bundle was easy to use and they believed that fewer pressure ulcers developed as a consequence. Our findings are also in line with the Theoretical Framework for Acceptability (Sekhon, Cartwright, & Francis, 2017) which defines acceptability as a multifaceted construct reflecting the extent to which those delivering or receiving an intervention deem it as appropriate. The Theoretical Framework
for Acceptability proposes that people make judgements about how appropriate a healthcare intervention is based on their anticipated and experienced acceptability, which are influenced by seven component constructs: self-efficacy, affective attitude, burden, ethicality, intervention coherence, perceived effectiveness and opportunity costs (Sekhon et al., 2017).

The positive response of the care staff towards the care bundle intervention may be partly due to the collaborative approach taken during the care bundle development involving nursing home care staff, specialist nurses and researchers. We incorporated the views of the care staff into the design and implementation processes; which is in line with knowledge translation perspectives where an intervention should be developed to be relevant, usable and acceptable to the target audience (Grimshaw et al., 2012; Straus, Tetroe, & Graham, 2013). However, based on the opinions of the participants using the care bundle intervention in practice, some revisions are required. Firstly, some of the participants explained that the wording of the care bundle documentation sheet did not accurately reflect the care provided. Ensuring the content is meaningful to those using the bundle is vital for a successful implementation (Bowen et al., 2009). Secondly, the participants stated that it would be beneficial to include ‘continence care’ within the bundle. However, further prognostic research is required to gain a better understanding of whether and how incontinence can cause pressure ulcers (Coleman et al., 2013).
Moreover, it is important that the care bundle does not contain too many elements (Resar et al., 2012). Currently, adherence to all of the elements was poor and incorporating additional elements may compromise the extent to which all of the bundle aspects are implemented and completed.

As well as gaining an understanding of the feasibility of the care bundle in practice, we identified three key findings. Firstly, our findings suggest that the participants viewed the risk assessment aspect of the care bundle intervention as unnecessary. A limited application of the risk assessment tools is reported in the literature with hospital staff demonstrating a preference for clinical judgement (e.g., Kaddourah et al., 2016; Nuru, Zewdu, Amsalu, & Mehretie, 2015). Thus, the limited application and/or documentation of risk assessments continue to be problematic across different healthcare settings. Whilst the pressure ulcer prevention guidelines recommend conducting a risk assessment (European Pressure Ulcer Advisory Panel, 2016; National Institute for Health and Care Excellence: Pressure ulcers, 2014), there is little evidence to suggest that using a risk assessment scale reduces the incidence of pressure ulcers (Moore & Cowman, 2014). Therefore, this may be one reason why the use of risk assessment tools is limited in practice.

Secondly, the care staff reported that they felt that they provided more comprehensive care when using the bundle and the before-after findings
demonstrated an increase in the reported delivery of the research-informed pressure ulcer prevention practices. However, according to the Institute for Healthcare Improvement’s guidance (Resar et al., 2012), adherence rates were inadequate as the all-or-none adherence rates should have been at least 95%. In addition, adherence to the different elements of the care bundle varied with the care staff completing the repositioning element more often than the support surfaces and skin inspection elements. It is also possible that the care provided by the care staff appears to be more comprehensive due to the improvements in the documentation of the individual care elements from baseline, and documentation is something that has previously been reported as problematic (Källman & Suserud, 2009).

Thirdly, the participants reported that including staff signatures on the care bundle documentation sheet motivated them to complete all of the care bundle elements. As their signatures were a requirement of the care bundle, the participants explained that they felt accountable for their actions and were aware of the legal ramifications associated with pressure ulcers. However, despite feeling accountable, adherence rates were poor. Thus our findings suggest that there may be a complex relationship between knowledge, beliefs about the consequences and behavioural regulation, and this relationship may have moderated the extent to which the care bundle was implemented. These theoretical domains may be the mechanisms of action and can be categorised
more broadly in to reflective motivation and psychological capability within the COM-B model (Michie et al., 2011). Similar findings have been reported for other areas of healthcare such as sepsis where the implementation of a sepsis prevention care bundle was investigated using the Theoretical Domains Framework (Steinmo, Fuller, Stone, & Michie, 2015). Thus through the standardised approach taken within this study, and other similar studies, comparisons between care bundle interventions are possible and this will aid our understanding of the potential active ingredients and the mechanisms of action in the interventions.

9.5.1 Strengths and limitations

It can be difficult to engage nursing homes in research (e.g., Jenkins, Smythe, Galant-Miecznikowska, Bentham, & Oyebode, 2016; Simpson et al., 2013) and we too faced challenges surrounding the recruitment and retention of the nursing home sites, as well as the collection of data. Firstly, staff shortages and sickness led to the withdrawal of one nursing home thus, this was a small-scale study and we relied on self-reported behaviours of how the care bundle was used in practice. Research of other health behaviours has demonstrated incongruence between reported behaviours and actual behaviours (e.g., Celis-Morales et al., 2012; Otten, Littenberg, & Harvey-Berino, 2010). Thus, observation methods which enable data collection within the naturally occurring environment (Silverman, 2005) would have been beneficial in
addition to the self-reported data. Nevertheless, our mixed methods research design was advantageous as the qualitative data supported the quantitative data suggesting the self-reports are truthful, if not an underestimation.

Secondly, we were not able to collect any demographic information about the residents which would have provided richer detail about those who were receiving the care bundle. Finally, the poor adherence rates may have been due to a number of implementation issues including the limited tissue viability nurse input in terms of education and training. Unfortunately, the care bundle training was too abstract as the care bundle was not yet part of the participants’ everyday practice. Moreover, the nursing home which implemented the care bundle had not been involved in co-designing the care bundle intervention. As the care bundle became more relevant to the day-to-day practice of the nursing home care staff, ongoing input from the tissue viability nurses may have yielded different findings. In addition, the implementation period was only nine weeks. Understaffing and high staff turnover are commonly reported barriers to research-informed practices in nursing homes (Demarré et al., 2012; Donoghue, 2009) thus, implementing a new intervention into everyday practice may take longer (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004).

Despite these limitations, this study has considerable strengths. Our findings are similar to other studies assessing the use of pressure ulcer prevention care
bundles in hospital settings; with increased awareness of pressure ulcer prevention practices, good communication and positive attitudes towards the care bundle being reported (e.g., Roberts et al., 2016; Tayyib & Coyer, 2017). The care bundle has a strong theoretical and research-base which will enhance our understanding of the potential mechanisms of action, aiding the reproduction of the intervention and processes.

9.5.2 Future research

Pressure ulcer prevention care bundles implemented in hospital settings have demonstrated a reduction in pressure ulcer incidence (e.g., Anderson et al., 2015; Tayyib & Coyer, 2017; Tayyib, Coyer, & Lewis, 2015; Visscher et al., 2013). Our findings suggest that with some minor amendments, the care bundle intervention is feasible within the nursing home context. Further work is necessary to gain an understanding of the recruitment and retention issues we encountered during this study which will allow appropriate sample size calculations to be made. Together, these findings support the rationale for developing a more robust evaluation of the care bundle intervention using a cluster-randomised pilot study prior to a full trial.

9.5.3 Conclusions

This study demonstrated how a pressure ulcer prevention care bundle intervention was feasible in a nursing home context and may improve the
provision of care. The use of this care bundle intervention appeared to motivate the care staff to provide care that was more comprehensive. The care bundle acted as an aide memoire reminding staff of the expected pressure ulcer prevention procedures, as well as a regulator of behaviour due to the inclusion of staff signatures. Implementing this care bundle intervention may lead to reductions in the incidence of pressure ulcers. However, further in-depth evaluations are required and the recruitment and retention issues need to be addressed.

Authors’ contributions

All of the authors conceived the study and contributed to its design. JL coordinated the study, interviewed all of the participants and transcribed the data, analysed and interpreted the data and completed the drafting of the paper. TG independently coded the data. All of the authors contributed to the interpretation of the data.
Chapter 10. Discussion

In March 2017, approximately 4.5% of individuals across different healthcare settings in England had pressure ulcers during the 24 hour period when these data were reported (NHS Safety Thermometer, 2017). Pressure ulcers are viewed as an indicator of the quality of care provided by organisations as pressure ulcers are generally considered to be preventable (Amir, Lohrmann, Halfens, & Schols, 2017). Thus the limited adherence to evidence-based pressure ulcer prevention guidelines can lead to sub-optimal outcomes for patients in any healthcare setting (Chaboyer et al., 2017; Soban, Hempel, Munjas, Miles, & Rubenstein, 2011; Vanderwee et al., 2011). Care bundles have been proposed as a mechanism for increasing the quality and reliability of care and improving patient outcomes (Resar et al., 2012). Care bundles in themselves are complex interventions and for this work I aimed to co-design with tissue viability nurses and nursing home care staff, a pressure ulcer prevention care bundle intervention and assess the feasibility of implementing it within nursing homes. Guided by the MRC guidance for the development and evaluation of complex interventions (Craig et al., 2008), I took a step-by-step approach to address eight key objectives:

(1) To evaluate the effects of care bundles on patient outcomes and healthcare delivery by synthesising the current best research evidence.
To identify effective approaches to care bundle implementation and to explore the factors that could plausibly modify the effects of care bundles (e.g., healthcare settings, fidelity with the bundle, the number of care bundle elements, different implementation techniques).

To understand the context of pressure ulcer prevention in nursing homes within Greater Manchester.

To explore the potential barriers and facilitators to research-informed practices within nursing homes.

To develop the first theory and research-informed pressure ulcer prevention care bundle intervention specifically for use in nursing home settings.

To implement the care bundle intervention within a nursing home setting.

To determine the feasibility of the care bundle intervention in relation to implementation fidelity and acceptability to staff.

To determine the potential impact of the care bundle intervention on the incidence of pressure ulcers.

The aims and objectives of this research were derived from the literature and stakeholder meetings, which suggested that the use of research-informed practices for the prevention of pressure ulcers may be particularly challenging in nursing homes (Chaboyer et al., 2017; Kwong, Lee, & Yeung, 2016). In addition, the extent to which behaviour change theory informed healthcare
worker behaviour change within this context was unknown. Thus, I conducted an iterative developmental process via a series of studies including: a systematic review and meta-analysis (Chapter Six); a qualitative study involving semi-structured interviews to explore the context of pressure ulcer prevention in nursing home settings and the associated barriers and facilitators (Chapter Seven); care bundle intervention development (Chapter Eight) and a feasibility study (Chapter Nine). The purpose of this Discussion chapter is to expand on the discussions presented in the journal papers (Chapters Six, Seven, Eight and Nine), which are limited in scale and scope by the journals’ word limit requirements. Within this chapter I present the implications of the key findings from the individual projects. I also discuss the strengths and limitations, the contribution of the studies to the literature, proposals for future research and the key conclusions of the research.

10.1 Implications of key findings

Key findings from this research enrich our understanding of care bundles and pressure ulcer prevention in nursing homes; and both of these will be discussed now.

10.1.1 Care bundle literature

Existing systematic reviews are mainly condition-specific and indicate that care bundles may be effective in preventing and managing a range of conditions
such as sepsis (Damiani et al., 2015), central line-associated bloodstream infections (Ista et al., 2016) and chronic obstructive pulmonary disease (Ospina et al., 2017). Some systematic reviews are setting-specific, focusing for example on care bundles in hospital settings (e.g., Bannan & Tully, 2016; Luangasanatip et al., 2015; Marwick & Davey, 2009). Across all of the existing reviews, the certainty of the evidence was deemed to be low and the high risk of bias in the included studies continues to be reported, limiting the certainty of the conclusions about the effectiveness of care bundles. Thus, the first objective of this research was to examine and synthesise the current evidence for the effectiveness of care bundles across health conditions and healthcare settings. The systematic review (Chapter Six) provides a detailed understanding of care bundles and assesses the quality of existing empirical evaluations of care bundles and the extent to which the development and implementation of care bundles have been theoretically informed.

I systematically searched the literature to ensure the comprehensive identification of eligible studies. The search identified a large, heterogeneous body of research which when taken together, suggests that the implementation of care bundles may be effective in reducing negative patient outcomes in acute settings. However, the certainty of this conclusion is limited due to the low or very low quality of the evidence (with most of the evidence derived from controlled before-after studies). Controlled before-after studies are at a high risk
of selection bias as the researcher does not use a random sequence generation to allocate the participants to the various study groups. Thus, there may be unidentified differences between the groups which can impact on the outcomes being measured and the studies are also at risk of performance bias. The randomised trial design is pre-eminent for determining the effectiveness of intervention because the random allocation avoids selection bias and ensures a “fair test” (Higgins & Green, 2011). If the random allocation is properly executed and the sample size sufficiently large, the only systematic difference between groups should be the exposure to the intervention as there should be an even distribution of other factors which might affect the outcome.

The most pressing issues arising from the systematic review in Chapter Six, which need to be addressed to enable the application of care bundles into other contexts, are as follows:

- The absence of a consistent definition of what constitutes a “care bundle”.
- The limited use of theory in the development and implementation of care bundles.
- The limited reporting of important implementation fidelity issues such as the frequency and duration of the intervention components (e.g., training sessions).
10.1.1.1 Care bundle definition

For an intervention to be considered as a care bundle, the Institute for Healthcare Improvement suggests it should:

- have a maximum of five research-informed elements agreed by the multidisciplinary team;
- include elements that are relatively independent;
- have elements that are descriptive rather than prescriptive to allow for clinical judgment and customisation;
- be specific to a particular population and care setting.

Importantly, many of the studies identified did not evaluate care bundles that met this original definition (Resar et al., 2012). Of the 466 full text research reports I examined for inclusion in the systematic review, 28% (n = 130) were ineligible as they reported the findings of care packages with more than five elements. For example, one study (Azab et al., 2015) assessed whether a ‘ventilator-associated pneumonia prevention bundle’ was effective in reducing ventilator-associated pneumonia in neonatal intensive care. However, this care bundle consisted of seven elements. Similarly, Baldelli and Paciella (2008) developed and implemented a care bundle containing eight elements to prevent hospital-acquired pressure ulcers. Care bundles were developed as a simplification of more lengthy and complex protocols (Resar et al., 2012).

Therefore, it may be misleading to refer to care packages comprising more than
five elements as ‘care bundles’ as they appear to be evaluations of multiple care practices, which are more in line with a checklist or guideline.

As well as the number of elements, there is much confusion within the literature regarding what constitutes a care bundle “element”. For example, Stolbrink et al. (2014) reported ‘increasing the availability of walking aids’ and ‘encouraging staff to promote mobility’ as elements of an early mobility care bundle which aimed to reduce the incidence of hospital-acquired pneumonia. However the definition provided by the Institute for Healthcare Improvement (Resar et al., 2012) used in the systematic review refers to an element of care delivered to a patient. For example, ‘administer antibiotics’ is an element of care included in the Institute for Healthcare Improvement’s severe sepsis 3-hour resuscitation care bundle (Dellinger et al., 2013). Thus, ‘social support’ in the form of encouraging staff to use the care bundle may be an implementation strategy used to facilitate the uptake of the care bundle and influence care provision, but it is not an element of care. The variation in care bundle definitions and the lack of consistency in the application of these definitions may lead to heterogeneity between the care bundles, imprecise results and limited conclusions.

Consequently, when developing my own care bundle intervention (Chapter Eight), I decided to adhere to the Institute for Healthcare Improvement’s definition of a care bundle (Resar et al., 2012) and develop a care bundle comprising five elements of care or fewer. I also used clear and consistent
terminology throughout the development of the care bundle intervention. For example, I referred to skin inspection, support surfaces and repositioning as the care bundle elements (i.e. elements of care). To facilitate and increase the likely uptake of the care bundle within practice, I included an education session and feedback which were aspects of the care bundle intervention.

10.1.1.2 Use of theory in care bundles

To increase the likelihood of complex interventions such as care bundles being effective and sustainable, we need to know how and why they lead to change as well as whether or not they are effective (Moore et al., 2015). Behaviour change theory can assist with the development, implementation and evaluation of interventions targeting healthcare workers’ behaviours (Michie et al., 2005). Theory can be used to: gain a greater understanding of the factors that might influence the target behaviour; identify which techniques may facilitate changing the behaviour and clarify how the techniques exert their effect on the target behaviour (Michie et al., 2005; Michie & Prestwich, 2010). There was little attention to behaviour change theory in the care bundle interventions evaluated within the systematic review (Chapter Six) despite the current recommendations to include theory within the design and implementation of complex interventions (e.g., Craig et al., 2008; NICE Behaviour Change: Individual Approaches, 2014; Prestwich, Kenworthy, & Conner, 2017). The lack of apparent attention to theory may be due to poor reporting (theory was
addressed but not reported, which seems unlikely), a limited knowledge of how to develop and evaluate complex interventions or confusion as to which behaviour change theory to use (Prestwich et al., 2015).

Using the language associated with theories can facilitate comparisons with other interventions and this would enhance the generalisations made across the different healthcare settings and conditions. Currently, such generalisations are missing from the care bundle literature. Eight studies included within the systematic review (Chapter Six) (Battersby et al., 2014; Berenholtz et al., 2011; Boesch et al., 2012; Conway-Morris et al., 2011; El Azab et al., 2013; Huddart et al., 2014; Power et al., 2014; Smith, 2017) did report the use of theories or models, but did not clearly link these with the desired behavioural outcomes, consequently limiting the generalisability of the findings. Moore et al. (2015) argue that theory should inform the development of complex interventions to enable an understanding of the intervention’s causal mechanisms and at the very least, the theoretical assumptions underlying the intervention need to be stated even if the particular theory is not. The factors contributing to the successful development and implementation of care bundles need to be identified and defined before an understanding of the causal mechanisms can begin. This research was the first step towards gaining such an extensive understanding of care bundles in general.
10.1.1.3 Implementation fidelity

Implementation fidelity can moderate the relationship between an intervention and the intended outcome (Carroll et al., 2007; Damschroder et al., 2009; Mihalic, 2004). In this work I used the conceptual framework for implementation fidelity developed by Carroll et al. (2007) to enhance the evaluation of the feasibility of the care bundle intervention (Chapter Nine).

Within the implementation fidelity framework, implementation is measured by assessing the extent to which the intervention was delivered and implemented as outlined by its designers (adherence) (Carroll et al., 2007). Carroll et al. (2007) recommend that the reporting of adherence should include the intervention content, frequency, coverage and duration. In addition there are four moderator variables that can influence the level of adherence: intervention complexity, facilitation strategies, quality of delivery and participant responsiveness.

Incorporating the conceptual framework for implementation fidelity into this research enabled me to assess whether the proposed active ingredients described during the development of the care bundle intervention (Chapter Eight) were delivered as intended (Chapter Nine). Understanding how and why an intervention works is important for facilitating the reproducibility, applicability and generalisability of the findings and enhancing the current care bundle literature.
The type of strategies used to facilitate the implementation of care bundles such as education, training and feedback, and the format of the delivery including the mode of delivery, duration and frequency, can all influence the effectiveness of care bundles (Michie et al., 2014). Failure to implement an intervention or programme as designed may lead to a false conclusion that the intervention is ineffective (an example of a Type III error) (Dobson & Cook, 1980). Thus, when evaluating the effectiveness of an intervention, it is important to include clear and explicit descriptions of the intervention as well as the implementation fidelity issues such as the quality of delivery (Carroll et al., 2007).

A systematic review of 47 non-randomised studies (Borgert et al., 2015) reporting the strategies used to facilitate the implementation of care bundles employed on intensive care units, found the most frequently used strategies were audit and feedback, education and reminders. Unfortunately the findings were inconclusive as implementation fidelity was rarely reported and the certainty of the evidence was assessed as being low. Thus, it was not possible to determine the most effective strategies used to improve the uptake of the care bundles. Similarly, reports of adherence to various aspects of the care bundle interventions were limited in the studies included in my systematic review (Chapter Six) and in a review of 14 studies (five controlled trials, two interrupted time series studies, seven before-after studies) evaluating the effectiveness of chronic obstructive pulmonary disease discharge care bundles
(Ospina et al., 2016). The poor reporting of the implementation fidelity issues may restrict the utility and reproducibility of the systematic review findings (Hoffman et al., 2017). Thus, clear reporting of intervention components and of implementation fidelity are essential to the complete interpretation of data about the effectiveness of behaviour change interventions.

10.1.2 Pressure ulcer prevention in a nursing home context

Throughout this research I have gained detailed insights into pressure ulcer prevention in nursing home settings and I will now discuss the overall findings with particular reference to pressure ulcer risk assessments, the role of “the signature” and the advantages of tailoring an intervention to a particular context.

10.1.2.1 Pressure ulcer risk assessment

Pressure ulcer prevention guidelines all recommend the regular conduct and documentation of pressure ulcer risk assessment for every patient or resident (e.g., European Pressure Ulcer Advisory Panel, 2016; NICE: Pressure ulcers, 2014). During the interviews with the nursing home care staff I discovered that the responsibility for completing a pressure ulcer risk assessment for each resident in the nursing home lay with the registered nurses and was required on a monthly basis (Chapters Seven and Nine). How the risk assessment scores informed clinical practice however, was not clear. Studies exploring the use of
pressure ulcer risk assessments (standardised and unstandardised assessments) have focused on registered professionals (e.g., Kaddourah et al., 2016; Nuru, Zewdu, Amsalu, & Mehretie, 2015; Webster et al., 2011). By contrast most staff in nursing homes are not registered health professionals. The two qualitative projects in this thesis (Chapters Seven and Nine) found that unregistered nursing home care staff did not report using a risk assessment tool or score and did not view the risk assessment score as an important factor influencing their daily pressure ulcer prevention practices. Instead, they relied on their own and colleagues’ judgement highlighting the routine and informal nature of pressure ulcer risk assessment that is embedded within daily practice.

Participants’ reliance on their own and colleagues’ risk assessment judgements may be an acceptable form of risk assessment, however we cannot be sure. A systematic review of one randomised trial (N = 1,231) and one cluster-randomised trial (N = 256), comparing the effectiveness of using a structured risk assessment tool with clinical judgement to prevent pressure ulcers, found no current evidence to suggest that using a structured risk assessment tool reduced pressure ulcer incidence rates more effectively than clinical judgement (Moore & Cowman, 2014). However, this existing research compares the judgements of registered nurses with risk assessment tools and furthermore “no evidence of an effect” of risk assessment tools is not the same as saying they are
ineffective. More research is needed on pressure ulcer risk judgements and prevention behaviours in both registered and unregistered staff.

10.1.2.2 The importance of “the signature”

The qualitative findings presented in the feasibility study (Chapter Nine) suggest that the inclusion of staff signatures next to an outline of the expected care (i.e. the care bundle documentation sheet) may improve the pressure ulcer prevention behaviours of nursing home care staff. The participants explained that the inclusion of their signature made them feel personally accountable for the care that was documented on the care bundle sheet as this indicated whether or not care was provided and by whom. However in this research, adherence to the care bundle intervention was low (Chapter Nine). Thus, further research is needed to gain a better understanding of the potential influence of “the signature” on behaviours.

The findings presented in this thesis suggest that the requirement for a signature may have influenced (increased/decreased) staff commitment, impacting on how they completed an element of care within the bundle in two ways. Firstly, the fear of subsequent litigation for example, if the nursing home care staff did not conduct or complete an aspect of care and this resulted in a negative outcome for a resident (e.g., pressure ulcer development) there may be personal or legal ramifications such as disciplinary procedures (Chapter Seven).
Thus, the fear of litigation may lead to positive outcomes such as improved documentation. However the ‘blame culture’ within healthcare can be a barrier to transparent, high quality patient care (Department of Health, 2003; Rydon-Grange, 2015) and can lead to defensive behaviours and a lack of openness (Department of Health, 2003; Robertson & Thomson, 2016). Some participants reported that the fear associated with potential litigation and blame may have resulted in some staff leaving the care bundle documentation sheet blank (Chapter Nine).

Secondly, signatures may act as a behavioural contract and a “public” commitment to the pressure ulcer prevention behaviours included within the care bundle intervention. A study of five primary care outpatient clinics with a total of 954 adult patients and 14 clinicians (doctors and nurses) evaluated the effect of a public commitment made by clinicians to reduce the number of inappropriate antibiotic prescriptions for acute respiratory infections (Meeker et al., 2014). The intervention involved the clinicians displaying a commitment letter that included their photograph and signature in the examination room, and the rate of unnecessary antibiotic prescriptions reduced by 34% whilst the rates of inappropriate antibiotic prescriptions in the control (standard practice) group increased by 53%. However, only a small number of clinicians participated and allocation to either the intervention or control group was not based on a random sequence generation. It is possible therefore, that there were
unidentified differences between the two groups at baseline. Nevertheless, in my study, “the signature” appeared to be important for nursing home care staff. Social desirability may have motivated some of the nursing home care staff to complete the care bundle elements and documentation sheet as they did not wish to be viewed unfavourably by colleagues, the residents or the residents’ families.

10.1.2.3 Care bundle interventions in a nursing home context

Across healthcare, strategies to facilitate behaviour change in healthcare workers, including promoting the use of clinical practice guidelines and research-informed practice, have had limited and inconsistent effects (Hibbert et al., 2016; Jeffrey et al., 2015; McNamara et al., 2014). The context and the implementation strategies employed can impact on effectiveness (Grimshaw et al., 2004). It can be challenging to select the strategy which is most likely to facilitate the uptake of the intervention (e.g., monitoring and feedback) as well as the strategy that is the most relevant to a particular context (Powell et al., 2017). This research highlights the importance of identifying the barriers and facilitators to behaviour change amongst the population of interest prior to developing the intervention. A wide range of determinants of pressure ulcer prevention and research-informed practice were elicited (Chapter Seven) and using the Behaviour Change Wheel processes (Chapter Eight), it was possible to
develop a care bundle intervention which appeared to be feasible in a nursing home environment (Chapter Nine).

A Cochrane review of 15 studies reporting on interventions tailored to identify and address the barriers to behaviour change in healthcare workers concluded that the evidence of effectiveness is uncertain due to statistical heterogeneity and high risk of bias of the included studies (Shaw, O’Rourke, Del Mar, & Kenardy, 2005). Baker and colleagues, who compared tailored interventions with no intervention or untailored interventions, updated this review in 2010 (Baker et al., 2010). Following a meta-regression of 12 randomised trials, Baker et al. (2010) concluded that tailored interventions addressing prospectively identified barriers are more likely to improve healthcare workers’ behaviours when compared with no intervention or the dissemination of guidelines. Despite this, many implementation studies do not appropriately match strategies with contextual factors (Grol, Bosch, & Wensing, 2013) or relevant theory and evidence (Wensing, Bosch, & Grol, 2009). My research aimed to overcome some of the limitations reported in the literature and the findings support the potential utility of tailoring interventions to the context. However, tailoring interventions can be resource-intensive depending on the methods used to identify the barriers (e.g., semi-structured interviews). Thus, more research is needed into the most efficient and effective methods to tailor behaviour change interventions in healthcare settings.
In this research, the care bundle intervention was designed to address the barriers already identified (Chapter Seven). The barriers were mapped onto the COM-B model (Michie et al., 2011) and psychological and physical capability, physical opportunity and reflective motivation were targeted as part of the intervention (Chapter Eight). Psychological capability may have improved as the participants reported having a greater awareness of the pressure ulcer prevention practices due to the knowledge gained through having to complete the care bundle intervention. The participants reported improvements in their physical capability through the development of new skills. However, certain skills require further development (e.g., conducting and documenting a formal risk assessment).

