Discontinuing Neuroleptic Medication for Psychosis: A Systematic Review of Functional Outcomes and a Qualitative Exploration of Personal Accounts

A thesis submitted to The University of Manchester for the degree of Doctorate in Clinical Psychology (ClinPsyD) in the Faculty of Medical and Human Sciences

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Thesis Abstract

Discontinuing Neuroleptic Medication for Psychosis: A Systematic Review of Functional Outcomes and a Qualitative Exploration of Personal Accounts

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Doctorate in Clinical Psychology (ClinPsyD) The University of Manchester

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This thesis sought to explore the phenomenon of discontinuing neuroleptic medication for psychosis. It comprises three standalone papers. Papers one and two have been prepared for submission to journals and in accordance with the journal guidelines. Paper one is a systematic literature review synthesising studies investigating the association between neuroleptic discontinuation and functional outcomes. Databases were systematically searched and thirteen studies were included in the review. Evidence regarding the association between discontinuation from neuroleptic medication and functional outcomes was mixed. Findings are limited by the scarcity of evidence, diversity in the study methods and designs used, and methodological and design quality issues.

Paper two is a qualitative study exploring personal accounts of making choices about neuroleptic medication, specifically considering decisions to discontinue. Twelve participants were interviewed and a constructivist grounded theory approach was used to analyse transcripts. The findings suggest that making sense of choices relates to a continuation-discontinuation spectrum and involves three interrelated tasks. The tasks are: forming a personal theory of the need for, and acceptability of, neuroleptic medication; negotiating the challenges of forming alliances with others; and weaving a safety net to safeguard wellbeing. A theoretical model explaining the processes involved in the tasks and the mediating factors is presented and discussed. The clinical implications of the findings are discussed with reference to existing literature.

Paper three is not intended for publication and is a critical review of the research process, in which the strengths and weaknesses of the systematic review and empirical study are evaluated. Personal and professional reflections on the experience of conducting a systematic review and an empirical qualitative study are discussed and the implications of the research for future clinical practice and research are considered.
Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.
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I am so grateful to the twelve participants who generously gave their time to share their experiences and insights with me - thank you so much. I felt privileged to spend an hour with each of you in person and many more hours with your words and wisdom thereafter. Thank you also to all of the organisations that helped me during recruitment, especially Stockport and District Mind and Stockport Progress and Recovery Centre.

To my wonderful family and friends who have supported me unconditionally during the past three years and understood without complaint when I have buried my head in my laptop, I dedicate this thesis to you. Thank you especially to my husband Andy. Your unwavering belief, love and patience has been incredible and you’ve never failed to raise a smile with your humour and hugs. To Mum and Dave also, thank you so much for your emotional and practical support and for letting me use your home as my research retreat! Finally to Ann and Dave, thank you for your warm words of encouragement throughout.
Paper 1.

Functional Outcomes Associated with Discontinuation of Neuroleptic Medication for Psychosis: A Systematic Review of Evidence

Paper 1 has been prepared for submission to Clinical Psychology Review in accordance with the journal guidelines for contributors (Appendix 1).

Word Count (excluding abstract, tables, figures and references): 7650
Abstract Word Count: 198
Abstract

Neuroleptic medication is the primary treatment for schizophrenia-related disorders and psychosis. Discontinuation rates are high and research has associated poor symptomatic outcomes with neuroleptic withdrawal. Recovery literature has identified functional outcomes as priorities for service users with psychosis. The aim of this review is to synthesise evidence investigating functional outcomes associated with neuroleptic discontinuation. A systematic literature search of databases and citation searching identified thirteen articles investigating functional outcomes associated with neuroleptic withdrawal. Three broad domains of functioning were investigated: quality of life, employment, and personal, social and occupational functioning. The evidence was mixed and it was not feasible to derive firm conclusions. A trend toward poorer outcomes was apparent when medication was withdrawn abruptly, during acute exacerbation of illness and when outcomes were measured soon after discontinuation. A trend was also observed toward equivalent or better functional outcomes for participants who were medication-free or receiving minimal doses of neuroleptic medication over long-term follow-ups compared with participants receiving maintenance medication. The limitations of the current evidence base are outlined and priorities for future research highlighted. Tentative recommendations for evaluating neuroleptic withdrawal are made within the context of the limited evidence base and NICE guidelines for schizophrenia and psychosis.
Highlights

- Neuroleptic medication is the main treatment for psychosis but frequently discontinued by service users
- Functional outcomes are identified by service users as priorities in the treatment of psychosis
- Evidence is synthesised in a systematic review of functional outcomes associated with neuroleptic discontinuation
- Limitations of the evidence base are discussed and recommendations for future research are made

Keywords

Neuroleptic medication; Antipsychotic medication; Discontinuation; Withdrawal; Psychosis; Schizophrenia; Functional outcomes; Quality of life; Employment; Personal, social and occupational functioning
Introduction

Neuroleptic medication is the primary treatment for people with diagnoses of schizophrenia-related disorders and psychosis (National Institute for Health and Care Excellence [NICE], 2014). There is an established evidence base supporting the efficacy of these drugs for managing psychotic symptoms and reducing the risk of relapse (Gilbert, Harris, McAdams, & Jeste, 1995; Leucht et al., 2012). As such, the prevailing recommendation is that neuroleptic medication is required for acute treatment of psychosis and relapse prevention (NICE, 2014). Long-term maintenance neuroleptic use is therefore common.

There is evidence however, that neuroleptic medication is not accepted or tolerated as a maintenance treatment by many service users. Studies have found that up to 84% of people discontinue neuroleptic medication (Lieberman et al., 2005a; Kreyenbuhl et al., 2011) and this often occurs without professional input (Hogman & Sandamas, 2000; Mitchell & Selmes, 2007; Read, 2005). Evidence also indicates that adverse effects are common (Barbui et al., 2005; Hofer et al., 2007; Van Putten, 1974; Awad, 1993) and a report published by the British Psychological Society advised that unwanted effects might be experienced as worse than the original problem by service users (Kinderman & Cooke, 2000). Correspondingly, research has found that neuroleptic medication might adversely affect quality of life (QoL: Awad & Voruganti, 2012).

Research regarding the safety and efficacy of neuroleptic medication continues to be a priority. A number of negative outcomes are associated with long-term neuroleptic use. These include increased mortality (Reilly, Ayis, Ferrier, Jones, & Thomas, 2002; Ray, Chung, Murray, Hall, & Stein, 2009), reduced brain volume (Weinmann & Aderhold, 2010; Ho, Andreasen, Ziebell, Pierson, & Magnotta, 2011; Lieberman et al., 2005b), and tardive dyskinesia that is irreversible in up 75% of people (Hill, 1986). Metabolic and cardiovascular adverse events are also complications associated with prolonged neuroleptic use (Newcomer, 2007).

Psychosis is associated with impaired functional outcomes, including social and vocational functioning, and QoL (Priebe, 2007). Knowledge about the effectiveness of neuroleptic medication is based largely on short-term randomised controlled trials (RCTs) evaluating active medication against placebo for symptomatic outcomes.
Consequently, associations between neuroleptic use and functional outcomes are yet to be established.

Taking neuroleptic medication can therefore confer both advantages and disadvantages to service users. Discontinuing these drugs is also associated with a number of risks. A systematic review by Gilbert et al. (1995) concluded that over a mean period of 9.7 months, the relapse rate for individuals withdrawn from neuroleptic medication was 53% compared with 16% for those maintained. Subsequent reviews of discontinuation studies have also considered outcomes associated with relapse and symptom recurrence and concur there is a high risk of relapse (Leucht et al., 2012; Zipursky, Menezes, & Streiner, 2014). Whether relapse represents a re-emergence of underlying mental health problems or is associated with biopsychosocial changes following neuroleptic withdrawal is debated. Moncrieff (2006) suggests that for some, relapse might be associated with iatrogenic factors. Tranter and Healy (1998) associate withdrawal of neuroleptic medication with a number of adverse effects, collectively referred to as neuroleptic discontinuation syndromes. Though many studies indicate that stopping abruptly is worse than tapered withdrawal from neuroleptic medication (Viguera, Baldessarini, Hegarty, van Kammen, & Tohen, 1997), the association between discontinuation strategy and symptomatic or functional outcomes remains unclear (Leucht et al., 2012). Knowledge about the long-term effects of discontinuation is also limited due to the predominance of short-term discontinuation studies in the literature.

Recovery in mental health is understood in a variety of ways. In the context of biomedical illness or impairment-based approaches, outcomes associated with symptom reduction or remission are fundamental (Pilgrim, 2008). The primary aim of psychosis treatment within these approaches is to maximise symptomatic remission and minimise relapse rates using neuroleptic medication.

Novick, Haro, Suarez, Vieta, and Naber (2009) highlight that by focusing on symptomatic outcomes, neuroleptic research fails to capture psychosocial domains, including functional independence in the community, and social and vocational functioning. This approach conflicts with current understandings of ‘outcome’ as a complex phenomenon involving clinical, social and occupational domains and complete versus partial recovery (Cooke, 2014).
Broader, multifaceted understandings of recovery in psychosis have emerged through qualitative research exploring service users' experiences. A key finding from a review of studies exploring service user priorities and preferences for outcomes associated with the treatment of psychosis highlighted that social and functional outcomes were prioritised more than the treatment and monitoring of positive psychotic symptoms (Byrne, Davies, & Morrison, 2010). This corresponds with literature that suggests that QoL for people with schizophrenia and psychosis diagnoses might be better predicted by psychosocial factors than disorder-related covariates (Awad & Voruganti, 2012).

There is evidence from longitudinal studies that global outcomes are moderately good in approximately half of people with schizophrenia diagnoses and that periods of remission are possible for some (Harrison et al., 2001). There are also indications that some people who are unmedicated or who receive low doses in combination with community or residential treatment following acute psychosis, can achieve equal or better outcomes than for those who are medicated (Fenton & McGlashan, 1987; Calton, Ferriter, Huband, & Spandler, 2008) and that psychological therapy without neuroleptic medication can be beneficial (Morrison et al., 2011). Traditional paradigms of recovery in psychosis and schizophrenia research might therefore overlook other meaningful outcomes for service users.

Assessments of functional outcomes and QoL align well with psychosocial, user-led approaches to recovery, which extend beyond symptom reduction to include themes of “rebuilding life,” “rebuilding self” and “hope for a better future” (Pitt, Kilbride, Nothard, Welford, & Morrison, 2007: p.55). The Global Assessment of Functioning Scale (GAF; Hall, 1995) is one such measure, which adopts a continuum approach to mental health and eschews categorical representations of outcomes associated with psychosis. When a continuum approach is taken, evidence suggests that more meaningful information is gained concerning individuals’ needs and outcomes (Verdoux & van Os, 2002). In addition to the GAF, a number of tools exist to define and measure functional and QoL outcomes for people with psychosis and schizophrenia diagnoses (Figueira & Brissos, 2011; Awad & Voruganti, 2012). The extent to which these measurements have been incorporated within discontinuation research to evaluate functional outcomes with or without neuroleptic medication is unknown.
Discontinuation of neuroleptic medication is a common clinical issue. The relationship between neuroleptic discontinuation and functional outcomes including personal, social and vocational functioning is poorly understood. Previous reviews have investigated symptomatic outcomes using RCTs; therefore, a systematic review considering costs and benefits of neuroleptic discontinuation related to functional outcomes is needed.

The current review aimed to address a gap in the evidence by examining the following question: ‘What are the functional outcomes associated with discontinuation of neuroleptic medication in people with diagnoses of schizophrenia-related disorders?’ A systematic review strategy was chosen to identify and synthesise studies that have addressed this question. For the purposes of the review, outcomes were defined according to the most widely studied functional outcome experiences in the schizophrenia literature (Andreasen et al., 2005; Schennach, Musil, Moller, & Riedel, 2012; Karow, Moritz, Lambert, Schottle, & Naber, 2012; McEvoy, 2008) and include psychosocial factors such as social and occupational functioning, social inclusion, wellbeing, QoL and relationships. This review also aimed to evaluate whether functional outcomes are associated with the following factors: duration of neuroleptic medication use before discontinuation, withdrawal strategy, and length of follow-up.

Methods

Search strategy and selection criteria

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009: Appendix 2) were followed to develop a systematic search strategy and protocol (Appendix 3), which guided the systematic review. PRISMA is an evidence-based checklist compiled to guide the reporting of systematic reviews. Review registration was completed using Prospero (Centre for Reviews & Dissemination [CRD], 2015). Registration number: CRD42015017815.

Four search categories were developed, which were combined using the Boolean operator “AND.” Within each category, the instruction “OR” was applied and Medical
Subject Headings (MeSH) and wildcard asterisks were used to capture related terms, where relevant.

The first category comprised search terms associated with schizophrenia, and included “psychos*;” “psychotic;” “schizophren*;” “schizoaffective disorder;” and “first episode psychosis.”

The second category regarded neuroleptic medication, and included both pharmaceutical and trade names (Appendix 3); these were accessed from the British National Formulary website (BNF, 2014). The search terms “neuroleptic” and “antipsychotic” were also used.

The third category comprised terms associated with discontinuation and included, “disconti*;” “withdraw*;” “cessation;” “drug-free;” “medication-free;” “stop;” “terminat*;” and “suspen*.”


A systematic database search from the year 1946 to May 2015 was performed on PsychINFO, Medline, Embase, and Web of Science. Combined category searches in all databases were limited to English language and human populations. Additional limits of “peer review article” and “article” were applied to searches performed in PsychInfo and Web of Science respectively. Neither Embase nor Medline offered a corresponding limit. Searches performed using Ovid (Medline, PsychInfo and Embase) were limited to keyword and abstracts. Web of Science did not offer such limits; therefore the “topic” field was used.

Citation searching was also completed to identify further relevant articles and the reference lists of three previous reviews were searched (Gilbert et al., 1995; Leucht et al., 2012; Zipursky et al., 2014).
**Inclusion criteria**

Studies were included when the following criteria were met: (i) they were published in a peer-reviewed journal and (ii) written in English language; (iii) they used quantitative or qualitative methodologies; (iv) participants were identified as having a diagnosis of a schizophrenia-related disorder and (v) had engaged in discontinuation of, or withdrawal from neuroleptic medication; (vi) the results discussed functional outcomes following discontinuation and (vii) study participants were aged 16 years or older.

Exclusion criteria were defined as: (i) studies that only investigated switching of medications; (ii) studies investigating discontinuation of neuroleptic medication in participants with diagnoses other than those within the schizophrenia cluster (for example: bipolar disorder, depression, dementia, intellectual disabilities), or where there was an organic cause for psychosis; (iii) studies where participants were medication-free from onset; (iv) studies that only reported on outcomes associated with relapse or symptoms.

Decisions regarding the eligibility of studies for this review were discussed between the three members of the study team. Papers were included when all reviewers unanimously decided that the study conformed to the criteria.

**Quality appraisal**

The methodological rigour of the included studies was examined to identify potential bias and the relevance of studies to the review question. The Effective Public Health Practice Project tool (EPHPP, Thomas, Ciliska, Dobbins, & Micucci, 2004; Appendix 4) was used as a standardised and validated quality assessment tool to aid this process. The EPHPP was chosen as it supports a domain-based evaluation of the risk of bias for a variety of study designs. It also offers a clear framework for quality appraisal and is reported to have good inter-rater reliability (Armijo-Olivo, Stiles, Hagen, Biondo, & Cummings, 2010). A global rating is offered in addition to the following domain specific evaluations: selection bias, study design, confounders, blinding, data collection method, and withdrawals/dropouts. Another advantage of the EPHPP is that by eschewing dichotomous ratings, it supports quality appraisal that is less restrictive than other available tools. Two members of the research team completed independent quality
appraisals assessments. Inter-rater reliability calculations were completed on the global ratings and Kappa was calculated as 0.67, demonstrating substantial agreement. The EPHPP domain ratings were used during data synthesis to evaluate the strength of the evidence presented. Global ratings are recorded in Table 1.

The included studies were considered too diverse both clinically and methodologically to combine in a meta-analysis or narrative synthesis (CRD, 2009). Many also lacked controlled experimental data meaning that formal statistical analysis was unsuitable. Instead, the main findings of the included studies have been synthesised by exploring relationships within and between them and assessing the robustness of the evidence (CRD, 2009). The PRISMA checklist was used to ensure the appropriateness and transparency of reporting in this systematic review.

**Results**

In accordance with PRISMA guidelines, a flowchart detailing the selection process of articles was completed (see Figure 1). Database searching produced 4060 records, which were exported to the reference manager Endnote where 1066 duplicates were removed. An additional 59 records were identified through other sources and a title and abstract screen was performed on the remaining 3053 records. Following this, a further 2886 articles were excluded because papers did not meet the review inclusion criteria. The remaining 167 remaining articles were retrieved and examined during a full text screen.

Twenty-one studies were considered for inclusion and subject to a panel discussion. The reviewers agreed that eight of these did not satisfy the inclusion criteria and were excluded. Of these eight studies, two did not clearly report on functional outcomes for discontinuation participants (Atkinson, Douglas-Hall, Fischetti, Sparshatt, & Taylor, 2007; Arnold et al., 2013); one stated that many participants had never taken neuroleptic medication (Fenton & McGlashan, 1987); and one did not detail whether medication-free participants had discontinued from neuroleptic medication (Harding, Brooks, Ashikaga, Strauss, & Breier, 1987). Two studies had no distinct discontinuation group: Hill et al. (2010) set a criteria for non-adherence rather than discontinuation and included participants who were taking medications between 0-75% of the time; the authors of the other study (Novick et al., 2009) were contacted to clarify the definition
of ‘non-compliance’, which was reported as “physician defined” and agreed by consensus as not meeting the inclusion criteria.

Drew, Griffiths and Hodgson (2002) were contacted to determine whether the group discontinuing neuroleptic medication had remained withdrawn from all neuroleptic medication during the study. A response was not received; therefore the study was excluded, as the inclusion criterion could not be met. Finally, Rappaport, Hopkins, Hall, Belleza and Silverman (1978) reported on functional disturbance, which related to symptoms rather than the outcomes of interest for this review.