Lack of time is often cited as a barrier to conducting pressure ulcer prevention practices (Beal & Smith, 2016; Kaddourah et al., 2016; Martin et al., 2017; Moore & Price, 2004) but in this study, the participants who used the care bundle actually reported having more time as a consequence of using the care bundle in practice (Chapter Nine). Moreover the participants explained that they were motivated to find the time to complete the pressure ulcer prevention practices due to the inclusion of “the signature” and their beliefs about the consequences of not completing the care bundle documentation sheet. Thus, reflective motivation may have improved through using the care bundle intervention. However, actual adherence to the care bundle intervention was low. It is
possible that the nursing home care staff who participated in the interviews as part of the feasibility study (Chapter Nine) were more motivated to complete the care bundle documentation sheet. The importance of “the signature” may represent the views of the interview participants rather than the opinions of those who did not complete the care bundle documentation sheet. Nevertheless, developing a theory-informed care bundle intervention has enabled the identification of the potentially active ingredients of the intervention (e.g., behavioural regulation) that can be tested more robustly in future studies.

The care bundle intervention developed in this research appeared to be an acceptable approach for the nursing home staff to use to improve the prevention of pressure ulcers in nursing home settings. The documentation of the pressure ulcer prevention practices appeared to improve following the introduction of the care bundle intervention. However, the findings highlighted a number of feasibility issues that need to be addressed including: the recruitment and retention of nursing home sites; collecting outcome data; and improving staff adherence to the care bundle intervention. Moreover, the feasibility study was a before-after study design, therefore causality cannot be inferred and there may be a number of unidentified reasons for the apparent improvements. Nevertheless, the participants explained that they felt the pressure ulcer prevention care they were providing when using the care bundle was more comprehensive when compared to the care they provided previously.
Further improvements are required in terms of adherence to the care bundle intervention.

I assessed the adherence to the care bundle using the “all-or-none approach” and deemed it to be inadequate (i.e. below 95%) (Resar et al., 2012). This is in line with the other findings including the systematic review (Chapter Six), which reported that the adherence rates documented for other care bundles were generally inadequate. Previous studies assessing pressure ulcer prevention interventions implemented across a range of healthcare settings including nursing homes and long-term care facilities (Abel et al., 2005; Beeckman et al., 2013; Yap et al., 2013), a hospital (Rich, Shardell, Margolis, & Baumgarten, 2009) and an intensive care unit (Tayyib & Coyer, 2017) have also reported inadequate levels of adherence. Thus, the limited adherence to research-informed pressure ulcer prevention guidelines appears to be a widespread problem across various healthcare settings. Whilst the study design employed here to test the feasibility of a pressure ulcer prevention care bundle in nursing homes precludes an assessment of its effectiveness, the research process has enabled an in-depth understanding of the potential approaches to improving the pressure ulcer prevention behaviours of nursing home care staff.
10.2 Strengths and limitations

This thesis presents a clear definition of a behavioural problem (i.e. the limited implementation of pressure ulcer prevention guidelines in nursing homes) and an intervention which aimed to improve the relevant behaviours. Throughout this work I employed a number of different methods each with strengths and weaknesses. Each study’s specific methodological issues are outlined in the Results chapters (Chapters Six to Nine). I will now highlight the strengths and weaknesses most likely to influence the strength of the conclusions drawn from the findings presented.

10.2.1 Systematic review and meta-analysis

The first strength of this thesis is the systematic review and meta-analysis presented in Chapter Six. The findings are notable for their contribution to, and advancement of, the care bundle literature. By conducting a rigorous systematic review I was able to ground my research in the existing literature, build on existing findings and identify the current gaps in knowledge. Thus the systematic review is a piece of research in itself, which has made contributions to the literature and is the foundation of this thesis.

The review questions were precise, relevant and in line with recommended frameworks (e.g., Centre for Reviews and Dissemination, 2009; Cochrane Effective Practice and Organisation of Care, 2017; Higgins & Green, 2011).
Analytical decisions were made *a priori* and the systematic review protocol was registered and available online (CRD42016033175), increasing the transparency of the methods (Weir, Grimshaw, Mayhew, & Fergusson, 2012). In addition I applied a strict definition of a care bundle which other systematic reviews have not, as some have evaluated care bundles with more than five elements of care. The systematic review and meta-analysis acted as the starting point for exploring the potential causal mechanisms through which care bundle interventions might be effective.

Existing systematic reviews have taken a more narrow, condition or setting-specific approach, so reducing the potential for drawing overall conclusions about the effects of care bundles. One of the aims of the systematic review was to evaluate the evidence of care bundles in general to assess the generalisability and consistency of the research findings across a wide range of study populations. As the review question was broad, I did not apply narrow inclusion criteria for the systematic review which is likely to have increased the number of eligible studies and allowed a more detailed exploration of heterogeneity as well as reducing the likelihood of Type I error (Weir et al., 2012).

By “lumping” studies together initially, a more detailed understanding of care bundles was possible through the subgroup analyses (specified *a priori*). The
subgroup analysis assisted in strengthening the process as the advantages of lumping and splitting were combined (Squires et al., 2013). Whilst the existing reviews provide information about the effectiveness of care bundles in highly specified situations, there is little understanding of their effects in general and this could impact on the effectiveness of future care bundles and evaluations. Consequently, this systematic review was the first step towards identifying and addressing gaps in the care bundle literature. However, taking such a broad scope was problematic for two reasons. Firstly, it was likely to have increased the level of statistical heterogeneity. Secondly, it was difficult to balance the impact of the exploration with the clarity required for a meta-analysis. A cautious approach to interpreting the findings from the subgroup analysis is necessary as they are observational in nature (Deeks et al., 2011) and therefore are at risk of bias through confounding by other study-level characteristics (Sun et al., 2010).

The findings from the subgroup analyses indicated that care bundles may reduce negative patient outcomes (Chapter Six), however I assessed the certainty of the evidence for the effectiveness of care bundles as low. Whilst these findings are helping to generate discussion about the quality of the care bundle literature, the statistical and methodological limitations of subgroup analyses limit the certainty of the conclusions. Nevertheless, the identification of the gaps in the care bundle literature and the findings from the systematic
review provided the rationale for developing a new theory and research-informed pressure ulcer prevention care bundle intervention.

10.2.2 Theoretical basis of this thesis

It is recognised widely that theory should be used to inform intervention development when encouraging healthcare workers to implement research-informed guidelines (Craig et al., 2008; NICE, 2005; 2014). Therefore, the theoretical approach taken throughout this research is a strength. The theoretical basis underpinning the development of the care bundle intervention developed here, enabled the potential behavioural determinants of the nursing home care staff to be identified by the participants (Chapter Seven) and targeted (Chapters Eight and Nine). This is a novel approach to applying the Theoretical Domains Framework and therefore, represents an innovative methodological process. The Behaviour Change Wheel (Michie et al., 2014; Michie et al., 2011) provided a comprehensive framework for the design of the care bundle intervention. The Behaviour Change Wheel provides a step-by-step guide to intervention development ensuring each intervention component is considered and addressed. To my knowledge, the Behaviour Change Wheel has not informed the development of other pressure ulcer prevention care bundle interventions designed specifically for use in a nursing home context.
The behaviour change literature recognises that insufficient intervention descriptions limit our understanding and ability to replicate interventions (Michie, Johnston, Francis, Hardeman, & Eccles, 2008). Thus, a further strength of this project is the detailed and systematic reporting of the care bundle intervention using standardised behaviour change language (Chapters Eight and Nine). In line with the guidelines for the comprehensive reporting of intervention content (Hoffman et al., 2014), the standardised terminology provided by the Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013) will facilitate the reproducibility of the intervention processes and comparisons with other care bundle interventions.

10.2.3 Collaborative approach to the care bundle intervention design

Practical considerations are also important when implementing complex interventions aimed at changing the behaviour of healthcare workers, as focusing only on the theoretical aspects may limit the success of the interventions (Craig et al., 2008; Moore et al., 2015). Thus, another main strength of this work is the collaborative and pragmatic approach used to design the care bundle which incorporated the issues and outcomes relevant for healthcare workers and decision makers (Glasgow & Chambers, 2012). Within this research I aimed to explore the feasibility of implementing a care bundle intervention within ‘usual conditions’, whilst recognising the importance of the theoretical basis; both of which are likely to be important for future evaluations.
and understanding the causal mechanisms. Both the pragmatic and theoretical approaches will improve the generalisability of the findings as I have presented a potential solution to a real world problem (i.e. the care bundle intervention for pressure ulcer prevention in nursing home settings). Combining theory with the preferences of the nursing home care staff and the tissue viability nurses, as well as the practical considerations, should facilitate the sustainability of the care bundle intervention for wider implementation in the future.

The research-practice gap may in part, be due to the methods used to create and use knowledge (Harvey, 2013). For example there is a distinction between knowledge translation (i.e. researchers make their findings accessible and usable for healthcare staff) and knowledge production (i.e. knowledge is multidisciplinary and created within its context of application) (Gibbons et al., 1994; Nowotny, Scott, & Gibbons, 2003). The co-design approach taken within the development of the care bundle intervention encouraged the active involvement of both users and designers within knowledge production. The active involvement of the nursing home care staff and the tissue viability nurses in the development of the care bundle was in line with a person-based approach, which can enhance acceptability and feasibility in the early phases of development and evaluation (Yardley, Ainsworth, Arden-Close, & Muller, 2015). Taking a collaborative approach can facilitate the identification of the
most appropriate procedures to implement research into clinical practice (Buckley, Grant, & Glazener, 2013).

Within this research I incorporated staff preferences, current research evidence, guidelines and theory into the final care bundle intervention. However, the tissue viability nurses have an integral role in assisting with the prevention of pressure ulcers in nursing home settings and a limitation of this work is the lack of resident input as well as the limited tissue viability nurse participation. The limited involvement of the tissue viability nurses in the development and implementation of the care bundle was problematic, as both could have benefitted from specialist input. For example, only one tissue viability nurse attended the care bundle development workshop (Chapter Eight) limiting the specialist input during the discussions about the particular pressure ulcer prevention guidelines.

Patient and public engagement is believed to be important in the improvements of health services, and patients should be empowered to take an active role (Department of Health, 2015; Lawton et al., 2017). However, it was not possible for nursing home residents to be part of the research team given their health and the limited resources at my disposal to support their participation. Moreover, the focus of the research was the behaviour of the nursing home care staff rather than of the residents and a greater resident involvement within a
single home could have created difficult tensions. The workshop reported in Chapter Eight may have provided a suitable environment for the residents to be involved in the development of the care bundle, but it was important that all those attending provided informed consent and were able to discuss pressure ulcer prevention practices openly and freely with a full understanding of the processes. There is extensive literature detailing the difficulties and ethical challenges of including nursing home residents in research in general (e.g., residents with dementia) (West, Stuckelberger, Pautex, Staaks, & Gysels, 2017). Consequently, involving residents in the research was deemed to be unachievable and beyond the scope of the aim and objectives of this research.

Another limitation concerns the lack of resident demographic information. Unfortunately, as part of the University’s ethics procedures and requirements, the ethics committee deemed it not to be appropriate for me to collect even anonymised resident data without the residents’ consent. Collecting information about the residents’ characteristics (e.g., age, sex, co-morbidities, pressure ulcer risk, existing pressure ulcers) would have enabled a more detailed understanding of whether all of the residents at risk of developing a pressure ulcer were receiving the care bundle intervention in line with their level of risk.
10.2.4 Mixed methods research

The mixed methods approach taken has greatly strengthened the triangulation and integration of all of the data sources, facilitating a comprehensive approach and increasing the confidence in the findings. I justified the methodological decisions (Chapters Three to Five) and believe they were appropriate to achieve the aims of this research. I clearly stated the suitability of a critical realist perspective which provided guidance for the mixed methods approach taken (Chapter Three). I reflected on the role of the participants and myself within the context of the nursing home and considered how all of these aspects influenced data collection, analyses and interpretation. Undertaking a systematic review and meta-analysis may appear to be in line with a more positivist perspective due to the attempt to capture an overall effect. However, I also aimed to answer contextual questions about care bundles, in particular relating to ‘under what circumstances do care bundles work?’ and ‘what are the mechanisms of action?’. Thus, overall the critical realist perspective taken throughout this thesis was a particular advantage as I was able to incorporate the context of the nursing home within the findings.

The combination of qualitative and quantitative methods has resulted in a deeper understanding of the pressure ulcer prevention behaviours in nursing home settings as well as the feasibility of implementing the care bundle intervention. For example, the qualitative approach taken to explore the barriers
and facilitators to pressure ulcer prevention (Chapter Seven) and the participants’ experiences of implementing the care bundle intervention (Chapter Nine) was appropriate for the exploratory nature of this research. As this was the first theory and research-informed care bundle intervention designed specifically for use in a nursing home context, gaining an in-depth understanding of the participants’ views was vital and may not have been possible if I had taken a purely quantitative approach. However, the research could have benefitted from some participant observational data whereby the observer collects and generates data within the participants’ naturally occurring environment (Silverman, 2005). Therefore, observational methods may have increased my understanding of implementation fidelity and how the care bundle intervention was used in real time in terms of adherence to the care bundle elements (i.e. skin inspection, support surfaces, repositioning).

Constrained resources (principally researcher time) precluded observation and I was reliant upon self-reported data which may have been subject to bias. Nevertheless, other studies exploring the use of pressure ulcer prevention care bundles have used similar data collection methods to those described within this thesis (Chapter Nine) (e.g., Chaboyer et al., 2016).

The systematic and transparent reporting of the research processes involved enhanced the validity of the findings and conclusions presented in this thesis. The clarity of purpose provided in the introduction to this thesis (Chapters One
and Two) gives substantive focus and informs the direction of the investigations of this research (Chapters Six to Nine). The thesis presents appropriate, thorough and effective methods, data and conclusions which are logical and inform our understanding of pressure ulcer prevention in nursing home settings, as well as the feasibility of implementing a pressure ulcer prevention care bundle intervention within this context.

There is little agreement on how best to ensure rigour within mixed methods research (Chapter Three). As the aim of my research was exploratory, I chose to ensure the rigour of the studies through credibility, transferability, dependability and confirmability (Lincoln & Guba, 1985). Credibility and dependability are apparent throughout this thesis through the transparent and explicit reporting of the methods, analyses and conclusions. Credibility and confirmability were enhanced through the careful examination of data, interpretation and triangulation during discussions with my supervisory team to ensure the findings and conclusions reflected the data. ‘Member checks’ from the participants would have increased credibility but this was not practical due to the high staff turnover and shift patterns of the nursing home care staff. The dependability of the findings of this research is demonstrated through the appropriate methodological decisions and the ‘methodological coherence’, increasing the ability of other researchers to repeat the project and the likelihood of achieving similar results. Clear research questions were stated and
through the inclusion of theory, there is a clear description of the active ingredients and potential mechanisms of action.

The care bundle intervention was developed specifically for use in nursing homes, therefore the findings may not be transferable to other healthcare settings. In total four nursing homes participated in the projects within this thesis (Chapters Seven to Nine) but only one nursing home implemented the care bundle intervention, limiting the transferability of the findings. However, the study context and demographic details of the participants and nursing homes were outlined clearly throughout Chapters Seven to Nine. The inclusion of theory also increases the transferability of the findings as clear descriptions of the intervention components, their actions and interactional elements were explained already (Corbin & Strauss, 2008). This reduces the possibility of chance associations and augments confidence in the research findings (Lincoln & Guba, 1985). Finally, reflexivity is regarded as an important component in qualitative research and has therefore been incorporated into the work. I have explored and clearly stated my experience, values and biases which may have influenced the research processes.

The evaluation of behaviour change interventions can involve delivering the intervention to the population of interest in controlled settings using standardised programmes (Glasgow, Lichtenstein, & Marcus, 2003) with a focus
on outcome measures and/or considering implementation issues (e.g., process measures). If process measures are not well understood it may be difficult to apply the intervention within less controlled settings (Glasgow & Chambers, 2012; Glasgow et al., 2003). The implementation of interventions within clinical settings requires tailoring the intervention to the local context and incorporating contextual factors into the implementation strategies. Thus, assessing feasibility prior to conducting a larger, more controlled study is advised (Arnold et al., 2009; Craig et al., 2008; Thabane et al., 2010).

### 10.2.5 Recruitment and retention

Recruiting and retaining nursing home participants can be difficult and challenging (e.g., Buckwalter et al., 2009; Hanson, Gilliam, & Lee, 2010). A limitation of this research concerns the recruitment issues faced in all of the projects I conducted (Chapters Seven to Nine). In total, I contacted 57 nursing homes and only 7% (4/57) agreed to participate in any aspect of this research. The nursing home managers who agreed to participate explained that they would like to improve the pressure ulcer prevention care provided in their nursing homes and saw this research as a good opportunity to make changes within their daily practice. Therefore, it is unlikely that the nursing homes and staff who participated in my research are representative as they may have been more motivated to change their pressure ulcer prevention behaviours. In addition, the staff from one nursing home participated in both the qualitative
interviews (Chapter 7) and the care bundle development workshop (Chapter 8).

It may be possible, therefore, that the care bundle intervention reflects the priorities and beliefs of this particular nursing home. However, this is unlikely as:

- The participating NHS Foundation Trust covers four of the Greater Manchester boroughs and the qualitative interviews conducted to gain an understanding of the barriers and facilitators to pressure ulcer prevention (Chapter Seven) involved participants from each of the four boroughs. Therefore, a wide range of views were included within the behavioural analyses (Chapters Seven and Eight), and the issues raised were deemed to be relevant to other nursing homes and NHS community-based tissue viability services.

- The qualitative findings regarding the barriers and facilitators of pressure ulcer prevention and the implementation of the care bundle intervention (Chapters Seven and Nine) have reflected those of similar studies (Hartmann et al., 2016; Roberts et al., 2016); thereby increasing the credibility of the findings and the overall conclusions.

- The target behaviours included in the care bundle intervention (i.e. checking the support surfaces, skin inspection, repositioning) reflect the national and international guidelines (e.g., European Pressure Ulcer Advisory Panel, 2016; National Institute for Health and Care Excellence: Pressure ulcers, 2014).
In addition to the recruitment issues faced throughout this research, I also experienced difficulties in retaining the nursing home sites during the feasibility study (Chapter Nine). Only one of the three nursing homes who had participated in the qualitative semi-structured interviews about the barriers and facilitators to pressure ulcer prevention in nursing homes (Chapter Seven) agreed to participate in the feasibility study (in addition to one other nursing home who had not participated in any of the former aspects of this research). However, following the baseline data collection period one nursing home withdrew from the study due to staff and resident sickness. I asked the manager from this nursing home whether I could conduct research interviews with her and the nursing home care staff as I wished to understand why the study could not continue, however I received no response. Of the other two nursing homes who had previously participated in this research (Chapter Seven), one had a new manager who did not consent for her staff to participate in the implementation aspect; and the funding for the tissue viability service involved in the pressure ulcer prevention care of the other nursing home changed. The change in the provision of funds to the tissue viability service meant that this nursing home was not under the remit of the NHS Foundation Trust recruited as part of this research thus, the tissue viability nurse could not deliver the training aspect of the care bundle intervention. As a consequence, the nursing home manager did not wish to participate. Therefore, only one
nursing home participated in the feasibility study in Chapter 9 which is a limitation of the current research.

One aspect of feasibility studies is to determine the sample size needed for future evaluations. Part of the sample size calculation involves estimating recruitment and retention to the study. As the care bundle intervention is delivered at the level of the care home, it is likely that future evaluations of the care bundle intervention will employ a cluster-randomised study design to avoid contamination between participants (see Chapter 10.3). However, as only one nursing home completed the feasibility study, it was not possible to investigate the intra-cluster correlation values that is required for a sample size calculation.

10.3 Future research

The findings from this research have identified a number of unanswered questions and have led to the development of the following recommendations for future research to build on the current findings. Firstly, initial findings suggested that care bundle interventions may be effective in reducing negative patient outcomes (Chapter Six) and the pressure ulcer prevention care bundle intervention was acceptable in a nursing home context (Chapter Nine). These findings support the conduct of:
- Further feasibility work to explore the issues identified in the feasibility study presented in Chapter 9 (i.e. the recruitment and retention of nursing home sites; collecting outcome data; and improving staff adherence to the care bundle intervention).

- A more robust evaluation of the care bundle intervention’s efficacy and effectiveness. Due to the likelihood of ‘contamination’ between the intervention and control participants, the care bundle intervention would be delivered at the level of the nursing home rather than the individual. A cluster-randomised trial is likely to be the most appropriate research design for future evaluations. Contamination can occur if the control group are exposed to aspects of the intervention (Torgerson, 2001). For example, within the same nursing home, if randomisation occurred at the level of the participants, some of the nursing home care staff would be allocated to the intervention group and others to the control group. However, within a nursing home, staff work together and discuss the care of their residents. Therefore, it is likely that some of the participants from the control group would be exposed to various aspects of the care bundle intervention. Thus, contamination is problematic as the true effect of the intervention would not be apparent, with the potential for a Type II error (i.e. concluding that an effective intervention is ineffective).
Secondly, insufficient sample sizes are commonly reported in cluster-randomised trials (Moberg & Kramer, 2015) and as discussed, recruitment within this project posed some difficulties. Thus future studies would benefit from focusing on understanding how to engage and maintain nursing home care staff involvement in research. Much of the literature focuses on the challenges of conducting research within nursing homes, namely the ethical issues posed when including residents as participants (Hall, Longhurst, & Higginson, 2009). Whilst cluster-randomised trials have been conducted in UK nursing homes (e.g., Sackley et al., 2015), there is little published about the difficulties of engaging nursing homes and private health organisations in research in the UK.

Thirdly, this research has highlighted the importance of the multidisciplinary approach to the prevention of pressure ulcers in nursing homes; in particular the role of the tissue viability nurse. However, to my knowledge, there are no detailed explorations into the professional relationships between nursing home care staff and NHS tissue viability nurses. Therefore, there is scope for future research to focus on understanding how the NHS and nursing homes can assist each other in the delivery of pressure ulcer prevention care.

Finally, the findings from this research have posed questions relating to when, how and why pressure ulcer risk assessment tools are used and by whom. The
use of risk assessments in the current research appeared inconsistent. Before conducting an implementation study to improve the use of risk assessment tools in nursing homes it is important to understand the beliefs of nursing home care staff, who are not registered nurses, surrounding the utility and importance of risk assessments.

10.4 Conclusion

In this thesis I have synthesised the existing relevant evidence and justified the development of a pressure ulcer prevention care bundle intervention for use in nursing home settings. During the intervention development process I have followed good practice and unlike most descriptions of care bundle interventions, transparently described how the intervention was underpinned by behaviour change theory. This thesis demonstrates that care bundles may reduce negative patient outcomes and that it is possible to co-design a theory and research-informed pressure ulcer prevention care bundle intervention with key stakeholders. Moreover, it is acceptable to the nursing home staff to deliver the care bundle intervention within a nursing home context and staff reported increased awareness of pressure ulcer prevention practices, which contributed to care becoming more comprehensive. Important feasibility issues have been highlighted and the need for further work has been specified. I have discussed the strengths and limitations of this research, as well as posing the recommendations for future work including the robust evaluation of the care
bundle intervention using a cluster-randomised trial. Overall, this thesis describes the first theory and research-informed pressure ulcer prevention care bundle intervention specifically for use in nursing homes. The thesis has contributed to the body of evidence which supports the use of care bundle interventions; advancing our knowledge relating to the development of a care bundle intervention using the steps outlined in the Behaviour Change Wheel and the application of care bundles to nursing home settings. This provided support for the continuation of research aiming to improve pressure ulcer prevention in nursing home settings and having proved acceptable, the next stage is to progress onto further feasibility evaluations through a pilot cluster-randomised trial before wider evaluation and implementation.
References


Alexander, K. E., Brijnath, B., & Mazza, D. (2014). Barriers and enablers to delivery of the Healthy Kids Check: an analysis informed by the


barriers to change: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews, 3.


Cochrane Effective Practice and Organisation of Care (EPOC), (2017). What study designs should be included in an EPOC review? *EPOC Resources for review authors*. Retrieved from http://epoc.cochrane.org/resources/epoc-resources-review-authors


Effective Practice and Organisation of Care (EPOC) (2014). *EPOC resources for review authors*. Retrieved from http://epocoslo.cochrane.org/epoc-specific-resources-review-authors


theories for designing behaviour change interventions: Using methods based on theoretical construct domains to understand clinicians’ blood transfusion behaviour. *British Journal of Health Psychology, 14*, 625-646.


Ista, E., van der Hoven, B., Kornelisse, R. F., van der Starre, C., Vos, M. C., Boersma, E., & Helder, O. K. (2016). Effectiveness of insertion and
maintenance bundles to prevent central-line-associated bloodstream infections in critically ill patients of all ages: a systematic review and meta-analysis. The Lancet Infectious Diseases, 16, 724-734.


Kitzinger, J. (1994). The methodology of focus groups: the importance of interaction between research participants. *Sociology of Health & Illness, 16*, 103-121.


Little, P., Stuart, B., Francis, N., Douglas, E., Tonkin-Crine, S., Anthierens, S., ... Coenen, S. (2013). The effect of web-based training in communication skills and an interactive patient booklet and the use of a CRP point of


Prevention Program That Can Guide Evidence-Based Practice.

*Worldviews on Evidence-Based Nursing*, 1-11.


to achieve consensus from key stakeholders. Research Involvement and Engagement, 2(1), 14-33.


Middleton, S., Levi, C., Dale, S., Cheung, N. W., McInnes, E., Considine, J., ... Gerraty, R. (2016). Triage, treatment and transfer of patients with stroke...
in emergency department trial (the T 3 Trial): a cluster randomised trial protocol. *Implementation Science, 11*, 139-137.


National Institute for Health and Care Excellence: Pressure ulcers (2014)
Pressure ulcers: Prevention and management [CG179]. Retrieved from
https://www.nice.org.uk/guidance/cg179

National Institute for Health Research (2015). NIHR Evaluation, Trials and
Studies: Pilot studies 2015. Retrieved from
http://www.nets.nihr.ac.uk/glossary

pressure ulcers. Retrieved from

National Pressure Ulcer Advisory Panel (2012). Shear: A contributory factor in
pressure ulceration [PowerPoint slides]. Retrieved from


National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory
Panel and Pan Pacific Pressure Injury Alliance (2014). Prevention and
Treatment of Pressure Ulcers: Quick Reference Guide. Osborne Park, Western
Australia: Cambridge Media.

Niederhauser, A., Lukas, C. V., Parker, V., Ayello, E. A., Zulkowski, K., &
ulcers: a review of the literature. Advances in Skin & Wound Care, 25, 167-188.

Nikolakopoulou, A., Mavridis, D., & Salanti, G. (2014). Demystifying fixed and
random effects meta-analysis. Evidence-Based Mental Health, 17, 53-57.


Gondar University Hospital, Northwest Ethiopia. *BioMed Central Nursing*, 14, 34-41.


Powell, B. J., Beidas, R. S., Lewis, C. C., Aarons, G. A., McMillen, J. C., Proctor, E. K., & Mandell, D. S. (2017). Methods to improve the selection and


barriers to change: effects on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews*, CD005470.


department—a qualitative study using the Theoretical Domains Framework. *Implementation Science, 9*, 8-17.


Weir, M. C., Grimshaw, J. M., Mayhew, A., & Fergusson, D. (2012). Decisions about lumping vs. splitting of the scope of systematic reviews of complex interventions are not well justified: a case study in systematic reviews of
health care professional reminders. *Journal of Clinical Epidemiology, 65*, 756-763.


Preventing pressure ulcers in nursing homes: the development and feasibility assessment of a theory and research-informed care bundle intervention

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Appendix

Appendix 1. Systematic Review Protocol

Review title
Effectiveness of care bundles to improve patient outcomes. A systematic review.

Background
To improve care quality and patient outcomes within healthcare, the best available research evidence should be used alongside clinical expertise and professional judgement (known as evidence-based practice; Sackett et al., 1996). Adherence to evidence-based recommendations varies, and a research–practice gap has been widely reported in many areas of healthcare (Chu et al., 2004; Simmons et al., 2003; Thakur and Blazer, 2008). This gap can lead to sub-optimal clinical practices which are associated with increased financial costs and poorer health care quality and safety for patients (Hines and Joshi, 2008; Moore et al., 2010). Thus, it is important to ensure that, where appropriate, guidelines and evidence-based practices are being implemented.

Recently, care bundles have been developed with the aim of improving care quality and reducing the variations in care (Resar et al., 2012). Care bundles typically contain a maximum of five evidence-based practices which should be delivered collectively and reliably to improve patient outcomes. They have been widely applied within healthcare and usually involve a focus on healthcare professional clinical behaviours to increase reliability in care.

Description of intervention
The first reference to care bundles I have been able to identify was made by the Institute for Healthcare Improvement (IHI) in 2001 where they were used with
the aim of improving the reliability of critical care processes of intensive care teams. Thus, the current review will use the description of a care bundle provided by the IHI (Resar et al., 2012) to guide the inclusion and exclusion of studies. Thus, to be considered as a care bundle, the intervention must:

- Have a maximum of five evidence-based elements agreed by clinicians.
- Ensure that each element is relatively independent.
- Specify the population and care setting.
- Be developed by a multidisciplinary team.
- Have elements which are descriptive rather than prescriptive to allow for clinical judgment and customisation.

An example of a care bundle is the IHI Central Line bundle which aimed to reduce the number of central line-associated blood stream infections (How-to Guide, 2012). It was hoped that through bundling the elements together, communication and teamwork would improve. This care bundle included five components (hand hygiene, maximal barrier precautions, chlorhexidine skin antisepsis, optimal catheter site selection avoiding the femoral vein for central venous access in adults, daily review of whether the line is necessary and the prompt removal of unnecessary lines).

**How the intervention might work**

A care bundle can also be defined as a complex intervention (interventions with a number of interacting components), and guidance on the development and evaluation of complex interventions has been published by the Medical Research Council (MRC; 2008). When developing a complex intervention, the first phase should be to accumulate the evidence and a theory base. However, a narrative review of fourteen studies conducted by myself found both the theoretical underpinnings of the development of care bundles and the literature relating to the potential pathways of effect between the intervention and
outcomes were limited. It is believed that improved outcomes are a consequence of applying several care practices collectively and reliably (Resar et al., 2012).

A care bundle contains a few focused elements. However, these are delivered in the context of standard care practices, which may in themselves have an important role in patient outcomes. Thus, when assessing the effectiveness of care bundles it is important to consider whether the outcomes are a consequence of the care bundle alone or in collaboration with additional standard care elements. For example, in the case of the central line care bundle, it may be that daily site care and the selection of particular dressings are also being applied in addition to the care bundle.

Whilst care bundles are composed of five or less specific care elements, it is important to note that they will likely require the use of implementation processes which are thus an important feature of the care bundle. Ultimately, the aim of implementing a care bundle is to cause a change and / or maintain clinical behaviours to improve patient outcomes. Thus, the use of behaviour change techniques are vital in the success of the intervention (see Abraham and Michie, 2008; Albarracin et al., 2005). Behaviour change techniques are specific strategies used during the intervention to facilitate behaviour change (e.g., goals and planning, feedback and monitoring). Improved communication and teamwork are thought to be important factors in the success of care bundles (Resar et al., 2012). Thus, implementation strategies, namely behaviour change techniques may impact the effects of the care bundle. However, beyond these suggestions understanding is narrow.
**Why is it important to do this review?**

Care bundles are currently being devised and employed across the NHS. Examples of care bundles within the NHS are those developed to improve the reliability of critical care (Mid-Trent Critical Care Network, 2011) and to reduce variations in outcomes for patients with chronic obstructive pulmonary disease who are discharged from hospital (Hopkinson et al., 2011). Following a scoping search of the literature, many of the existing systematic reviews focus on a particular condition for example, central line-associated bloodstream infections (e.g., Blot et al., 2014). Others have reviewed care bundles implemented in specific environments such as intensive care units (e.g., Borgert et al., 2015). However, to my knowledge there are no systematic reviews generally examining the effectiveness of care bundles. Thus, it has not been possible to answer the questions of the current review and it has been difficult to ascertain the effectiveness of care bundles to improve clinical outcomes. Moreover, identifying the evidence base and / or developing theory is the first stage of the Medical Research Council’s (MRC; Craig et al., 2008) guidance on how to develop a complex intervention such as a care bundle.

In addition, some studies report the use of implementation strategies (e.g., check lists, training sessions, nurse champions) which are used to facilitate the implementation of the care bundle. Through the investigation of the effectiveness of care bundles it may be possible to explore the different components of a care bundle, the various implementation methods, and the behaviour change theories and techniques involved in the development and implementation of care bundles.
Objectives

Primary objectives
To assess:

(1) The effects of care bundles on patient outcomes.
(2) Staff adherence with the care bundle elements.
(3) Which strategies were used to facilitate the implementation of the care bundles.
   (i) To examine the intervention structure and content, including whether any of these strategies were informed by behaviour change theory.

Secondary objectives
(4) To examine whether there are important and plausible differences in effect among different sub-groups:
   (i) Health conditions.
   (ii) Healthcare practitioners.
   (iii) Healthcare settings.
   (iv) Use of implementation strategies.

Inclusion criteria

Types of studies
The methodologies which will be considered for inclusion within this review include randomised controlled trials (RCTs), which is an experimental study where people are randomly assigned to a group (intervention/control). RCTs can facilitate understanding about the effectiveness of an intervention and possible implementation strategies through the use of a control group and several experimental groups, however in healthcare settings RCTs are often not feasible or appropriate (see Silverman, 2009). Consequently, cluster-randomised trials will also be considered where groups of people are randomly allocated to the interventions.
Non-randomised controlled trials (NRCTs) will also be considered for inclusion within the review as they are also experimental studies, but people are not randomly allocated to the intervention or control groups (e.g., controlled before-and-after studies, interrupted-time-series studies, quasi-randomised studies). Interrupted time series studies involve data being collected at multiple time points to allow the detection of an effect over time. Quasi-randomised studies include those where participants are allocated to a group using quasi-random methods (e.g., date of birth, medical record number). Thus, these participants are not truly randomised. Other study designs will not be included as they are generally believed to provide little reliable evidence (Effective Practice and Organisation of Care, 2013). Studies will not be excluded based on the language of the report. A date filter will be used as the first care bundle was developed in 2001, therefore only studies conducted after this date will be included.

To enable an assessment of effectiveness, the reviewed studies must include a control group. Within healthcare it may not always be appropriate to conduct a randomised controlled trial or to include an experimental control. For example, limiting the exposure of a control group to possible superior interventions may be considered unethical. In addition, there may be difficulties recruiting participants and strong patient preferences for health care can bias outcomes (Brewin and Bradley, 1989). Randomised controlled trials can be costly and time-consuming which may make this design infeasible for some research groups. This has been acknowledged by the choice of study designs which are considered eligible for inclusion. Findings from a scoping review conducted by myself suggest that care bundles vary in terms of the frequency and duration of delivery. Thus, studies will not be excluded based on this especially as the care bundles will differ due to being condition- and setting-specific.
**Types of participants**

At present, it is unknown whether there are important differences in effects of care bundles among different subgroups and healthcare settings. Therefore, all of the relevant subgroups will be included and we will summarise data by subgroups where possible, potentially testing for differences in effect in the analyses if this is feasible with the available data.

**Types of interventions**

The primary intervention is a care bundle, and using the definition provided by Resar *et al.* (2012) a study will be deemed eligible for inclusion if:

1. The care bundle consists of no more than 5 evidence-based elements.
   - Within the literature, the meaning of evidence-based practice within a study is often not well reported. Thus, to maximise the review literature, studies reporting care bundle development based on guidelines and/or clinician agreement will be included within the data extraction process as these are the two common components in evidence-based practice (Sackett *et al.*, 1996), and this will be assumed unless otherwise stated.

2. The elements must be relatively independent of each other.
   - This will be assumed unless otherwise stated.

3. The studies must specify the population and care setting the care bundle is intended for.

4. A multidisciplinary team developed the care bundle.
   - This will be assumed unless stated otherwise.

Some of the care bundle criteria suggested by Resar *et al.* (2012) would be too restrictive to apply to the current review search. For example, it is suggested that care bundles should be descriptive rather than prescriptive to allow for clinical judgement and customisation. However, due to the objectives of the current review studies will not be excluded on this basis. Some authors have also stated that care bundles should also have an all-or-none compliance rate of
at least 95%. All-or-none compliance refers to the completion of all bundle elements. If one element is not completed, unless medically contraindicated, the whole care bundle will be considered as not having been adhered to. However, we have not used this as an inclusion/exclusion criterion as it would be too restrictive and may lead to the inappropriate exclusion of studies.

We will include studies of the appropriate design deemed to evaluate a care bundle as defined above. As well as details of the care bundle itself we will also record information about the implementation approaches used, although this will not influence eligibility. As stated earlier, behaviour change techniques are sometimes used to facilitate the implementation of care bundles. Michie et al. (2013) have developed a behaviour change technique taxonomy of 93 different techniques. This taxonomy was developed using a Delphi exercise where international behaviour change experts were asked to develop a list of behaviour change labels and assess for reliability before developing a hierarchical structure. Thus, to be considered a behaviour change technique, the strategy used must be listed within this taxonomy (see Appendix 6 for full list).

**Types of outcomes measures**

Decisions surrounding study inclusion will be based on the presence of at least one of the primary outcomes. Studies will still be considered for review if an area of a study is unclear or if no ‘usable’ data are provided as the authors will be contacted for clarification. If clarification is not provided, studies will be excluded.

**Primary outcomes**

(1) Condition-specific outcomes.

(2) Compliance with the care bundle.

   (i) Overall compliance (percentage across all elements).
(ii) All-or-none compliance (every element of the bundle must be completed).

Search methods

A scoping search within MEDLINE and CINAHL will be undertaken to enable the identification of relevant words and index terms. This search will include the initial keywords (care bundle, evidence-based practice, quality improvement, complex intervention). Detailed searches will be conducted in six databases (British Nursing Index, CINAHL, MEDLINE, EMBASE, CENTRAL, PsycINFO). These databases have been chosen as they hold articles concerned with healthcare and it is hoped that a thorough search of these databases will enable the identification of all eligible studies. In addition, the reference lists of identified reports and articles will be searched. In order to minimise unintentional publication bias and language bias, a search for unpublished data will be conducted which will include searches in the British Library, Conference Proceedings Citation Index, and OpenGrey. Searches of the Cochrane library and the Centre for Reviews and Dissemination will also be undertaken and, where possible, contact will be made with potentially relevant individuals and organisations.

Searches will be stored in Covidence, an online review manager which aims to improve the process of evidence synthesis (Covidence, 2013). Using Covidence, reviewers can conduct citation importation and screening, study selection, full-text review, data extraction, data exportation, and quality assessment. Several researchers can have access to the review which is a benefit of the program. Towards the end of the review process the searches will be repeated to ensure the most up-to-date research is included.
Data collection and analysis

Selection of studies
Duplicate records of the same report will be removed, and independently two reviewers will screen the titles and abstracts of the studies retrieved for relevance against the eligibility criteria. Following this, full-text copies of the potentially relevant studies will be obtained and independently reviewed by two reviewers for eligibility. Any disputes will be resolved through discussion with a third person. If eligibility is unclear, contact will be attempted with the study authors for clarification and process papers associated with the study which outline further information will be sought when referred to in the primary study. Multiple reports of the same study will be collated so that each study is the unit of interest in the review rather than each paper. This will also ensure maximal extraction of the relevant data. Reasons for excluding studies obtained as full-text will be recorded and demonstrated using a PRISMA flowchart (Moher et al., 2009).

Data extraction and management
Details of the relevant studies will be extracted and summarised. Data will be extracted independently by two reviewers and any disagreements will be resolved through discussion with a third person. If data is missing from the reports, contact with study authors to obtain this information will be attempted. Before the extraction for the current review begins, the extraction sheet will be piloted to assess its’ suitability, and if necessary changes will be made (Appendix 3). Where possible, the following data will be extracted from the studies eligible for review:

- Authors, year of study, date of completion of extraction.
- Publication type (journal article, abstract, other), country of study, funding source, potential conflicts of interest.
- Study characteristics (title, aims/objectives, design, patient population, settings,
care bundle, implementation strategies, duration of follow-up, outcome measures and outcome data).

This information will be reported within a ‘Characteristics of included studies’ table.

**Assessment of risk of bias in included studies**

There is the potential that some studies over/underestimate the true intervention effect, thus it is important to assess a study’s risk of bias. A study design or procedure can result in uncertainties regarding the validity of a study’s findings, and levels of risk differ depending on study design. For example, controlled before-and-after studies are at high risk of bias due to possible unidentified differences between the control and intervention groups which could potentially result in differences in the outcome measure. Due to the nature of an interrupted time series design, the impact of any simultaneous events on the outcomes of interest cannot be assessed. Cluster randomised trials have an issue of baseline imbalance in cluster level variables. The number of clusters also needs to be considered carefully and there may be more risk of unequal distribution of factors that could potentially impact the outcomes of interest. Therefore, assessments of the similarities in baseline characteristics and baseline outcome measures should be pre-specified.

A baseline confounding variable is a pre-intervention prognostic factor which could predict the intervention received at baseline (Sterne et al., 2014). Within the current review a baseline confounding variable may be:

- The presence of co-morbidities as they may affect whether or not a person is eligible for the intervention. Consequently, there may be a ceiling effect if only those who are likely to respond to the intervention are included.

An unmeasured confounding variable occurs if a confound has either not been
measured or is not controlled for in the analysis. An unmeasured confounding variable which may affect the current review is:

- Whether participants continue to receive usual care/other care elements in addition to the intervention. Only if a study states this will it be possible to trace such a potentially strong confound.

For the current review, the Cochrane collaboration tool for assessing risk of bias (Higgins et al., 2011) will be used for RCTs and cluster-randomised trials. Seven specific domains are addressed by this tool (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias; see Appendix 5). It may not always be possible for a study to include such measures to minimise bias (e.g., blinding of participants and personnel, allocation concealment), however this will be recorded where information is provided.

To assess the risk of bias for non-randomised studies, there are two tools which could be used (A Cochrane Risk of Bias Assessment Tool: for Non-Randomised Studies of Interventions (ACROBAT-NRSI; Sterne et al., 2014) and the Effective Practice and Organisation of Care (EPOC) risk of bias tool. As the ACROBAT-NRSI is a relatively new tool, it is important to compare and contrast the risk of bias results with the EPOC risk of bias tool. Thus, a pilot study involving 5 studies will be conducted using both of the tools and a decision regarding which tool to continue using will be made by the reviewers. If the EPOC risk of bias tool is used there are two tools which will be utilised depending on the study design:

- For non-RCTs (but not interrupted time series), the Effective Practice and Organisation of Care (EPOC) risk of bias tool will be used. This tool contains the standard Cochrane risk of bias tool items, as well as additional items (e.g., were baseline outcome measurements similar? Were baselines
characteristics similar? Did the study authors appropriately adjust for important confounders in their analysis? See Appendix 17).

- For interrupted time series, the EPOC risk of bias tool for interrupted time series will be used. This tool contains four items from the standard Cochrane risk of bias tool (assessing performance, attrition, detection, reporting bias). There are an additional three items also included (was the intervention independent of other changes? Was the shape of the intervention effect prespecified? Was the intervention unlikely to affect data collection? See Appendix 17).

The ACROBAT-NRSI tool can be used with any non-randomised study design. Seven specific domains of bias are addressed by this tool (bias due to confounding, bias in selection of participants into the study, bias in measurement of interventions, bias due to departures from intended interventions, bias due to missing data, bias in measurement of outcomes, bias in selection of reported outcomes; see Appendix 4).

The risk of bias assessment will be presented in a ‘Risk of bias’ summary figure. Where possible, the risk of bias in each of the outcome measures will be examined and included within a separate summary figure. Based on the considerations given to study design and the potential impact on the results, outcomes are likely to be judged as at ‘low’, ‘medium’, or ‘high’ risk of bias. Conclusions will be made based on the findings and the level of risk of bias. If risk of bias is medium-high, conclusions will be drawn with caution.

**Measures of treatment effect**

Where possible, studies will be grouped according to health condition. Where data are dichotomous (e.g., presence/absence of clinical condition), the summary ratio will be presented as a risk ratio (RR) with 95% confidence intervals. Continuous data (e.g., percentage of compliance rates) will be
presented as mean differences and overall effect sizes with 95% confidence intervals.

When measuring the effect of the intervention, intention-to-treat analysis (participants are analysed in the intervention group they were randomly assigned to) or per protocol (analysis based on the intervention described in the trial protocol) analysis are often used. The per protocol effect is sometimes used instead of the intention-to-treat analysis because major protocol violations (e.g., non-adherence, missed measurements) are taken into account (Sainani, 2010). Whilst the per protocol analysis may reflect the maximum potential benefits of the intervention, it may also introduce attrition bias due to the removal of non-compliant participants; and therefore potentially provide a lower level of evidence. Nevertheless, if an intention-to-treat (ITT) analysis was conducted, the estimated treatment effect may not reflect the true treatment effect due to the dilution of non-compliance. Therefore, ITT is more susceptible to a type II error (Fergusson et al., 2002; Hollis and Campbell, 1999).

Unit of analysis issues

Unit of analysis issues may arise with studies employing a cluster-randomised trial design. For example, analyses are sometimes conducted as if the individuals were randomised rather than the clusters being randomised. Nevertheless, if this occurs it is possible to conduct an approximate analysis if information on the following has been provided:

- The average size of each cluster or the number of clusters in each intervention group;
- The outcome data for each of the participants (ignore the cluster design); and
- An estimated intracluster correlation coefficient which is the estimated relative variability within and between clusters (Donner and Koval, 1980).
If this information has been provided or is attainable, adjusting for clustering will be performed and a meta-analysis of the effect estimates and standard errors will be conducted. If this data is not provided, a narrative review will be written.

**Dealing with missing data**

Where additional information and data are required, an e-mail will be sent to the first author of the relevant study with one reminder e-mail. If these requests are not met, these studies will not be included within the meta-analysis. Only the data obtained will be analysed using a complete case analysis.

We will also conduct a sensitivity analysis by making assumptions about missing categorical data for the primary outcomes where possible. Where the primary outcome is a negative event such as death or a positive event such as wound healing for those with missing data we will assume that they did not have the event of interest occur (that participants with missing data will be included in the denominator but not the numerator).

**Assessment of heterogeneity**

Heterogeneity refers to the variability across studies and may be clinical heterogeneity (e.g., differences in participants, interventions, outcome measures) or methodological heterogeneity (e.g., differences in study design and implementation). Statistical heterogeneity is the variability in observed treatment effects caused by clinical and/or methodological heterogeneity. To consider the extent of the consistency of results between studies, confidence intervals may be plotted using horizontal lines. When there is poor overlap between the lines, this usually indicates statistical heterogeneity. Whereas, good overlap would suggest less statistical heterogeneity.
The chi² test is a more formal test for statistical heterogeneity, which assesses whether differences in results are due to chance alone. Heterogeneity of intervention effects is assumed when there is a low $p$ value or a large chi² statistic relative to its degrees of freedom. However, when used in a meta-analysis, if studies have a small sample size or not many studies are included, the chi² test has low power. Therefore, whilst a statistically significant result suggests some heterogeneity, caution must be taken when interpreting non-statistically significant results as these do not necessarily indicate the absence of heterogeneity. Consequently, a $p$ value of .1 will be used to determine statistical significance rather than $p < .05$.

Rather than assessing whether heterogeneity is present, it is now believed to be important to test its impact on the meta-analysis. To quantify inconsistency, the $I^2$ metric is used (Higgins and Thompson, 2002):

$$I^2 = \left( \frac{Q - df}{Q} \right) \times 100\%$$

$Q = \text{chi}^2$ statistic.  
$df = \text{degrees of freedom}$.

Here, the percentage of the variability that is due to heterogeneity instead of the sampling error is described by the $I^2$ statistic. Generally, interpretation is as follows:

- 0% - 40%: may not be important;
- 30% - 60%: possible moderate heterogeneity*;
- 50% - 90%: possible substantial heterogeneity*;
- 75% - 100%: considerable heterogeneity*.

* Two factors which impact the value of $I^2$ are:
  - Direction and magnitude of effects;
  - Strength of evidence for heterogeneity (e.g., $p$ value from chi² test, confidence interval for $I$).
There are a number of strategies available for addressing heterogeneity once it has been identified (Schunemann et al., 2011):

1. Re-assess the data again. It is possible the data have been incorrectly extracted or imported.

2. Do not conduct a meta-analysis. When there is inconsistency in the direction of effect or the results vary, the average value of the intervention effect may be misleading.

3. Explore heterogeneity when there are many studies. Understanding the reasons for heterogeneity is important, however there may be many characteristics which vary across the studies making this process difficult. Consequently, it may be useful to explore heterogeneity by conducting subgroup analyses or meta-regression. In order to make any conclusions as reliable as possible, I have pre-specified all of the study designs and characteristics of studies which could potentially be associated with heterogeneity within this protocol and have proposed the following hypotheses:

   **Hypothesis 1:** Studies employing a randomised trial to evaluate care bundles are likely to be associated with a lower estimate of effect.

   **Hypothesis 2:** Care bundles will have a greater effect on processes and outcomes when they are implemented in more “controlled” healthcare settings (e.g., intensive care units).

   **Hypothesis 3:** Care bundles will be similarly effective for different health conditions.

   **Hypothesis 4:** Care bundles will be similarly effective despite the number of behaviour change techniques used.

   **Hypothesis 5:** The more elements in the care bundle (to a maximum of five), the greater the reduction in negative patient outcomes.

   **Hypothesis 6:** The higher the implementation fidelity, the greater the reduction in negative patient outcomes.
(4) However, as the author is familiar with the care bundle literature, this is not a true pre-specification. Consequently, all conclusions must be reported with caution.

(5) Ignore heterogeneity and conduct a fixed-effect meta-analysis. During a fixed-effect meta-analysis, a confidence interval is calculated under the assumption that the true intervention effect (in magnitude and direction) is the same for every study; and the pooled effect estimate is considered to be a good estimate of the intervention effect. Therefore, any observed differences between the studies are believed to be due to chance, not statistical heterogeneity. However, if heterogeneity is present it is possible that there is not a single intervention effect, rather a distribution of intervention effects. Consequently, the pooled fixed-effect estimate may provide an intervention effect which does not exist. Although, the $p$ value does enable the null hypothesis to be tested.

(6) Perform a random-effects meta-analysis. When heterogeneity cannot be explained, a random-effects meta-analysis maybe conducted to incorporate the heterogeneity among the studies. When conducting a random-effects meta-analysis, it is assumed that the estimated intervention effects follow a distribution. Due to not knowing the reasons for heterogeneity, this model considers the differing intervention effects as random. The average of the effects is demonstrated in the centre of the distribution, and heterogeneity is shown through the width of the distribution. Whilst the choice of distribution is a normal distribution, establishing the validity of a distributional assumption can be difficult. If there are enough studies to adequately do so, it is still important to explore the possible causes of heterogeneity as the random-effects model does not explain heterogeneity and there may still be a large amount of heterogeneity even when a study has a tight confidence interval around the random-effects estimate of the mean. The confidence interval demonstrates uncertainty in the location of
the mean.

(7) Change the effect measure. The choice of effect measure may cause heterogeneity.

(8) Exclude studies. Heterogeneity can be caused by a few studies which have results that conflict with the majority of the other studies. The study should only be removed from the meta-analysis if there is an obvious reason for the outlying results. Before removing the study, it is advised that a sensitivity analysis is conducted with and without the study.

Statistical heterogeneity will be assessed using $I^2$ and Chi$^2$ statistics (statistically significant levels of heterogeneity, $p < .1$). Where high heterogeneity exists, a random-effects model will be used to pool data and a prediction interval will be considered for the assessment of clinical importance. If statistical heterogeneity is believed to be due to clinical diversity, it will not be appropriate to conduct a random-effects model as the random-effects estimate may not reflect the real effect in any of the populations being studied. However, if heterogeneity is too high ($I^2 > 75\%$) the pooling of studies will not be carried out. Where clinical or statistical data are homogeneous, a random-effects model will also be conducted.