Thirteen studies were therefore included in the final review (see Table 1). One study was completed over two time points (Wunderink et al., 2007; Wunderink, Nieboer, Wiersma, Sytema, & Nienhuis, 2013) and explored full and partial discontinuation. A consensus decision agreed the study sufficiently met the inclusion criteria; however the limitations of this design are discussed. One article was a summary of one study completed over twenty years, at six time points (Harrow, Jobe, & Faull, 2012).
Figure 1: PRISMA Flowchart
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Illness phase</th>
<th>Study design</th>
<th>Sample size</th>
<th>Method of discontinuation; follow up period</th>
<th>Functional outcomes conclusion</th>
<th>EPHPP Global rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beasley et al. (2006)</td>
<td>19 sites in 6 countries (Croatia, Poland, Romania, Russian Federation, United States and Yugoslavia)</td>
<td>Minimally symptomatic</td>
<td>RCT</td>
<td>326</td>
<td>Abrupt; short term</td>
<td>Reduced QoL for the discontinued group compared with the maintenance group</td>
<td>Moderate</td>
</tr>
<tr>
<td>Chen et al. (2010)</td>
<td>Hong Kong</td>
<td>In remission</td>
<td>RCT</td>
<td>178</td>
<td>Gradual tapering; short term</td>
<td>No differences in employment status changes between the discontinued group compared with the maintenance group</td>
<td>Strong</td>
</tr>
<tr>
<td>Dencker et al. (1980)</td>
<td>Sweden</td>
<td>Minimally symptomatic</td>
<td>Cohort Study</td>
<td>50</td>
<td>Not reported; short term</td>
<td>Relatively high personal, social and occupational functioning in a discontinuation group</td>
<td>Weak</td>
</tr>
<tr>
<td>Hamilton et al. (1998)</td>
<td>United States</td>
<td>Acute exacerbation</td>
<td>RCT</td>
<td>325</td>
<td>Abrupt; short term</td>
<td>No differences in QoL between the discontinued group compared with the maintenance group</td>
<td>Weak</td>
</tr>
<tr>
<td>Harrow et al. (2012)</td>
<td>United States</td>
<td>Acute at intake; varied at follow up</td>
<td>Cohort study</td>
<td>139</td>
<td>Not reported; long-term</td>
<td>Better functional outcomes for the discontinued group compared with the maintenance group</td>
<td>Weak</td>
</tr>
<tr>
<td>Authors</td>
<td>Location</td>
<td>Condition</td>
<td>Study Type</td>
<td>Sample Size</td>
<td>Duration</td>
<td>Findings</td>
<td>Quality</td>
</tr>
<tr>
<td>--------------------</td>
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<td>---------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Johnson et al.</td>
<td>United Kingdom</td>
<td>Relapse free</td>
<td>Cohort study</td>
<td>116</td>
<td>Abrupt; short term</td>
<td>Poorer level of retained employment status for the discontinuation group compared with the maintenance group</td>
<td>Weak</td>
</tr>
<tr>
<td>Kane et al.</td>
<td>47 centres in Europe and 6 centres in India</td>
<td>Acute exacerbation</td>
<td>RCT</td>
<td>628</td>
<td>Abrupt; short term</td>
<td>Poorer personal, social and occupational functioning in the discontinuation group compared with the maintenance group. 1/3rd of the discontinued group had reduced functioning; 1/3rd had equivalent functioning; 1/3rd had improved functioning.</td>
<td>Moderate</td>
</tr>
<tr>
<td>Kramer et al.</td>
<td>45 centres in 6 countries (United States, Romania, Turkey, Latvia, Lithuania, and India)</td>
<td>Acute exacerbation</td>
<td>RCT</td>
<td>205</td>
<td>Abrupt; short term</td>
<td>Poorer personal, social and occupational functioning in the discontinuation group compared with the maintenance group</td>
<td>Weak</td>
</tr>
<tr>
<td>Moilanen et al.</td>
<td>Finland</td>
<td>Varied</td>
<td>Cohort study</td>
<td>70</td>
<td>Not reported; long term</td>
<td>Greater rate of employment in the discontinuation group compared with the maintenance group; better personal, social and occupational functioning in the discontinuation group compared with the maintenance group</td>
<td>Weak</td>
</tr>
<tr>
<td>Nasrallah et al.</td>
<td>United States</td>
<td>Symptomatic</td>
<td>RCT</td>
<td>369</td>
<td>Abrupt; short term</td>
<td>Reduced QoL for the discontinued group compared with the maintenance group</td>
<td>Moderate</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Status</td>
<td>Study Type</td>
<td>N</td>
<td>tapering</td>
<td>Functioning</td>
<td>Methodological Quality</td>
</tr>
<tr>
<td>-------------------------------</td>
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<td>------------------------</td>
</tr>
<tr>
<td>Nishikawa et al., (2007)</td>
<td>Japan</td>
<td>In remission</td>
<td>Case control study</td>
<td>30</td>
<td>Gradual tapering; long term</td>
<td>Equivalent functioning between discontinuation group and the maintenance group</td>
<td>Weak</td>
</tr>
<tr>
<td>Suzuki &amp; Uchida (2014)</td>
<td>Japan</td>
<td>Chronic</td>
<td>Case studies</td>
<td>4</td>
<td>Individual strategies; short term</td>
<td>Equivalent pre and post functioning in a discontinuation group</td>
<td>Weak</td>
</tr>
<tr>
<td>Wunderink et al. (2007/2013)</td>
<td>The Netherlands</td>
<td>In remission</td>
<td>Prospective 2 year RCT</td>
<td>131 (2007) 103 (2013)</td>
<td>Gradual tapering; long term</td>
<td>Equivalent QoL between the discontinuation group and the maintenance group; move from equivalent to greater functional remission in the discontinuation strategy group and in a subgroup who successfully discontinued compared with maintenance group from 2 years to 7 years.</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
Descriptive synthesis

Study characteristics

Table 1 provides an overview of the studies in author order. Of the thirteen studies, seven were RCTs evaluating discontinuation against maintenance neuroleptic medication. Six of these studies investigated full discontinuation of neuroleptic medication compared to ongoing maintenance neuroleptic medication (Beasley et al., 2006; Chen et al., 2010; Hamilton, Revicki, Genduso, & Beasley, 1998; Kane et al., 2007; Kramer et al., 2007; Nasrallah, Duchesne, Mehnert, Janagap, & Eerdekens, 2004) and one studied both full and partial discontinuation compared with maintenance neuroleptic medication (Wunderink et al., 2007/2013). The other six studies employed a mixture of methods: one compared participants who withdrew from neuroleptic medication with those maintained on medication in a non-randomised study (Johnson, Pasterski, Ludlow, Street, & Taylor, 1983); three involved neuroleptic withdrawal without comparison groups (Dencker, Lepp, & Malm, 1980; Nishikawa, Hayashi, Koga, & Uchida, 2007; Suzuki & Uchida, 2014), and two were retrospective long-term follow-up studies comparing participants discontinued from neuroleptic medications with those taking ongoing maintenance medication (Harrow et al., 2012; Moilanen et al., 2013).

The studies used a mixture of methods. Some only reported on functional outcomes associated with successful discontinuation of neuroleptic medication (Dencker et al., 1980; Harrow et al., 2012; Moilanen et al., 2013; Suzuki & Uchida, 2014); nine studies reported on outcomes associated with all attempts to discontinue, successful or unsuccessful (Beasley et al., 2006; Chen, 2010; Hamilton et al., 1998; Johnson et al., 1983; Kane et al., 2007; Kramer et al., 2007; Nasrallah et al., 2004; Nishikawa et al., 2007; Wunderink et al., 2007; 2013); and four of these also completed subgroup analyses of participants who successfully discontinued neuroleptic medication (Beasley et al., 2006; Johnson et al., 1983; Nishikawa et al., 2007) or achieved substantial dose reduction, defined as participants taking mean daily doses below 1mg of haloperidol equivalents (Wunderink et al., 2007; 2013).

The studies were published between 1980 and 2014 and were conducted in a variety of countries. Two were in Japan, three in the United States, one in the Netherlands, one in
the United Kingdom, one in Hong Kong, one in Sweden, one in Finland and three in multiple countries.

**Participant characteristics**

Study sample sizes ranged from 4 to 628 participants. Quality appraisal identified that six of the studies were considered at moderate risk of selection bias during quality appraisal and four were rated high risk in this domain. Many studies did not report their referral source or selection procedure. Studies that did report this information had recruited participants through referral by a source, for example a clinic.

All participants were categorised as having first episode psychosis or a diagnosis of a schizophrenia-related disorder. The target population of the thirteen studies varied, with several different phases of illness being investigated. Four studies recruited participants who were relapse-free or in remission (Chen et al. 2010; Johnson et al., 1983; Nishikawa et al., 2007; Wunderink et al., 2007/2013); two studies recruited participants who were minimally symptomatic (Beasley et al., 2006; Dencker et al., 1980); and three studies recruited participants who were experiencing acute exacerbations, defined as a Positive and Negative Symptom Scale (PANSS) score between 70 and 120 (Kane et al., 2007; Kramer et al., 2007) or Brief Psychiatric Rating Scale total score of at least 24 (Hamilton et al., 1998). Nasrallah et al. (2004) studied symptomatic participants using a PANSS score of between 60 and 120, and Suzuki and Uchida (2014) studied elderly male inpatients with a diagnosis of chronic schizophrenia. Harrow et al. (2012) and Moilanen et al. (2013) conducted retrospective cohort studies, therefore phase of illness at outcome varied. Only five of the studies were considered to have controlled well for confounders. The remaining studies were evaluated as having outcomes that were at high or moderate risk of bias from confounding variables.

**Functional outcomes**

The target outcomes for the current review were those associated with functioning. Symptomatic outcomes, including relapse, were not the primary focus however they have been discussed where relevant in the data synthesis.
The thirteen studies assessed outcomes in three broad domains of functioning. Five studies assessed QoL, four considered employment status and nine measured personal, social and occupational functioning.

Twelve different standardised measures were used (see Table 2), four studies employed self or other report, and one study used a functioning interview. Only two of the twelve measures were used in more than one study: the Quality of Life Scale (QLS; Heinrichs, Hanlon, & Carpenter, 1984) and the Personal and Social Performance Scale (PSP; Morosini, Magliano, Brambilla, Ugolini, & Pioli, 2000).

Quality appraisal revealed that the measures used to assess functioning were considered valid and reliable in eight of the thirteen studies (Beasley et al., 2006; Chen et al., 2010; Dencker et al., 1980; Hamilton et al., 1998; Kane et al., 2007; Moilanen et al., 2013; Nasrallah et al., 2004; Suzuki & Uchida, 2014). Harrow et al. (2012) reported high inter-rater reliability for the LKP (intraclass correlation coefficient: 0.92) and a correlation of \( r = 0.85 \) \((p < .0001)\) between the LKP and the global assessment scale; however the validity and reliability was not reported for the Strauss Carpenter level of functioning scale or the functioning interview and therefore a weak rating was applied. Kramer et al.’s (2007) study was also rated weak in this domain as the authors used an unreferenced measure of QoL without a unique name, therefore validity and reliability could not be ascertained. A weak rating was also given to Johnson et al.’s (1983) study because a modified version of the Medical Research Council Social Performance Schedule was used and validity and reliability could not be established. Nishikawa et al. (2007) only used qualitative data to investigate functional outcomes; therefore this study was also rated as weak for the data collection methods.
<table>
<thead>
<tr>
<th>Functional Domain</th>
<th>Measure</th>
<th>Studies employing measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life</td>
<td>QLS</td>
<td>Beasley et al. (2006); Hamilton et al. (1998)</td>
</tr>
<tr>
<td></td>
<td>SQLS</td>
<td>Kramer et al. (2007)</td>
</tr>
<tr>
<td></td>
<td>WHOQoL Bref</td>
<td>Wunderink et al. (2007/2013)</td>
</tr>
<tr>
<td></td>
<td>SF-36</td>
<td>Nasrallah et al. (2004)</td>
</tr>
<tr>
<td>Employment status</td>
<td>Self / other report</td>
<td>Chen et al. (2010); Nishikawa et al. (2007); Moilanen et al. (2013); Johnson et al. (1983)</td>
</tr>
<tr>
<td>Personal, social and occupational functioning</td>
<td>KAS</td>
<td>Dencker et al. (1980)</td>
</tr>
<tr>
<td></td>
<td>LKP Scale; Strauss-Carpenter SLOF; a functioning interview</td>
<td>Harrow et al. (2012)</td>
</tr>
<tr>
<td></td>
<td>Medical Research Council Social Performance Schedule</td>
<td>Johnson et al. (1983)</td>
</tr>
<tr>
<td></td>
<td>PSP</td>
<td>Kane et al. (2007); Kramer et al. (2007)</td>
</tr>
<tr>
<td></td>
<td>SOFAS</td>
<td>Moilanen et al. (2013)</td>
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<tr>
<td></td>
<td>FACT-SZ</td>
<td>Suzuki &amp; Uchida (2014)</td>
</tr>
<tr>
<td></td>
<td>GSDS</td>
<td>Wunderink et al. (2007/2013)</td>
</tr>
<tr>
<td></td>
<td>Self-report</td>
<td>Nishikawa et al. (2007)</td>
</tr>
</tbody>
</table>

*Note: QLS = Quality of Life Scale; SQLS = Schizophrenia Quality of Life Scale; WHOQoL-Bref = World Health Organisation Quality of Life Brief; SF-36 = Medical Outcomes Study Short-Form 36-item questionnaire measuring Health-Related Quality of Life; KAS = Katz Assessment Scale; LKP Scale = Levenstein–Klein–Pollack; SLOF = Specific Level of Functioning Questionnaire; PSP = Personal and Social Performance Scale; SOFAS = Social and Occupational Functioning Assessment Scale; FACT-SZ = Functional Assessment for Comprehensive Treatment of Schizophrenia; GSDS = Groningen Social Disability Schedule.*

**Data synthesis**

**Quality of life**

Four studies looked at the effect of discontinuation on QoL generally (Beasley, 2006; Hamilton et al., 1998; Kramer et al., 2007; Wunderink et al., 2007/2013), and one considered health-related QoL (HRQoL: Nasrallah et al., 2004). Four different measures were used: the QLS (Heinrichs, Hanlon, & Carpenter, 1984), the WHOQoL-Bref (O’Carroll et al., 2000), the SF-36 to measure HRQoL (Ware, Snow, Kosinski, &
Gandek, 1993), and an unreferenced measure, the SQLS. Neuroleptic withdrawal group sample sizes ranged from 62 (Hamilton et al., 1998) to 102 (Beasley et al, 2006). All studies were RCTs comparing discontinuation with the use of maintenance medication. One of the five studies used a graded discontinuation strategy (Wunderink et al., 2007; 2013) and the other four used abrupt discontinuation procedures.

Overall, findings relating to the effect of discontinuation on QoL were inconsistent. Between-group differences in QoL for participants withdrawn from neuroleptic medication compared with those receiving maintenance medication were found to be non-significant in two of the five studies (Hamilton et al., 1998; Wunderink et al., 2007/2103) and statistically significant in two studies (Beasley et al., 2006; Nasrallah et al., 2004), where discontinuation was associated with poorer QoL than maintenance (p<0.001 and p<0.05 respectively). Nasrallah et al. (2004) also reported non-significant within-group decreases from baseline in seven of the eight domains of HRQoL measured and a non-significant improvement in one domain (role-emotional) for the discontinuation group. QoL scores were difficult to interpret in one study (Kramer et al., 2007); the direction of effect was ambiguous and the unreferenced scale did not have a unique name to establish scoring guidelines or reliability and validity. The authors however, reported significantly less deterioration in the maintenance group compared with the discontinuation group. Beasley et al. (2006) provided subgroup analyses of stable participants, who had either been discontinued from, or maintained on neuroleptic medication; this analysis indicated no statistically significant between group differences in QoL.

A limitation of all studies is that the clinical significance of within-group changes in QoL scores was not reported. This has been identified as a more meaningful measure of the impact of treatment on client functioning (Kazdin, 1999), thus relevant to functional outcomes. An examination of the within-group raw scores detailed in the three studies reporting statistically significant between group differences revealed small changes from baseline. Establishing the clinical significance therefore, would have been useful. Conclusions were further limited by the length of follow-up, which ranged from 29 days (Kramer et al., 2007) to 35 weeks (Beasley et al., 2006) in the RCTs investigating full discontinuation compared with maintenance medication. QoL outcomes in Wunderink et al.’s (2007/2013) study were measured in long-term follow-ups at two and seven-
years post-discontinuation. Conclusions derived from these findings however, remain limited as QoL analyses were completed for all participants in the discontinuation strategy group of the trial at both time points; yet only 20% achieved full discontinuation. Subgroup QoL analysis of these 20% would have been useful.

Only one study used a self-report measure of QoL (Wunderink et al., 2007/2013) with clinician-rated scales used in the other four. The validity of the results might therefore be limited, as participants’ subjective QoL was not assessed. This is especially an issue in Hamilton et al.’s (1983) study where baseline QoL scores were carried forward for participants classed as “non-responders,” an approach that assumes no changes. Small sample sizes in this study also reduce the power of analysis.

Inconsistencies in findings might be explained by the different phases of illness studied. In two of the studies, participants were experiencing acute exacerbations of symptoms (Hamilton et al., 1998; Kramer et al., 2007); in one a criterion of mild to severe symptoms was set (Nasrallah et al., 2004); another studied minimally symptomatic patients (Beasley et al., 2006); and one reported on outcomes for “the best half” of the FEP population (Wunderink et al., 2007/2013). The generalisability of findings is therefore limited.