Heterogeneity can be caused by differing methodologies which cause biases and affect study results. Only when the biases are symmetrically distributed will the random-effects pooled estimate provide an estimate of the average treatment effect due to a mixture of over- and under-estimations. However, it can be difficult to assess whether heterogeneity is due to methodological or clinical diversity. Where heterogeneity exists, these studies will be analysed and presented separately. Only when there is sufficient homogeneity among a group of studies will a meta-analysis be considered.
Assessment of reporting biases

Bias can be introduced in many ways and publication bias is commonly reported. Publication bias occurs when significant results are more likely to be published than non-significant results (Easterbrook et al., 1991). Published studies with significant results are also more likely to be published in English (Egger et al., 1997), be repeatedly published (Gotsche, 1989; Tramer et al., 1997), and are more likely to be cited (Ravnskov, 1995). Thus, an English language bias, a multiple publication bias, and a citation bias are more likely to occur, also known as ‘small study effects’ bias. In addition, the inclusion criteria of a review or meta-analysis may be influenced by beliefs surrounding the potential results of studies which can lead to inclusion bias. Sensitivity analyses and funnel plots should be used to routinely examine the potential presence or absence of bias (Egger and Smith, 1998). Reporting bias is also problematic as many studies report positive findings (e.g., efficacy measures) rather than data about the harms of an intervention or adverse events (Smyth et al., 2011). To assess such potential effects and reporting biases, when more than 10 studies are included within the meta-analysis, funnel plots will be used to provide a visual assessment of whether small study effects are potentially present.

Data synthesis

The details of the included studies will be combined in a narrative review according to the relevant comparators. Where possible the pooling of data using a meta-analysis will be conducted. All of the studies will be combined and a pooled estimate and confidence interval for the effect of care bundles will be calculated.

'Summary of findings' tables

The main results of the review will be presented in a ‘summary of findings’ table. Key information concerning the following will be included:
• The quality of the evidence.
• The magnitude of the effects of the care bundles.
• The sum of the available data for the main outcomes.

The studies selected for retrieval will be assessed for methodological quality and this rating will also be presented in the ‘summary of findings’ table. The GRADE (2004) tool will be used to assess the quality of evidence using the study design (high, moderate, low, very low) and based on five factors (limitations in the design and implementation which suggests a high level of bias is likely, indirectness of evidence, unexplained heterogeneity or inconsistent results, imprecise results, a high chance of publication bias). Consequently, a randomised-controlled trial would receive the highest grade. The GRADE (2004) tool also enables an assessment of the evidence for each outcome (patient outcomes, compliance with care bundle) and the magnitude of the effect. Using this tool enables the methods to be systematic and transparent, and impacts the confidence in an estimate of effect.

**Sensitivity analysis**

ITT and per protocol analyses have advantages and disadvantages; therefore, to minimise the introduction on bias during the analysis, a sensitivity analysis will be conducted where an ITT analysis is conducted and compared with a per protocol analysis. If possible, a sensitivity analysis will be conducted to explore the influence of risk of bias on effect sizes. A meta-analysis will be conducted which will include studies classed as being at high risk and unclear risk of bias, and a separate meta-analysis will be carried out without these studies to assess their impact on the overall findings. Those considered to be at low risk of bias in all key domains (adequate generation of the randomisation sequence, adequate allocation concealment and blinding of outcome assessor, for the estimates of treatment effect; GRADE Assessment) will always be included.
**Dissemination**

This systematic review will be conducted as part of wider PhD project. The results will be disseminated within the final thesis and publications.

**Conflicts of interest**

There are no known conflicts of interest.
Appendix 2. Search strategy performed in each database

OVID Databases (inc. PsycInfo and EMBASE and Medline)

1 Patient care bundle*.tw,fs,sh,mp.
2 exp Care bundle/
3 Care adj bundle*
4 exp Patient care bundle
5 Care adj checklist
6 Care checklist.mp,fs.
7 Prevention adj bundle
8 Prevention bundle.mp.
9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

10 guidelines as topic/ or practice guidelines as topic/
11 Guideline Adherence/
12 exp Critical Pathways/
13 (guideline? not (guideline? adj2 author?)).ti,ab.
14 ((pathway? or protocol? or algorithm?) adj2 (clinical or treatment? or diagnos$ or 15 management or infection? or infectious? or antibiotic?)).ti,ab.
16 critical pathway?.ti,ab.
17 guidance.ti,ab.
18 (quality adj2 (improv$ or manag$ or care or healthcare)).ti,ab.
19 (guideline? adj2 (impact or effect$)).ti,ab.
20 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19

21 9 and 20

CENTRAL

1 Patient care bundle*
2 Patient care bundle* MeSH descriptor
3 Patient care bundle*:ti
4 Patient care bundle*:ab
5 Patient care bundle*:kw
6 Care NEXT bundle*
7 Care NEXT checklist
8 Care checklist:ti
9 Care checklist:ab
10 Care checklist:kw
11 or/1-10

12 Prevention NEXT bundle
13 Prevention bundle*
14 Prevention bundle*:ti
15 Prevention bundle:ab
16 Prevention bundle:kw
17 or/12-17

18 11 and 17

CINAHL:
1 Patient care bundle*MH
2 Patient care bundle*MH+
3 Patient care bundle*Wn
4 “Patient care bundle”
5 “care bundle”
6 care bundleMH+
7 Care checklistWn
8 Care checklistMH
9 Care checklistMH+
10 “Care checklist”
11 Prevention bundleWn
12 Prevention bundle*
13 Prevention bundle*MH
14 Prevention bundleMH+
15 “prevention bundle”
16 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

**PROQUEST databases:**
1 Patient care bundle*
2 Patient care bundle*P/n
3 “Patient care bundle”
4 “care bundle”
5 Care checklist
6 Care checklistP/n
7 “Care checklist”
8 Prevention bundle*
9 “Prevention bundle”
10 Prevention bundle/n
11 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10

**British nursing index:**
(Patient OR patient care team OR caregivers OR medical staff OR nurs* OR nurse practitioners OR nurse clinicians OR nurses community health OR nurses public health OR nurse’s aides OR health personnel OR humans) AND (patient care bundle OR patient safety OR patient care management OR guideline OR complex intervention OR quality improvement OR guideline adherence OR practice guideline OR evidence-based practice OR nursing process OR evidence-based nursing OR evidence-based medicine OR evidence-based emergency medicine OR nursing OR care package OR care checklist OR prevention bundle OR care intervention OR care pathway) AND (control groups OR normal care) AND (intervention studies OR controlled before-after stud* OR interrupted time series analysis OR historically controlled stud* OR non-randomised controlled trial as topic OR control groups) AND (mortality
OR patient care OR treatment outcome OR nurs* practice patterns OR quality improvement OR patient outcome assessment OR treatment outcome* OR effectiveness OR outcome assessment OR quality of healthcare OR comparative effectiveness research OR program evaluation OR patient harm OR compliance OR adherence OR incidence)

Search term key: exp = explode subject heading; adj = adjacency searching, / = subject heading, .tw. = textword, $ = truncation; .mp. = searches title, abstract, full text, caption text, ti = title, ab = abstract, mh = subject heading
Appendix 3. Data extraction sheet for included studies

<table>
<thead>
<tr>
<th>General information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Authors</td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Publication type (journal article, abstract, conference)</td>
<td></td>
</tr>
<tr>
<td>Reference details (journal and issue number, page number, doi, duplicates)</td>
<td></td>
</tr>
<tr>
<td>Date of extraction and who</td>
<td></td>
</tr>
<tr>
<td>Country of study</td>
<td></td>
</tr>
<tr>
<td>Funding source</td>
<td></td>
</tr>
<tr>
<td>Potential conflicts of interest</td>
<td></td>
</tr>
<tr>
<td>Contact author</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>Study characteristics</td>
<td>Stated</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Type of study</td>
<td>Randomised controlled trial</td>
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<tr>
<td></td>
<td>Yes</td>
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<tr>
<td></td>
<td>Non-randomised controlled trial</td>
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<td></td>
<td>Yes</td>
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<tr>
<td>Study design (e.g., interrupted time series, cluster)</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Details:</td>
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<tr>
<td>Unit of allocation (e.g., individuals, cluster)</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Details:</td>
</tr>
<tr>
<td>Outcome measures stated</td>
<td>Yes</td>
</tr>
<tr>
<td>Start date</td>
<td>Yes</td>
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<td></td>
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<td>End date</td>
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<td></td>
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<tr>
<td>Total study duration</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Details:</td>
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<tr>
<td>Population and setting</td>
<td>Stated</td>
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<td>----------------------------------------</td>
<td>--------</td>
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<tr>
<td>Care setting</td>
<td>Yes</td>
</tr>
<tr>
<td>Inclusion criteria</td>
<td>Yes</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>Yes</td>
</tr>
<tr>
<td>Methods of recruitment</td>
<td>Yes</td>
</tr>
<tr>
<td>Statistical method used</td>
<td>Yes</td>
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<tr>
<td>Sample size calculation</td>
<td>Yes</td>
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<tr>
<td>Power</td>
<td>Not reported</td>
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<tr>
<td>Informed consent gained</td>
<td>Yes</td>
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<tr>
<td>Notes</td>
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<tr>
<td>Intervention</td>
<td>Description as stated in report/paper</td>
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<tr>
<td>--------------</td>
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<tr>
<td>Interventions</td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td></td>
</tr>
<tr>
<td>Number of care bundle elements (include timing and delivery)</td>
<td>Yes  No  Unclear N = Details:</td>
</tr>
<tr>
<td>Were co-interventions used to facilitate the implementation? (include timing and delivery)</td>
<td>Yes  No  Unclear Details:</td>
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<tr>
<td>Theoretical basis (include key references)</td>
<td>Yes  No  Unclear Details:</td>
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<tr>
<td>Duration of treatment period</td>
<td>Yes  No  Unclear Details:</td>
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<td>Outcome 1</td>
<td>Description as stated in report/paper</td>
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<tr>
<td><strong>Outcome (with definition)</strong></td>
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</tr>
<tr>
<td><strong>Time points measured</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Person measuring/reporting</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Unit of measurement (if relevant)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Scales (indicate whether high or low score is good)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is outcomes/tool validated?</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>Details:</td>
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<tr>
<td>Outcome 2</td>
<td>Description as stated in report/paper</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Outcome (with definition)</td>
<td></td>
</tr>
<tr>
<td>Time points measured</td>
<td></td>
</tr>
<tr>
<td>Person measuring/reporting</td>
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<tr>
<td>Unit of measurement (if relevant)</td>
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<tr>
<td>Scales (indicate whether high or low score is good)</td>
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</tr>
<tr>
<td>Is outcomes/tool validated?</td>
<td>Yes  No  Unclear</td>
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<tr>
<td>Details:</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Description as stated in report/paper</td>
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<tr>
<td>---------</td>
<td>---------------------------------------</td>
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<tr>
<td>Participant characteristics (those implementing the care bundle)</td>
<td>Yes  No  Unclear</td>
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<tr>
<td>Patient characteristics (those receiving the care bundle)</td>
<td>Yes  No  Unclear</td>
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<tr>
<td>Condition(s):</td>
<td>Co-morbidities:</td>
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<tr>
<td>Other</td>
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<tr>
<td>Baseline imbalances</td>
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</tr>
<tr>
<td>Outcome 1</td>
<td>Intervention n =</td>
</tr>
<tr>
<td>Outcome 2</td>
<td>Intervention n =</td>
</tr>
<tr>
<td>Outcome 3</td>
<td>Intervention n =</td>
</tr>
<tr>
<td>Subgroup analyses (if relevant)</td>
<td></td>
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<tr>
<td>-------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Time points reported</td>
<td>Reported as pre and post bundle only</td>
</tr>
<tr>
<td>Attrition and exclusions</td>
<td>Yes</td>
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<tr>
<td>Imputation of missing data</td>
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</tr>
<tr>
<td>Reanalysis required?</td>
<td>Yes</td>
</tr>
<tr>
<td>Reanalysis possible?</td>
<td>Yes</td>
</tr>
<tr>
<td>Reanalysed results</td>
<td></td>
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<tr>
<td>Applicability</td>
<td>Description as stated in report/paper</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Have important populations been excluded from the study?</td>
<td>Yes No Unclear</td>
</tr>
<tr>
<td>Is the intervention likely to be aimed at disadvantaged groups?</td>
<td>Yes No Unclear</td>
</tr>
<tr>
<td>Does the study directly answer the review question?</td>
<td>Yes No Unclear</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other information</th>
<th>Description as stated in report/paper</th>
<th>Location in text (page number, table)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key conclusions of study authors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>References to other relevant studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correspondence required for further information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4. Non-randomised studies risk of bias assessment tool (Sterne et al., 2014)

6 The ACROBAT-NRSI tool (1): At protocol stage

6.1 Specify the research question by defining a generic target randomized trial

<table>
<thead>
<tr>
<th>Participants</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental intervention</td>
<td></td>
</tr>
<tr>
<td>Control intervention</td>
<td></td>
</tr>
</tbody>
</table>

6.2 Specify the nature of the target comparison (effect of interest)

e.g. effect of initiating intervention (as in intention-to-treat analysis), or effect of initiating and adhering to intervention (as in a per-protocol analysis)

6.3 List the confounding domains relevant to all or most studies

6.4 List the possible co-interventions that could differ between intervention groups and could have an impact on study outcomes


7 The ACROBAT-NRSI tool (2): For each study

7.1 Specify a target trial specific to the study.

The protocol-specified target randomized trial fully applies OR Experimental intervention
Control intervention

7.2 Specify the outcome

Specify which outcome is being assessed for risk of bias (typically from among those earmarked for the Summary of Findings table). Specify whether this is a proposed benefit or harm of intervention.

7.3 Specify the effect of interest

e.g. effect of initiating intervention (as in an intention-to-treat analysis), or effect of initiating and adhering to intervention (as in a per-protocol analysis)

7.4 Specify the specific result being assessed

In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

7.5 Preliminary consideration of confounders

a. Within each confounding domain listed in the review protocol, list the relevant variables, if any, measured in this study.
### 7.5.1 Relationship between confounding domains and potential confounders.

In the table below, "critically important" confounding domains are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention. "Validity" refers to whether the confounding variable or variables fully measure the domain, while "reliability" refers to the precision of the measurement (more measurement error means less reliability).

<table>
<thead>
<tr>
<th>Confounding domain</th>
<th>Is the domain critically important?*</th>
<th>Measured Variable</th>
<th>Did the authors demonstrate that controlling for this variable was unnecessary?*</th>
<th>Is the domain measured validly and reliably by this variable (or these variables)?</th>
<th>OPTIONAL: Is adjusting for this variable (alone) expected to move the effect estimate up or down? **</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes / No</td>
<td></td>
<td></td>
<td>Yes / No / No information</td>
<td>Up / Down / No information</td>
</tr>
</tbody>
</table>

* In the context of a particular study, variables can be demonstrated not to be confounders and so not included in the analysis: (a) if they are not predictive of the outcome; (b) if they are not predictive of intervention; or (c) because adjustment makes no or minimal difference to the estimated effect of the primary parameter. Note that "no statistically significant association" is not the same as "not predictive".

** For example, if the crude effect estimate is 1.3, adjustment to 1.6 is up, while adjustment to 0.7 is down. If the effect estimate is 0.7, adjustment to 1.1 is up while adjustment to 0.4 is down.
7.6 Preliminary consideration of co-interventions

a. Are the (pre-specified) co-interventions likely to be administered in the context of this study?

b. List additional co-interventions, if any, specific to the setting of this particular study.

7.6.1 Co-interventions

In the table below, "critically important" co-interventions are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention. "Validity" refers to whether the variables fully measure the co-intervention, while "reliability" refers to the precision of the measurement (more measurement error means less reliability).

<table>
<thead>
<tr>
<th>Co-intervention</th>
<th>Is the co-intervention critically important?</th>
<th>Did the authors demonstrate that controlling for this co-intervention was unnecessary?</th>
<th>Is the co-intervention measured validly and reliably?</th>
<th>Is presence of this co-intervention likely to favour outcomes in the experimental or the control group?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes / No</td>
<td>Yes / No / No information</td>
<td></td>
<td>Favour experimental / Favour comparator / No information</td>
</tr>
<tr>
<td></td>
<td>Yes / No</td>
<td>Yes / No / No information</td>
<td></td>
<td>Favour experimental / Favour comparator / No information</td>
</tr>
<tr>
<td></td>
<td>Yes / No</td>
<td>Yes / No / No information</td>
<td></td>
<td>Favour experimental / Favour comparator / No information</td>
</tr>
</tbody>
</table>
## 7.7 Risk of bias assessment (cohort-type studies)

<table>
<thead>
<tr>
<th>Bias due to confounding</th>
<th>Y or PY to 1.1: the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered</th>
<th>Y / PY / PN / N</th>
<th>[Description]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If N or PN to 1.1:</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td>1.2. Were participants analysed according to their initial intervention group throughout follow up?</td>
<td></td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td></td>
<td>If Y or PY to 1.2, answer questions 1.4 to 1.6, which relate to baseline confounding</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td>1.3. If N or PN to 1.2: Were intervention discontinuations or switches unlikely to be related to factors that are prognostic for the outcome?</td>
<td></td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
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<tr>
<td></td>
<td>If Y or PY to 1.3, answer questions 1.4 to 1.6, which relate to baseline confounding</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td></td>
<td>If N or PN to 1.1 and 1.2 and 1.3, answer questions 1.7 and 1.8, which relate to time-varying confounding</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
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<tr>
<td></td>
<td>If Y or PY to 1.2, or Y or PY to 1.3</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
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<tr>
<td>1.4. Did the authors use an appropriate analysis method that adjusted for all the critically important confounding domains?</td>
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<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
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<tr>
<td>1.5. If Y or PY to 1.4. Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?</td>
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<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
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<tr>
<td>1.6. Did the authors avoid adjusting for post-intervention variables?</td>
<td></td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td></td>
<td>If N or PN to 1.2 and 1.3</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td>Risk of bias judgement</td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>Support for judgement</td>
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</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------</td>
<td>-----------------------</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to confounding?</td>
<td>Favour experimental / Favour comparator / Unpredictable</td>
<td>Rationale</td>
<td></td>
</tr>
</tbody>
</table>

### Bias in selection of participants into the study

| 2.1. Was selection into the study unrelated to intervention or unrelated to outcome? | Y / Y / PN / N / NI | Description |
| 2.2. Do start of follow-up and start of intervention coincide for most subjects? | Y / Y / PN / N / NI | Description |
| 2.3. If N or PN to 2.1 or 2.2: Were adjustment techniques used that are likely to correct for the presence of selection biases? | NA / Y / Y / PN / N / NI | Description |

### Bias in measurement of interventions

| 3.1 Is intervention status well defined? | Y / Y / PN / N / NI | Description |
| 3.2 Was information on intervention status recorded at the time of intervention? | Y / Y / PN / N / NI | Description |
| 3.3 Was information on intervention status unaffected by knowledge of the outcome or risk of the outcome? | Y / Y / PN / N / NI | Description |

### Bias due to departures from intended

<p>| 4.1. Were the critical co-interventions balanced across intervention groups? | Y / Y / PN / N / NI | Description |
| 4.2. Were numbers of switches to other interventions low? | Y / Y / PN / N / NI | Description |
| 4.3. Was implementation failure minor? | Y / Y / PN / N / NI | Description |</p>
<table>
<thead>
<tr>
<th>Interventions</th>
<th>Y/N/P/Y/P/N/N/N</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Risk of bias judgement</strong></td>
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<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to departures from</td>
<td></td>
<td></td>
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<tr>
<td>the intended interventions?</td>
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<tr>
<td><em>Bias due to missing data</em></td>
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<td></td>
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<tr>
<td>5.1 Are outcome data reasonably complete?</td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
</tr>
<tr>
<td>5.2 Was intervention status reasonably complete for those in whom it was</td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
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<tr>
<td>sought?</td>
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<td></td>
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<tr>
<td>5.3 Are data reasonably complete for other variables in the analysis?</td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
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<tr>
<td>5.4 If N or PN to 5.1, 5.2 or 5.3: Are the proportion of participants and</td>
<td>N/A/Y/P/Y/P/N/N/N</td>
<td>[Description]</td>
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<tr>
<td>reasons for missing data similar across interventions?</td>
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<td></td>
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<tr>
<td><strong>Risk of bias judgement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to missing data?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bias in measurement of outcomes</em></td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
</tr>
<tr>
<td>6.1 Was the outcome measure objective?</td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
</tr>
<tr>
<td>6.2 Were outcome assessors unaware of the intervention received by study</td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
</tr>
<tr>
<td>participants?</td>
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<td></td>
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<tr>
<td>6.3 Were the methods of outcome assessment comparable across intervention</td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
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<tr>
<td>groups?</td>
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<tr>
<td>6.4 Were any systematic errors in measurement of the outcome unrelated to</td>
<td>Y/P/Y/P/N/N/N/N</td>
<td>[Description]</td>
</tr>
<tr>
<td>intervention received?</td>
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<tr>
<td><strong>Risk of bias judgement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to measurement of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>outcomes?</td>
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<td></td>
</tr>
<tr>
<td><em>Bias in selection of outcomes</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the reported effect estimate unlikely to be selected, on the basis of the</td>
<td></td>
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<tr>
<td>results, from...</td>
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<td></td>
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<tr>
<td>the reported result</td>
<td>7.1 ... multiple outcome measurements within the outcome domain?</td>
<td>Y / PY / PN / N / NI</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td></td>
<td>7.2 ... multiple analyses of the intervention-outcome relationship?</td>
<td>Y / PY / PN / N / NI</td>
</tr>
<tr>
<td></td>
<td>7.3 ... different subgroups?</td>
<td>Y / PY / PN / N / NI</td>
</tr>
<tr>
<td>Risk of bias judgement</td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to selection of the reported result?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
</tr>
<tr>
<td>Overall bias</td>
<td>Risk of bias judgement</td>
<td>Low / Moderate / Serious / Critical / NI</td>
</tr>
<tr>
<td>Optional: What is the overall predicted direction of bias for this outcome?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
</tr>
</tbody>
</table>
### 7.8 Risk of bias assessment (case-control studies)

<table>
<thead>
<tr>
<th>Bias due to confounding</th>
<th>1.1 Is confounding of the effect of intervention unlikely in this study?</th>
<th>Y / PY / PN / N</th>
<th>[Description]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>If Y or PY to 1.1:</strong></td>
<td>the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td><strong>If N or PN to 1.1:</strong></td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>1.4. Did the authors use an appropriate analysis method that adjusted for all the critically important confounding domains?</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>1.5. <strong>If Y or PY to 1.4:</strong> Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>1.6. Did the authors avoid adjusting for post-intervention variables?</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias judgement</strong></td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to confounding?</td>
<td>Favours experimental / Favours comparator / Unpredictable</td>
<td>[Rationale]</td>
<td></td>
</tr>
<tr>
<td><strong>Bias in selection of participants into the study</strong></td>
<td>2.4 Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td><strong>Risk of bias judgement</strong></td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to selection of participants into the study?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
<td></td>
</tr>
<tr>
<td><strong>Bias in measurement of interventions</strong></td>
<td>3.1 Is intervention status well defined?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
</tr>
<tr>
<td>3.2 Was information on intervention status recorded at the time of intervention?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>3.3 Was information on intervention status unaffected by knowledge of the outcome or risk of the outcome?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias judgement</strong></td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Bias due to departures from intended interventions</td>
<td>Optional: What is the predicted direction of bias due to measurement of outcomes or interventions?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>4.1. Were the critical co-interventions balanced across intervention groups?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>4.2. Were numbers of switches to other interventions low?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>4.3. Was implementation failure minor?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias judgement</strong></td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to departures from the intended interventions?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bias due to missing data</th>
<th>5.1 Was outcome status reasonably complete for those in whom it was sought?</th>
<th>Y / PY / PN / N / NI</th>
<th>[Description]</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2 Were data on intervention status reasonably complete?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>5.3 Are data reasonably complete for other variables in the analysis?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>5.4 If N or PN to 5.1, 5.2 or 5.3: Are the proportion of participants and reasons for missing data similar across cases and controls?</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>5.5 If N or PN to 5.1, 5.2 or 5.3: Were appropriate statistical methods used to account for missing data?</td>
<td>NA / Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias judgement</strong></td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to missing data?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bias in measurement of outcomes</th>
<th>6.1 Was the definition of case status (and control status, if applicable) based on objective criteria?</th>
<th>Y / PY / PN / N / NI</th>
<th>[Description]</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.2 Was the definition of case status (and control status, if applicable) applied without knowledge of the intervention received?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td><strong>Risk of bias judgement</strong></td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to definitions of case and control status?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Bias in selection of the reported result</td>
<td>Is the reported effect estimate unlikely to be selected, on the basis of the results, from...</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>7.1 ... multiple definitions of the intervention?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>7.2 ... multiple analyses of the intervention-outcome relationship?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>7.3 ... different subgroups?</td>
<td>Y / PY / PN / N / NI</td>
<td>[Description]</td>
<td></td>
</tr>
<tr>
<td>Risk of bias judgement</td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the predicted direction of bias due to selection of the reported result?</td>
<td>Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</td>
<td>[Rationale]</td>
<td></td>
</tr>
<tr>
<td>Overall bias</td>
<td>Risk of bias judgement</td>
<td>[Support for judgement]</td>
<td></td>
</tr>
<tr>
<td>Optional: What is the overall predicted direction of bias?</td>
<td>Low / Moderate / Serious / Critical / NI</td>
<td>[Rationale]</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 5. The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
<th>Review authors’ judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence generation</td>
<td>Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.</td>
<td>Was the allocation sequence adequately generated?</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.</td>
<td>Was allocation adequately concealed?</td>
</tr>
<tr>
<td>Blinding of participants, personnel and outcome assessors Assessments should be made for each main outcome (or class of outcomes)</td>
<td>Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.</td>
<td>Was knowledge of the allocated intervention adequately prevented during the study?</td>
</tr>
<tr>
<td>Incomplete outcome data Assessments should be made for each main outcome (or class of outcomes)</td>
<td>Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.</td>
<td>Were incomplete outcome data adequately addressed?</td>
</tr>
<tr>
<td>Selective outcome reporting</td>
<td>State how the possibility of selective outcome reporting was examined by the review authors, and what was found.</td>
<td>Are reports of the study free of suggestion of selective outcome reporting?</td>
</tr>
<tr>
<td>Other sources of bias</td>
<td>State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review’s protocol, responses should be provided for each question/entry.</td>
<td>Was the study apparently free of other problems that could put it at a high risk of bias?</td>
</tr>
</tbody>
</table>
## Appendix 6: Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013)

<table>
<thead>
<tr>
<th>Grouping and BCTs</th>
<th>Grouping and BCTs</th>
<th>Grouping and BCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Goals and planning</strong></td>
<td><strong>6. Comparison of behaviour</strong></td>
<td><strong>12. Antecedents</strong></td>
</tr>
<tr>
<td>1.1. Goal setting (behavior)</td>
<td>6.1. Demonstration of the behaviour</td>
<td>12.1. Restructuring the physical environment</td>
</tr>
<tr>
<td>1.2. Problem solving</td>
<td>6.2. Social comparison</td>
<td>12.2. Restructuring the social environment</td>
</tr>
<tr>
<td>1.3. Goal setting (outcome)</td>
<td>6.3. Information about others’ approval</td>
<td></td>
</tr>
<tr>
<td>1.4. Action planning</td>
<td>7. Associations</td>
<td>12.3. Avoidance/reducing exposure to cues for the behaviour</td>
</tr>
<tr>
<td>1.5. Review behavior goal(s)</td>
<td>7.1. Prompts/cues</td>
<td>12.4. Distraction</td>
</tr>
<tr>
<td>1.6. Discrepancy between current behavior and goal</td>
<td>7.2. Cue signalling reward</td>
<td>12.5. Adding objects to the environment</td>
</tr>
<tr>
<td>1.7. Review outcome goal(s)</td>
<td>7.3. Reduce prompts/cues</td>
<td>12.6. Body changes</td>
</tr>
<tr>
<td>1.8. Behavioral contract</td>
<td>7.4. Remove access to the reward</td>
<td></td>
</tr>
<tr>
<td>1.9. Commitment</td>
<td>7.5. Remove aversive stimulus</td>
<td></td>
</tr>
<tr>
<td><strong>2. Feedback and monitoring</strong></td>
<td>7.6. Satiation</td>
<td></td>
</tr>
<tr>
<td>2.1. Monitoring of behaviour by others without feedback</td>
<td>7.7. Exposure</td>
<td></td>
</tr>
<tr>
<td>2.2. Feedback on behaviour</td>
<td>7.8. Associative learning</td>
<td></td>
</tr>
<tr>
<td>2.3. Self-monitoring of behaviour</td>
<td>8. Repetition and substitution</td>
<td></td>
</tr>
<tr>
<td>2.4. Self-monitoring of outcome(s) of behaviour</td>
<td>8.1. Behavioural practice/rehearsal</td>
<td></td>
</tr>
<tr>
<td>2.5. Monitoring of outcome(s) of behaviour without feedback</td>
<td>8.2. Behaviour substitution</td>
<td></td>
</tr>
<tr>
<td>2.6. Biofeedback</td>
<td>8.3. Habit formation</td>
<td></td>
</tr>
<tr>
<td>2.7. Feedback on outcome(s) of behaviour</td>
<td>8.4. Habit reversal</td>
<td></td>
</tr>
<tr>
<td><strong>3. Social support</strong></td>
<td>8.5. Overcorrection</td>
<td></td>
</tr>
<tr>
<td>3.1. Social support (unspecified)</td>
<td>8.6. Generalisation of target behaviour</td>
<td></td>
</tr>
<tr>
<td>3.2. Social support practical)</td>
<td>8.7. Graded tasks</td>
<td></td>
</tr>
<tr>
<td><strong>9. Comparison of outcomes</strong></td>
<td><strong>10. Reward and threat</strong></td>
<td></td>
</tr>
<tr>
<td>9.1. Credible source</td>
<td>9.2. Pros and cons</td>
<td></td>
</tr>
<tr>
<td>9.3. Comparative imagining of future outcomes</td>
<td>9.4. Behaviour cost</td>
<td></td>
</tr>
<tr>
<td><strong>13. Identity</strong></td>
<td>13.1. Identification of self as role model</td>
<td></td>
</tr>
<tr>
<td><strong>14. Scheduled consequences</strong></td>
<td>13.2. Framing/reframing</td>
<td></td>
</tr>
<tr>
<td>14.1. Behaviour cost</td>
<td>13.3. Incompatible beliefs</td>
<td></td>
</tr>
<tr>
<td>14.3. Remove reward</td>
<td>13.5. Identity associated with changed behaviour</td>
<td></td>
</tr>
<tr>
<td>14.4. Reward approximation</td>
<td>14.7. Reward incompatible behaviour</td>
<td></td>
</tr>
<tr>
<td>14.5. Rewarding completion</td>
<td>14.8. Reward alternative behaviour</td>
<td></td>
</tr>
<tr>
<td>14.7. Reward incompatible behaviour</td>
<td>14.10. Remove punishment</td>
<td></td>
</tr>
</tbody>
</table>
| 3.3. Social support  
(emotional) | 10.1. Material incentive  
(behaviour) | 15. Self-belief |
|-----------------|-------------------------|----------------|
| **4. Shaping knowledge** | **10.2. Material reward  
(behaviour)** | **15.1. Verbal persuasion about capability** |
| **4.1. Instruction on how to perform the behaviour** | **10.3. Non-specific reward** | **15.2. Mental rehearsal of successful performance** |
| **4.2. Information about Antecedents** | **10.4. Social reward** | **15.3. Focus on past success** |
| **4.3. Re-attribution** | **10.5. Social incentive** | **15.4. Self-talk** |
| **4.4. Behavioural experiments** | **10.6. Non-specific incentive** | |
| **5. Natural consequences** | **10.7. Self-incentive** | |
| **5.1. Information about health consequences** | **10.8. Incentive (outcome)** | |
| **5.2. Salience of consequences** | **10.9. Self-reward** | |
| **5.3. Information about social and environmental consequences** | **10.10. Reward (outcome)** | |
| **5.4. Monitoring of emotional consequences** | **10.11. Future punishment** | |
| **5.5. Anticipated regret** | **11. Regulation** | |
| **5.6. Information about emotional consequences** | **11.1. Pharmacological support** | |
| | **11.2. Reduce negative emotions** | |
| | **11.3. Conserving mental resources** | |
| | **11.4. Paradoxical instructions** | |
| | **11. Covert learning** | |
| | **16.1. Imaginary punishment** | |
| | **16.2. Imaginary reward** | |
| | **16.3. Vicarious consequences** | |
Appendix 7. Participant Information Sheets

Appendix 7.1 Participant Information Sheet (Chapter Seven)

Preventing pressure ulcers in nursing homes: Barriers and facilitators to evidence-based practice.

Participant Information Sheet Version 2

You are invited to take part in a research interview (as part of a student project) to discuss the challenges of pressure ulcer prevention in nursing homes. This information will be used to inform a study which will be assessing how feasible pressure ulcer prevention is in practice. We would like to take this opportunity to explain why we would like you to take part and what this will involve. Please take a few minutes to read the following information and, if you wish, discuss it with your colleagues. If anything is unclear or you have any questions, please do not hesitate to contact us using the details provided at the end of this information sheet.

Who will conduct the research?
Jacqueline Lavallee, a PhD student is managing the project and will conduct the interview. This project is part of a wider programme of wound care work developed by the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester. It is funded by the National Institute for Health Research (NIHR) with matched funding from four community NHS Foundation Trusts (Central Manchester University Hospitals, Pennine Care, Salford Royal, and the University Hospital of South Manchester), who have partnered with CLAHRC Greater Manchester to deliver this work. The conduct of this project is being overseen by Professor Dame Nicky Cullum, Dr. Jo Dumville, and Dr. Trish Gray who will ensure the project is managed appropriately. The University of Manchester is sponsoring the study, therefore,
will provide monitoring and audit mechanisms as part of the sponsorship agreement.

**What is the purpose of this project?**
We would like to talk with you about your experience of pressure ulcers in nursing homes as we are trying to gain an understanding of the strategies that can be used to facilitate pressure ulcer prevention in nursing homes and what some of the challenges can be. We will not be making judgements about care, we simply want to understand the context of caring for residents who are at risk of developing a pressure ulcer (e.g., the elderly, people who don’t move easily). Understanding these issues will help us to develop pressure ulcer prevention strategies which can be used within nursing homes.

**Why have I been chosen?**
As you provide care for people who are at risk of developing pressure ulcers, we would really like to hear your views.

**What would I be asked to do if I took part?**
You are invited to participate in a research interview which will be arranged at a time that is convenient for you. The interview will be with a researcher and is anticipated to last for a maximum of 60 minutes. The researcher will ask you questions about your daily routines and the different things that help or hinder pressure ulcer prevention.

**What happens to the information I give during the interview?**
You will be asked to provide some demographic information (e.g., age, gender), but the information you provide will be anonymous and direct quotes from your interview will not be traceable to yourself or the nursing home. All information you provide will be confidential, however if you disclose
something which suggests you or someone else is at risk, then the researcher will have to inform the appropriate personnel but she will discuss this with you first.

**How is confidentiality maintained?**

Your name will not be included within any parts of the research and all personal information will be anonymised. The interview will be audio recorded, anonymised, and your responses will not be linked to your voice. You will not be identified in any written reports or publications, however anonymised quotations from your interview may be used. The data will be stored in a secure locker at the University of Manchester and/or in a password protected zip file on a University laptop.

**What happens if I do not want to take part or if I change my mind?**

If you choose to participate in the interview, you are free to withdraw before or during the interview without giving a reason, and your data will be destroyed.

**Will I be paid for participating in the research?**

The interview will be conducted at your place of work, therefore you will not incur travel expenses and you will not be paid for your participation.

**Will the outcomes of the research be published?**

The findings will be published on the CLAHRC Greater Manchester website, written in a PhD thesis, and may be written for publication in a peer-reviewed journal.

**Who has reviewed this study?**

This study has been reviewed and approved by The University of Manchester Research Ethics Committee (ref: 15409; 15446) and given a favourable opinion.
What if something goes wrong?
If you wish to make a complaint, please contact Jacqueline Lavallee in the first instance, using the contact details below. If you then wish to take this further please contact Professor Karina Lovell, Director of Research by email karina.lovell@manchester.ac.uk or telephone on 0161 306 7853. If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Governance and Integrity Team by either writing to ‘The Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL’, by emailing: Research.complaint@manchester.ac.uk, or by telephoning 0161 275 8093 or 275 2674.

What do I need to do now?
If you have any questions please contact Jacqueline Lavallee using the contact details below. If you are happy with the information provided and wish to proceed, please email Jacqueline by (date). If you do not wish to proceed, we would be grateful if you could still email Jacqueline to let us know.

Thank you for taking the time to read this information sheet and we look forward to hearing from you soon.

For further information, please contact Jacqueline Lavallee:
jacqueline.lavallee@postgrad.manchester.ac.uk
Appendix 7.2 Participant Information Sheet (Chapter Eight)

Developing a Pressure Ulcer Prevention Care Bundle for Nursing Homes

Participant Information Sheet Version 2

You are invited to take part in a workshop (as part of a student project) that will involve prioritising pressure ulcer prevention practices that are suitable for use in nursing homes. These practices will form a care bundle which is a set of 3-5 evidence-based practices. We would like to take this opportunity to explain why we would like you to be involved and what this will involve. Please take a few minutes to read the following information and, if you wish, discuss it with your colleagues. If anything is unclear or you have any questions, please do not hesitate to contact us using the details provided at the end of this information sheet.

Who will conduct the research?

Jacqueline Lavallee, PhD student is managing the project and will conduct the workshop. This project is part of a wider programme of wound care work developed by the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester. It is funded by the National Institute for Health Research (NIHR) with matched funding from four community NHS Foundation Trusts (Central Manchester University Hospitals, Pennine Care, Salford Royal, and the University Hospital of South Manchester), who have partnered with CLAHRC Greater Manchester to deliver this work. The conduct of this project is being overseen by Professor Dame Nicky Cullum, Dr. Jo Dumville, and Dr. Trish Gray who will ensure the project is managed appropriately. The University of Manchester is sponsoring the study, therefore, will provide monitoring and audit mechanisms as part of the sponsorship agreement.
What is the purpose of this project?
We would like you to develop a care bundle that can be easily used within nursing homes.

Why have I been chosen?
As you provide care for people who are at risk of developing pressure ulcers, we would really like you to be involved in developing the care bundle.

What would I be asked to do if I took part?
You are invited to participate in a workshop which should last for 90 minutes. Before the workshop you will be sent some information about pressure ulcer prevention practices and asked to identify the 5 you feel are the most appropriate for nursing homes. If a practice which you feel is really important but is not included within the list you will have the opportunity to add this. These will be collated and presented to you at the workshop. During this workshop you will have the opportunity to discuss the different pressure ulcer prevention practices with colleagues and come to a consensus opinion regarding the top 5 practices. If you choose to participate in the workshop you can withdraw in the time before or during the workshop without giving a reason. However, due to the nature of the workshop, it will not be possible to destroy your data but personal information will be destroyed.

What happens to the information I give during the workshop?
You will be asked to provide some demographic information (e.g., age, gender), but the information you provide will be anonymous and direct quotes from the workshop will not be traceable to yourself or the nursing home. All information you provide will be confidential, however if you disclose something which suggests you or someone else is at risk, then the researcher will have to inform the appropriate personnel but she will discuss this with you first.
How is confidentiality maintained?
Your name will not be included within any parts of the research and all personal information will be anonymised. Notes may be taken during the workshop but this will be anonymised. You will not be identified in any written reports or publications. The data will be stored in a secure locker at the University of Manchester and/or in a password protected zip file on a University laptop.

What happens if I do not want to take part or if I change my mind?
If you choose to participate in the workshop, you are free to withdraw before or during without giving a reason. If you withdraw during the workshop, all identifiable personal data will be destroyed. However, the voting data you provide during the workshop will not have any identifiable information on it, therefore, it would not be possible to withdraw this information.

Will I be paid for participating in the research?
No you will not be paid for your participation.

Will the outcomes of the research be published?
The findings will be published on the CLAHRC Greater Manchester website, written in a PhD thesis, and may be written for publication in a peer-reviewed journal.

Who has reviewed this study?
This study has been reviewed and approved by The University of Manchester Research Ethics Committee (ref: 15451) and given a favourable opinion.
What if something goes wrong?
If you wish to make a complaint, please contact Jacqueline Lavallee in the first instance, using the contact details below. If you then wish to take this further please contact Professor Karina Lovell, Director of Research by email karina.lovell@manchester.ac.uk or telephone on 0161 306 7853. If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Governance and Integrity Team by either writing to ‘The Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL’, by emailing: Research.complaints@manchester.ac.uk, or by telephoning 0161 275 8093 or 275 2674.

What do I need to do now?
If you have any questions please contact Jacqueline Lavallee using the contact details below. If you are happy with the information provided and wish to proceed, please email Jacqueline by (11.03.16). If you do not wish to proceed, we would be grateful if you could still email Jacqueline to let us know.

Thank you for taking the time to read this information sheet and we look forward to hearing from you soon.

For further information, please contact Jacqueline Lavallee:
jacqueline.lavallee@postgrad.manchester.ac.uk
Appendix 7.3 Participant Information Sheet (Chapter Nine)

Preventing Pressure Ulcers in Nursing Homes using a Care Bundle:
A feasibility study.

Participant Information Sheet Version 1

You are invited to take part in a research study (which is part of a PhD student project). The project aims to assess the feasibility of implementing a pressure ulcer prevention care bundle in nursing homes. We would like to take this opportunity to explain why we would like you to take part and what this will involve. Please take a few minutes to read the following information and, if you wish, discuss it with your colleagues. If anything is unclear or you have any questions, please do not hesitate to contact us using the details provided at the end of this information sheet.

Who will conduct the research?
Jacqueline Lavallee, a PhD student, is managing the project and will conduct all aspects of the research. This project is part of a wider programme of wound care work developed by the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester. It is funded by the National Institute for Health Research (NIHR) with matched funding from four community NHS Foundation Trusts (Central Manchester University Hospitals, Pennine Care, Salford Royal, and the University Hospital of South Manchester), who have partnered with NIHR CLAHRC Greater Manchester to deliver this work. The conduct of this project is being overseen by Professor Dame Nicky Cullum, Dr. Jo Dumville, and Dr. Trish Gray who will together ensure the project is managed appropriately. The University of Manchester is sponsoring the study, therefore, will provide monitoring and audit mechanisms as part of the sponsorship agreement.
What is the purpose of this project?
We would like to see whether a care bundle is something that care staff in nursing homes find useful and whether it is a helpful tool to aid pressure ulcer prevention. We will not be making judgements about the care being delivered; we simply want to assess whether the care bundle is feasible in practice and explore which aspects were helpful or not so helpful.

Why have I been chosen?
As you provide care for people who are at risk of developing pressure ulcers we would really like you to be involved in this project.

What would I be asked to do if I took part?
You are invited to take part in the implementation of the pressure ulcer prevention care bundle (a set of 3-5 evidence-based practices). Initially, this will involve a 3 month baseline data collection period where anonymous demographic information about your residents will be collected, anonymous information about current practices and the numbers and severity of pressure ulcers will be collected alongside data from two questionnaires. Following this, staff will receive some training from a Tissue Viability Nurse in pressure ulcer prevention and using the care bundle prior to implementation. Training will be conducted across one afternoon and you will be given the opportunity to explore any uncertainties you have. Implementation will involve conducting and documenting a maximum of 5 pressure ulcer prevention practices with residents who are at risk of developing pressure ulcers. Once the care bundle has been implemented for 3 months, you will be invited to participate in a research interview which will be arranged at a time that is convenient for you. The interview will be with a researcher and is anticipated to last for a maximum of 60 minutes. The researcher will ask you questions about how easy or difficult
the care bundle was to use, and whether it was a useful tool which could be used in practice.

**What happens to the information I give during the study?**
You will be asked to provide some demographic information (e.g., age, gender), but the information you provide will be anonymised. All documentation will be confidential and anonymous. Direct quotes from your interview will not be traceable to yourself or the nursing home. This data will be kept for 10 years, and some of the information you provide may be used to inform future studies.

**How is confidentiality maintained?**
All of the information you provide will be confidential, however if you disclose something which suggests you or someone else is at risk, then the researcher will have to inform the appropriate personnel but she will discuss this with you first. Your name will not be included within any parts of the research and all personal information will be anonymised using a unique identity code. The interview will be audio recorded, and as per demographic information, this will be anonymised and your responses will not be linked to your voice. You will not be identified in any written reports or publications. The data will be stored in a secure locker at the University of Manchester and/or on an encrypted University laptop/PC.

**What happens if I do not want to take part or if I change my mind?**
If you choose to participate in the study, you are free to withdraw before or during the study without giving a reason, and any identifiable data will be destroyed. All questionnaire data will be anonymous and interview data will be anonymised on the same day, and it will not be possible to withdraw your data after this point.
Will I be paid for participating in the research?
The study will be conducted at your place of work; therefore, you will not incur travel expenses and you will not be paid for your participation.

Will the outcomes of the research be published?
The findings will be published on the NIHR CLAHRC Greater Manchester website, written in a PhD thesis, and may be written for publication in a peer-reviewed journal.

Who has reviewed this study?
This study has been reviewed and approved by The University of Manchester Research Ethics Committee (ref 16284) and given a favourable opinion.

What if something goes wrong?
If you wish to make a complaint, please contact Jacqueline Lavallee in the first instance, using the contact details below. If you then wish to take this further please contact Professor Dame Nicky Cullum by email nicky.cullum@manchester.ac.uk or telephone on 0161 306 7610. If you wish to make a formal complaint or there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Governance and Integrity Team by either writing to ‘The Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL’, by emailing: research.complaints@manchester.ac.uk, or by telephoning 0161 275 8093 or 275 2674.
What do I need to do now?
If you have any questions please contact Jacqueline Lavallee using the contact details below. If you are happy with the information provided and wish to proceed, please email Jacqueline by (30.09.16).

Thank you for taking the time to read this information sheet and we look forward to hearing from you soon.

For further information, please contact Jacqueline Lavallee:
jacqueline.lavallee@postgrad.manchester.ac.uk
Appendix 8. Study consent forms

Appendix 8.1. Consent form (Chapter Seven)

Preventing Pressure Ulcers in Nursing Homes: Barriers and facilitators to evidence-based practice.

Consent Form Version 2

I confirm that I have read the information sheet ‘Preventing Pressure Ulcers in Nursing Homes: Barriers and facilitators to evidence-based practice’ version 2 dated 17.08.15 and I have been given the opportunity to ask questions, and they were satisfactorily answered.

I understand that my participation is voluntary and I am free to withdraw at any time during the interview without giving a reason.

If I withdraw, I understand that any identifiable data will be destroyed.

I understand that the interview will be audio recorded and notes may be taken, but once the recording has been transcribed it will be destroyed.

If I agree to take part, I understand that the verbal and written information I provide will be anonymous when reported. This includes the use of direct/verbatim quotes.

I understand that study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities, or from the NHS trusts, for monitoring and auditing purposes, and this may well include access to personal information.

I understand that the anonymised data I provide may be used by the research team in future research projects related to this work.

I agree to take part in the interview.

Name of participant........................................................................................................Date............................................
Signature........................................................................................................................................

Name of researcher ..........................................................Date.............................
Signature........................................................................................................................................

This project has been approved by the University of Manchester’s Research Ethics Committee [15409; 15446].
Appendix 8.2 Consent form (Chapter Eight)

**Developing a Pressure Ulcer Prevention Care Bundle for Nursing Homes**

**Consent Form Version 2**

I confirm that I have read the information sheet ‘Developing a Pressure Ulcer Prevention Care Bundle for Nursing Homes’ version 2 dated 28.08.15 and I have been given the opportunity to ask questions, and they were satisfactorily answered.

I understand that my participation is voluntary and I am free to withdraw at any time during the workshop without giving a reason, but once the workshop has ended it will not be possible to withdraw any personal identifiable data due to anonymisation.

If I withdraw, I understand that any identifiable data will be destroyed.

I understand that notes may be taken during the workshop but once the data have been recorded all notes will be destroyed.

If I agree to take part, I understand that the verbal and written information (including the use of verbatim quotes) I provide will be anonymous when reported.

I understand that study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities, or from the NHS trusts, for monitoring and auditing purposes, and this may well include access to personal information.

I understand that the anonymised data I provide may be used by the research team in future research projects related to this work.

I agree to take part in the workshop.

Name of participant....................................................Date........................Signature.......................................................................................

Name of researcher ....................................................Date........................Signature.............................................................................

This project has been approved by the University of Manchester’s Research Ethics Committee [15451].
Appendix 8.3 Consent form (Chapter Nine)

Preventing pressure ulcers in nursing homes using a care bundle:
A feasibility study.
Nursing Home Consent Form Version 1; 10.05.16

I confirm that I have read the information sheet ‘Preventing Pressure Ulcers in Nursing Homes using a care bundle: A feasibility study’ version 1 dated 10.05.16 and I have been given the opportunity to ask questions, and they were satisfactorily answered.

I understand that the nursing homes participation is voluntary and we are free to withdraw at any time during the intervention without giving a reason.

If, as a nursing home, we withdraw we understand that any identifiable data will be destroyed.

I understand that the verbal and written information I provide will be anonymous when reported. This includes the use of direct/verbatim quotes. I understand that study data and material may be looked at by individuals from the University of Manchester, for monitoring and auditing purposes, and this may well include access to personal information.

I understand that the anonymised data I provide may be used by the research team in future research projects related to this work.

I agree to the nursing home taking part in the study.

Name of participant .......................................................... Date ..........................
Signature ........................................................................................................

Name of researcher .......................................................... Date ..........................
Signature ........................................................................................................

This project has been approved by the University of Manchester’s Research Ethics Committee [16284].
Appendix 9. Demographic questionnaire

Preventing Pressure Ulcers in Nursing Homes using a Care Bundle:
A feasibility study.
Demographic questionnaire

To help us describe the participants involved in this study we would be really grateful if you could provide some information below regarding your professional experience and training. This information is anonymous.

1. I am

<table>
<thead>
<tr>
<th>Female</th>
<th>18-25 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>26-35 years</td>
</tr>
<tr>
<td></td>
<td>36-50 years</td>
</tr>
<tr>
<td></td>
<td>51 years or over</td>
</tr>
</tbody>
</table>

2. Which Borough do you work in (please tick appropriate box).

   □ Bury      □ Trafford      □ Oldham

3. Please tick the description that best matches your role (if other, please state).

   □ Healthcare assistant
   □ Qualified nurse
   □ Manager
   □ Other (please specify) ..........................................................

4. How long have you been caring for those at risk of developing a pressure ulcer?

<table>
<thead>
<tr>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months</td>
</tr>
</tbody>
</table>

5. How long have you been in your current role?

<table>
<thead>
<tr>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months</td>
</tr>
</tbody>
</table>

6. Please list any professional healthcare qualifications you have (e.g., NVQ) with the approximate date when you completed the course.

<table>
<thead>
<tr>
<th>Professional healthcare qualification</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. Do you hold an accredited wound care qualification?
   - Yes
   - No (go to Q8)

   Please provide details with approximate length of time since accreditation.