The effect of neuroleptic discontinuation on QoL therefore remains unclear. Two of the five studies reported no differences in the QoL of participants withdrawn from neuroleptic medication when compared with those maintained on neuroleptic medication and three of the five studies reported statistically significant decreases in QoL. The raw score changes from baseline in the three reporting changes were small and the clinical significance of the changes is unknown. Each of these three studies completed short-term follow-ups and used an abrupt withdrawal strategy, which might indicate a trend for poorer functional outcomes in these conditions.

Employment status

Three studies measured employment status changes pre and post baseline (Johnson et al., 1983; Chen et al., 2010; Nishikawa et al., 2007) and one measured prevalence of employment following discontinuation (Moilanen et al., 2013). All used self or other-
Neuroleptic withdrawal group sample sizes ranged from 24 (Moilanen et al.) to 89 (Chen et al. 2010).

Johnson et al. (1983) reported that 53% of discontinued participants were in an equivalent job role at 18-months post study entry compared with 84% of participants randomised to maintenance neuroleptic medication. This statistically significant difference indicates poorer functional outcomes associated with discontinuation. A subgroup analysis of non-relapsed participants in each group demonstrated no significant differences in work or social function, with good overall adjustment reported. Taken together, the results suggest there might be a link between functional and symptomatic outcomes for this cohort.

This trend was not however replicated by Chen et al. (2010); no statistically significant differences in employment status changes were found comparing medicated and withdrawn participants despite greater relapse rates in the discontinuation group. Both studies were conducted with remitted participants, over similar durations (Johnson et al: 18 months; Chen et al: 12 months). Differences might be explained by variation in cultural setting (Johnson et al: Manchester; Chen et al: Hong Kong) and discontinuation procedure (Johnson et al: abrupt; Chen et al: gradual). Quality appraisal demonstrated that Chen et al.’s study had greater strengths than Johnson et al.’s study in a number of domains, including study design and measures, and received a higher overall rating. The sample size was also larger in Chen et al.’s study; therefore these results can be interpreted with greater confidence than findings from Johnson et al.’s study.

Nishikawa et al. (2007) followed up 30 participants over an average period of 10.7 years who had engaged in a neuroleptic drug withdrawal program. The authors found that eight participants successfully withdrew neuroleptic medication and employment and vocational status remained unchanged for this sample regardless of whether discontinuation was achieved. Twenty-two (73.3%) of these participants were in full-time jobs. A number of quality issues were identified during quality appraisal for this study however, including a weak design and poor control of confounders, which limits the conclusions that can be drawn.
Moilanen et al. (2013) measured prevalence of employment and found that medication-free participants were more likely to be employed than those maintained on neuroleptic medication (63% and 39% respectively). Whether this association indicates that better occupational functioning is an outcome of discontinuation or a predictor for successful withdrawal cannot be ascertained due to the study design, which was rated weak on the appraisal exercise.

As with QoL therefore, the effect of neuroleptic discontinuation on employment status reveals a mixed picture with quality issues limiting the strength of findings.

**Personal, social and occupational functioning**

A broad domain comprising personal, social and occupational outcomes was reported in nine studies. Eight different standardised measures were used. Dencker et al. (1980) used the KAS (Katz & Lyerly, 1963); Harrow et al. (2012) used the LVK (Levenstein, Klein, & Pollack, 1966), the Strauss-Carpenter SLOF (Strauss & Carpenter, 1972), and a functioning interview (Endicott & Spitzer, 1978; Grinker & Harrow, 1987); Johnson et al. (1983) used a modified version of the Medical Research Council Social Performance Schedule (Hurry, Sturt, Bebbington, & Tennant, 1983); Kane et al. (2007) and Kramer et al. (2007) used the PSP (Morosini et al, 2000); Moilanen et al. (2013) used an earlier version of the PSP, the SOFAS (Spitzer, Gibbon, & Endicott, 2000); Suzuki and Uchida (2014) used the FACT-SZ (Suzuki et al., 2008); Wunderink et al. (2007/2013) used the GSDS (Wiersma, DeJong, & Ormel, 1988); and Nishikawa et al. (2007) used self-report. Neuroleptic withdrawal group sample sizes ranged from 4 (Suzuki & Uchida) to 126 (Kane et al.).

Four articles reported equivalent functioning in this domain (Johnson et al, 1983; Nishikawa et al. 2007; Suzuki & Uchida, 2014; Wunderink et al., 2007), three of which used individualised discontinuation strategies. “Weak” global ratings were applied to three of these studies during quality appraisal however, with risk of bias resulting from poor control of confounders and the use of data collection methods without established reliability or validity. Study quality was further compromised by small sample sizes. Results of Wunderink et al’s. (2007) study can be interpreted with greater confidence;
however there were still moderate risks of bias due to the use of a measure without established validity.

Three articles, all long-term follow-ups, reported statistically better functional outcomes for participants who had discontinued neuroleptic medication when compared with participants maintained on them (Moilanen et al., 2013; Harrow et al., 2012; Wunderink et al., 2013; $P$ values: $P < 0.001; P < 0.01; P = 0.001$ respectively). The findings from Wunderink et al.’s study are extracted from a subgroup analysis comparing participants who achieved full discontinuation or substantial dose reduction of neuroleptic medication (mean daily dose <1mg) from either the discontinuation strategy or the maintenance treatment groups, with participants maintained on neuroleptic medication. This demonstrated greater functional remission (55.9% vs. 21.7%; $P = .001$) and recovery (52.9% vs. 17.4%; $P < .001$) for participants achieving discontinuation or dose reduction. Although the quality of this study was evaluated as moderate, the ability to interpret the findings within the context of the review question is limited because the discontinuation group included participants who reduced their dose to <1mg but did not discontinue completely. This group also included participants initially allocated to the maintenance group who chose to discontinue of their own volition; therefore it is not possible to draw conclusions about the effect of discontinuation strategy on outcomes.

Wunderink et al. (2013) also reported a move from equivalent functioning at two years to greater functional remission at seven years in participants who had been randomised to the discontinuation strategy group, regardless of whether they discontinued neuroleptic medication. The authors suggest that this demonstrates an advantage of a discontinuation strategy over maintenance treatment; however, interpretation of these results within the context of this review question is again limited.

Dencker et al. (1980) reported “relatively high” functional outcomes for non-relapsing discontinued participants; however statistical analysis for this subgroup was not provided and outcomes for those who relapsed were absent. Inadequate reporting of data analysis methods, incomplete follow-up, a small sample and areas of weakness identified on the quality appraisal tool limits this study, therefore no firm conclusions can be derived.
Equivalent or clinically significant improvements in functioning from baseline were also found for two-thirds of participants who discontinued neuroleptic medication in Kane et al.’s (2007) study. One-third of these participants showed clinically significant declines in functioning. Both Kane et al. (2007) and Kramer et al. (2007) used the PSP and concluded that discontinuation was associated with worse functional outcomes overall when compared with medicated groups. The majority of participants in these studies had a diagnosis of paranoid schizophrenia, all were experiencing severe symptoms, and all were withdrawn from neuroleptic medication abruptly. These characteristics therefore limit the generalisability of conclusion to this population.

Therefore, while methodological problems and unsystematic measuring of outcomes limit the validity and reliability of findings, seven of the nine studies associate discontinuation with equivalent or better personal, social and occupational functioning when compared to baseline or participants maintained on neuroleptic medication. Discontinuation strategy was known for six of these nine studies; two used abrupt strategies and reported poorer outcomes compared with medicated participants and four used a graded or personalised approach and reported equivalent or better outcomes for this group. There might be a trend therefore, associating equivalent or better personal, social and occupational outcomes with non-abrupt strategies, however there are too few studies to draw firm conclusions.

The effect of duration of neuroleptic use on outcomes

Only three studies detailed duration of neuroleptic use before withdrawal, each with disparate designs (Chen et al., 2010, Johnson et al., 1983; Nishikawa et al., 2007). As such, evidence regarding the relationship between duration of neuroleptic use and functional outcomes associated with discontinuation remains absent.

The effect of withdrawal strategy on outcomes

Discontinuation procedure was recorded for ten of the thirteen studies. Four involved tapering neuroleptic medication to either total cessation or lowest feasible dose using individualised approaches (Chen et al., 2010; Nishikawa et al., 2007; Suzuki & Uchida, 2014; Wunderink et al., 2007/2013). Six involved abrupt discontinuation; all were RCTs (Beasley et al., 2006; Hamilton et al., 1998; Johnson et al., 1983; Kane et al.,
Two studies were naturalistic follow-ups therefore discontinuation was not experimentally controlled and details of withdrawal strategy were not reported (Moilanen et al., 2013; Harrow et al., 2012). This was also the case for a subgroup of participants in Wunderink et al.’s (2013) follow-up, who had stopped neuroleptic medication of their own accord. Dencker et al. (1980) did not detail discontinuation procedure.

Gradual discontinuation was associated with equivalent functioning from baseline to follow-up between medicated and non-medicated groups across the domains (Chen et al., 2010; Wunderink et al., 2007; Nishikawa et al., 2007) and within participants (Nishikawa et al., 2007; Suzuki & Uchida, 2014). At a seven-year follow-up, Wunderink et al. (2013) reported a move from equivalent functioning to greater functional remission in participants who had been randomised to the discontinuation strategy. A subgroup analysis of participants achieving successful discontinuation or substantial dose reduction (mean daily dose <1mg) revealed greater functional remission and recovery compared with participants maintained on neuroleptic medication.

Outcomes associated with abrupt discontinuation were inconsistent between and within studies, however there was a trend toward poorer functional outcomes when compared with medicated participants (Beasley et al., 2006; Johnson et al., 1983; Kane et al., 2007; Kramer et al., 2007; Nasrallah et al., 2004). Inconsistencies are likely to relate to differences in sample characteristics, length of follow up, and confounding variables.

The effect of follow-up duration on outcomes

Length of follow-up from withdrawal of neuroleptic medication ranged from 29 days to 20 years. Three studies completed long-term follow-ups (≥7 years) comparing participants who had discontinued from medication, or achieved substantial dose reduction (mean daily dose <1mg; Wunderink et al., 2013) with those maintained on neuroleptic medication (Harrow et al., 2012; Moilanen et al., 2013; Wunderink et al., 2013). All three studies reported statistically better functional outcomes for participants taking no or minimal doses of neuroleptic medication compared with participants taking neuroleptic medication ($P < 0.01$; $P < 0.001$; $P = 0.001$ respectively). These results indicate that the proportion of participants who had successfully withdrawn from
neuroleptic medication (35%; 33%; 33% respectively) did better functionally than those who were maintained on them. While the design of these studies conferred high relevance to the review question and good generalisability for the population studied, the lack of control over confounders and experimental data was a potential source of bias for all studies. This therefore limits the extent to which functional outcomes can be attributed to discontinuation rather than other variables, especially in Wunderink et al.’s study where 50% of participants were taking mean daily neuroleptic doses below 1mg. Further, these results represent the minority of people who had successfully discontinued.

Nishikawa et al. (2007) also completed long-term follow-ups (average 10.7 years). The authors found equivalent functioning from baseline to follow-up for all participants, regardless of whether discontinuation was achieved or neuroleptic medication maintained. This study had a small sample and received a global rating of weak, which limits how confident any interpretations of these findings can be. The percentage of participants who successfully discontinued in this study was 26.7%.

Short-term follow-ups (≤18 months) were more frequently associated with poorer functional outcomes when compared with medicated participants (Beasley et al., 2006; Johnson et al., 1983; Kane et al., 2007; Kramer et al., 2007; Nasrallah et al., 2004). Within group changes from baseline however, were not reported frequently enough to derive meaningful conclusions about the association between discontinuation and functional outcomes. The rate of successfully discontinued participants was clearly reported in Johnson et al.’s study, which was 20%.

**Discussion**

Mental health services have increasingly recognised that outcomes associated with recovery do not relate exclusively to the absence of symptoms (Shepherd, Boardman & Slade, 2008). The recovery literature highlights that service users want meaningful lives. For many people this includes symptom relief. Functional outcomes including productivity, employment, QoL and social functioning have also been identified as important (Pitt et al, 2007). This review highlights that functional outcomes are rarely measured in studies of neuroleptic discontinuation.
Several reasons can be suggested for this omission. The gap might reflect the dominance of the biomedical paradigm of psychosis, within which remission and recovery is equated with symptom relief (Andreason, 1985). Harvey and Bellack (2009) also acknowledge that it is easier to define the presence or absence of psychotic symptoms than conceptualise and measure functional outcomes or QoL. This is likely to contribute to the predominance of discontinuation studies that focus on relapse as the outcome of interest.

Correspondingly, this review revealed a lack of consensus regarding the conceptualisation, measurement and interpretation of functional outcomes, which limits meaningful comparisons. The use of measures that did not have established validity or reliability was also an issue for some of the studies.

Qualitative studies highlight that recovery is not an end result, as might be considered for symptom remission or relapse, but an ongoing process (Pitt et al, 2007). Within this review only four studies considered long-term functional outcomes (≥7 years) by comparing participants who successfully discontinued neuroleptic medication (range = 26.7% to 35%) with participants maintained on them. This finding corresponds with Leucht et al.’s (2012) systematic review, which highlighted that evidence regarding outcomes associated with discontinuation is based mainly on short-term studies. Three of the four long-term follow-ups in this review demonstrated better functioning for participants who were medication free than those who were maintained on neuroleptic medication and the other study indicated equivalent functioning. This evidence, albeit from only four studies, suggests that between one-quarter and one-third of participants might be able to function well following neuroleptic withdrawal.

There is a need for further research to understand the consistency of these results, and the direction of association between functioning and discontinuation to establish whether better functioning predicts successful discontinuation or is a consequence of it.

Many of the studies in this review reported equivalent functioning pre and post discontinuation within and /or between groups. Although these findings might be interpreted as rationale for the use of neuroleptic medication over discontinuation in the context of reduced relapse risk, service users might appraise these outcomes differently.
Research shows that service user discontinuation often occurs due to intolerable side effects or few perceived benefits (Mitchell & Selmes, 2007). It is therefore possible that maintained levels of functioning within the context of alleviated side effects could represent positive outcomes for some service users. Further research is therefore needed to understand participants’ interpretations of functioning, through greater use of self-report measures or qualitative methods.

Dedicated empirical guidelines for the withdrawal of neuroleptic medications are absent. Available literature however, recommends gradually tapering drugs during non-acute periods, with regular monitoring to optimise service user opportunities to become medication-free and to minimise adverse withdrawal effects (NICE, 2014; Hall, 2007). Only four of the thirteen studies in this review detailed a procedure where this advice was followed (Chen et al, 2010; Nishikawa et al, 2007; Suzuki & Uchida, 2014; Wunderink et al, 2007). Conversely, six study designs used abrupt discontinuation procedures, and three of these were studies of participants who were experiencing acute exacerbations of psychosis. This review found a trend toward poorer outcomes associated with abrupt discontinuation, but in keeping with the findings of a previous review (Leucht et al., 2012), functional outcomes associated with discontinuation strategy were mixed.

A specific challenge facing discontinuation research therefore, is related to the study design. An ideal design has been suggested as a fixed dose RCT comparing a discontinuation group with a group maintained on neuroleptic medication and matched for confounders (Undurraga, Murru, & Vieta, 2014). An advantage of this design is that it is likely to afford high experimental quality, a condition highlighted as problematic during quality appraisal for this review. In practice however, this approach does not afford personalised withdrawal strategies or the recommended conditions for participants to discontinue neuroleptic medication, which would reduce the clinical relevance and ecological validity of findings.

One study (Wunderink et al, 2007) used an individualised approach of dose reduction and discontinuation where feasible within an RCT design. Although this resulted in limitations for conclusions as half the participants in this group remained on low doses
of neuroleptic medication, it presented a more clinically and experimentally relevant design than most of the studies in this review.

It is possible that not every available article on the subject of functional outcomes associated with neuroleptic withdrawal will have been retrieved, despite the best efforts of the research team to do so. It is also unlikely that all studies investigating the review question will have been published, as non-publication of research is known to be common (Jones et al., 2013). This can relate to publication bias, where findings that support a particular view are more likely to reach publication than either studies with non-significant results, or results that do not support the view in question (CRD, 2009). This might be an area of weakness for this review, as this type of bias is known to have affected trials of psychiatric drugs (Turner, Matthews, Linardatos, Tell, & Rosenthal, 2008). The conclusions of this review are therefore based only on the available material.

A related limitation of this review is the risk of sponsorship bias. Important discrepancies have been identified between findings of psychiatric clinical trials with and without pharmaceutical industry support. Perlis et al. (2005) found that positive findings, i.e. effectiveness of trial medication over placebo or comparator, were nearly five times more likely to be reported in trials with pharmaceutical industry sponsorship than without. They also reported that 60% of trials reviewed were completed with such sponsorship, and 47% had at least one author with a financial conflict of interest. Consistent with this finding, seven of the thirteen studies identified in this review were completed with pharmaceutical company sponsorship (Beasley et al., 2006; Chen et al., 2010; Hamilton et al., 1998; Kane et al., 2007; Kramer et al., 2007; Nasrallah et al., 2004; Wunderink et al., 2007); therefore this bias might weaken the strength of the evidence.

Challenges were experienced in synthesising the data because of the differences in the conceptualisation and measurement of functional outcomes. The diversity of the studies identified further limits the findings of this review. Various measures of functioning and discontinuation strategies were used; participant characteristics regarding phase of illness were mixed; and length of follow up ranged widely. It was therefore unfeasible to draw reliable conclusions about the association of discontinuation with functional outcomes in current research.
Outcomes associated with neuroleptic withdrawal might differ in research settings from those in the ‘real world’ due to biases relating to both participant-factors and research methods (Gilbert, 1995: p.184). In an attempt to overcome this issue and ensure that studies completed in naturalistic settings were not overlooked, the study design inclusion criteria set for this review was broad. Studies therefore included RCTs, cohort studies and case studies. Although this strategy afforded access to a greater pool of data, the methodological quality was found to be weak or moderate in all but one of the included studies. There were also few studies retrieved, therefore understandings of functional outcomes associated with discontinuation in ‘real world’ settings remains limited.

Another limitation of this review is that many of the studies included did not report on the functional outcomes of participants who were reinstated on neuroleptic medication; in these cases associations are limited to a subgroup of successfully discontinued participants.

Evidence regarding the impact of discontinuation or maintenance neuroleptic use on employment status was mixed; therefore further research is required to better understand whether discontinuation affects this domain of functioning. Further research would also be beneficial to understand whether duration of neuroleptic use before discontinuation has an effect on functional outcomes as there were insufficient studies reporting on these variables to permit data synthesis.

Greater reporting of clinical significance for within-group changes in measures of functioning and QoL would be beneficial to allow more meaningful conclusions to be derived regarding the impact of discontinuation or maintenance neuroleptic use on participant functioning (Kazdin, 1999). Designing studies in line with NICE guidelines would also improve the clinical relevance of research findings.

Conclusions
This review identifies that there is some evidence to suggest that poorer functional outcomes might be associated with discontinuation of neuroleptic medication in certain conditions, including when neuroleptic medication is withdrawn abruptly, when functioning is measured soon after discontinuation and when participants are acutely...
unwell. There appears to be a trend toward better outcomes when there is a clear discontinuation strategy that can be adapted to suit participants. The rates of participants withdrawing successfully appears to increase with time and positive functional outcomes were also reported more frequently over longer follow-up periods. These conclusions are to be interpreted cautiously as they are limited by the paucity of studies, flaws in methodological quality, low generalisability, disparate research designs, and diversity in the measures of functioning used.

A clear understanding is yet to be reached therefore, regarding functional outcomes associated with discontinuation, the feasibility of withdrawing neuroleptic medications and the optimal conditions supporting discontinuation.
References


Paper 2.

Personal Accounts of Discontinuing Neuroleptic Medication for Psychosis

Paper 2 has been prepared for submission to Qualitative Health Research in accordance with the guidelines for contributors (Appendix 5).

Word Count (excluding abstract, figures, author biographies and references): 7876
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Abstract

We conducted this study to explore personal accounts of making choices about taking medication prescribed for the treatment of psychosis (“neuroleptics”). Service users frequently discontinue neuroleptics; therefore we specifically considered decisions and attempts to discontinue medication. We used a constructivist grounded theory approach to analyze transcripts from interviews with twelve participants. We present a preliminary grounded theory of the processes involved in making sense of choices within a continuation-discontinuation spectrum. We identified three overarching tasks as important in mediating participants’ choices. Forming a personal theory of the need for, and acceptability of, neuroleptic medication was undertaken simultaneous to negotiating the challenges of forming alliances with others, and weaving a safety net to safeguard wellbeing. Progress in the tasks reflected a developmental trajectory of becoming an expert over time and was influenced by systemic factors. Our findings highlight the importance of developing resources for staff to facilitate service user choice.

Keywords
Schizophrenia; bipolar; decision making; adherence / compliance; health and well-being; health care, culture of; users’ experiences; interviews, semistructured; lived experience; recovery; medication; mental health and illness; psychiatry; psychology; psychosocial issues; qualitative analysis; grounded theory
Introduction

Every year in the United Kingdom, approximately one person in every two thousand enters mental health services with distressing experiences commonly termed psychosis (National Health Service [NHS], 2014). These experiences include hearing voices, having unusual beliefs, and being confused or apparently out of touch with reality (National Institute for Health and Care Excellence [NICE], 2014). The main treatment for psychosis is the use of neuroleptic medication\(^1\) (NICE, 2014). For many people, neuroleptic medication can reduce the intensity, frequency or distress associated with psychotic experiences (Rofail, Heelis, & Gournay, 2009) and it is recommended for acute treatment and relapse prevention (NICE, 2014). A pharmaceutical approach to treating psychosis is aligned with traditional biomedical models of mental health that emphasize symptomatic outcomes (Pilgrim, 2008). This approach is supported by an established evidence base demonstrating that neuroleptic medication is efficacious in reducing psychotic symptoms and relapse rates (Gilbert, Harris, McAdams, & Jeste, 1995; Leucht et al., 2012).

Many service users with psychosis are maintained on long-term neuroleptic medication. This approach is subject to debate and there are concerns amidst some researchers, clinicians, service users and service user groups that there is an overreliance on neuroleptic medication in mental health care (Morrison, Hutton, Shiers, & Turkington, 2012; Whitaker, 2004; Moncrieff, 2006; Hall, 2007; Read, 2005). Concerns exist within the context of emerging evidence that the effectiveness of neuroleptic medication might have been overestimated (Leucht, Arbter, Engel, Kissling, & Davis, 2009) and their toxicity underestimated (Moncrieff & Leo, 2010). Although many people experience benefits, up to 40% of service users have a poor response to neuroleptic medication and continue to experience moderate to severe psychotic symptoms (NICE, 2014). There are also considerable problems with adverse side effects, including insomnia, depression, difficulty thinking, sedation, and weight-gain (Williams & Pinfold, 2006). These have

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\(^1\) Neuroleptic medication is more commonly referred to as antipsychotic medication. Although both terms refer to the same group of drugs, the descriptions differ in the way the drugs are hypothesised to work. A drug-centered model of action suggests that the medication alters brain functioning and by suppressing or replacing experiences of psychosis, can offer useful effects (Moncrieff & Cohen, 2005). From this perspective the term neuroleptic is more accurate as it is does not assume the drug corrects an underlying disease or abnormal state with an ‘anti psychotic’ effect. Other researchers propose that such a disease-centered model of action does occur (Yilmaz et al., 2012). To avoid making assumptions where interpretations of the evidence are inconsistent, we use the term neuroleptic throughout this article.
been associated with psychological distress in some service users (Fakhoury, Wright, & Wallace, 2001). Prolonged neuroleptic use might also present clinical risks. Research has associated long-term neuroleptic use with reduced brain volume (Weinmann & Aderhold, 2010; Ho, Andreasen, Ziebell, Pierson, & Magnotta, 2011), tardive dyskinesia (Hill, 1986), metabolic events and cardiovascular disease (Newcomer, 2007).

Recent research has suggested that certain long-term outcomes might be better for some people who discontinue neuroleptic medication than for those who remain on maintenance doses (Wunderink, Nieboer, Wiersma, Sytema, & Nienhuis, 2013; Harrow, & Jobe, 2012; Moilanel et al., 2013); however these findings are limited by a small evidence base and methodological issues. There is growing evidence that some non-pharmaceutical treatments might be viable treatment options, such as psychological interventions (Calton, Ferriter, Huband, & Spandler, 2008; Morrison et al., 2011); however more research is required to understand the feasibility of these approaches. Studies show high rates of medication discontinuation among service users, indicating that neuroleptic treatment for psychosis is not universally acceptable to all. The Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) schizophrenia study demonstrated that 74% of people discontinued neuroleptics within 18-months of starting them. (Lieberman et al., 2005). Rates are also high in routine clinical care settings; one study showed 84% of participants discontinued their neuroleptic medication within a 33-month period (Kreyenbuhl et al., 2011), consistent with previous research (Cooper, Moisan, Gaudet, Abdous, & Gregoire, 2005; Mullins, Obeidat, Cuffel, Naradzay, & Loebel, 2008; Moisan & Grégoire, 2010). Significant numbers of people are observed to discontinue without professional involvement; this often occurs covertly and abruptly (Hogman & Sandamas, 2000; Read, 2005). Correlates of discontinuation include adverse effects, few perceived benefits, and reluctance to take neuroleptic medication long-term (Read, 2005; Mitchell & Selmes, 2007; Roe & Goldblatt, 2009; Darton, 2013).

This is an important clinical issue as neuroleptic withdrawal is associated with high risk of relapse (Gilbert et al., 1995; Leuch et al., 2012; Zipursky, Menezes, & Streiner, 2014) and can involve a number of adverse health consequences, collectively referred to as neuroleptic discontinuation syndromes (Tranter & Healey, 1998). Symptom return following withdrawal has traditionally been accepted to indicate the chronicity of
mental health problems and necessity of medication. Some researchers however, suggest that for some people adverse outcomes might relate to the process of neuroleptic withdrawal itself rather than represent the reemergence of an underlying condition (Moncrieff, 2006). Despite these inconsistencies, there is clear evidence that service users engaging in unsupported discontinuation risk withdrawing in an unsafe way, which might increase their vulnerability to additional physical and mental health difficulties and poor outcomes.

To date, neuroleptic discontinuation has been studied largely from a medicines adherence perspective and conceptualized globally as “non-adherence” (Dolder, Lacro, Leckband, & Jeste, 2003). Although biopsychosocial factors, including intolerable side effects, are often acknowledged by researchers as rational reasons to discontinue (Mitchell & Selmes, 2007), the majority of studies remain oriented to increasing adherence, rather than investigating discontinuation processes. As such, no evidence-based clinical guidelines exist regarding safe discontinuation strategies. Professionals suggest that this absence is likely to contribute to the reluctance of clinicians to support service users wishing to discontinue and limit service user perceptions of choice (Datta, 2013). Given the complex risk-benefit analysis involved in neuroleptic use for psychosis, informed choice and shared decision-making between professionals and service users, as recommended by NICE (2009, 2014) and the Department of Health (DH; National Institute for Mental Health England [NIMHE], 2008) is imperative. In practice however, collaboration is sometimes inadequate with some researchers finding that provision of choice can be poor (Olofinjana & Taylor, 2005; Hogman & Sandamas, 2000; Goossensen, Zijlstra, & Koopmanschap, 2007; Goss et al, 2008).

Only one study has been identified that reveals some of the processes involved in choosing to discontinue. Roe and Goldblatt (2009) proposed a five-stage linear model of discontinuation from the perspectives of seven individuals who were medication-free for at least one year. The model illustrates the importance of resolving conflict about adherence, resulting in a personal perspective on medication use. Roe and Goldblatt’s study provides valuable information about successful discontinuation processes. Research however, shows that attempts to discontinue are often unsuccessful or only achieved after multiple attempts (Read, 2005) and frequently have poor outcomes (Gilbert, 1995; Leucht et al, 2012). There is an urgent need therefore, to advance
understandings of how service users negotiate choices to identify the factors that mediate outcomes.

We aimed to address this gap by considering personal accounts of successful and unsuccessful attempts to discontinue neuroleptic medication prescribed for psychosis. We aimed to develop an understanding of the psychosocial processes underpinning service user choices about neuroleptic medication. We chose qualitative methods to explore these issues with a view to enhance professional understandings of the experiences, perspectives and priorities of recipients of neuroleptic medication. In raising awareness of these processes, we hope to support clinicians who wish to help service users make informed decisions about their treatment. This might also provide a foundation for the development of guidance and support for prescribers and service users.

Methods

Ethics
We obtained ethical approval from the regional NHS ethics committee (Appendix 6) and the Research and Development departments of four NHS Foundation Trusts (Appendix 7).

Sample
Participants were included in the study if they met the following criteria: eighteen years or over; had taken neuroleptic medication for psychosis for at least three months; had attempted to discontinue neuroleptic medication; were proficient in English; and able to provide informed written consent. Participants were excluded if they had an organic basis for psychosis; an organic cognitive impairment that would impede participation; were residing in an inpatient unit; or subject to a Community Treatment Order.

Recruitment
We recruited between 13th May 2014 and 23rd August 2014 in the North West of England. Once ethical approval was confirmed, we contacted managers, staff and facilitators of local voluntary mental health services, service user organizations and mental health charities to discuss opportunities to promote the study and recruit participants. We also provided information about the study to relevant professionals
(Appendix 8). A number of organizations displayed the study advert in their community spaces and emailed it to recipients on their mailing lists (Appendix 9).

We invited potential participants via the study advert to express their interest by contacting the principal researcher by email or telephone. For those who responded, the principal researcher assessed eligibility to participate then emailed or posted the participant information sheet to eligible participants to consider (Appendix 10). The principal researcher also obtained consent to contact their General Practitioner, Care Coordinator or Psychiatrist to complete a risk assessment (Appendix 11) and once this was complete arranged a face-to-face interview at a location convenient to the participant.

**Design**
A brief literature review revealed a dearth of evidence regarding the experiential processes of discontinuing neuroleptic medication. As little is known about the phenomenon, we used a qualitative, grounded theory design as its principles afford a vehicle through which the essence of human behavior concerning psychological and social phenomena can be understood (Chenitz & Swanson, 1986).

Within grounded theory, we took an epistemological stance of constructivism. This asserts that people construct their own understandings of reality as they participate in the world and assign meanings to their experiences (Charmaz, 2006). We considered this method and stance appropriate because it could provide us with the flexibility required to discover new understandings of discontinuation processes by exploring beyond predefined parameters of adherence to understand the perspectives of those who take neuroleptic medications (McLeod, 2011).

We considered the inductive reasoning implicit in grounded theory an advantage of the approach, as it would support the development of a preliminary theory of the phenomena that was “grounded” in the data. Specifically, the parallel processes of interviewing and constant comparative analysis in this approach allow theories to emerge from interviewees’ experiences, rather than be imposed on the data (Charmaz, 2006).
Grounded theory has been used in previous research to effectively explore experiences relating to medication taking in different populations (Cormier, 2012; Landier et al., 2011) and in psychosis research to understand how service users make sense of their experiences (Geekie, 2013; Jackson, Haywood, & Cooke, 2011). We therefore considered there was a strong rationale for using grounded theory in this study.

Procedure
The principal researcher obtained written consent (Appendix 12) then administered a short demographics questionnaire to participants (Appendix 13). Informed by a brief literature review, research team discussions and input from a service user consultation meeting we developed a topic guide to facilitate semistructured interviews (Appendix 14). This comprised eight broad topics: starting neuroleptic medication; experiences of taking neuroleptic medication; decision to stop or reduce neuroleptic medication; expectations and hopes; timescale of discontinuing; process of discontinuing; experience of discontinuing/reducing; and outcome.

Within each topic were a series of open-ended questions and prompts to elicit experiences. Charmaz (2006) advocates that interviews should take the form of a directed conversation; therefore the principal researcher’s questions were guided and reflexive to afford opportunities for participants to explore personal accounts within a flexible framework.

Consistent with grounded theory procedures of constant comparative analysis, the principal researcher conducted data collection and analysis in parallel. We reviewed the topic guide following each interview and made further iterations to accommodate participant generated areas of exploration and emergent themes in future interviews. The principal researcher ensured participants were fully debriefed following their interview (Appendix 15) and adhered to a distress protocol (Appendix 16).

Data analysis
Inductive design
Unlike deductive designs, where data is analyzed within a predetermined framework to elicit answers to specific questions, inductive designs start with the data and explore themes as they emerge. Using an inductive approach, we initially considered raw data in
detail, made links, and derived a data driven theory from the lived experiences presented. Specifics of the analysis process are discussed below.

**Immersion**

Grounded theory analysis requires researchers to “immerse” themselves in the data (McLeod, 2011). To achieve this, we undertook several stages of data analysis within the constant comparative method. The principal researcher listened to recordings and commenced memo writing and diagramming following each interview. Recording successive memos is considered an important process in synthesizing data and facilitating theory development (Glaser, 1998); therefore we continued this throughout the research.

Data preparation followed, which involved the principal researcher transcribing interview recordings verbatim. Riessman (1993) considers transcription a form of analysis itself due to the decision-making processes involved. This facilitated immersion and achieved insight and theoretical sensitivity into the data (Corbin & Strauss, 2008). The principal researcher continued this through close reading of transcripts, during which we undertook cross-case analysis to check reliability (Yin, 2003).

**Constant comparative analysis**

The principal researcher completed formal analysis within a framework of theoretical sampling. This involves a cyclical, constant comparative process of identifying meanings (codes), creating data summaries (memos), categorizing, and integrating these understandings to support theoretical integration.

**Line-by-line coding**

To achieve the goal of generating emergent categories and properties (Glaser, 1978) the principal researcher divided the data into units of meaning by line-by-line coding. To capture the nuances of the data and remain open to explanatory processes, the principal researcher gave multiple codes to single units of meaning and recorded in vivo codes where participants’ phrases exemplified a phenomenon.
**Focused coding**
We merged codes identified as synonymous into single codes to streamline the process then commenced focused coding. This involved the principal researcher identifying the most salient codes by comparing data with data, data with codes, and codes with codes.

**Categorizing**
We organized and synthesized salient codes to support category development and further theoretical integration. We identified core categories under which existing categories were linked or combined.

**Axial coding**
We considered a category an axial code when it connected all other core categories as an “axis.” This supported reintegration of the data following data dispersion into units of meaning during early analysis.

**Methodological rigor**
To enhance the quality of the study, we followed guidelines for qualitative research (Elliott, Fischer, & Rennie, 1999) and employed strategies to facilitate a systematic and rigorous approach. Keeping a reflective diary allowed us to maintain awareness of and bracket concepts considered inherent to us and not indicated by the data. This permitted reflexivity and theoretical sensitivity to be intrinsic in the research. A reflexive stance is endorsed by Charmaz (2006) and defined as the need to examine the extent to which researchers’ interests, assumptions and opinions influence their decisions, experiences and interpretations of the data. Other ways we achieved this was by responding reflexively to the issues inherent in the researcher-participant dynamic (Hall & Callery, 2001); for example we sought to minimize how much the data was influenced by our own perspectives by maintaining neutrality regarding the issues discussed (Glaser & Strauss, 1967). Regular meetings between the research team further afforded transparency about these issues and encouraged us to own our interpretations as constructions of the data (Charmaz, 2006).
Results

Data collection
Twelve participants, seven women and five men, gave consent to be interviewed. Participants were aged between 21 and 60 years; nine identified as white British, two as white-black African and one as white Irish. Participants had diverse experiences of taking neuroleptic medication; durations of use ranged from three months to forty years, and the number of attempts to withdraw ranged from one to six. Thirteen varieties of neuroleptic medication were either reduced or withdrawn by participants. Discontinuation strategies included stopping abruptly, tapering gradually and reducing the frequency of neuroleptic use. Four participants attempted discontinuation in conjunction with their prescriber, five unsupported and three with mixed experiences of collaboration. Outcomes of attempts varied; only two participants were medication-free at the time of interview. Of the ten who remained on neuroleptic medication, three stated intentions to continue neuroleptic use indefinitely and seven reported hopes to withdraw completely if possible in the future.