<table>
<thead>
<tr>
<th>Wound care qualification</th>
<th>Date of accreditation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Not including an accredited course listed above, have you attended a wound care training course in the past year?
   - Yes
   - No

   Please provide details (e.g., who provided the training, training content)

   

   Thank you for completing this questionnaire
## Appendix 10. Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Participants</th>
<th>Care bundle and implementation strategies</th>
<th>Outcomes</th>
<th>Study author reported findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al-Tawfiq et al. (2010)</td>
<td>Controlled before-after study.</td>
<td>Conducted in Saudi Arabia in an adult ICU.</td>
<td>Sample size, and inclusion and exclusion criteria unclear. Those involved in delivering the care bundle: multidisciplinary team (including infection control professional, critical care nurses, respiratory therapist,</td>
<td>Intervention: Ventilator-associated pneumonia (VAP) care bundle consisting of 5 elements (head of bed elevation; a daily ‘sedation vacation’; readiness to wean assessment; peptic ulcer disease prophylaxis; deep vein thrombosis prophylaxis). Comparator: usual care.</td>
<td>Primary outcome: (1) cases of VAP/1,000 ventilator days; Secondary outcome: (1) fidelity with the care bundle.</td>
<td>Cases of VAP/1,000 ventilator days reduced from 9.3 to 2.1. Fidelity with the care bundle improved from 20% to 82%.</td>
</tr>
</tbody>
</table>
| **Anderson et al. (2015)** | Controlled before-after study. | Conducted in USA on a level 1 trauma centre. | 327 adult patients.  
Inclusion criteria:  
Patients admitted from emergency department/ transferred from inpatient units to ICUs.  
Exclusion criteria:  
Patients less than | Intervention (n = 146):  
Universal pressure ulcer prevention bundle care bundle consisting of 5 elements (skin emollients, assessment of skin head to toe, floating heels off bed, early identification of sources of pressure, using pressure redistribution surfaces, repositioning). | Primary outcome:  
(1) incidence of unit-acquired pressure ulcers.  
Secondary outcome:  
(1) fidelity with the care bundle. | Unit-acquired pressure ulcer incidence rates reduced from 15.5% (28 patients [pressure ulcers were stage 2]) to 2.1% (3 patients [pressure ulcers were stage 1, 2, and 3]). |
| 18 years of age, presence of a pressure ulcer, previous study enrolment, ICU length of stay less than 24 hours. | Comparator (n = 181): standard care. Behaviour change techniques: Instruction on how to perform behaviour; feedback on outcome(s) of behaviour; problem solving; identification of self as role model. Study duration: 12 months. | In the pre-intervention phase, 7 patients developed multiple stage 2 pressure ulcers (2-5 per patient); whereas in the post-intervention phase, of the patients who developed pressure ulcers, it was one pressure ulcer. Fidelity with the practices included in the care bundle did not differ |
Anthony et al. (2011) Randomised trial, randomisation by block method (computer generated 50 subjects per group). Undertaken in USA. 210 adult patients. Those delivering the care bundle: Unclear. Inclusion criteria: Patients having laparotomy. Intervention (n = 106): Care bundle made up of 5 elements (omission of mechanical bowel preparation, use of preoperative and intraoperative warming designed to maintain body temperature). Primary outcomes: (1) surgical site infections (overall infection rate at 30 days after surgery); (2) time to identification. 45% of the patients in the intervention group developed a surgical site infection compared with 24% in the control group. Those receiving the intervention had a significantly lower overall infection rate.
| block generated by principle investigator), randomisation sequence concealed prior to assignment, allocation 1 to 1 between intervention and control arms. | elective transabdominal colorectal procedures (undergoing laparoscopic and open procedures, and diverting and bypassing procedures). Exclusion criteria: Patients undergoing emergency operations, transrectal procedures, normothermia, maintenance of increased concentration of inspired oxygen during and immediately after surgery, reduction of intravenous fluids during the operation, use of wounds edge protection). Also received anti-biotics prior to surgery. Comparator (n = 104): Received anti-biotics prior to surgery and current practices. | Secondary outcome: (1) fidelity with the care bundle. care bundle were at significantly more risk of developing a surgical site infection when compared with the control group ($P = 0.003$). The median time to identification of infection was 9 days and there were no significant differences between the 2 groups ($P = 0.71$). |
| Antworth et al. (2013) | Controlled before-after study. | Conducted in a level 1 trauma centre in USA. | 78 patients. | Inclusion criteria: candidemia >1 positive blood culture; adult and paediatric patients. | Exclusion criteria: | Intervention (n = 41): Comprehensive care bundle consisting of 5 elements (selection of appropriate antifungal therapy based on culture and susceptibility results, removal of intravascular catheters, repeat blood cultures at Primary outcome: (1) fidelity with the care bundle. | Secondary outcomes: (1) length of stay; (2) time to clearance of blood cultures; Fidelity with the care bundle was higher in the post intervention group (78%) compared with the pre intervention group (40.5%; \( P = 0.002 \). | Fidelity with the care bundle: 84% patients received all 5 elements, 99% received at least 4 elements. |
|----------------------|---------------------------------|-----------------------------------------------|-------------|---------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| procedures involving only small bowel or appendix. | Identification of self as role model; practical social support; monitoring of behaviours by others without feedback; instruction on how to perform behaviour. | Study duration: 35 months. | | | | | | | |
Patients who died during the study period.

Those delivering care bundle: infectious diseases physicians, pharmacists, physicians.

least every 48 hours until negative, appropriate duration of antifungal treatment, ophthalmologic examination to evaluate candida endophthalmitis).

Behaviour change techniques:
Instruction on how to perform behaviour.

Comparator (n = 37):
Usual care.

Study duration: 18 months.

(3) persistent blood cultures within 72 hours;
(4) recurrent candidemia within 4 weeks.

No differences in the secondary outcomes from pre intervention to post intervention were found:
Length of stay (21 days and 20 days respectively; $P = 0.918$).
Time to clearance of blood cultures (3 days for both groups; $P = 0.61$).
Persistent blood cultures > 72 hours
Inclusion criteria: ≤32 +6 weeks gestation admitted to neonatal unit.  
Exclusion criteria: None stated. | Intervention (n = 3680): Care bundle consists of 4 elements (promotion of early milk expression, ongoing support for expressing and breast feeding up to discharge, standardised enteral feeding practice, aseptic non-touch technique for | Primary outcomes: (1) monthly percentage of infants receiving exclusive maternal breast milk at discharge; (2) monthly percentage of infants receiving any maternal breast milk | Percentage of infants receiving exclusive maternal breast milk at discharge increased faster in the intervention group (P = 0.01).  
Recurrent candidemia within 4 weeks (5.4% and 4.9% respectively; P = 0.916). |
Those delivering the care bundle: Multidisciplinary team (including: midwives, lactation specialists, maternity support workers, neonatologists, neonatal nurses, neonatal support workers, nursery nurses, breastfeeding specialists, dieticians, speech and language milk preparation).


Implementation based on Plan-do-Study-Act framework proposed by Bevan et al. (2011)

Behaviour change techniques:
Instruction on how to perform behaviour; self-monitoring of behaviour.

Study duration: 4 years.

at discharge;
(3) monthly percentage of care days where any maternal breast milk was received.

Secondary outcome:
(1) fidelity with care bundle;
(2) completeness of discharge feeding data.

Infants receiving any maternal breast milk at discharge increased faster in the intervention group ($P = 0.001$).

The percentage of care days where infants received maternal breast milk significantly increased ($P = 0.03$).

Fidelity with the care bundle increased from
<p>| Berenholtz et al. (2011) | Controlled before-after study. | Conducted in USA in 112 ICUs across 72 hospitals. | Sample size and inclusion/exclusion criteria unclear. Those delivering care bundle: unclear. | Intervention (80 ICUs): Ventilator care bundle consisting of 5 elements (semi-recumbent positioning to decrease risk of VAP, stress ulcer prophylaxis to reduce deep | Primary outcome: (1) VAP cases per 1,000 ventilator days. Secondary outcome: (1) fidelity with the | Decrease in VAP cases per 1000 ventilator days from 5.5 cases (pre-intervention) to 0 cases (post-intervention; $P &lt;$ |</p>
<table>
<thead>
<tr>
<th>Comparator (81 ICUs): Usual care.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation based on model for organisational change (2013).</td>
</tr>
<tr>
<td>Behaviour change techniques: Instruction on how to perform behaviour; care bundle.</td>
</tr>
</tbody>
</table>

Fidelity with the care bundle elements increased from 32% (pre-intervention) to 84% (post-intervention; $P < 0.001$).
<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Setting</th>
<th>Patients</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Primary Outcome</th>
<th>Secondary Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boesch et al. (2012)</td>
<td>Controlled before-after study</td>
<td>Undertaken in USA in an 18 bed ventilator unit</td>
<td>843 paediatric patients</td>
<td>Intervention (n = unclear): Tracheostomy-related pressure ulcer prevention bundle made up of three elements (pressure risk and skin assessment, moisture-free device interface, pressure-free device interface).</td>
<td>Comparator (n = unclear): No details provided.</td>
<td>(1) tracheostomy-related pressure ulcers (new pressure ulcer developed after patient admitted/transferred to unit and in direct contact with tracheostomy).</td>
<td>The number of tracheostomy days also decreased from 12.5% to 0.2%.</td>
</tr>
<tr>
<td><strong>Chaboyer et al. (2016)</strong></td>
<td>Cluster-randomised trial. Random number generating software was used to randomise hospitals</td>
<td>Conducted in Australia in 8 tertiary referral hospitals with acute medical, surgical and rehabilitative services.</td>
<td>1598 adult patients.</td>
<td>Plan-Do-Study-Act cycles (1996). Behaviour change techniques: Instruction on how to perform behaviour. Study duration: 30 months.</td>
<td>1598 adult patients.</td>
<td>Intervention (n = 799): Pressure ulcer prevention care bundle consisting of three elements (keep moving, look after your skin, eat a healthy diet). Comparator (n = 799): Standard pressure ulcer</td>
<td>Primary outcome: (1) incidence of hospital-acquired pressure ulcers/1000 patient follow up days. Secondary outcomes: Hospital-acquired pressure ulcer incidence reduced from 20.1/1000 person-days (control group) to 9.6/1000 person-days (intervention) ($P &gt; 0.05$).</td>
</tr>
</tbody>
</table>
(clusters) within strata, with random 1:1 block allocation of hospitals to intervention or control group. Measured by limited mobility (i.e. requiring physical or mechanical assistance to reposition or ambulate); able to read English and provide informed consent. A screening log was kept to identify patients who did and who did not meet the inclusion criteria. Limited mobility rather than prevention care.

The care bundle was informed by the concept of patient participation in care (Sahlsten et al., 2008), pressure ulcer prevention clinical practice guidelines (Australian Wound Management Association, 2012), and five systematic reviews on pressure ulcer prevention (Chou et al., 2013; Niederhauser et al., 2012; Reddy et al., 2006; Soban et al., 2011; Sullivan & Schoelles, 2013). No theoretical basis for (1) severity of hospital-acquired pressure ulcers; (2) patient participation in pressure ulcer prevention. There was no significant difference between intervention and control groups in the severity of new pressure ulcers or in patient participation in pressure ulcer prevention. No adverse events or harms were reported.
than a pressure ulcer risk assessment score was used by recruiters to screen for eligibility.

Exclusion criteria:
Patients were excluded if they were: admitted to the hospital for >36 h prior to recruitment; admitted to day surgery, critical care, emergency, maternity,

implementation. Behaviour change techniques used included instruction on how to perform behaviour, prompts/cues, monitoring of behaviour by others without feedback.

Study duration:
11 months.
paediatrics, mental health or dialysis; previous trial participants; palliative, or receiving end of life care.

Those delivering the bundle: nurses, dieticians.

| Chipps et al. (2016) | Randomised trial. Upon extubation, randomisation occurred using a | Conducted in USA in a large academic medical centre (including ICUs and cardiac) | 69 adult patients. Inclusion criteria: Patients who were mechanically ventilated for at least 48 hours and | Intervention (n = 30): Oral care protocol consisting of 5 elements (tooth brushing; tongue scraping; flossing; mouth rinsing; lip care). | Primary outcomes: (1) R-THROAT score; (2) incidence of MRSA and MSSA. Secondary | R-THROAT scores decreased significantly in the intervention group demonstrating a large effect size (d = 0.79) and significant |
computer-generated table of random numbers.

were being considered for ventilator liberation (criteria PEEP < 8 and FiO2 < 50%) or had been recently extubated. In addition, subjects were required to have a minimum of three teeth and be able to provide informed consent, either directly or through a legally authorised representative.

Comparator (n = 39):
Usual care (Patients who can manage their secretions are provided with hospital-purchased dental products, and oral care is provided per hospital policy including tooth brushing, mouth rinsing, and lip balm. Nursing assistance is provided as needed. Patients who have difficulty managing their secretions post-extubation receive routine oral care by the nursing staff using a toothbrush attached to suction. In this setting, outcomes:
(1) symptom burden using the Edmonton Symptom Assessment System;
(2) patient satisfaction with the oral care products and oral hygiene program.

The incidence of MRSA and MSSA did not differ between the intervention and control groups ($P = 0.45$).

Patients receiving the intervention reported less drowsiness than

improvements when compared with the control group ($P = 0.04$).
Exclusion criteria:
- Allergy to products or components of the oral care protocol or a history of oral or facial surgery or trauma in the 3 months prior to enrolment.
- Bleeding disorders (identified as an INR > 3.5 or platelet count < 20,000), planned hospital discharge within 48 hours, routine documentation of oral hygiene does not include the type of product used).

Behaviour change techniques: instruction on how to perform the behaviour; demonstration of the behaviour.

Study duration: 36 months.

Those receiving usual care ($P < 0.05$), there were no differences in other aspects of symptom burden ($P > 0.05$).

Subjects in the intervention group reported higher staff attention to oral care ($P = 0.05$). Overall, patients in the intervention group rated their toothbrushes, toothpaste,
<p>| current diagnosis of mucositis, current chemotherapy or radiation therapy, and presence of tracheostomy; or when family or the attending physician was not in favour of continued medical treatment. | Those delivering the care bundle: clinical nurse specialists from the | mouthwash, and lip balm products higher than the usual care group. |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Participants</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Primary outcomes</th>
<th>Secondary outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conway-Morris et al. (2011)</td>
<td>Controlled before-after study.</td>
<td>Conducted in Scotland, UK in an 18-bed medical/surgical ICU.</td>
<td>1961 patients.</td>
<td>Inclusion criteria: patients admitted to ICU for 48 hours or more during study period.</td>
<td>Standard infection control precautions.</td>
<td>Primary outcomes: (1) VAP cases per 1,000 ventilator days; (2) anti-biotic use; (3) rates of MRSA.</td>
<td>Secondary outcomes: (1) duration of mechanical ventilation; (2) ICU length of stay; (3) ICU mortality; (4) fidelity with the care bundle.</td>
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<td></td>
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<td></td>
<td>Exclusion criteria: unclear.</td>
<td></td>
<td>VAP cases/1000 ventilator days reduced from 14 (pre-intervention) to 6 (post-intervention; $P &lt; 0.001$). This included a reduction in the rates of both clinical VAP rates from 15% to 9% ($P &lt; 0.001$) and microbiologically confirmed VAP rates from 9% to 4% ($P = 0.002$).</td>
<td></td>
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</tbody>
</table>
Implementation was based on Plan-Do-Study-Act cycles.

Behaviour change techniques:
- Goal setting (behaviour);
- action planning;
- self-monitoring of behaviour,
- monitoring of behaviours by others with feedback;
- feedback on outcomes of behaviour;
- practical social support;
- emotional social support.

Study duration: 4.5 years.

Antibiotic use did not change ($P = 0.2$).

MRSA incidence decreased from 10% (pre-intervention) to 3.6% (post-intervention; $P = 0.001$).

The duration of mechanical ventilation did not change ($P = 0.17$).

No differences were found in length of
Mortality rates reduced from 25% to 20% ($P = 0.03$).

Fidelity with all bundle elements was 70%. Fidelity with oral chlorhexidine and 30-degree head-up tilt were consistently $>95\%$, whereas the wake and wean element was achieved less

<p>| stay | ($P = 0.5$). | Mortality rates reduced from 25% to 20% ($P = 0.03$). | Fidelity with all bundle elements was 70%. Fidelity with oral chlorhexidine and 30-degree head-up tilt were consistently $&gt;95%$, whereas the wake and wean element was achieved less |</p>
<table>
<thead>
<tr>
<th>Duzkaya et al. (2016)</th>
<th>Controlled before-after study.</th>
<th>Conducted in Turkey in a paediatric ICU.</th>
<th>750 child patients.</th>
<th>Intervention (n = 390): Catheter-associated urinary tract infections (CAUTI) prevention bundle consisting of five elements (perform hand washing before and after contact with each patient’s catheter and drainage system, and use sterile gloves when inserting the catheter; for female patients, separate the labia minora and cleanse the vulval area with sterile water before catheterisation;</th>
<th>Primary outcome: (1) CAUTI/1000 catheter days. Secondary outcomes: (1) length of stay; (2) mean mechanical ventilation; (3) mean catheterisation time; (4) mean catheterisation time in patients with CAUTI.</th>
<th>CAUTI reduced significantly from 6.1/1000 catheter days to 1.8/1000 catheter days ($P = 0.001$). CAUTI rate was 6% at baseline compared with 1.5% post-intervention. Length of stay reduced from 14 days to 13 days following the introduction of the care bundle.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Inclusion criteria: Patients aged between 1 month and 18 years who stayed in the paediatric ICU for over 48 hours and had no symptoms of urinary infection during this time.</td>
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<td>Exclusion criteria: Patients staying less than 48 hours, patients with</td>
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<tr>
<td>positive urine culture before admission or within 48 hours of stay on paediatric ICU.</td>
<td>Those delivering the care bundle: 13 nurses.</td>
<td>for male patients, clean the urethral meatus with sterile water and ensure the foreskin is retracted if present; use a new silicone catheter per insertion with a closed sterile drainage system using a sterile technique; evaluate daily catheter requirement). Comparator (n = 360): Usual care. Behaviour change techniques employed included instruction on how to perform the</td>
<td>There were no differences in the mean mechanical ventilation. The mean catheterisation time reduced from 10 days to 8 days, and the mean catheterisation time in patients with CAUTI reduced from 20 days to 17 days.</td>
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<td>Inclusion criteria:</td>
<td>not stated.</td>
<td>Inclusion criteria:</td>
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<td>Exclusion criteria:</td>
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<tr>
<td>Those involved in</td>
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<td>Those involved in delivering the</td>
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<tr>
<td>delivering the care</td>
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<td>care bundle:</td>
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<tr>
<td>bundle:</td>
<td></td>
<td>multidisciplinary team (ICU nurses,</td>
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<td>Intervention (n = 800):</td>
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<td></td>
<td>Ventilator care bundle consisting</td>
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<td></td>
<td>of 4 elements</td>
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<td>(head of bed 30-45°; daily sedation</td>
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<td></td>
<td></td>
<td>vacation; peptic ulcer disease</td>
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<td>prophylaxis; deep vein thrombosis</td>
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<td>prophylaxis). An additional care</td>
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<td>element not stated as part of the</td>
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<td></td>
<td></td>
<td>care bundle was regular oral care</td>
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<td></td>
<td></td>
<td>with chlorhexidine (every 8 hours).</td>
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<td></td>
<td></td>
<td>Fidelity with the care bundle.</td>
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<td></td>
<td></td>
<td>Secondary outcomes:</td>
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<td></td>
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<td>(1) mortality; (2) length of stay.</td>
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<tr>
<td>Study duration:</td>
<td>24 months.</td>
<td>VAP rate was reduced by 65.4%</td>
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<td>(from 16.2 to 5.6 patient/1000</td>
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<td></td>
<td>ventilator day).</td>
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<td></td>
<td>Fidelity with the care bundle reached</td>
<td>100%</td>
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<td></td>
<td>Mortality rates reduced from 23.4%</td>
<td>to 19.1% (P = 0.024).</td>
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</tbody>
</table>
Eom et al. | Controlled | Undertaken in | Sample size, and | Intervention: | Primary outcome: | Incidences of VAP |
--- | --- | --- | --- | --- | --- | --- |
respiratory therapist, clinical pharmacist, infection control coordinator, quality management department | Comparator (n = 192): Usual care. Implementation based on the Theory of Planned behaviour as described by O'Keefe-McCarthy et al. (2008). Behaviour change techniques: monitoring of behaviours by others with feedback; self-monitoring of behaviour; instruction on how to perform behaviour. Study duration: unclear. | Length of stay reduced from 11 days to 9 days ($P < 0.001$). |
<p>| (2014) before-after study in Korea in adult ICUs in 6 hospitals. | inclusion and exclusion criteria were not stated. Those delivering the care bundle (N = 324): Doctors (n = 23), nurses (318). | Ventilator-associated pneumonia care bundle consisting of 4 elements (head of bed elevation check 4-hourly; peptic ulcer disease prophylaxis daily; deep vein thrombosis daily; oral decontamination with chlorhexidine 0.12% 8-hourly) with an optional fifth element (continuous aspiration of subglottic secretions). | Comparator: Usual care. Behaviour change reduced from 4.1 (57 cases) to 1.16 (7 cases). Overall fidelity with the care bundle increased from 41.1% to 71.8%. Fidelity with each element increased, except for peptic ulcer disease prophylaxis which decreased by 2%. | (1) (VAP/1000 ventilator days. Secondary outcome: (1) fidelity with the care bundle. |</p>
<table>
<thead>
<tr>
<th>Study: Hakko et al. (2015)</th>
<th>Controlled before-after study.</th>
<th>Conducted in Turkey in a medical/surgical ICU.</th>
<th>Total sample size is unclear.</th>
<th>Intervention (n = 725): Central line care bundle consisting of 4 elements (removal of all lines placed in the emergency room/in another hospital within 24 hours; use of aseptic</th>
<th>Primary outcome: (1) Central line-associated bloodstream infection (CLABSI) rates/1,000 catheter days.</th>
<th>CLABSI/1,000 catheter days reduced from 22.9 to 0 following the introduction of the care bundle.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Techniques:</strong> Instruction on how to perform behaviour; self-monitoring of behaviour; monitoring of behaviours by others with feedback; practical social support; identification of self as role model.</td>
<td>Study duration: 12 months.</td>
<td><strong>Inclusion criteria:</strong> Patients admitted to ICU requiring central venous</td>
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<td>catheter.</td>
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<tr>
<td>Exclusion criteria: unclear.</td>
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<tr>
<td>Those involved in delivering the care bundle: head physician of the ICU, infectious disease physician, nurse manager of the unit, infection control nurse, physicians, nurses, technicians.</td>
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<tr>
<td>technique, hand hygiene, and maximum barrier precautions; use of a dedicated lumen for total parenteral nutrition; total parenteral nutrition infusion sets changed in 24 hours). Had an addition 5 infection control precautions which were not part of the care bundle but were also implemented.</td>
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<tr>
<td>Comparator (n = unclear).</td>
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<tr>
<td>Behaviour change techniques: Instruction on how to</td>
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<tr>
<td>Fidelity with the care bundle was maintained at 100% in the post-intervention phase.</td>
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<tr>
<td>Secondary outcome: (1) Fidelity with the care bundle. There was a strong negative correlation between fidelity with the care bundle and CLABSI rates ($P &lt; 0.001$).</td>
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</table>
perform behaviour; self-monitoring of behaviour; monitoring of behaviours by others with feedback; feedback on outcomes of behaviour; prompts/cues; practical social support.

Study duration: 4 years.

Undertaken in New Zealand in a critical care complex which includes an ICU and high-dependency beds.
Sample size, patient characteristics, those delivering the care bundle, inclusion and exclusion criteria are unclear.

Intervention:
Depending on their clinical status patients received: Institute for Healthcare Improvement central line insertion care bundle with 5 elements (hand hygiene and use of chlorhexidine 2% and alcohol to cleanse the skin.

Primary outcomes:
(1) number of central line days; (2) monthly number of central line associated bacteraemia per 1000 central line days; (3) fidelity with the

The number of central line days did not significantly differ following the introduction of the bundles (P = 0.14); but there were significant differences between
prior to inserting central line, using subclavian vein as preferred site, full barrier precautions [hat, mask, sterile gown, gloves], full body drape, sterile technique whilst inserting central line and applying the dressing).

**Maintenance care bundle** consisting of 3 elements (infusing intravenous nutrition via a dedicated lumen, daily checking of the central line site for inflammation, cleaning of all ports with 2% chlorhexidine and 70% care bundle (all-or-none).

Reduction in the line days for the pre and each of the post bundle periods. There were fewer line days in the post insertion bundle period ($P = 0.01$) and high risk bundle period ($P = 0.18$), but there was an increase in the number of central line days in the maintenance bundle period ($P = 0.02$).
alcohol prior to accessing the central line).

A high risk care bundle consisting of 2 elements (chlorhexidine impregnated dressings and/or antibiotic impregnated central lines) was given to those with: burns, neutropenia, prescribed immune-suppressants or central lines that had been rewired or inserted in other hospitals or during emergencies).

Comparator: usual care.

Fidelity with the care bundle increased with the elements of the insertion bundles from 36% to 81%, as well as the maintenance bundle from 76% to 80%.

mean central line associated bacteraemia per 1000 line days from 6.43 to 1.83 cases ($P < 0.001$).

Fidelity with the care bundle increased with the elements of the insertion bundles from 36% to 81%, as well as the maintenance bundle from 76% to 80%.
| Huddart et al. (2014) | Controlled before-after study. | Undertaken in England, UK (4 UK hospitals). | 726 adult patients. Those delivering the care bundle: Unclear | Intervention (n = 427): Received emergency laparotomy pathway quality improvement care bundle with 5 elements (initial assessment with | Primary outcomes: (1) number of lives saved; (2) 30 day mortality rate; (3) hospital | The number of lives saved per 100 patients increased in the post-intervention group (12.44%) compared |

Behaviour change techniques:
Instruction on how to perform behaviour; monitoring of behaviours by others with feedback; feedback on outcomes of behaviour; practical social support; identification of self as role model.

Study duration: 3.5 years.
<table>
<thead>
<tr>
<th>Inclusion criteria:</th>
<th>early warning scores, early antibiotics, interval between decision and operation less than 6 h, goal-directed fluid therapy, and postoperative intensive care.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparator (n = 299):</td>
<td>Comparator (n = 299): Usual care.</td>
</tr>
<tr>
<td>Behaviour change techniques:</td>
<td>Behaviour change techniques: None reported.</td>
</tr>
</tbody>
</table>

Overall risk of death decreased from 15.6% to 9.6% (P = 0.002).

The risk of 30-day mortality reduced from 14% in the pre-intervention group to 10.5% in the post-intervention group (P = 0.152). When mortality rates were adjusted for the with the pre-intervention group (6.47%; P < .001).
| procedure via an abdominal incision (laparoscopically assisted open surgery or vice versa), patients requiring simultaneous general surgical thoracotomy, all emergency laparotomies irrespective of the root cause; for some patients this will be the first presentation of the abdominal | Study duration: 8 months. | person’s risk of morbidity and mortality, this decrease became statically significant ($P = 0.003$). Hospital mortality decreased from 17.4% to 10.1% ($P < 0.001$). |
pathology, others may be experiencing complications of earlier elective or urgent surgery; expedited, urgent or emergency major abdominal laparoscopic surgery, but excluding appendectomy or cholecystectomy.

Exclusion criteria: Appendectomy of any type as the sole
surgical procedure; cholecystectomy of any type as the sole surgical procedure; gynaecological laparoscopy or laparotomy of any type unless the primary pathology is proven to be general surgical; pancreaticectomy of any type; surgery related to organ transplantation; surgery relating to sclerosing peritonitis;
emergency laparotomy for vascular surgery; laparotomy or laparoscopy following trauma or penetrating injuries to the abdomen (e.g., blunt injury, gunshot or stabbing).