Analysis
The stories shared by the participants captured a range of experiences related to a continuation-discontinuation spectrum. Choices within this spectrum included continuing, reducing, switching, stopping, reinstating, and developing idiosyncratic approaches to using neuroleptic medication. A unified theoretical model emerged from the data identifying three overarching processes or “tasks” as pivotal when making choices about neuroleptic medication:

1) Developing a personal theory of the need for, and acceptability of, neuroleptic medication
2) Negotiating the challenge of forming alliances with others
3) Weaving a safety net to safeguard wellbeing

We found that an evaluative cycle informed the progression of the tasks and comprised the categories: “acquiring knowledge,” “evaluating information,” “developing and testing hypotheses,” and “making a change or staying the same.” The categories “completing costs-benefits analyses” and “negotiating the acceptability of taking
neuroleptic medication” interacted with the evaluative cycle and mediated the tasks. We found the tasks to be dynamically interrelated and linked by three axial codes: “becoming an expert,” “time,” and at the heart of the tasks, “making sense of choices.” See Figure 1.
Weaving a safety net to safeguard wellbeing

Negotiating the challenge of forming an alliance

Developing a personal theory of the need for, and acceptability of, neuroleptic medication

Evaluating Information

Making sense of choices

Costs-benefits analysis

Negotiating the acceptability of taking neuroleptic medication

*Making sense of choices

Making a change or staying the same

Developing & testing hypothesis

Acquiring Knowledge

Time

Figure 1: Model of sense making within a continuation-discontinuation spectrum

Becoming an expert
**Task 1: Developing a personal theory**

*Acquiring and evaluating knowledge*

The first task involved participants striving to understand the need for, and acceptability of, taking neuroleptic medication within the context of their lives by developing an evolving theory of these issues over time. This involved acquiring knowledge to support sense making. One participant describes the value of this: “I’ve always maintained that if you’ve got a mental illness . . . getting more knowledgeable about it somehow empowers your brain to sort itself out a bit more.” Other participants shared the opinion that proactively acquiring knowledge about mental health issues and medication was important in facilitating empowerment and recovery.

Opportunities for participants to become knowledgeable included receiving information (from professionals, peers, family, the media) and actively seeking information (researching the advantages and disadvantages of neuroleptic medication and the causes of psychosis on the internet and in books, questioning doctors or others perceived as knowledgeable). Mediating this process was the challenge of communicating with others, including mental health professionals and family. Overcoming this barrier involved developing skills and expertise in engaging effectively with professionals and learning about neuroleptic medication: “Over the years, you get better at talking to doctors and psychiatrists in particular . . . so you start asking questions and you start getting answers. Over the years I’ve got to know quite a lot about the medication.” This statement emphasizes the temporal nature of learning about treatment options.

Transitions from novice to increasing expertise were frequently captured in participants’ narratives and involved acquiring experiential knowledge: “I had no idea of any of them [non-pharmacological interventions]. You have to go through mental health services a bit to actually know what’s out there.” As novices to issues of mental health, gaps in knowledge were inevitable and participants described relying initially on information provided by professionals. The adequacy of this was often considered insufficient; consequently, some participants felt ill prepared for the subjective experience of taking neuroleptic medication and found it contrasted with their early theory of acceptability:
They gave me a little leaflet … but it didn’t tell me all the nasty side effects I’ve experienced since I’ve been on it. I didn’t know the half when I first took it, about how it was really gonna be.

Many participants considered that they had been better informed about the benefits of neuroleptic medication than the potential risks:

I don’t really remember much discussion about what kind of effect it was going to have on me in terms of this feeling of being hit by a truck . . . it was explained to me in terms of reducing the arousal and the agitation, uh, that was clearly explained to me.

The degree to which gaps in knowledge were bridged through acquiring information and experience over time mediated transitions from novice to expert and influenced theories of need and acceptability.

*Developing hypotheses*

Forming a personal theory involved participants taking an inquiring stance, which emulated a scientific approach to making sense of their experiences. Based on their developing knowledge, participants formed hypotheses about their need for neuroleptic medication. Like scientists, they sought answers to the questions that arose from hypotheses. Common questions related to the personal validity and utility of neuroleptic medication:

I’d done some research and looked into this stuff. “What exactly is this medication doing for me, what’s it doing to me?” . . . That information and my own experiences made me start questioning the validity of it for me personally. So I was questioning: “do I really need this medication?”

Making informed decisions is pivotal for service users in mental health care; however unresolved questions and ambivalent theories of need and acceptability presented barriers to informed decision-making. The transformative potential of establishing the truth was emphasized by one participant: “I’m a seeker of the truth, and I don’t want to be biased in any way, I want to stick to the truth. The truth will set you free.”
participant discussed truth in the context of wanting to weigh up the costs and benefits of neuroleptic medication when making decisions. The truth was described as having liberating qualities. In the context of making choices about neuroleptic medication, establishing clear answers to questions and forming a coherent theory of need and acceptability appeared important in resolving ambivalence about the continuation-discontinuation spectrum. Other participants discussed the right to form personal decisions:

Psychiatry put a lot emphasis on making sure people do take medication. And that might be alright if it’s like taking paracetamol to cure a headache, you know? It’s well established that paracetamol cures headaches and does very little harm whatsoever, but it’s not like that with psychotic medication and you can’t expect people to be willing to take it erm, without being able to make some sort of query or decision about it or whatever, dependent on their own experiences because the medication is, as I say it can be quite harmful.

Most participants demonstrated awareness of the risks associated with neuroleptic use. This quote highlights the complexity of making decisions within the context of psychiatric frameworks, which were perceived as emphasizing adherence. Other participants identified this as an issue that posed major barriers to collaborative care planning. The perceived reluctance of psychiatrists to explore service users’ personal theories of need and acceptability motivated many participants to advance their understanding by testing out hypotheses independently. This involved reducing or discontinuing neuroleptic medication without professional support, usually referred to in professional literature as “covert non-adherence.” One participant provided their rationale for this:

I was like, “well maybe let’s see where I’m at, see where I’m really at, where I am really, can I really take this stuff?” ’Cause I knew I didn’t want to have to take these pills for a long time, so I was like, “let’s see what I will be like in real life without being on them . . . if I come off the pills I’ll know how much I’m kind of, recovered.”
Testing hypotheses provided opportunities for participants to understand their need for neuroleptic medication better. By evaluating the outcomes of medication changes, participants became equipped with new insights into their experiences and real life examples to make sense of and progress their theories. For three participants, adverse experiences associated with withdrawing neuroleptic medication prompted resolutions to never attempt discontinuation again, as this participant explains:

I just wouldn’t do it again . . . But I suppose I’m glad I had that experience because, if I hadn’t had that experience I wouldn’t know, I could just be on a drug for the sake of being on it, couldn’t I?

Establishing a clear rationale for neuroleptic use was pivotal for all participants. Rationales were mediated by the way participants made sense of their experiences and were highly individual.

*Negotiating the acceptability of taking neuroleptic medication*

The acceptability of taking neuroleptic medication varied widely between the twelve participants; fluctuations were also apparent within individual experiences. A continuum ranged from total acceptance to total rejection, with the space between containing ambivalence, resistance, and compromise. The majority of participants recalled initial relief, hope and optimism when told by their treating clinician that their experiences were treatable with medication, as captured in the following statement:

I thought . . . “something can be done, this is like a thing, it’s not just me being a freak, this is a thing that people have and there’s a thing for it.” I had a very sort of reductionist attitude really in many ways. I thought, “well my brain doesn’t work, just as somebody’s heart might not work, so they go on, I don’t know, beta-blockers.”

Receiving professional explanations of psychosis and treatment gave many participants a way to make sense of their experiences, which fitted with cultural expectations of illness and cure and was both normalizing and validating. From a novice perspective, personal theories were often shaped by professional theories in a “top down” process. As such, early theories of acceptability and need were initially high in favor of
neuroleptic use for many participants and consistent with biomedical models of mental illness. This became the dominant theory for some participants and acceptability remained high: “So they [medical professionals] were saying this [psychosis] is a chemical imbalance, and I’ve no other explanation, that’s good enough for me. I think it is a chemical imbalance and the tablets help to counteract it.” Others reevaluated initial assumptions as their early theory was challenged by new experiences and knowledge:

It [Risperidone\(^2\)] did start to sort of lessen the paranoia and hearing voices . . . But I also started thinking, “I need to sort me mind out properly” and that’s why I started paying to go to therapy . . . I want it to be sorted out properly, I can just limp on for what’s left of me life, or I could actually sort of take control.

This quote captures the desire many participants had to exert autonomy over their lives, take control of their recovery and make sense of their experiences using a “bottom up” approach. Related processes, including stage of expertise and perceptions of power mediated the continuum of acceptability. In one participant’s words:

I didn’t really have any understanding about them [neuroleptic medications], I just knew that I didn’t like them . . . I didn’t like the effect they had on me, I didn’t like the fact that I was told that I was psychotic and had to take them. I was very, uh, resistant to taking them. There wasn’t much information . . . there just wasn’t.

Making sense of experiences was limited for this participant by lack of information and a non-collaborative approach by clinicians to exploring psychosis and medication. Adverse effects were their main source of knowledge and formed the basis for their personal theory of need and acceptability. Systemic variables echoed throughout the narratives and were found to mediate progress in all three tasks. Subsequently choices about neuroleptic medication were often shaped according to whether systems facilitated or hindered sense making.

\(^2\) All medication names cited by participants are neuroleptic medications.
Cost-benefits analyses

A process evident in all participants’ narratives involved completing costs-benefits analyses of choices. Most participants discussed adverse effects as tipping the balance in favor of discontinuing. These were often perceived as producing paradoxical difficulties, as illustrated in this reflection on a personal experience: “If you have body image issues and eating issues and then they put you on a tablet that just makes you balloon then it’s obviously going to affect your mental health.” This exemplifies how the balance of costs and benefits is highly individual; yet for many participants, important personal costs of continuing neuroleptic medication were experienced as being overlooked by services. For some, important losses were identified during cost benefits analyses: “I became very reclusive, had no energy, no get up and go, my same power, same vibrancy had gone. I just had a real non-existence.” Drawing comparisons between experiences on and off medication helped participants identify their values and goals, and gauge the distance between their ideal circumstances and current situation. Participants could then evaluate what role, if any, medication played in facilitating or hindering the achievement of their goals or values.

Task 2: Negotiating the challenge of forming alliances

The desire to understand whether medication was needed and if so, in what dose, was of foremost concern to participants. Simultaneously most participants aspired to develop a shared understanding with others, particularly their treating clinicians whose opinions were perceived as influential. One participant discussed the conditions they perceived necessary to discuss discontinuation with a psychiatrist: “They’d have to listen to me, take my suggestions seriously, take me seriously. Really understand the nature of the illness properly, rather than just the medication side. Because that’s what psychiatrists do really, isn’t it?” A discrepancy was highlight by participants between personal approaches to making choices, guided by theories of need and acceptability, and the limitations of the pharmaceutical approach. A challenge discussed by all participants in varying degrees was experiencing that their perspectives were heard and understood by others, including GPs, mental health professionals, family and friends; this presented barriers to forming alliances.
Forming an alliance or going solo

The desire to reach out to others in the context of collaboration barriers presented a dilemma for many participants about involving others in decisions to discontinue. The dilemma was resolved with the following solutions: “forming an alliance” or “going solo.” Although juxtaposed, these approaches were not static; many participants chose going solo at some point, however this often followed unsuccessful attempts to form alliances, as this participant experienced:

You sort of speak to the doctor and say “I’d like to come off this medication” and what happened to me . . . they said “we won’t take you off this medication that you want to, the Olanzapine, but we will try and take you off a different medication.” Well that wasn’t what I wanted. So if I was feeling like I was a few years back, what I’d now do was go home and stop taking the Olanzapine . . . “because you’re not going to help me.”

For many participants, forming alliances with professionals was hindered by medication being prescribed and managed in a way that established a perceived power imbalance. This dynamic resulted in some participants feeling coerced into taking medication and out of control. For one respondent, going solo was seen as a way to reestablish autonomy: “By doing that [discontinuing] . . . I’d claw back some control of my own life from the doctors and psychiatrists that had taken it away from me by forcing me to take the medication.” Themes of feeling controlled, dismissed and deprived of independence were prevalent within this sample, whether experienced as subtle suggestions of inequality or as being at the mercy of a powerful, paternalistic system. In contrast, there were participants who were able to form effective alliances without these issues. The following statement is from a participant who initially went solo, then formed an alliance during discontinuation:

Having the support of my doctor who didn’t take a hard line with me and say “you must go back on your medication,” that in itself was very helpful. ’Cause I think if he’d said otherwise, that would have been very difficult. And one of the reasons I didn’t tell him initially was because I was scared that he would take that line. I was scared that because of previous history he might have had me
sectioned or . . . said “oh you can’t you’ll have to go back to statutory services because you’re too high a risk.”

This participant evaluated the value of collaboration and support, while being aware of alternative, restrictive and coercive practices, the fear of which guided their initial approach. When the option to discontinue neuroleptic medication was not explicit, participants were left with uncertainty regarding the level of support they could expect from clinicians.

*Predicting responses*

Resolving uncertainty about the potential for alliances involved participants predicting, inferring or anticipating the likely attitudes, opinions, and responses of others. This was completed through the lens of experience and direct feedback; it involved putting oneself in the shoes of others to understand their perspectives, as one participant explained: “Doctors have to be risk averse. He’s saying exactly the same things I’d have said in his position . . . they have every right to do that, even if it’s not what I wanted to do.” Many participants predicted that others’ views on discontinuation would be discrepant with their own theories of need and costs-benefits analyses. Where discontinuation was concerned, support from others was often appraised as unavailable or conditional on adherence, which narrowed the scope for supported discontinuation:

> If I told my mum, who lives nearly 200 miles away, she’d have panicked and she’d have been like, “oh you can’t not take your medication” and du-du-du, “Doctor’s know what they’re talking about”. You know mums. “Uh, I’m the one living with it”.

Predicting panic, concern or resistance was common in this sample and gave rise to emotional conflict regarding choices. Concealing attempts and going solo often resolved this conflict. The majority of participants recognized the potential value of forming alliances and the limitations of going solo:

> I didn’t have too many people to discuss it with, to get a sounding board for whether it was wise or not. There’s an old testament phrase which I value, which says, “lean not to your own understanding,” and I had to, because if you just
have yourself to debate with or think about or decide what’s a course of action, you, you might be going doolally and make a wrong decision.

This participant deviated from their personal values in the context of perceived collaboration barriers; however they implied that developing shared theories of need and acceptability has the potential to support wise decisions. When support was deemed unavailable, unwise decisions or adverse outcomes became more likely:

At the end of the day it should be an individual’s choice what they put into their body and I’m making a choice and I mean, whether that choice is good or bad? But if you were given more support to make the choices, then they’d probably be less disastrous because you wouldn’t just be left on your own doing it by your own means.

This emphasizes how participants attributed importance to personal choice and how effectively formed alliances were considered pivotal in facilitating choice and optimizing positive outcomes.

**Task 3: Weaving a safety net to safeguard wellbeing**

All participants acknowledged the risks of withdrawing neuroleptic medication. This awareness often increased following discontinuation attempts. Equipped with experiential knowledge, many participants reevaluated their expectations, as this participant discussed:

When you attach so much importance to medication, you know it’s often a let down as to what your life’s going to be like, because it’s, it’s not like opening the gateway to heaven . . . if anything you’re more vulnerable . . . because you don’t have that cushion.

As participants developed expertise and awareness of the risks, many took precautionary steps before removing the “cushion” of neuroleptic medication. Two participants described this as weaving a “safety net.” Weaving a safety involved participants identifying and drawing together resources to safeguard their psychological
wellbeing during this potentially vulnerable time. For some, safety nets existed to catch them in case attempts proved problematic, for example keeping a supply of medication or self-monitoring:

People need support but they also need information, and the goal may not necessarily be to come off completely. It might be to be on low doses, you have some control and recognize if you feel, you or your family think you’re going “off,” take some more of the stuff temporarily until you put up the support mechanisms in place.

Other participants’ safety nets comprised contingency plans and constructive strategies aimed at optimizing success. One participant referred to this as standing a “fighting chance” alluding to the struggle involved in withdrawing. Medication was also considered a “stitch in the net” of an overall approach to supporting mental wellbeing. Unanimously, participants believed that medication should not be the only approach to mental health, as one participant explained: “So the drug has helped reduce the fear but then they’re not the only thing that should be relied upon to reduce fear. Cognitive behavioral therapy should be used, support of family and friends.”

The safety nets in this study were woven with many strands. Successfully formed alliances (family, friends, professionals); peer support (self-help groups, community groups); practical resources (having written indicators of relapse to aid self/other-monitoring of mental health); access to alternative treatment (talking therapy); skills in relaxation; healthy lifestyles; and access to resources online or in libraries were some of the elements described by participants’ to serve as ideal safety nets. A condition binding the strands together was knowledge:

The knowledge of all the various other things, it’s like the safety net is getting stronger because you’ve got so many other things that are in place, that if something does go wrong because you’ve come off the medication, then other things’ll compensate, you know, other things in your life are there.

Weaving a safety net offered a way for participants to act according to their personal theories of need for, and acceptability of, medication, while managing conflicting
emotions of hope and fear, confidence and doubt. Safety nets provided a way to safeguard against losses and threats identified during costs-benefits analyses. As participants became experts in making choices about neuroleptic medication, both the importance of weaving a safety net, and the strength of the net was perceived to grow.