Jennings et al. (2014)
Single-centre randomised trial; randomised using a computer
Undertaken in USA.
172 adult patients. Those delivering the care bundle: Unclear.
Intervention (n = 93):
Received care bundle with 5 elements (tobacco and smoke exposure, gastroesophageal reflux disease, anxiety/depression
Primary outcomes:
(1) readmission to hospital (within 30 days of discharge);
(2) emergency department visits for Readmission rates to hospital were lower in the intervention group (19.4%) compared to the control group.
<p>| generated list to allocate a 1:1 ratio stratified by age and sex. | Inclusion criteria: Diagnosis of chronic obstructive pulmonary disease (COPD) with presence of acute exacerbation. &gt; 40 years old. Current / ex-smoker of at least 20 pack-years. | Exclusion criteria: Medical history of asthma, interstitial lung disease, bronchiectasis, presence of airway screening, COPD education, communication within 48 hours of being discharged. Also received additional care (systemic steroids, antibiotics, inhaler therapy at the teams discretion). Comparator (n = 79): Standard care. Behaviour change techniques: None reported. Study duration: 3 years acute exacerbations of COPD in the 30 days following discharge. Secondary outcome: (1) Time to readmission. (22.8%), but there was not a significant difference ($P &gt; 0.05$). The risk of emergency department visits did not significantly differ between the 2 groups ($P &gt; 0.05$). Time to readmission was similar between groups ($P &gt; 0.05$). Note: This study was stopped earlier than anticipated due to... |
| hardware, lung cancer, any other cancer expected to impact life expectancy, &lt; 1 year active chemotherapy / radiation, active substance abuse, neuromuscular disorders affecting respiratory system, language barriers, living in nursing home, ICU stay during admission, significant delirium / | lack of effect. |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Participants</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Jeong et al. (2013) | Controlled before-after study | Undertaken in South Korea in ICU department of a university-affiliated hospital | 541 patients (388 adult, 153 children) | Intervention (309 adults, 139 children): Central line bundle consisting of 5 elements (hand hygiene; maximal use of barrier precautions during insertion; chlorhexidine skin antisepsis; daily review of CVC necessity and prompt removal of unnecessary lines; optimised catheter site selection that avoids femoral veins in adults). | Comparator (79 adults, 114 children): | Primary outcomes: (1) CLABSI incidence rates (number of central line infections/1,000 central venous catheter days); (2) length of time until CLABSI occurrence. Secondary outcome: (1) fidelity with the care bundle. | CLABSI reduced from 4.7 cases/1,000 central venous catheter days to 1.8 cases ($P = 0.076$) in the adult population. CLABSI rates reduced in the paediatric population from 3.7 cases to 0 cases ($P = 0.014$). The mean length of time until central line-associated bloodstream
Behaviour change techniques:  
Instruction on how to perform behaviour;  
demonstration of the behaviour.  
Study duration: 33 months. | infection occurrence increased from 11.3 days (pre-intervention) to 13.4 days (post-intervention; \( P = .477 \)).  
Fidelity with the care bundle in adult populations increased from 0% to 37.1% (\( P < .001 \)). Increases in fidelity with maximum barrier precautions increased from |
| 31.0% to 83.7% (P < .001), and chlorhexidine skin antisepsis from 0.0% to 40.0% (P < .001) were observed. No differences in fidelity with hand hygiene were observed (P = 0.317; and a decrease in fidelity with the use of alcohol and povidone-iodine from 100% to 43.2% (P < .001), and the selection of the |
femoral vein as the insertion site from 6% to 2.7%, \( (P = 0.118) \).

Fidelity with the care bundle in the paediatric population increased from 0.8% to 20.1% \( (P < 0.001) \).

Fidelity with the hand hygiene element did not increase \( (P > 0.05) \).

Fidelity with maximum barrier precautions
increased from 79.0% to 89.9% (P < 0.01).

Chlorhexidine skin antisepsis increased from 0.8% to 21.1% (P < .001), as did the selection of the femoral vein as the insertion site increased after the intervention from 4.8% to 11.2% (P > 0.05). The use of povidone-iodine alone or a mixture of alcohol and povidone-iodine
| Lawrence & Fulbrook (2012) | Controlled before-after study. | Undertaken in Brisbane in two ICU departments in two metropolitan hospitals. | 315 adult patients. Inclusion criteria: Ventilated patients on ICU. Exclusion criteria: Unclear. Those delivering the bundle: intensive care nurses. | Intervention (n = 151): Ventilator care bundle consisting of 4 elements (sedation hold, head of bed elevation, gastric ulcer prophylaxis, deep vein thrombosis prophylaxis) with feedback about ventilator care bundle levels of fidelity. Comparator (n = 164): The above care bundle without feedback. Behaviour change techniques: | Primary outcomes: (1) fidelity with the care bundle (all-or-nothing and overall). Fidelity with the care bundle increased in the experimental group, but this increase was non-significant ($P > 0.05$). | was 77%. |
Levy et al. (2014) Controlled before-after study. Conducted in hospitals in USA, Europe, and South America. 29,470 patients. Inclusion criteria: Patients with a suspected site of infection; two or Intervention (n = 20,086): Depending on clinical status a patient would receive one of the following care bundles: Surviving Sepsis Campaign Primary outcomes: (1) mortality rates; (2) sepsis severity score. Secondary outcome: Management care bundle: Mortality rates were lower in the high adherence group (32.3%) compared to the low adherence group.

Instruction on how to perform behaviour; monitoring of behaviour by others without feedback; prompts/cues; practical social support; goal setting (outcome); adding objects to the environment; restructuring the environment.

Study duration: 1 year.
| more systemic inflammatory response syndrome criteria; one or more organ dysfunction criteria. | sepsis management care bundle consisting of 4 elements (low-dose steroids administered for septic shock, drotrecogin alfa (activated) administered, glucose control maintained > lower limit of normal, but < 150 mg/dl (8.3 mmol/L), inspiratory plateau pressures maintained < 30 cm H2O for mechanically ventilated patients). | (1) fidelity with the care bundle. | with the low adherence group (33.8%; \(P < .05\)). |
| Exclusion criteria: None stated. | Surviving Sepsis Campaign sepsis resuscitation care bundle consisting of 5 elements (serum lactate) | High levels of fidelity were found at 47.2% of sites. Sites which participated for at least 2 years had higher levels of fidelity (\(P = 0.01\)). | Resuscitation care bundle: Rates of mortality were reduced in the high adherence group. |
measured, blood cultures obtained prior to antibiotic administration, broad-spectrum antibiotics administered within 3 hours for emergency department admissions and 1 hour for non-emergency department ICU admissions, in the event of hypotension and/or lactate $> 4$ mmol/L (36 mg/dl): a) Deliver an initial minimum of 20 ml/kg of crystalloid (or colloid equivalent); b) Apply vasopressors for hypotension not responding to initial fluid resuscitation

<table>
<thead>
<tr>
<th>Group when compared with the low adherence group (29% and 38.6%, respectively; $P &lt; .001$).</th>
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<tbody>
<tr>
<td>Median severe sepsis scores were lower in the high adherence group (51) compared with the low adherence group (58; $P &lt; .001$).</td>
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<tr>
<td>High levels of fidelity were found</td>
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</table>
to maintain mean arterial pressure (MAP) > 65 mm Hg, in the event of persistent hypotension despite fluid resuscitation (septic shock) and/or lactate > 4 mmol/L (36 mg/dl):

- a) Achieve central venous pressure (CVP) of > 8 mm Hg;
- b) Achieve central venous oxygen saturation (ScvO2) of > 70%.

Comparison (n = 6,609):
Low adherence group (fidelity levels of < 15%).

at 46.8% of sites. Sites which participated for at least 2 years had higher levels of fidelity ($P < 0.001$).
| Lim et al. (2015) | Controlled before-after study. | Conducted in UK hospitals. | 2,563 adult patients. Inclusion criteria: Aged over 16 years with symptoms suggestive of lower respiratory tract | Intervention (n = 196): Community-acquired care bundle consisting of four elements including (chest X-ray obtained within 4 h of hospital admission in all adults with suspected CAP; oxygen assessment and (3) adherence to BTS | Primary outcomes: (1) time to first chest x-ray <4h from admission; (2) time to first antibiotic dose <4h from admission; (3) adherence to BTS | Time to chest X-ray ≤4h and oxygenation assessment were not associated with bundle delivery. | Time to first |
infection, radiologically confirmed community-acquired pneumonia (CAP) and treatment for CAP by the admitting clinical team.

Exclusion criteria:
Adults previously discharged from hospital within 10 days of admission.
Those delivering prescription in keeping with BTS oxygen guideline; severity assessment, supported by the CURB-65 score; timely and targeted antibiotics given according to CAP severity within 4 h of admission)

Comparator (n = 1552):
Usual care.

Behaviour change techniques:
Unclear as implementation was reported to be at the discretion of each hospital.

CAP Guidelines-recommended antibiotic choice;
(4) adherence to BTS CAP Guidelines-recommended antibiotic route of administration;
(5) assessment of oxygenation status.

Secondary outcomes
(1) 30-day inpatient (30-day IP) mortality; (2) length of hospital stay.

Guideline adherence according to antibiotic route and type did not differ significantly between the bundle and no bundle groups. Antibiotic route: 44% and 37% adherence,

antibiotic ≤4 h was significantly better in the bundle group (adjusted OR 1.52, 95% CI 1.08 to 2.14, P = 0.016).
the care bundle: Unclear.

Study duration: 13 months.

respectively (OR 1.34, 95% CI 0.95 to 1.90, $P = 0.094$). Antibiotic type: 29% and 25% adherence, respectively (OR 1.25, 95% CI 0.86 to 1.82, $P = 0.247$).

30-day IP mortality was significantly lower in the bundle group (9%) compared with the no bundle group (14%) (OR 0.59, 95%
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Sample details</th>
<th>Intervention</th>
<th>Primary outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lindsay et al. (2013)</td>
<td>Controlled before-after study</td>
<td>Conducted in USA in internal and family medicine clinics.</td>
<td>N = 4,111 adult patients.</td>
<td>Hypertension in diseases care bundle consisting of 3 elements (standardised blood pressure process; order set of medications; a patient-identified behavioural goal).</td>
<td>(1) fidelity with the care bundle; (2) percentage of change in patients achieving a blood pressure less than 130/80.</td>
<td>Fidelity with the care bundle unclear. Overall, the number of patients with blood pressure &gt; 130/80 reduced from 36.1% (baseline) to CI 0.37 to 0.95, $P = 0.030$. Length of stay was longer in the bundle group (median days: 6) compared with the no bundle group (median days: 5).</td>
</tr>
<tr>
<td>Study: Loftus et al. (2012)</td>
<td>Study Design: Single blinded randomised trial</td>
<td>Setting: Undertaken in USA in a tertiary and Adult patients, sample size unclear (572 operating)</td>
<td>Intervention: Received care bundle with 2 elements (hibiscrub,</td>
<td>Primary outcome: (1) case-end bacterial contamination of ≥ 1</td>
<td>The incidence of bacterial contamination of</td>
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<tr>
<td>Exclusion criteria: Unclear.</td>
<td>Comparator (n = unknown): Usual care.</td>
<td>Study duration: 34 weeks.</td>
<td>Behaviour change techniques: Instruction on how to perform behaviour.</td>
<td>Secondary outcome: (1) stakeholder satisfaction with care processes.</td>
<td>Overall satisfaction levels did not change; but patients reported to have become more engaged with their care following the introduction of the care bundle ($P = 0.007$).</td>
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<tr>
<td>randomisation occurred via a computer generated list.</td>
<td>level 1 trauma centre.</td>
<td>rooms).</td>
<td>DOCit).</td>
<td>Comparator: Received sterile set of IV tubing and open lumen stopcock set, 24 inch with 3-gang 4-way stopcocks, and T-connector.</td>
<td>Behaviour change techniques: Instruction on how to perform behaviour; monitoring of behaviours by others with feedback; feedback on outcomes of behaviour; prompts/cues; demonstration of the internal lumens of the patient IV stopcock (primary stopcock lumen samples).</td>
<td>the primary stopcock was reduced when compared with standard caps (OR 0.79, 95% CI 0.63–0.98, P = 0.034).</td>
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<tr>
<td>Muszynski et al. (2013)</td>
<td>Controlled before-after study.</td>
<td>Undertaken in USA in paediatric ICU.</td>
<td>725 paediatric patients.</td>
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<td></td>
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<td>Inclusion criteria:</td>
<td>Patients admitted to ICU.</td>
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<tr>
<td></td>
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<td>Patients admitted to ICU, patients with tracheostomy and</td>
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<td>Intervention (n = 387):</td>
<td>Paediatric ventilator-associated pneumonia care bundle consisting of 5 elements (elevate head of bed at least 30 °; oral care with chlorhexidine rinse at least every 4 hours; extubate as soon as possible; suction oral secretions before the endotracheal tubes (ETT)</td>
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<td>Primary outcomes:</td>
<td>(1) cases of ventilator-associated tracheobronchitis/1,000 ventilator days;</td>
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<td>(2) cases of VAP.</td>
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<td>Secondary outcome:</td>
<td>(1) fidelity with the care bundle.</td>
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<td>Cases of ventilator-associated tracheobronchitis/1,000 ventilator days reduced from 3.9 to 1.8 (P = 0.04).</td>
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<td>There was one case of VAP in the pre-intervention phase and none in the post-intervention</td>
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<tr>
<td>chronic need for mechanical ventilation.</td>
<td>using separate catheter for oral secretions and use closed suctioning systems for ETT suctioning; perform hand hygiene between patient contacts).</td>
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<tr>
<td>Behaviour change techniques: Instruction on how to perform behaviour; feedback on outcomes of behaviour; prompts/cues.</td>
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<tr>
<td>Study duration: 33 months.</td>
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</table>

Fidelity with the care bundle was unclear.
| Pena-Lopez et al. (2016) | Controlled before-after. | Undertaken in Denmark in a 16-bed medical–surgical paediatric intensive care unit. | 312 children. | Interventions (n = 108): Ventilator care bundle consisting of 5 elements (Elevation of the patient’s head from the bed to at least 30°; a structured oral care protocol, including oral care with chlorhexidine solution 0.12% every 6 h and tooth brushing with a standard toothpaste every 12 hours; use of cuffed endotracheal tubes when not contraindicated; maintenance of tracheal tube/tracheostomy cuff pressure between 20 and 30 cmH2O; circuit changes | Primary outcomes: (1) ventilator-associated respiratory infection rate (VARI) including pneumonia/1000 ventilator days and ventilator-associated tracheobronchitis/1000 ventilator days; (2) median time to development of a VARI from onset of mechanical ventilation. | Overall, VARI reduced from 11.03/1000 ventilator days to 6.27/1000 ventilator days. VAP reduced from 4.14/1000 ventilator days to 1.05/1000 ventilator days and VAT reduced from 6.89/1000 ventilator days to 5.23/1000 ventilator days (P > 0.05). The median time to the development of VAT from the onset |
only if the circuit becomes soiled or damaged.

Comparator (n = 96):
Usual care.

Behaviour change techniques included shaping knowledge and feedback on outcomes of behaviour.

Study duration: 23 months

(1) Paediatric ICU mortality;
(2) ICU staff knowledge of evidence-based guidelines for the prevention of VAP.

Power et al. (2014) Cluster-randomised trial, stratified-randomisation approach;
Undertaken in England.
N = 6,592
Inclusion criteria (for participating sites):
Intervention (n = 3,533):
Early hours care bundle consisting of 4 elements (brain imaging, delivery of aspirin/alternative

Primary outcome:
(1) fidelity with the care bundles.

Fidelity with the early hours care bundle:
Increased in intervention from
<table>
<thead>
<tr>
<th>hospitals stratified by stroke performance. Computer-generated list used to randomly allocate 12 hospitals to intervention and 12 to control group. Not possible to blind patients due to nature of study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum of 10 inpatient stroke beds, agreement to participate by chief executive and consultant, dedicated MDT stroke team, availability of case notes for review. Exclusion criteria: None stated. Those delivering the care bundle: Unclear.</td>
</tr>
<tr>
<td>antiplatelet, swallow screen, weight assessment). Rehabilitation care bundle consisting of 5 elements (physiotherapy assessment, occupational therapy assessment, mood assessment, documented evidence of multidisciplinary team goals set for rehabilitation, 50% of patients’ hospital stay on stroke unit).</td>
</tr>
<tr>
<td>Comparator (n = 3,059): Normal care.</td>
</tr>
<tr>
<td>19.6% at baseline to 42.3%. Also increased in control group from 24.3% at baseline to 37.5%. Significant difference between control and intervention group ($P &lt; 0.05$). Largest relative difference in administering aspirin ($P &lt; 0.05$). Fidelity with the rehabilitation care bundle: increased in intervention from...</td>
</tr>
</tbody>
</table>
Implementation based on Model for Improvement.
Behaviour change techniques:
None reported.

Study duration: 12 months

27.3% at baseline to 46.2%. Increased in control group from 21.9% at baseline to 33.2%. Significant difference between control and intervention ($P < 0.05$). Use of mood assessment and rehabilitation goals significantly increased in intervention group when compared with control group ($P < 0.05; P < 0.001$, respectively).
Rinke et al. (2013)  | Controlled before-after study.  | Undertaken in USA in a children’s centre in a tertiary care hospital paediatric oncology group.  | 520 unique paediatric patients.  | Intervention (n = 339): Central line maintenance care bundle consisting of 3 elements (aseptic entry, aseptic central line component change, family assessment).  | Primary outcomes: (1) CLABSI per 1000 central line days; (2) bacteremia per 1000 central line days.  | Reduction central line-associated bloodstream infections (pre: 0.63/1000 central line days, post: 0.32/1000 central line days; \( P = 0.005 \)). Bacteremia infections also decreased (pre: 1.27/1000 central line days, post: 0.59/1000 central line days; \( P < .001 \)).


Those delivering the care bundle: clinic staff, homecare agency nurses, patient families.  | Behaviour change techniques: Instruction on how to perform behaviour; monitoring of behaviour by others without feedback.  |
Roquilly et al. (2013) | Controlled before-after study. | Undertaken in France at two ICUs in a university hospital. | 499 adult patients with a brain injury (traumatic brain injury, subarachnoid haemorrhage, stroke, or other). Those delivering care bundle: physicians, | Study duration: 4 years. | Fidelity: Aseptic entries (100%); aseptic central line component change (85%); family assessment (81%). |
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<td>Significant reduction in the mean duration of mechanical ventilation from 14.9 days in the pre-intervention group to 12.6 days in the post-intervention group ($P = 0.02$).</td>
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<td>Primary outcomes: (1) duration of mechanical ventilation; (2) fidelity with the care bundle.</td>
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<td>Secondary outcomes: (1) percentage of patients with</td>
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<td>Evidence-based weaning bundle consisting of 4 elements (lung protective ventilation, nutrition support, probabilistic antibiotic therapy, systematic approach to extubation).</td>
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<td>Comparator (n = 299): Usual care.</td>
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<tr>
<td>residents, physiotherapists, nurses.</td>
<td>Inclusion criteria: Those requiring mechanical ventilation for more than 24 hours.</td>
<td>Exclusion criteria: early decision to withdraw care (taken in the first 24 hours in ICU); death in the first 24 hours; or</td>
<td>Behaviour change techniques: None reported.</td>
<td>Study duration: 4 years.</td>
<td>hospital-acquired pneumonia; (2) ventilator-free days (at day 90); (3) ICU-free days (at day 90); (4) mortality.</td>
</tr>
</tbody>
</table>
inclusion in a randomised trial.

The mean number of ventilator-free days also significantly reduced from 54 to 64 days ($P = 0.01$).

The mean number of ICU-free days significantly decreased from 50 to 57 days ($P = 0.01$).

Mortality rates reduced in the experimental group but not
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Population</th>
<th>Intervention Details</th>
<th>Primary Outcome</th>
<th>Secondary Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salama et al. (2016)</td>
<td>Controlled before-after study.</td>
<td>Undertaken in an adult ICU in a teaching hospital in Kuwait.</td>
<td>7161 patient days. Inclusion criteria: All patients who were admitted to the ICU with a stay longer than 48 hours during the study period and those fulfilling criteria for healthcare-associated infection.</td>
<td>Intervention (n = unclear; 6474 patient days): Central venous line bundle consisting of 5 elements (hand hygiene by inserter; maximal barrier precautions upon insertion by the physician inserting the catheter and sterile drape from head to toe to the patient; use of a 2% chlorohexidine gluconate (CHG) in 70% ethanol scrub for the insertion site;</td>
<td>Primary outcome: (1) CLABSI rate/1000 catheter days; (2) central line days. Secondary outcome: (1) fidelity with care bundle.</td>
<td>CLABSI/1000 catheter days reduced from 14.9 at baseline to 11.08 during the intervention (P = 0.08). Central line days reduced from 5367 at baseline to 5052 during the intervention (P = 0.34).</td>
</tr>
</tbody>
</table>

Mortality at day 90 significantly: 0.51; mortality in ICU 0.22.
Exclusion criteria: None stated.
Those delivering the care bundle: unclear.
Comparator (n = unclear; 7161 patient days):
Usual care.
Behaviour change techniques:
Monitoring of behaviours by others without feedback; instruction on how to perform behaviour.
Study duration: 26 months.
Fidelity with the care bundle ranged from 51% to 91%.
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Care Bundle</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>et al. (2010)</td>
<td>before-after study</td>
<td>USA in a paediatric intensive care unit</td>
<td>Children admitted to PICO (0-3m)</td>
<td>None stated.</td>
<td>SKIN bundle consisting of 4 elements (support surface, keep turning every 2 hours, improve moisture management/incontinence management, nutrition consultation).</td>
<td>Usual care including pressure relieving surface.</td>
<td>(1) pressure ulcers. Secondary outcomes: (1) severity of pressure ulcers; (2) mortality; (3) barriers/facilitators to implementation.</td>
<td>Pressure ulcers reduced from 28 patients in the pre-intervention phase to 17 in the post-intervention phase ($P &lt; .001$). Pressure ulcer severity in intervention group: 17.4% stage 1, 60.9% stage 2, 4.3% stage 3, 17.4% not stages. Mortality rates did not differ between the 2 groups ($P =$</td>
</tr>
<tr>
<td>Schweizer et al. (2015)</td>
<td>Controlled before-after study.</td>
<td>Undertaken in 20 hospitals in USA.</td>
<td>42,534 operations on 38,049 adult patients.</td>
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<tr>
<td>Inclusion criteria: 18 years or older; patients who have undergone</td>
<td>Intervention (n = 14,316): Evidence-based bundle consisting of 3 elements (screening for S aureus, decolonising carriers, prescribing optimal perioperative anti-biotics).</td>
<td>Primary outcome: (1) complex (deep incisional/organ space) S aureus surgical site infections (SSIs).</td>
<td>Secondary</td>
<td>Care bundle was associated with a reduction in complex S aureus SSIs ($P &lt; 0.05$). This decrease was also observed in those</td>
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</table>
| Exclusion criteria: Patients with pre-existing infections at surgical site. Hospitals who already implement all three elements. Those delivering the bundle: unclear. | Comparator (n = 28,218): standard practice. Behaviour change techniques: Instruction on how to perform behaviour; self-monitoring of behaviour; feedback on outcomes of behaviour; prompts/cues; practical social support. Study duration: 48 months. | Outcomes: (1) all SSIs; (2) the patient’s postoperative length of stay during the index admission; (3) readmissions for treatment of SSIs within 90 days post-operation; (4) adverse events; (5) fidelity with the care bundle. | Who received scheduled operations, but not emergency/urgent operations. The number of complex *S. aureus* SSIs-free months increased (*P* = 0.006). The rates of all *S. aureus* SSIs (mean rate per 10,000 operations) did not decrease significantly (*P* >
The care bundle did not decrease the postoperative length of stay or readmission rates ($P > 0.05$).

Adverse events: 4 patients reported mild skin irritation.

When fidelity with the care bundle was 100%, complex *S. aureus* SSI rates decreased.
<p>| Silva Resende et al. (2011) | Controlled before-after study. | Conducted in Brazil in a neonatal ICU. | 251 neonatal patients. Inclusion criteria: all neonates admitted to neonatal ICU requiring central venous catheter. | Intervention (n = 107): Care bundle consisting of five elements (hand hygiene, using full-barrier precautions during the insertion of CVCs, cleaning the skin with chlorhexidine 0.2%, avoiding the femoral site if possible, removing unnecessary catheters). | Primary outcomes: (1) cases of catheter-associated bloodstream infection/1,000 central venous catheter days; (2) number of bloodstream infections. | Catheter-associated bloodstream infections reduced from 24.1/1,000 central venous catheter days to 14.9 (P &lt; 0.05). Blood stream infections decreased significantly (P &lt; 0.05), but the rates did not significantly decrease in the partially adherent/non-adherent groups (P &gt; 0.05). |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Participants</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Primary outcomes</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith et al. (2017)</td>
<td>Controlled before-after</td>
<td>Conducted in the USA</td>
<td>447 adult patients</td>
<td>Delirium prevention bundle</td>
<td>Usual care</td>
<td>(1) delirium status</td>
<td>The risk for delirium reduced by</td>
</tr>
<tr>
<td>Study</td>
<td>Inclusion criteria: Patients admitted to a 10-bed medical-surgical ICU who were delirium-negative.</td>
<td>Exclusion criteria: ICU patients who were delirium-positive on admission, resided in the ICU for 4 months or longer.</td>
<td>Those delivering care bundle: nurses.</td>
<td>Consisting of five elements (sedation cessation for patients receiving mechanical ventilation; pain management; sensory stimulation; early mobilisation; sleep promotion).</td>
<td>Using the CAM-ICU; (2) arousal using the RASS scale.</td>
<td>Comparator (n = unclear): Usual care.</td>
<td>Secondary outcome: (1) adherence with the bundle.</td>
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<td>Study duration: 244 days</td>
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<td>Study duration: 244 days</td>
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<tr>
<td>Stano et al. (2013)</td>
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<tr>
<td>Controlled before-after study.</td>
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<td>Conducted in Italy on one ICU.</td>
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<td>1,008 patients.</td>
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<tr>
<td>Inclusion criteria: unclear.</td>
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<tr>
<td>Exclusion criteria: unclear.</td>
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<td>Those delivering care bundle: unclear.</td>
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<td>Intervention (n = 577): MRSA antibiotic care bundle consisting of 4 elements (rapid screening on admission to ICU, contact precautions, single room or cohort isolation, and nasal decolonisation (mupirocin 2% ointment three times-a-day for five days).</td>
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<td>Comparator (n = 431): Usual care.</td>
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<td>Primary outcomes: (1) total MRSA infection rate per 1,000 admissions.</td>
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<td>20.8 patients per 1,000 admissions developed MRSA in the pre-intervention phase compared with 3.4 per 1,000 admissions in the post-intervention phase (P &lt; 0.001).</td>
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<td><strong>Steiner et al. (2015)</strong></td>
<td>Controlled before-after study.</td>
<td>Undertaken in Austria in a neonatal ICU.</td>
<td>526 very low birth weight neonatal patients.</td>
<td>Intervention (n = 358): Simulation-based prevention bundle consisting of 3 elements (a simulation-based standardisation and education of a peripherally inserted central catheter (PICC) insertion technique; improvement of breast milk hygiene management by standardised hand hygiene trainings for mothers;</td>
<td>Primary outcome: (1) CLABSI/1000 central line days reduced significantly from 13.9 at baseline to 9.5 during the following year and 4.7 in the year after ($P &lt; 0.001$). The reduction remained significant when subgroups were separated by birth</td>
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</table>
Stolbrink et al. (2014) | Controlled before-after study. | Undertaken in the UK in 1 respiratory and 1 elderly care medicine ward. | 1179 adult patients. Those delivering the care bundle: Unclear. Inclusion criteria: Patients admitted to the ward. | Intervention (n = 678): Received ‘Early mobility’ care bundle made up of 5 elements (enhance availability of walking aids, provision of occupational theory equipment to maximise independence, mobility charts, individual instructions and... | Primary outcome: (1) hospital-acquired pneumonia incidence. Secondary outcomes: (1) length of stay; (2) rate of falls. Early mobility care bundle was associated with hospital-acquired pneumonia incidence (P = 0.001) and a shorter length of stay (P = 0.009).
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Patients</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria: Patients admitted electively or whose primary reason was surgical.</th>
<th>Comparator (n = 501): Received usual physiotherapy care only.</th>
<th>Behaviour change techniques: Instruction on how to perform behaviour.</th>
<th>Study duration: 6 months.</th>
<th>There was no difference in the rate of falls between the pre- and post-intervention groups ($P &gt; .05$).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subramanian et al. (2013)</td>
<td>Controlled before-after study.</td>
<td>Conducted in Malaysia in an ICU</td>
<td>266 patients.</td>
<td>Inclusion criteria:</td>
<td>Intervention (n = 130): Ventilator care bundle consisting of 5 elements</td>
<td>Primary outcomes: (1) nurses’ knowledge;</td>
<td>Nurses’ knowledge of VAP and the care bundle increased</td>
<td></td>
<td></td>
</tr>
<tr>
<td>department.</td>
<td>all patients admitted to ICU during study period.</td>
<td>(elevation of head of bed to $30^\circ \sim 45^\circ$ (constant assessment unless medically contraindicated), daily sedation hold, peptic ulcer disease prophylaxis using pantoprazole or ranitidine, deep vein thrombosis prophylaxis via administration of subcutaneous heparin or enoxaparin and application of anti-embolism stockings, daily oral care with the help of a suction toothbrush and chlorhexidine gluconate 0.05%).</td>
<td>(2) fidelity with the care bundle. Secondary outcome: (1) VAP incidence per 1,000 ventilator days. Fidelity with the care bundle elements increased ($P &lt; 0.001$). VAP incidence reduced from 39.01 (22 cases pre-intervention) to 15.11 (7 cases post-intervention; $P &lt; 0.001$).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Comparator (n = 136):
Usual care.