The conditions that weakened safety nets or prevented them from being created were also recognized. These included limited resources within the NHS, unhealthy lifestyles and social isolation. Going solo was perceived a vulnerability factor but in the context of choice was often considered unavoidable, as this participant empathized:

It’s a really common situation for people to be in, that they’re on those medications and they’re finding such horrible side effects and want to come off them and aren’t getting the help that they need to. Maybe their GP doesn’t feel confident to, to sort of do the reduction thing for them and maybe . . . you’d have to do it on your own, wouldn’t you?

The choice to discontinue was often experienced as not an option within mental health services. Experiencing professionals as risk-averse to discontinuation and relapse was a barrier identified by many participants, which negatively influenced progress in the tasks:

I wish instead of immediately putting me on medication, they spent some time trying to talk to me, some kind talking therapy . . . to see if there was a way I could learn to manage my symptoms that way, without having to go straight back on the medication . . . because in many ways I was coping . . . I might have come to understand things better and come round a bit better without having to be back on medication.

Reinstating medication in response to the reemergence of symptoms was not consistent with this participant’s preference and priorities, which involved taking a more explorative approach, encompassing values of self-efficacy and autonomy. This suggests that responses aligned with biomedical understandings of psychosis and values of symptom reduction might limit sense making for some service users. For several
participants, personal theories of the need for, and acceptability of, medication remained incomplete.

**Discussion**

In this research we sought to understand the psychosocial processes relevant to service users when making choices about neuroleptic medication. We discovered three overarching tasks as pivotal in making sense of choices within a continuation-discontinuation spectrum. The first task, “developing a personal theory of the need for, and acceptability of, neuroleptic medication” is in keeping with previous research that identified “developing a personal perspective on the use of medication” as an end stage for people who had successfully discontinued neuroleptic medication (Roe and Goldblatt, 2009). Our findings extend Roe and Goldblatt’s conclusions by identifying the core issues considered in personal theories and two interrelated tasks. The model we present also illustrates that making sense of choices is neither a linear nor static process; instead choices vary over time on developmental trajectory toward becoming an expert (see Figure 1).

Mental health professionals are increasingly using clinical formulations to collaboratively make sense of people’s experiences within the context of biological, social, psychological and systemic factors (Johnstone & Dallos, 2006). Similarities were evident between formulation-based approaches and the way participants’ constructed personal theories of medication use. Our findings are consistent with Kelly’s Personal Construct Theory (Kelly, 1963). Kelly emphasized that humans have a fundamental need to understand their personal psychology and discover truths about their experiences. Evoking Kelly’s analogy of people as scientists, the participants in this study sought to understand the validity and utility of neuroleptic medication within the context of their lives, by testing hypotheses and developing personal theories of the need for, and acceptability of taking medication. Within this understanding, intentional non-adherence can be reframed as truth seeking, which is completed alone or in collaboration. This finding is consistent with a metasynthesis of medicine taking in general health (Pound et al., 2005) and emphasizes the need for personal expertise to be embedded in service delivery and treatment. This aligns well with discourses in mental health settings that recognize service users as experts by experience (DH, 2001).
The majority of participants in this study experienced mental health services as risk-averse where discontinuation was concerned; this culture posed barriers to collaborative care. Although participants recognized the value of having a sounding board and the pitfalls of making decisions in isolation, many experienced professional or social support as conditional on adherence. This often resulted in participants going solo in discontinuation. Although this approach might be successful for some, service users are more likely to experience chaotic or disappointing outcomes without support and guidance. These outcomes conflict with the current recovery focus in mental health; therefore risk-averse, adherence frameworks might inadvertently set many service users up to fail. Some participants had resolved to never attempt discontinuation again; research however suggests that successful withdrawal often only occurs after multiple attempts (Read, 2005). When participants felt supported in making decisions about discontinuation, there were clear benefits.

Risk-aversion has been explored from practitioner perspectives where parallel issues emerged (Tickle, Brown, & Hayward, 2014). Tickle et al. found that concepts of risk within mental health services focused narrowly on avoiding harm and danger. Subsequently, practitioners felt limited in their ability to implement recovery-oriented approaches. Tickle et al. also discovered that professionals overlooked iatrogenic effects of psychiatric medication when evaluating risks. Our findings conversely, indicate that side effects were important factors in participants’ costs-benefits analyses and contributed considerably to theories of need and acceptability.

The implications of a risk-averse culture can be understood within the theoretical perspective of symbolic interactionism (Mead, 1934; Blumer, 1969). This assumes that people strive and act toward what represents meaning for them. Participants’ actions were guided by personal theories of need and acceptability, therefore going solo became more likely when participants perceived incongruence between the meanings guiding them and others, including family and professionals. This is likely to be exacerbated by traditional adherence/non-adherence dichotomies, which can create the experience of imposed compliance in service users (Usher, 2001) and might imply that being medication free is not an option. The problem of unsupported discontinuation might therefore be maintained by the mental health system.
Previous research has identified the importance of completing costs-benefits analyses when forming attitudes about neuroleptic medication (Roe and Goldblatt, 2009; Wiesjahn, Jung, Lamster, Rief, & Lincoln, 2014). Our findings have also shown that emotional conflict or “cognitive dissonance” (Festinger, 1962) can be elicited when analyses favor one course of action, yet costs of the decision remain significant. Participants sought to reduce this conflict by “weaving a safety net to safeguard wellbeing” against perceived costs of continuing or discontinuing medication, a solution-focused approach consistent with Festinger’s theory.

**Recommendations**

Supporting service users to be active partners in their care and management of medicines is advocated in national policies (NIMHE, 2008; Healthcare Commission, 2007; NICE, 2009, 2014). Collaboration has the potential to afford safe, meaningful opportunities for service users to experience control, autonomy and self-efficacy in their treatment and recovery (Shepherd, Boardman, & Slade, 2008). This approach implements recovery principles and contrasts with the alternative, more common approach identified in research and replicated in this study, where service users resort to going solo in discontinuation attempts (Read, 2005).

To facilitate recovery-oriented practice that supports informed service user choice and reduces rates of unsupported discontinuation a paradigm shift is required, as called for by Morrison, Hutton, Shiers and Turkington (2012). There are strong rationales from service user perspectives and national policies for services to move away from risk-averse cultures that limit neuroleptic medication management to increasing adherence, toward collaborative, person-centered models of choice within a continuation-discontinuation spectrum. The three tasks identified in this research form the basis of three main implications for clinical practice:

1) Practitioners should facilitate the development of individual formulations to guide the treatment of psychosis.

2) There is a need to form empathic, collaborative, non-judgmental alliances with clients; this must ensure that the choice to be medication-free is communicated.
3) There should be an emphasis on supporting service users prescribed neuroleptic medication to create effective, personalized care plans or safety nets.

The implementation of these recommendations is likely to be complicated as there are no evidence-based clinical guidelines for prescribers to support safe discontinuation (Datta, 2013). This is likely to limit how confident professionals feel in supporting service users choice. An evidence-based protocol to guide clinicians in supporting safe choices within the continuation-discontinuation spectrum is urgently needed. This should include:

- Information to support balanced and realistic costs-benefits analyses of choices that elicit service user preferences and values. Patient Decision Aids (Coulter & Collins, 2011) and harm reduction approaches (Hall, 2007) might facilitate this.
- Information about alternative psychosis interventions available to facilitate informed choices about treatment.
- Resources to support the development of personalized safety nets or care plans for continuing or discontinuing neuroleptic medication.
- Guidelines and staff training on how to facilitate safe withdrawal that is aligned with service user preferences.

**Limitations**

Although we took steps to minimize the amount of bias the data was subjected to by adhering to guidelines for qualitative research (Elliott, Fischer, & Rennie, 1999), there are potential limitations to this study. We recruited the sample from the North West of England; therefore it would be beneficial to use the variables we have identified to develop a survey for mass distribution, to evaluate experiences in different geographical and cultural settings. Although we aimed for theoretical sensitivity by using processes of reflection, reflexivity and cross coding, the interpretations will inevitable have been influenced by our views. This is true of all qualitative research and within a constructivist epistemological stance we acknowledge that the theory we present is only one possible interpretation of the data (Charmaz, 2006). Our inclusion criteria did not specify a limit to when discontinuation attempts occurred. Although this has the advantage of capturing a range of experiences, future research would benefit from
positioning accounts within the current socio-political and service provision context by specifying recent timeframes for attempts. Further research on professionals’ experiences of supporting service users in neuroleptic discontinuation would be useful to test the following hypothesis: professionals with shared understandings of service users’ personal theories of need and acceptability, and co-ownership of their safety nets feel more able to engage in positive risk taking and move away from risk-averse, adherence-focused treatment to facilitating service user empowerment.

Author Biographies

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Dr Sara Tai is a Senior Lecturer in Clinical Psychology at the University of Manchester and practicing Consultant Clinical Psychologist. She has twenty years experience working within acute psychiatric in-patient services, community mental health teams and early intervention psychosis services. Her research is predominantly focuses on the theory and practice of transdiagnostic psychological interventions for psychosis and bipolar disorders and mood-swings.
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Paper 3.

A Critical and Reflective Review of Papers 1 and 2: A Systematic Review and an Empirical Study on Discontinuation of Neuroleptic Medication for Psychosis

Word count: 7695
Overview

Neuroleptic medication is the cornerstone treatment for psychosis and clinical guidelines recommend neuroleptic use for both acute psychosis and relapse prevention (National Institute for Health and Care Excellence [NICE], 2014). Many service users choose to discontinue neuroleptic medication however (Lieberman et al., 2005; Kreyenbuhl et al., 2011), which presents a complex clinical issue. Evidence regarding the risks associated with neuroleptic withdrawal is well established and the majority of research in the field advises against discontinuation (Gilbert, Harris, McAdams, & Jeste, 1995; Leucht et al., 2012). Although the choice to withdraw from neuroleptic medication is included in NICE guidelines (2014), there are no evidence-based protocols for clinicians to support service users in this challenging task (Datta, 2013). As such professionals are often reluctant to support withdrawal (Read, 2005) and discontinuation frequently occurs covertly (Mitchell & Selmes, 2007), without professional guidance (Hogman & Sandamas, 2000), and within a climate of fear and uncertainty (Read, 2005).

In contrast with the extensive research that has been conducted into adherence and symptomatic outcomes associated with discontinuation of neuroleptic medication (Byerly, Nakonezny, & Lescouflair, 2007; Gilbert et al., 1995; Leucht et al., 2012, Zipursky, Menezes, & Strainer, 2014), there is a paucity of research into the psychosocial processes involved in service user choices about neuroleptic medication and the functional outcomes associated with discontinuation.

I have aimed to address these gaps in this thesis by exploring the discontinuation variables highlighted by service users as relevant. Paper 1 is a systematic literature review conducted to identify and synthesise evidence regarding functional outcomes associated with neuroleptic discontinuation. Within the systematic review, I have considered the domains of functioning that have been investigated in discontinuation research, the measures used, the effect of discontinuation procedures, and the effect of follow-up duration on outcomes.

In Paper 2, I have explored the psychosocial processes involved in making choices about neuroleptic medication using a qualitative, constructivist grounded theory approach. Choices reflect a process of sense making relating to a continuation-
discontinuation spectrum. This spectrum includes continuing, reducing, switching, stopping, reinstating, and developing idiosyncratic approaches to the use of neuroleptic medication. A preliminary grounded theory emerged, which identifies three tasks as pivotal to participants engaging in this process. The tasks are translated into recommendations for professionals that identify the optimal conditions and resources required to introduce and support informed choice and service user empowerment within a recovery-oriented approach.

In this paper (Paper 3), I provide a critical appraisal and reflective account of my experiences conducting the two distinct but related research studies. I have reviewed my choice of research area, the methodological decisions I made for each study, the alternative methods I considered, the strengths and weaknesses of my studies, and the clinical implications for practice and future research. I have also reflected on how the process of undertaking a systematic review and empirical study has contributed to my personal and professional development.

**Reflections on paper 1: a systematic review**

**Rationale for the review**

During preparation for my empirical study, I became aware of the high rates of service user discontinuation of neuroleptic medication, which was 84% in one study of participants in routine clinical care settings (Kreyenbuhl et al., 2011). Many explanatory factors have been proposed for the prevalence of discontinuation, including service users experiencing intolerable side effects and few perceived benefits (Mitchell & Selmes, 2007; Read, 2005). I was therefore motivated to understand the evidence base guiding recommendations for the use of neuroleptic medication in managing acute psychosis and as an ongoing maintenance treatment (NICE, 2014). I discovered a wealth of studies investigating relapse, hospitalisation and symptom recurrence as outcomes of interest in neuroleptic withdrawal studies, as synthesised in systematic reviews and meta-analyses (Gilbert et al., 1995; Leucht et al., 2012; Zipursky, Menezes, & Strainer, 2014). These studies contribute to the evidence base supporting the use of neuroleptic medication for relapse prevention. Through reading qualitative articles and literature within the recovery movement I became aware that many service users have identified treatment outcomes associated with rebuilding life and functioning as more meaningful than symptom management (Pitt, Kilbride, Nothard, Welford, & Morrison,
A scoping study revealed that a number of studies had investigated functional outcomes associated with discontinuation, but I identified no systematic review synthesising the evidence. Given that these were service user priorities, the research team and I considered that there was a strong rationale to complete a systematic review to address this topic.

**Reflections on the systematic search**

I used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) principles (Moher, Liberate, Tetzlaff, & Altman, 2009) throughout this research to ensure the search, screening process, selection of articles, quality appraisal, data synthesis, and reporting were systematic and transparent (Appendix 2). I aimed to generate an efficient search strategy that captured as many relevant articles as possible. Initial strategies returned unmanageable numbers of records, but refinements of the search terms afforded an efficient strategy that was not too narrow. This was important, as I did not want to miss articles.

To ensure my search terms accurately captured the phenomena I was interested in for this review, I familiarised myself with the literature on discontinuation, withdrawal, adherence and functional outcomes. Definitions of functional outcomes are often not clear or used comparatively (Harvey & Bellack, 2009). To most accurately reflect the current literature around functioning in psychosis research, I mapped my terms from key papers (Andreasen et al., 2005; Schennach, Musil, Moller, & Riedel, 2012; Karow, Moritz, Lambert, Schottle, & Naber, 2012; McEvoy, 2008). Although this ensured a clear focus for the review, the search strategy and citation searching might not have captured articles that employed different terms and understandings of “functional outcomes.” The systematic search might have benefited from measures of functioning being included in the outcomes category, for example the Personal and Social Performance Scale (PSP: Morosini, Magliano, Brambilla, Ugolini, & Pioli, 2000). However, due to the huge number and range of measures available, this was not considered feasible.

Although I was aware of common neuroleptic medications, I was surprised at the sheer variety of first and second-generation neuroleptic medications in production. To ensure a thorough search strategy, I used the British National Formulary (BNF, 2014) to
identify neuroleptic trade and generic pharmaceutical names. This list also formed the basis for a brief participant questionnaire in the empirical study. Although this strategy might have missed articles investigating discontinuation of neuroleptic medications no longer in circulation, these articles would have been limited in their clinical relevance; I therefore consider the search was appropriate.

To ensure record-searching identified articles that were relevant to a clear and focused review question, I set detailed inclusion and exclusion criteria, which I discussed in supervision. A potential disadvantage of such a focused criteria is that some sources of information might have been excluded; for example, studies published in non-peer review journals, unpublished literature, or reports written in languages other than English. These might have offered important insights into the subject; however I consider the parameters I set have afforded me the opportunity to identify a well-defined set of articles to review. Furthermore, this review can be replicated in the future to monitor progress.

**Screening**

My scoping search identified that the majority of articles considering neuroleptic discontinuation had relapse, hospitalisation or adverse events as primary outcomes. Where functional outcomes were measured, they were often secondary to symptomatic outcomes and not referred to in the title. To avoid missing relevant articles I completed the title screen alongside an abstract screen. This proved an arduous task; however it increased my confidence that I had systematically identified as many relevant articles as possible. There is a risk however, that I might have missed some articles that measured functioning associated with discontinuation but did not indicate this in the title or abstract.

During full text screening I encountered a reporting bias in some research. This involved absent or incomplete reporting of functional outcomes when they were investigated secondary to symptomatic outcomes. This was particularly apparent for randomised controlled trials (RCTs) measuring neuroleptic efficacy. The phenomenon of discontinuation also presented challenges during the screening phase due to the diverse ways that it has been conceptualised and researched. For example, many authors considered discontinuation broadly as “non-adherence,” however definitions included...
medication use between 0 and 75% of the time, therefore studies were excluded on this basis. Careful differentiation was also required between studies that measured functional outcomes following discontinuation of neuroleptic medication and those where participants had discontinued one neuroleptic but started on another. In some studies it was unclear whether participants had discontinued neuroleptic medication or had always been medication free. Contacting authors was a way I attempted to overcome these challenges. To ensure articles met the criteria for the review, I held panel discussions with the research team during full text screening to achieve consensus decisions regarding debatable texts.

I was surprised to find there were no qualitative studies addressing this question. This might reflect the relative infancy of the field. The absence of service user experiences of discontinuation relating to the functional outcomes experienced presents an area for future research to address.

**Quality assessment**

Identifying a suitable quality assessment tool to assist in the evaluation of the included studies was a process I found complicated. I appreciated the advantages a quality assessment tool offered in guiding critical appraisal, however I discovered there were few guidelines regarding the advantages of tools for different types of reviews and studies. This was particularly pertinent as the articles identified in this review included diverse research designs. Furthermore, many of the tools I identified were design-specific; for example, to appraise RCTs. Selecting a design specific tool to aid appraisal of the studies included would have risked floor effects in the ratings, thus limited the usefulness of the exercise. The Effective Public Health Practice Project tool (EPHPP; Thomas, Ciliska, Dobbins, & Micucci, 2004) was found to most accurately capture the issues relevant to the quality of the studies relating to the methodological rigour and bias of each and the extent studies addressed the review question (Appendix 4). This tool afforded evaluation of a range of study designs, provided a clear framework to aid critical appraisal, and eschewed dichotomous ratings. I considered these strengths of the tool as many of the other tools identified failed to adequately capture issues of bias by restricting options to binary responses. Another strength is that the EPHPP has been found to have good content and construct validity (Thomas et al., 2004) and inter-rater reliability (Armijo-Olivo, Stiles, Hagen, Biondo, & Cummings, 2010). Substantial inter-
rater reliability was also found between raters in this systematic review using the EPHPP. I found completing the quality assessment process beneficial, as I was able to consider the articles in greater depth, which supported critical data synthesis. For example, during this process I identified a reporting bias in many of the studies where statistical significance was reported in the absence of clinical significance. As this review investigated the association of discontinuation and functional outcomes, with a view to contributing to the evidence base regarding feasibility of neuroleptic withdrawal, meaningful findings may therefore be limited. Subsequently, I included a recommendation that future researchers should report the clinical significance of changes in functional outcomes associated with discontinuation to advance understandings.