Behaviour change techniques:
Instruction on how to perform behaviour; self-monitoring of behaviour; monitoring of behaviours by others with feedback; feedback on outcomes of behaviour; prompts/cues; practical social support; emotional social support; problem solving; action planning.

Study duration: 4 months.
Appendix 11. Summaries of the risk of bias for each risk of bias domain presented as percentages across all included studies

Figure 16. Risk of bias of included randomised trials (n = 6).

Figure 17. Risk of bias of included non-randomised studies (n = 31).
Appendix 12. Topic Guide (Chapter 7)

Introduction: The general aim of the interview is to help me understand the context of pressure ulcer prevention within nursing homes. I would like to know what influences you when you are preventing pressure ulcers. I will not be making any judgement about the practices conducted and there is no right or wrong answer. Some of my questions may seem repetitive but it is because I am trying to ensure that I understand, and some of the questions are related to different aspects of human behaviour change theories and I am trying to find out which theories are most suitable for this area of healthcare.
<table>
<thead>
<tr>
<th>Questions</th>
<th>Prompts for further exploration</th>
<th>Theoretical Domains Framework Domains</th>
</tr>
</thead>
<tbody>
<tr>
<td>What do you understand by the term pressure ulcer?</td>
<td></td>
<td>Knowledge</td>
</tr>
</tbody>
</table>
| How do you assess residents for pressure ulcer risk? | - Are all residents routinely assessed for pressure ulcers?  
- How do you decide which residents are at risk?  
- Is there a protocol to inform practice?  
- Do you refer to guidelines? Which ones?  
- What resources are available to help you decide e.g., risk assessment scales?  
- What might influence your decisions e.g., residents, staff, protocols, experience?  
- If you suspect a resident to be at risk of a developing a pressure ulcer, what preventative measures would you use?  
- Is pressure ulcer prevention something you consider as part of your daily routine?  
- Can you think of any situations where you worry about a resident developing a pressure ulcer?                                                                                                                                                                                                                                                                                                                                 | Knowledge  
Social/professional role and identity  
Behavioural regulation  
Memory, attention, and decision processes  
Emotion  
Optimism  
Reinforcement  
Intentions |
<table>
<thead>
<tr>
<th>Questions</th>
<th>Prompts for further exploration</th>
<th>Theoretical Domains</th>
</tr>
</thead>
</table>
| **How do you decide what preventative measures to take for at risk residents?** | -What action would you take first to prevent a pressure sore developing on a resident at risk?  
-Why and when would you implement this action/procedure?  
-Are there certain situations where it’s difficult/easy to think about an alternative approach?  
-How long would you continue to try to prevent the pressure ulcer?  
-What factors influence your decisions e.g., residents, staff, experience, protocols?  
-What kinds of processes might guide your decision to conduct a pressure ulcer prevention strategy e.g., protocols, risk?  
-Have you ever received any training or been provided with information about who is at risk of developing a pressure ulcer and how to prevent a pressure ulcer?  
-Are there practices that you are expected to do that you find easy? Why? Do you think they are effective?  
-Do you think there are practices that you do but your colleagues don’t? Why?  
-Are there practices you are expected to carry out but find difficult or impossible?  
-If a resident develops a pressure ulcer, how does that make you feel?  
-How confident are you in preventing a pressure ulcer?  
-What do you think the benefits are of preventing pressure ulcers? | Knowledge  
Social/professional role and identity  
Skills  
Behavioural regulation  
Beliefs about capabilities  
Beliefs about consequences  
Memory, attention, and decision processes  
Emotion  
Reinforcement  
Intentions |
### Questions

**How do you decide what measures to take once a pressure ulcer is identified?**

### Prompts for further exploration

- Are any of the following enablers or constraints: team support, staff availability, resource availability?
- What do you think would make pressure ulcer prevention more easy/difficult?
- Are there any benefits or potential harms associated with trying to prevent a pressure ulcer?
- What problems/difficulties do you usually encounter when trying to prevent a pressure ulcer?
- How do you overcome these difficulties?
- Are there any incentives to encourage pressure ulcer prevention e.g., funding for the home?
- Are there any competing tasks that might influence whether you conduct pressure ulcer prevention strategies?
- When time is limited due to work load pressures?
- If the resident has a visitor?
- If there is a more urgent matter to attend to?
- How high a priority would you say preventing a pressure ulcer is on a scale of 0 to 10 (0 = not a priority and 10 = a significant priority)?

### Theoretical Domains Framework Domains

- **Knowledge**
- **Memory, attention and decision processes**
- **Intentions**
- **Skills**
- **Beliefs about capabilities**
- **Environmental context and resources**
- **Beliefs about consequences**
- **Goals**
- **Optimism**
- **Reinforcement**
- **Intentions**
<table>
<thead>
<tr>
<th>Questions</th>
<th>Prompts for further exploration</th>
<th>Theoretical Domains</th>
</tr>
</thead>
</table>
| **Have other people or situations ever caused you to change your pressure ulcer prevention practices?** | - Has there been an incident, what happened?  
- Change in protocol?  
- How might the views of other team members affect your pressure ulcer prevention strategies?  
- Would other team members influence whether or not you conduct pressure ulcer prevention strategies?  
- Are there any processes in place to help you share pressure ulcer prevention practices?  
- If you wanted to change the strategies you use to prevent pressure ulcers, how would you/the home do this? Can you think of a recent example?  
- Who’s responsibility is it to prevent a pressure ulcer?  
- Has anyone ever asked you about the practices you use? Who? What was the reason? | **Social influences**  
**Behavioural regulation**  
**Social/professional role and identity**  
**Memory, attention, and decision processes**  
**Intentions**  
**Reinforcement** |
| **How do you know whether you are/the nursing home is making the right decisions regarding pressure ulcer prevention?** | - Do you have any influence over the practices conducted?  
- Who makes the overall decisions regarding pressure ulcer prevention practices?  
- Do you collect data on pressure ulcers, how?  
- When a resident develops a pressure ulcer, is there anything that as a team you think could have been done differently? Can you think of an example?  
What would you have done differently?  
- Do you ever meet as a team to discuss pressure ulcers? | **Behavioural regulation**  
**Optimism**  
**Intentions** |

That is all of my questions. Is there anything you think that I have missed or you would like to discuss? Thank you for taking the time for this interview.
**Appendix 13.** Voting for the steps to be included within in each of the care bundle elements

<table>
<thead>
<tr>
<th>Essential components of the element</th>
<th>Median</th>
<th>Interquartile range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin assessment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency should be specified</td>
<td>10</td>
<td>7-10</td>
</tr>
<tr>
<td>Check for changes in skin (e.g., reddening, blanching)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Changes to skin/resident’s condition will trigger re-assessment</td>
<td>7.5</td>
<td>4-10</td>
</tr>
<tr>
<td>All pressure areas checked?</td>
<td>10</td>
<td>8-10</td>
</tr>
<tr>
<td>Document redness/changes to skin</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Is the resident experiencing pain?</td>
<td>8</td>
<td>5-9</td>
</tr>
<tr>
<td><strong>Skin care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is skin clean and dry?</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Skin washed, cream applied</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Apply barrier cream</td>
<td>3</td>
<td>0-8</td>
</tr>
<tr>
<td>Specify topical creams applied</td>
<td>5</td>
<td>1-10</td>
</tr>
<tr>
<td>Frequency should be specified</td>
<td>4</td>
<td>1-10</td>
</tr>
<tr>
<td><strong>Repositioning</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surfaces checked?</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Frequency should be specified</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Specify repositioning (e.g., left side, right side, hoisted, other)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Equipment checked (including creases in sheets, equipment plugged in, all leads out of the way)</td>
<td>8</td>
<td>6-10</td>
</tr>
</tbody>
</table>
Appendix 14. Intervention manual

SSKIN
Pennine Care NHS Foundation Trust

Aims and Objectives

- To define what a pressure ulcer is
- What the causes of pressure damage are
- What are the risk factors.
- What to look for on skin inspection
- To identify what the early stages of pressure damage look like
- To identify which areas are of high risk
- Safeguarding Alerts
- Pressure relieving equipment
- Further education awareness including seating, repositioning, nutrition and family and carer education
• To eliminate all avoidable stage 2, 3 and 4 pressure damage

Avoidable pressure ulcers are a key indicator of the quality of nursing care. Preventing them happening will improve all care for vulnerable patients.

Pressure ulcer definition

“A pressure ulcer is a localised injury to the skin and/or underlying tissues usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of confounding factors are also associated with pressure ulcers; the significance of these is yet to be elucidated”

European Pressure Ulcer Advisory Panel 2009
What is the largest organ in the body?

What's its function?

- The skin is the largest organ in the body
- It protects and is a waterproof barrier
- It can protect from injury
- Helps to regulate body temperature
- The subcutaneous fat layer helps to insulate the body
Pressure

- Tissues are compressed between bone and hard surface (Sandwich effect).
- This causes the small blood vessels to collapse, causing the blood supply to the area to cease.
- Lack of oxygen causes tissue death (necrosis).

Every year in England 67,848 patients are reported as having a pressure ulcer (category III & IV) like these

70% of pressure ulcers are category IIIs

Shear

- Shear damage occurs when the skin is stopped from sliding over a surface while the underlying bone and tissue are forced to move, e.g., sitting up in bed or chair patient slides to a slouch whilst skin stuck to sheet.
- Use of Knee brake on profiling beds prevents slipping

Shear force generated—
for example, when a patient slides down a bed

Exacerbate

**FRICTION**
When the skin is moved over a surface with which it is in contact with causing the surface of skin to be removed

**MOISTURE**
Increases risk of tissue damage
- Keep skin clean and dry
- Avoid acet
- Use skin protectants/barrier
- Emollients
- Avoid plastic draw sheets
- Prolonged wetness
Group work

In your groups what risk factors would contribute to pressure damage?

Risk Factors

**Intrinsic Factors**
- Mobility problems – anything that affects your ability to move some or all of your body
- Poor nutrition – for your skin to remain healthy it requires nutrients that can only be supplied by eating a nutritious diet
- An underlying health condition, which disrupts your blood supply or makes your skin more vulnerable to injury and damage
- Being over 70 years old
- Urinary incontinence and/or bowel incontinence
- Serious mental health conditions

**Extrinsic Factor**
- Pressure from a hard surface, such as a bed or wheelchair
- Pressure that is placed on the skin through involuntary muscle movements, such as muscle spasms
- Moisture, which can break down the outer layer of the skin (epidermis)
How can YOU help?

What Can You Do?

Give a helping hand - 5 simple steps

S
Skin inspection: early detection means early treatment. Show patients & carers what to look for

K
Keep your patients moving

I
Incontinence / moisture: your patients need to be clean and dry

N
Nutrition / hydration: help patients have the right diet and plenty of fluids
S- surface

NICE Guidance on pressure relief
www.guidance.nice.org.uk/CG7

Why do we use equipment?

- Pressure relieving equipment can be a preventative
- To reduce the risk of patients sustaining pressure damage
- Comfort for existing damaged patients
- Ensure that valuable resources are targeted and used to best effect
S-Skin

Skin Inspection

early inspection means early detection. Show patients & carers what to look for
What to look for on inspection

- **Skin Inspection**
  - Early inspection means early detection.
  - Observe at least daily for changes in colour, temperature, texture.
  - Persistent redness (non-blanching)
  - Blisters
  - Discolouration – blue/purple
  - Hardness
  - Breaks in skin
  - Moisture/dryness
  - Check for indentations from:
    - Clothing, seams, elastic etc. creased bedclothes
    - Tubing
  - Report immediately Never ignore first sight

---

**Blanchable Erythema**

Reddened area that temporarily turns white or pale when pressure is applied with a fingertip. Blanchable erythema over a pressure site is usually due to a normal reactive hyperaemic response.
Category/Stage 1: Pressure Ulcer Non-blanchable erythema

**Definition of Stage 1:** non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.

---

Non blanchable erythema

**Finger Test**

- Does not turn white on finger pressure
Category/Stage 2: Pressure Ulcer: Blister/Abrasion

**Definition of Stage 2:** Partial thickness skin loss of dermis presenting as a shallow open ulcer with a red pink wound bed without slough. May also present as a clear or blood filled blister. There is no bruising.

Category/Stage 3: Pressure Ulcer: Superficial ulcer

**Definition of Stage 3:** Full thickness tissue loss. Fat may be visible but bone tendon or muscle are not. Slough may be present but does not obscure the amount of tissue loss.
Category/Stage 4 Pressure Ulcer: Deep ulcer

**Definition of Stage 4:** Full thickness tissue loss. Bone, tendon and muscle visible or palpable.

---

Potential deep tissue injury

A localized area of purplish discoloration over intact skin, or blood blisters, due to damage of underlying soft tissue.

It may be painful, firm, mushy, boggy, warmer or cooler compared to the adjacent skin. May develop into a category 3 or 4 but cannot be confirmed until extent of damage is evident. Damage may be recoverable with effective 'off-loading' of affected area.
Unstageable

Minimal category 3 but potential 4
The wound bed is not visible due to presence of slough or necrotic tissue.
Classification may not be possible until the ulcer is debrided.

Group Work

In your groups on the body maps write down the areas you feel are at risk to pressure damage.
Areas at risk

- Heels
- Sacrum
- Ischial tuberosities (space between buttocks and leg)
- Elbows
- Side and back regions of the skull
- Shoulders
- Toes.

- Ears
- Under Catheter tubing, bags and straps
- Clothing with thick seams
- Or sitting on studs, zips, buttons
- Ensure shoes & socks are not too tight – compression hosiery fitted correctly
K - Keep Moving

Keep moving

Keep your patients moving

NICE guidance on Pressure Ulcers. The management of pressure ulcers in primary and secondary care.
www.publications.nice.org.uk/pressure-ulcers-epg02

European Pressure Ulcer Advisory Panel – Pressure Ulcer Prevention: A Quick Reference Guide
www.epuap.org/guidelines/Final_Quiick_Prevention_01

Repositioning

- Regular repositioning
- Bed
- Wheelchair
- Armchair
I - Incontinence

Incontinence

Incontinence / moisture: your patients need to be clean and dry

NICE Guidance: Urinary Incontinence
www.nice.org.uk/guidance/hdi1.scope=download&o=30282

Wounds UK Article: The use of Barrier Films for patients with incontinence
www.wounds.uk.com/article/102331.pdf

- Continence issues – incontinence can contribute to sore excoriated skin – any concerns should be reported.

- Moisture –
  - People who sweat more due to size or health related problem
  - Creases/folds
N - Nutrition

Nutrition / Hydration
help patients have the right diet and plenty of fluids

NICE Guidance - Nutrition support in adults
www.publications.nice.org.uk/nutrition-support-in-adults-cq32/guidance
BAPEN - Introducing MUST
www.bapen.org.uk/screening-for-malnutrition/must/introducing-must
Hydration Matters

- Big factor in healing or breakdown of pressure sores
- Protected mealtimes
- Ill fitting dentures
- Sore mouth
- Monitor
- Well hydrated
### What to do if you suspect a patient has pressure damage

- Alert
- Remove
- Cascade
- Document
Safeguarding

- 95% Pressure ulcers preventable
- Could this have been prevented?
- Dignity Challenge
- All category 4 ulcers – safeguarding issues should be considered

To summarise

- Nutrition
- Observation
- Prevention is better than cure
- Risk assessment
- Equipment, aid and adaptations
- Skin care
- Some people are more vulnerable to pressure sores
- Understand individuals roles and responsibilities
- Repositioning
- Education and training
- Up and walking, turning and elevation
- Lift don’t drag
- Continence
- Everybody’s business
- Record keeping
- Safeguarding
Thank you

* Questions?

Working together
LIVING WELL

@PennineCareNHS
www.penninecare.nhs.uk
Implementing the Care Bundle

17th November 2016

Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester

Objectives

- To set goals about using the care bundle
- To have a clear plan of action of how to implement the care bundle
What is a goal?

- A goal is:
  - A statement of an end result
  - Achieved in a specified period of time
  - At a specific level of quality

Why set goals?
To establish priorities  To identify what we want to achieve

To keep us motivated  Can help to build self-confidence

To keep us on track  To focus our efforts

**Why set goals?**

SMART goals for the care bundle

- **Specific**
  - Who is involved?
  - What do I want to accomplish?
  - Which skills/resources do I need?
  - Why do it?
SMART goals for the care bundle

- Specific
- Measurable → How often?
- Achievable → Is the goal realistic?
SMART goals for the care bundle

- Specific
- Measurable
- Achievable
- Relevant
  - Is it appropriate?
- When does the goal need to be achieved by?
- Time bound
Care bundle goals

- To identify those at risk
- To know how often to use the care bundle
- To conduct every step in the care bundle
- To document

What is an action plan?

- Action plans make goals happen...
  - Sets the stage for achieving the goal
  - Lists what steps must be taken in order to achieve a specific goal
Implementation plan

Goal statement:
• Prevent pressure ulcers using each part of the care bundle

Measures of success:
• Carrying out the care bundle
• Filling in the care bundle sheet
• Number of pressure ulcers
Implementation plan

Actions:
• Conduct risk assessment every month

• IF a risk assessment has been conducted in the last month, THEN ...

• IF a risk assessment has not been conducted in the last month, THEN ...
**Implementation plan**

**Actions:**
- Ensure I understand how to use the care bundle
  - Frequency:
    - Is the resident at:
      - risk
      - high risk
      - very high risk
  - Practicalities:
    - Do I understand each step?
    - Do I know how to fill the care bundle in?
• **IF** a resident is not at risk of developing pressure ulcers, **THEN** …

• **IF** a resident is at risk of developing pressure ulcers, **THEN** …

• **IF** a resident is at high risk of developing pressure ulcers, **THEN** …

• **IF** a resident is at very high risk of developing pressure ulcers, **THEN** …
Implementation plan

Actions:
• When conducting one intervention (e.g., repositioning), ensure I complete the other interventions (i.e. skin assessment, skin care)

• IF I am checking the support surfaces a resident is resting on, THEN ...

• IF I am inspecting a resident’s skin, THEN ...

• IF I am repositioning a resident, THEN ...
Implementation plan

Actions:
- Document
• **IF** I have completed all of the steps in the care bundle, **THEN** ...

• **IF** I was unable to complete all of the steps in the care bundle, **THEN** ...

• **IF** I could not complete the care bundle at all, **THEN** ...

**Documentation**

- If I have completed all of the steps in the care bundle, then document reasons on the care bundle overleaf.
- If I was unable to complete all of the steps in the care bundle, then fill in the care bundle and document reasons on overleaf.
- If I could not complete the care bundle at all, then fill in the care bundle and add any additional comments on overleaf.
Any barriers to care bundle use?
Appendix 15. Care bundle intervention poster

Pressure Ulcer Prevention Care Bundle

Conduct pressure ulcer risk assessment every month, or sooner if there is a change to resident’s health status. Document findings and due date of next assessment and alert all concerned.

If yes, then...

Is the resident:  
- At risk?  
- At high risk?  
- At very high risk?

If no, then...

IMPLEMENT CARE BUNDLE

If at risk, then CHECK and DOCUMENT ALL care bundle steps at least every 6 hours

If at high risk, then CHECK and DOCUMENT ALL care bundle steps at least every 4 hours

If at very high risk, then CHECK and DOCUMENT ALL care bundle steps at least every 2 hours

Time – use 24 hour clock 00.00 – 24.00

Support surfaces
Surface checked for creases, tubing, personal items etc.?  
Equipment checked?

Skin inspection
All pressure areas checked?  
Redness/changes to skin? Yes (Y) No (N)?  
(If Y, document overleaf)  
Is the resident experiencing wound pain?

Repositioning
In bed: rotated onto right (R), left (L) side or hoisted (H)  
Sitting: stood (S) walked (W)  
Other (document overleaf)

All Care Staff PLEASE READ and ensure all residents ‘at risk’ have forms in their room. Please ask the nurse in charge to explain if unsure
Appendix 16. Topic guide for the interviews (Chapter 9)

Introduction: The general aim of the interview is to help me understand whether you liked using the care bundle and if there are any aspects you would change. In addition, I will talk to you about the adherence rates we have for the care bundle as I would like to understand more about what influenced the adherence rates. I will not be making any judgement about the practices conducted and there is no right or wrong answer.
<table>
<thead>
<tr>
<th>Questions</th>
<th>Prompts for further clarification</th>
<th>Potential themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can you describe the care bundle?</td>
<td>How did you assess residents for being at risk of developing a pressure ulcer?</td>
<td>Acceptability</td>
</tr>
<tr>
<td></td>
<td>Did you refer to the care bundle?</td>
<td>Memory, attention,</td>
</tr>
<tr>
<td></td>
<td>Did you discuss the care bundle with colleagues?</td>
<td>and decision processes</td>
</tr>
<tr>
<td></td>
<td>Did the care bundle influence your practice?</td>
<td>Environmental processes</td>
</tr>
<tr>
<td></td>
<td>What were the barriers to using the care bundle?</td>
<td>Skills</td>
</tr>
<tr>
<td></td>
<td>Were there situations where it was more difficult to complete the care bundle?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>What was helpful about the care bundle?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is there anything else that you feel should have been included in the care bundle?</td>
<td></td>
</tr>
<tr>
<td>How did you use the care bundle?</td>
<td>Did you plan to use the care bundle?</td>
<td>Implementation</td>
</tr>
<tr>
<td></td>
<td>How did the residents respond to you using the care bundle?</td>
<td>Integrity</td>
</tr>
<tr>
<td></td>
<td>Did you always have access to all of the resources you required to complete the care bundle?</td>
<td>Acceptability</td>
</tr>
<tr>
<td></td>
<td>How confident were you in using the care bundle?</td>
<td>Applicability</td>
</tr>
<tr>
<td></td>
<td>Do you think it is possible to prevent pressure ulcers using the care bundle?</td>
<td>Social influences</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Environmental context</td>
</tr>
<tr>
<td></td>
<td></td>
<td>and resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intentions</td>
</tr>
<tr>
<td>Questions</td>
<td>Prompts for further clarification</td>
<td>Potential themes</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Did you attend the training session about the care bundle?</td>
<td>Was the training useful? How satisfied were you with the training? Could anything have been improved?</td>
<td>Acceptability Skills Environmental context and resources Memory, attention, and decision processes</td>
</tr>
<tr>
<td>Did you ever have to adjust elements of the care bundle?</td>
<td>Which parts? Why? Were you always able to conduct all of the elements? Were some practices more difficult than others?</td>
<td>Implementation Integrity Acceptability Skills Social/ professional role and identity Memory, attention, and decision processes</td>
</tr>
<tr>
<td>Questions</td>
<td>Prompts for further clarification</td>
<td>Potential themes</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>Do you think the care bundle is something you will use in the future?</td>
<td>Is it sustainable?</td>
<td>Acceptability</td>
</tr>
<tr>
<td></td>
<td>Did the care bundle fit into your daily routine?</td>
<td>Applicability</td>
</tr>
<tr>
<td></td>
<td>Did it facilitate your daily routines?</td>
<td>Beliefs about</td>
</tr>
<tr>
<td></td>
<td>Was the documentation tool practical?</td>
<td>Consequences</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Memory, attention, and decision processes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Social/ professional role and identity</td>
</tr>
<tr>
<td>Can you see any differences between using the care bundle and the practices you used to conduct?</td>
<td>What are these differences?</td>
<td>Applicability</td>
</tr>
</tbody>
</table>

That is all of my questions. Is there anything you think that I have missed or you would like to discuss? Thank you for taking the time for this interview.
### Appendix 17. EPOC Risk of bias for studies with a separate control group

<table>
<thead>
<tr>
<th>Risk of bias assessment for all randomised trials, non-randomised trials and controlled before-after studies.</th>
<th>Risk of bias assessment for interrupted time series studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the allocation sequence adequately generated?</td>
<td>1. Was the intervention independent of other changes?</td>
</tr>
<tr>
<td>2. Was the allocation adequately concealed?</td>
<td>2. Was the shape of the intervention effect pre-specified?</td>
</tr>
<tr>
<td>3. Were baseline outcome measurements similar?</td>
<td>3. Was the intervention unlikely to affect data collection?</td>
</tr>
<tr>
<td>4. Were baseline characteristics similar?</td>
<td>4. Was knowledge of the allocated interventions adequately prevented during the study?</td>
</tr>
<tr>
<td>5. Were incomplete outcome data adequately addressed?</td>
<td>5. Were incomplete outcome data adequately addressed?</td>
</tr>
<tr>
<td>6. Was knowledge of the allocated interventions adequately prevented during the study?</td>
<td>6. Was the study free from selective outcome reporting?</td>
</tr>
<tr>
<td>7. Was the study adequately protected against contamination?</td>
<td>7. Was the study free from other risks of bias?</td>
</tr>
<tr>
<td>8. Was the study free from selective outcome reporting?</td>
<td></td>
</tr>
<tr>
<td>9. Was the study free from other risks of bias?</td>
<td></td>
</tr>
</tbody>
</table>