Publication bias might also have been an area of weakness for this review. This refers to when findings supporting a particular view are more likely to reach publication than either studies with non-significant results or results that do not support the view in question (Centre for Reviews and Dissemination [CDS], 2009). Studies investigating functional outcomes associated with discontinuation where results do not support the interests of the researcher, might not therefore reach publication. This might particularly be the case for efficacy trials of neuroleptic medication funded by pharmaceutical companies, as positive findings are substantially more likely to be reported in trials with industry sponsorship than without (Perlis et al., 2005). As six of the thirteen articles included in the review were efficacy trials funded by pharmaceutical companies, the strength of the evidence in this review might be weakened. Non-publication of research in general is also a known problem (Jones et al., 2013); therefore the review is only based on available evidence.

**Data synthesis**

The review revealed that few studies had investigated functional outcomes associated with neuroleptic discontinuation and the studies that were identified had adopted a variety of research designs and methods. As such, it was neither feasible nor appropriate to use statistical data synthesis techniques, i.e. meta-analysis (CDS, 2009). I considered a narrative data synthesis approach, however given the diversity between the articles regarding measures of functional outcomes, discontinuation strategies and participant characteristics regarding phase of illness, I deemed that this was also not appropriate. I
found synthesising the data particularly challenging and during this process I became aware of the inadequacies in the research regarding discontinuation and functional outcomes. Although an RCT might be the ideal study design given the high level of control that can be exercised over the data, this design might not reflect the processes of discontinuation advocated in NICE guidelines (2014), i.e. gradual, tapered withdrawal with symptom monitoring. A key task that emerged during my empirical study was that making choices about neuroleptic medication often involved people “weaving a safety net to safeguard wellbeing” during discontinuation, which included preparing to withdraw and monitoring progress. Many neuroleptic withdrawal studies however, involve double-blind placebo-controlled trials, a design does not allow participants to put in place processes to safeguard against vulnerabilities during discontinuation. Comparing discontinuation studies with and without participant blinding to the intervention might be useful in understanding whether this influences outcomes.

**Reflections on completing a systematic review**

Learning about the many stages involved in completing a systematic review has enhanced my skills in navigating multiple databases, making sense of large bodies of literature and especially in synthesising data. I anticipate a change in the way that I will relate to research in my clinical practice, having developed a more critical and evaluative approach to reading papers. Having an awareness of quality appraisal tools and PRISMA statement guidelines will also be beneficial for me in knowing which pieces of research I can confidently base my practice on.

**Reflections on paper 2: a qualitative, grounded theory study**

**Choice of research question and method**

A key responsibility for health care professionals is to facilitate and advocate informed choice, service user involvement, collaboration, self-efficacy and empowerment (NICE, 2011; Coulter & Collins, 2011) I have aimed to embed these values into my practice throughout my clinical psychology training, promoting strength-based, recovery-oriented approaches to support client autonomy. I have become aware that clinical challenges are present in some areas of mental health care, which affect opportunities to uphold these principles. This issue was highlighted by an editorial in the British Journal of Psychiatry, entitled: *Antipsychotics: is it time to introduce patient choice?* (Morrison, Hutton, Shiers, & Turkington, 2012). It struck me as counterintuitive that while service
user choice was recommended by NICE guidelines (2014), it was not embedded in neuroleptic medication management. I did some further reading and discovered that discontinuation of neuroleptic medication has been extensively researched using quantitative methods to investigate correlates of non-adherence. There is however, little evidence regarding service user processes involved in neuroleptic discontinuation. I also discovered that there were no evidence-based guidelines to support safe, guided withdrawal (Datta, 2013) and that service users often discontinue unsupported (Hogman & Sandamas, 2000; Read, 2005). I therefore chose to research personal accounts of neuroleptic withdrawal to address the gap in the literature and advance understandings about the choices and processes involved in service user discontinuation.

As quantitative research requires a level of prior understanding about the phenomenon being researched, this method was not considered appropriate. A quantitative approach would inevitably have overlooked idiosyncratic, personal understandings of making choices about neuroleptic medication. For instance, the preliminary grounded theory I present in paper 2 was not captured in a linear, sequential or dichotomised model of adherence or non-adherence, but in a dynamic, multifaceted model of three interrelated tasks and associated processes relating to a continuation-discontinuation spectrum. The participants’ narratives emphasised systemic variables as inherent in making choices about neuroleptic medication and evoked the theoretical perspective of symbolic interactionism (Mead, 1934; Blumer, 1969). This perspective highlights the importance of active meaning making through interactions with the world and others. The temporal and developmental nature of becoming an expert in making sense of neuroleptic medication, mental health, and treatment were also relevant to participants’ accounts. These nuances are unlikely to have been captured by quantitative approaches, which often reflect only a single point in time. The narrow scope of quantitative methods therefore, would have imposed restrictions on understanding service user processes and perpetuated professional frameworks of understanding medication taking behaviors. Consequently, the translation of findings into meaningful, client-centred recommendations would have been limited.

In contrast, qualitative research is particularly relevant where pre-existing knowledge and evidence is scarce. Qualitative research can afford valuable opportunities for professionals to learn from the insights of people who have first hand experiences of the
Phenomena being studied (Geekie & Read, 2009). I therefore considered qualitative methods the most appropriate and relevant approach to explore personal accounts of neuroleptic discontinuation.

I was also keen to advance my professional development and skills as a qualitative researcher. I have previously engaged in specific stages of qualitative research, including conducting semi-structured interviews with New Zealand and Pacific Island adolescents to explore resilience, completing focus groups with teachers and students, and transcribing interviews for a study on attitudes toward alcohol. This research provided me with an opportunity to apply and develop my existing competencies and gain experience of the analytical stage. I hope to use these skills in my future clinical work so I embraced this opportunity.

Additionally, conducting research that explores phenomenology aligns well with my personal and professional interests. Coming from an English Literature background, I have always enjoyed listening to peoples’ stories and perspectives. I am curious about the meanings individuals make of their subjective experiences and this interest has developed during my clinical psychology training.

**Choosing grounded theory**

There are a number of distinct approaches within qualitative methods, including interpretative phenomenological analysis, ethnography, and grounded theory. These approaches share a number of techniques, aims and principles that clearly differentiate them from quantitative approaches. For example, the methods of data collection used, the importance of reflexivity, and the focus on individual perspectives (Braun & Clarke, 2013). Each approach has unique strengths and weaknesses; however the research question ultimately determines which is most relevant. I undertook an exploration of a variety of approaches in the context of the research question and the current evidence base. Compared with other methods, I believed that there was a strong rationale for using grounded theory to explore discontinuation processes. Some qualitative approaches engage in deductive theorising; this involves seeking out evidence to verify a pre-existing theory or using predefined frameworks to interpret the data. Grounded theory outlines a set of procedures to ensure that researchers systematically build a substantive theory based on empirical data that relate to real life experiences (Glaser &
Strauss, 1967). In this way, grounded theory is distinct from other qualitative methods and offers an approach that allows clear understandings of processes and actions to be generated. Discontinuation is predominantly understood within the limits of adherence and non-adherence. I considered the opportunity to explore beyond these predefined parameters using a systematic approach a particular strength of grounded theory. The value placed on contextual factors in grounded theory was another advantage; discontinuation involves a number of cultural, social, psychological and political contexts, which are likely to influence service users choices and the responses of clinicians to these. Accordingly, current legislation, resources of the mental health system, and stigma were issues raised in the interviews, demonstrating how discontinuation processes are heavily influenced by systemic factors, which supports the use of grounded theory.

Grounded theory also strives to ensure that the strengths inherent in quantitative methods, including logic, rigour and systematic analysis are integrated within a qualitative framework (Glaser & Strauss, 1967). As a novice to qualitative analysis, the clear, systematic guidelines appealed to me and increased my confidence that I would be able to develop a coherent theory. I was also aware that the guidelines presented a steep learning curve due to the complexities of the techniques. This was further complicated by historical debates that have divided grounded theorists and led to a number of distinct but conceptually similar procedures being proposed (Glaser & Strauss, 1967; Glaser, 1978; Strauss, 1987; Strauss & Corbin, 1990; Glaser, 1998; Charmaz, 2006). Amateur grounded theorists have been criticised for selecting incompatible elements of the different versions while conducting their research (Cutcliffe, 2004). I therefore aimed to adhere to one distinct version and chose Charmaz’s (2006) contemporary, constructivist interpretation of grounded theory. Because this is an additional iteration of the original model, some critics have argued that rather than advancing the approach, it might cease to be grounded theory (Breckenridge, Jones, Elliott, & Nicol, 2012). I however reasoned that by maintaining the inductive creativity of classic grounded theory (Glaser, 1978), within an epistemological stance of constructivism, Charmaz’s interpretation offered an accessible and contemporary version. I also saw value in the constructivist approach as it asserts that individuals construct their reality through attributing meaning to their experiences (Appleton & King, 2002). Correspondingly, the research process involves the researcher
and participant constructing a shared reality. This resonated with several core issues underpinning this research, including the need for collaboration and choice about neuroleptic medication. In reflection, I am satisfied that my decision to use a constructivist grounded theory approach allowed me to generate a theoretical model that was succinct and analytically robust.

**Developing the research**

Classic grounded theorists espouse a blank slate approach to research development, data collection and analysis to limit the risk of preconceived ideas forcing the data into pre-existing frames of reference (Glaser, 1998). To ensure epistemological fidelity within this approach, literature reviews are traditionally delayed until after data analysis. Some contemporary grounded theorists recognise the challenge of adhering to this approach within academic research and criticise the underlying premise of theoretical naivety. Chamaz (2006) for example acknowledges that existing theories are often already familiar to the researcher and the process of research is rarely neutral. Within the doctorate programme requirements of academic rigour, it was necessary for me to undertake a literature review before data collection; therefore during the initial stages of developing the research I considered what theoretical and personal preconceptions and assumptions I was bringing to the research. Although I was aware that some participants might share my beliefs or opinions, I recognised that the factors underpinning discontinuation processes might differ significantly from my expectations. “The Psychologist’s Fallacy,” a phrase originally coined by James (1890), has been used to caution psychologists that as observers of human behavior, they risk ascribing the same motives and wishes to those they observe as they experience themselves. It was therefore important that I took steps to avoid imposing my beliefs on the research and potentially biasing the data. Developing my topic guide in consultation with the research team and a service user group was one way I aimed to mitigate against asking leading or loaded questions.

In developing the research, I engaged in service user consultation to help me understand the topics likely to be pertinent to individuals who have used the mental health system. This also supported me to consider the practical aspects of conducting interviews, arranging locations, developing rapport and recruiting participants.
As I had not identified any other research that had explored discontinuation processes using qualitative methods during my preliminary literature review, I was faced with a challenge regarding the scope of the research question. Keeping the question broad would allow me to explore the breadth of the phenomena; however narrowing the question to a specific area of interest would afford detailed descriptions of a process within discontinuation, for example the role of emotions on decisions. During the development of the research question, I considered the feasibility of addressing a broad area within the scope of both grounded theory methods and the doctorate. I was concerned that my interviews would be too long and that I might not reach theoretical sufficiency (Dey, 1999). To resolve these concerns, I read other grounded theory studies to explore the breadth and depth of questions and the sample sizes. I also consulted with the research team and the service user group and concluded that my concerns were unlikely to be issues as grounded theory is well equipped to explore broad topics and the topic guide was considered feasible. I therefore settled on a broad research question and found that in line with previous research and the advice I had received, interviews were completed in the time allowed and I was satisfied I reached theoretical sufficiency.

**Recruitment**

In this research, I was specifically interested in neuroleptic discontinuation processes for people prescribed medication for non-organic psychosis. Neuroleptic medication is also prescribed to children, people with diagnoses of dementia and learning disabilities, and people experiencing organic psychosis. As discontinuation processes were hypothesised to have important distinctions in these groups due to their added vulnerability, differences in rationales for neuroleptic use, and variation in the expected timeframes for use, these populations were detailed within the exclusion criteria. Much research into psychiatric medication focuses on samples with specific psychiatric diagnoses, such as schizophrenia-related disorders, bipolar disorder, or psychotic depression. An advantage of using diagnostic criteria to select samples might be that experiences are specific to a diagnostic cohort and implications are consistent with the prevalent psychiatric paradigm of understanding of mental health. Within a social constructionist approach diagnostic labels are understood as products of descriptions, rather than objective realities and some professionals have cautioned that functional psychiatric diagnoses have significant conceptual and empirical limitations (The British Psychological Society [BPS], 2013). Within this research, I applied an experiential
inclusion criterion of non-organic psychosis, rather a specific functional diagnosis, which would have been inconsistent with the social constructionist and constructivist approach and might have risked excluding potential participants.

This research was completed using a framework of theoretical sampling, which means I aimed to develop my emerging theory by seeking data that would refine and test the strength of my categories. An ideal recruitment method within theoretical sampling would have involved selecting participants who were likely to provide further reflections on the emerging constructs. Due to the popularity of the study, recruitment was completed in the early stages. To allow sufficient time for me to listen back to recordings, transcribe interviews, complete initial coding, and revise the topic guide before progressing to subsequent interviews, I scheduled all interviews in advance and at manageable intervals. I did not therefore recruit participants using theoretical sampling, which might be considered a limitation of this study. I did however, make adaptations to the topic guide in response to emerging themes, which allowed me to test early constructs and discover exceptions. This approach and the use of constant comparative methods supported theoretical sampling and I was satisfied that theoretical sufficiency was achieved with the data from the twelve participants.

I understood the positive uptake of the study to relate to a number of factors. Previous research has demonstrated that an important factor mediating peoples’ decisions to participate is when the research is considered worthwhile or likely to make a difference (Graham, Grewal, & Lewis, 2007). The feedback I received from participants in this study suggested that the research offered these qualities, for example:

I’d like to be able to help other people going through the same experience so maybe being part of this study means that I’ll be of some help to other people that are trying to do the same thing cause I know . . . it’s a really common situation for people to be in that they’re on those medications and they’re finding such horrible side effects and want to come off them and aren’t getting the help that they need to.

Geekie and Read (2009) discussed how the opinions of those who experience psychosis are often not heard in research. This study offered an opportunity for people to reflect
on their experiences, share their understandings and contribute to the evidence base around neuroleptic discontinuation.

**Interviews**

When qualitative interviews are used to collate data, the construction of meanings occurs during brief interpersonal interactions (Charmaz, 2006). The nature of these interactions will inevitably influence the quality of the data (Popay, Rogers, & Williams, 1998). Hall and Callery (2001) refer to issues inherent in the researcher-participant dynamic as “relationality” and emphasise the importance of attending to this to ensure rigour in grounded theory. I therefore adhered to principles of relationality, reflection and reflexivity while conducting the interviews and analysis. This involved me examining and attempting to minimise my potential impact on the research. For example, I aimed to create a safe, neutral and non-judgmental space within which participants could explore meanings. To facilitate this I reflexively noted when I experienced strong opinions about the experiences relayed. Rather than sharing these, which might have biased the data, I strived to remain impartial. This was particularly challenging when participants attempted to elicit my opinion. I managed this by providing sufficient feedback to demonstrate understanding, show empathy and maintain rapport, without imposing my opinion.

Finch (1993) identified ways to reduce the power imbalance during qualitative research; these include expressing gratitude for participants’ time and insights, which I did verbally and by providing accessible summaries of the findings with a thank you card. This was consistent with advice received during service user consultation and supported the ethical integrity of the study, as lack of feedback has been found to reinforce negative self-evaluations in mental health participants (Fossey, Epstein, Findlay, Plant, & Harvey, 2002). Power imbalances are however, inevitable within the researcher-participant dynamic. Despite my attempts to minimise this and promote a sense of equality and collaboration, I experienced being positioned in an expert role. At times I found this challenging, however I sought to re-establish equality by remaining open and curious to participants’ experiences.

A common issue in qualitative research is that researchers often occupy dual roles (Borbasi, Jackson, & Wilkes, 2005). At the time of the research, I was both a clinician
and a researcher. This afforded advantages, for example I was familiar with managing anxiety, containing distress and conveying empathy. It also posed challenges, for instance I occasionally experienced a pull to provide advice or a therapeutic response. These are acknowledged issues in qualitative research (Haverkamp, 2005) and to manage them, I mindfully noticed my experiences and reflexively re-position myself in a neutral researcher stance. I attended qualitative seminars with other trainees during my research, where I had the opportunity to role-play interviews. I found this helpful in anticipating and responding to such situations.

There were times within interviews when I strongly experienced participants’ frustrations and grievances with the mental health system. I reflexively noted these experiences and understood which frustrations were mine and which were the participants’. I also noticed countertransference processes; for example one participant elicited protective feelings in me. My reflective diary and supervision sessions were useful resources in understanding and managing these emotions and processes. This approach is consistent with qualitative guidelines (Elliott, Fischer, & Rennie, 1999), which were adhered to throughout the research, optimising the methodological rigour and quality of the study. For example, I endeavoured to end the interviews on a positive note and I went through the debrief sheet (Appendix 15) carefully, highlighting numbers to call should participants require further opportunities to talk.

**Theoretical sensitivity**

In line with grounded theory guidelines (Strauss & Corbin, 1998; Charmaz, 2006), a number of procedures were used to minimise the level of interpretation bias the data was exposed to and uphold the integrity of the data. To set aside presuppositions and ensure interpretations were data driven, I employed the technique of “bracketing.” This involved being mindful of preconceived ideas not yet indicated by the data and recording them separately to highlight that they were understandings owned by me and not grounded in the data. Occasionally, participants indicated these ideas and the code or category was subsumed within the analysis. This ensured that my interpretations were, as far as possible, data-driven and avoided “common sense theorising” (Charmaz, 2006, p.48).
Another analytic technique that provided a corrective to my ideas being superimposed on the data was line-by-line coding, which supported quick, spontaneous coding. I assessed the content validity of my codes by comparing them with codes generated by other members of the research team for the same section of transcript (Yin, 2003). This process indicated that there was a high level of agreement in interpretation. I also verbally checked my understanding of participants’ experiences within interviews and requested clarification when statements were ambiguous.

**Memo writing**

Memo writing provided a useful step in starting the analysis; this also supported constant comparative analysis (Charmaz, 2006). I noticed how memos could spark related ideas; some were grounded in the data, others I ensured I bracketed as they were informed by my pre-existing understanding of social and psychological phenomena rather than indicated by the data. Imagery was an important part of participants’ discourses and during the process of immersion I had repeated exposure to these powerful images. The opportunity to explore these creatively in memos helped me engage in constant comparisons.

**Coding**

Corbin and Strauss (1990, p. 12) identify coding as the “fundamental analytic process used by the researcher.” Although coding is inherent within qualitative traditions, grounded theorists aim to analyse codes with greater depth and specificity. Aware of the importance of coding in converting transcripts to theories, I regularly sought supervision about the method of analysis I was using to ensure rigour. In particular, Charmaz (2006) cautions against making conceptual leaps to theories when analysing the data. I experienced this during focused coding when I mapped the codes of a transcript to understand analytical relationships and I became aware that my interpretation of a later transcript appeared to replicate these findings. To avoid the emerging theory being shaped inordinately by early interviews and thus subject to confirmation bias, I individually mapped each transcript during focused coding to recognise within and between transcript links. This helped me to remain open and reflexive to the data, keep codes provisional, and ensure a constructivist approach to the emerging theory. It also supported case-by-case comparisons and theory integration.
**Sample size**

Dey's (1999) concept of theoretical sufficiency was the benchmark I used to determine the final sample size. This is arguably a more theoretically valid approach to data saturation, which is favoured in classic grounded theory approaches (Glaser, 1978). Data saturation asserts that data collection is only complete once no new insights are achieved. Dey however, challenged the ability to confirm this condition and highlighted that data collection would have to continue indefinitely to demonstrate saturation. Instead, I engaged in constant comparative analysis within a theoretical sampling framework, which allowed me to monitor the constructs that were emerging from the data, assess construct validity and make an informed decision with the research team about the level to which theoretical sufficiency was achieved. This was agreed at twelve participants; however, as with all novel theories, the model would benefit from further testing with different samples to explore exceptions and nuances in the data.

**Writing up**

As my research and clinical psychology training has progressed, my interest in social constructionism and constructivism has increased. I have become especially aware of the importance of language and terminology in psychology and the relevance to my research. Moncrieff and Cohen (2005) for example, challenge the accuracy of the term “antipsychotic.” They propose that neuroleptic medication might offer some useful general effects by suppressing or replacing experiences of psychosis with an altered brain state, but dispute that the drugs correct an underlying disease or abnormal state by offering specific “anti psychotic” effects. This distinction relates to the model of action attributed to neuroleptic medication. The authors assert that as psychoactive drugs, neuroleptic medications alter rather than normalise brain function, therefore drug-centered descriptions are more accurate than disease-centered terms; although this is disputed (Yilmaz et al., 2012). During the initial phases of the research I employed the term “antipsychotic medication.” This reflected my level of understanding regarding social constructionist theories and my choice to use mainstream terms to aid recruitment. During write up however, I used the term neuroleptic to avoid using language that perpetuates assumptions underpinned by a disputed evidence base.

Similarly, I was mindful of the language I used to describe participants’ experiences of mental health problems. Some researchers and practitioners have highlighted that the
limited reliability and disputed validity of functional diagnoses such as “schizophrenia” and “bipolar” disorder renders these terms problematic, especially as they form the basis for evidence-based practice (Bentall, 2004; BPS, 2013). The potential for literature to promote a paradigm shift by endorsing terminology that does not make assumptions provided me with a strong rationale for the choice of language I used. For example, within my systematic review, I used phrases such as, “participants with a diagnosis of schizophrenia,” rather than “participants with schizophrenia” to avoid assumptions that diagnoses relate to disease-based illnesses within individuals, which do not reflect biopsychosocial understandings of mental health problems. I did however consider that moving away from the dominant and widely accepted paradigm of psychiatric classification that underpins the majority of research in this field, might present problems regarding the accessibility of the research.

**Limitations**

A limitation that can be true of all qualitative research is that the study findings are not generalisable to everyone within the population studied. Instead, this preliminary grounded theory offers one perspective from countless possible interpretations of the rich and varied data collated. Findings are based on my own interpretations, which I acknowledge as constructions of reality within a constructivist approach (Charmaz, 2006). In line with qualitative guidelines, I have owned my perspective throughout the research and disclosed my values and theoretical orientation within an author biography. Other members of the research team also completed these. Such transparency within qualitative research allows readers to understand the findings within the context of the researcher’s perspective and form alternative interpretations (Braun & Clarke, 2013).

Another limitation is that the model I have presented emerged in the context of the research question. It is not therefore, assumed to be an exhaustive representation of the data collated, but a theory of the processes involved in making choices about neuroleptic medication, representative of the sample recruited. Using grounded theory however, has ensured that my theory is “grounded” in the data, rather than based on beliefs or intuition. Ascertaining the relevance of the theory beyond this sample would require it being tested with participants from different populations. This would also enhance the credibility and strength of the theory. For example, widening the
geographical area participants are recruited from in future studies would be beneficial, as this sample was restricted to the North West of England. This is a problem shared in other qualitative studies of the experiences of psychosis as identified in a metasynthesis by McCarthy-Jones et al (2011). The diversity of the sample recruited in terms of neuroleptic medication used, experiences of discontinuation, age and sex was a relative strength of this study. It is possible however, that including participants whose discontinuation attempts occurred at various points in history limits the extent to which conclusions can be understood within the current socio-political context. Health care practices, societal attitudes, and politics will inevitably differ across the years and decades; therefore establishing the current situation in future research would be of value.

The recruitment process of this study aimed to avoid coercion of participants, therefore the sample was self-selecting. A potential weakness of this preliminary grounded theory therefore is that it might reflect the experiences of a specific group of people more inclined to participate. Another limitation inherent in both qualitative and quantitative research is the potential for social desirability in the responses of participants; however one participant described the experience of openly discussing discontinuation experiences as “liberating” and social desirability did not appear to be an issue for this study.

There were however some specific challenges related to the population being studied and the topic of interest. I was asking participants to recall decisions and processes made during a time that for many of the participants was particularly difficult. Several participants reflected on how they perceived psychosis interventions might have adversely affected their perceptions, as explained by one participant:

It’s all like kind of a very, like a blurry time, I don’t know whether that’s due to the medication even, but erm, that time is all quite like hazy.

In the context of these challenges, validity could have been strengthened had I triangulated accounts with family members or participants’ clinicians. I could also have engaged in response validation, that is, recontacting participants to seek their opinions of the emerging theory and clarifying information.
Reflections on using a qualitative, grounded theory approach

The aim of grounded theory is to discover a unified theory of a phenomenon resulting from immersion and constant comparative analysis (Charmaz, 2006). I experienced both doubt and trepidation about whether this would occur. These feelings were replaced with optimism during focused and theoretical coding when the analysis gained momentum. I discovered that the emergence of constructs and theory progressed most when I was able to dedicate many consecutive hours or days immersed in data analysis. Due to the wealth of data to collate, listen back to, transcribe, and code, within the context of competing demands and time constraints however, data analysis was often opportunistic. Despite this challenge, I did feel satisfactory immersion, particularly once all the interviews were transcribed. Overall, I found that grounded theory provided me with a flexible yet systematic framework to analyse my data within and construct a preliminary theory. This made my transition from novice grounded theorist to one of developing experience and competence, manageable and less overwhelming.

Clinical implications of papers 1 and 2

The systematic review highlighted that evidence regarding functional outcomes associated with discontinuation is currently weak. This area of research warrants further attention to support evidence-based practice guidelines. In paper 1, I recommended that it is important for researcher to report clinical significance in research trials and consider the relevance of NICE guidelines (2014) when investigating the feasibility of discontinuation. The main finding in the empirical study (paper 2) was that three overarching tasks govern service user choices about a continuation-discontinuation spectrum and that a number of systemic factors facilitate or hinder progress in these tasks. By translating the three tasks into specific clinical recommendations, I hope to have clearly identified ways that services can facilitate rather than hinder positive outcomes for service users who make choices about neuroleptic medication. The approaches I have recommended in paper 2 include developing collaborative formulations with service users to guide the treatment of psychosis, with or without neuroleptic medication; clear communication about the option to be medication-free; and providing support to service users in the development of “safety nets” or care plans to safeguard their wellbeing at any point on the continuation-discontinuation spectrum. I made a related recommendation that there is an urgent need to develop evidence-based
clinical protocols to guide clinicians in supporting service users to make choices about neuroleptic medication use and discontinuation. Potential outcomes of professionals translating these recommendations into practice include establishing meaningful, collaborative alliances with service users that are underpinned by values of client-centred care, informed choice and empowerment. Reduced rates of unsupported discontinuation might also be an outcome of implementing these recommendations, which in turn might reduce harmful outcomes.

**Implications for my practice**

Conducting research with service users has afforded me unique insights into a number of clinical issues. Especially important was developing my understanding of the conditions that can facilitate or hinder positive alliances with service users. I envisage this awareness will benefit me in my individual work with clients and in supporting teams who are working with clients to make informed choices about their treatment. Gaining insights into service user experiences of psychiatric medication, including costs and benefits and the importance of developing a personal theory of need and acceptability has been exceptionally useful for me, and will support me to appreciate the contextual factors inherent when working with clients prescribed these medications. Balancing both clinical and research roles was challenging and enjoyable. A core competency for clinical psychologists is to work within a scientist practitioner stance and to contribute to the evidence base. I look forward to working this way as a qualified clinical psychologist and I believe that this research has equipped me with the skills required to execute a piece of large scale research alongside clinical work.

As previously discussed, my personal and professional understanding of social constructionist and constructivist stances has advanced considerably during this research. This has supported the development of my professional identity and equipped me with skills to engage in a more informed way in issues of psychiatric diagnosis and models of mental health.

**Conclusions**

My aims for this thesis were to contribute to the evidence base regarding discontinuation from neuroleptic medication for psychosis. By identifying and synthesising the available evidence on functional outcomes associated with neuroleptic
withdrawal, my systematic review highlights the many limitations of the existing literature. This includes there being few relevant studies, challenges in the way discontinuation is studied, and a lack of consensus regarding functional outcomes. I was somewhat disappointed to discover that it was unfeasible for me to derive firm conclusions from the synthesised evidence, however I also realised that by highlighting these issues, I was able to contribute to the evidence base and emphasise the need for further research that is aligned with NICE guidelines and service-user priorities for recovery outcomes. I also conducted a novel piece of empirical research with the intention of developing a unified theory of the processes involved in making choices about neuroleptic medication. I am satisfied that I have been able to achieve this and provide some useful clinical recommendations. Overall, I found that completing this thesis was a challenging yet rewarding experience, which has afforded me many professional and personal learning experiences.
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Appendix 1: Contributor guidelines for Clinical Psychology Review

CLINICAL PSYCHOLOGY REVIEW

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If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

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- All tables (including title, description, footnotes)
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# Appendix 2: PRISMA checklist

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<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>#</th>
<th>Checklist Item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background, objectives, data sources, study eligibility criteria, participants, and interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings; systematic review registration number.</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationales</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13</td>
<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I², for each meta-analysis).</td>
</tr>
</tbody>
</table>
## PRISMA 2009 Checklist

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk of bias across studies</strong></td>
<td>10</td>
<td>Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
</tr>
<tr>
<td><strong>Additional analyses</strong></td>
<td>16</td>
<td>Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study selection</td>
<td>17</td>
<td>Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.</td>
</tr>
<tr>
<td>Study characteristics</td>
<td>18</td>
<td>For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.</td>
</tr>
<tr>
<td>Risk of bias within studies</td>
<td>19</td>
<td>Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).</td>
</tr>
<tr>
<td>Results of individual studies</td>
<td>20</td>
<td>For all outcomes considered (benefits or harms), present, for each study (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>21</td>
<td>Present results of each meta-analysis done, including confidence intervals and measures of consistency.</td>
</tr>
<tr>
<td>Risk of bias across studies</td>
<td>22</td>
<td>Present results of any assessment of risk of bias across studies (see item 15).</td>
</tr>
<tr>
<td>Additional analysis</td>
<td>23</td>
<td>Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).</td>
</tr>
<tr>
<td><strong>DISCUSSION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of evidence</td>
<td>24</td>
<td>Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).</td>
</tr>
<tr>
<td>Limitations</td>
<td>25</td>
<td>Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).</td>
</tr>
<tr>
<td>Conclusions</td>
<td>26</td>
<td>Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
</tr>
<tr>
<td><strong>FUNDING</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding</td>
<td>27</td>
<td>Describe sources of funding for the systematic review and other support (e.g., supply of data), role of funders for the systematic review.</td>
</tr>
</tbody>
</table>


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Appendix 3: Review Protocol

**Literature review - Search protocol**

Discontinuation from antipsychotics and the relationship with functional outcomes in people with schizophrenia spectrum disorders.

A systematic literature search of the following databases will be conducted:

<table>
<thead>
<tr>
<th>Database</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMBASE</td>
<td>Also internet engines -</td>
</tr>
<tr>
<td>MEDLINE</td>
<td>Google Scholar</td>
</tr>
<tr>
<td>PsychINFO</td>
<td>Previous reviews</td>
</tr>
<tr>
<td>Web of Science</td>
<td></td>
</tr>
</tbody>
</table>

The following search terms will be used:

<table>
<thead>
<tr>
<th>Population/patient</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
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<td>psychosis</td>
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The reference list of all papers will also be searched. I will also do citation searching.

**Inclusion criteria**

- English Language
- Peer Review Journals
- Must report on people who were on antipsychotic medications for a diagnosis of schizophrenia spectrum disorder at any point, who engaged in discontinuation or withdrawal (for example, where non-antipsychotic interventions such as placebo or therapy were introduced; where no alternative treatment was introduced; or where individuals exerted choice to discontinue their medication independently)
- May include meds vs placebo if the participants were originally on an antipsychotic and withdrawn to placebo
- Aged 16 plus (to include first episode/early intervention group)
- Must discuss functional outcomes as delineated in the outcomes category
- No specification about published date
- Qualitative and quantitative

**Exclusion criteria**

- Only discusses switching meds
- Only reports on outcomes associated with relapse/symptom outcome
- Discusses a non-schizophrenia spectrum population, e.g:
  - Bipolar disorder
Aims:
Describe the functional outcomes associated with discontinuation of antipsychotic medications.
Review the evidence base.
Where are the gaps in the literature / areas of uncertainty?

Plan
OVID & Web of Science structured search
1. Input search terms, combine and run search in each platform
2. Apply limits:
   a. English Language
   b. Peer reviewed
   c. Human
   d. Articles
3. Remove duplicates (record number)
4. Export search data to endnote using complete reference and save in library with database name as title
5. Re-run search for subsequent platform and export results to endnote saving in separate libraries according to which database from.
6. Remove duplicates (record number)
7. Record the total number of articles returned before and after duplicates removed
8. Combine all separate libraries together saving as a new library; opt for title and abstract.
INITIAL SCREENING
9. Search through all and move any that are clearly not relevant by title or abstract to 'exclude' folder. RECORD HOW MANY.
10. Move those that are/may be relevant to 'include' folder. RECORD HOW MANY.
FULL TEXT SCREENING
11. Search those more closely e.g. by reading the whole article. Remove any not relevant and detail why not included. RECORD HOW MANY. Append list/table of studies
DATA EXTRACTION
12. Create an excel extraction table
13. Read each included article; complete quality appraisal checklist and fill in table of details about each
   a. Author

- Depression
- Organic cause of psychosis
- Neurological
- Neuropsychological
- Dementia
- Alzheimer’s
- Learning disability

Children (under 16)
Comments paper
Reply to articles
Correction papers
Review articles
b. Country
c. Ages
d. Genders
e. PICO
f. Research aims
g. design
h. appraise method
i. summarise results
j. present key findings
k. identify reasons for different results across similar studies
l. note conflicts of interest (e.g. study funded by pharmaceutical companies/author affiliated with companies)
m. cite limitations of current knowledge.

14. Good practice to have 5 – 10% of articles independently reviewed to check for consistency
Appendix 4: The Effective Public Health Practice Project tool

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1. Very likely
2. Somewhat likely
3. Not likely
4. Can’t tell

(Q2) What percentage of selected individuals agreed to participate?

1. 0% - 99% agreement
2. 60 - 79% agreement
3. Less than 60% agreement
4. Not applicable
5. Can’t tell

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B) STUDY DESIGN

Indicate the study design

1. Randomized controlled trial
2. Controlled clinical trial
3. Cohort analytic (two group pre + post)
4. Case control
5. Cohort (one group pre + post, before and after)
6. Interrupted time series
7. Other specify
8. Can’t tell

Was the study described as randomized? If NO, go to Component C.

No
Yes

If Yes, was the method of randomization described? (See dictionary)

No
Yes

If Yes, was the method appropriate? (See dictionary)

No
Yes

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C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?
   1. Yes
   2. No
   3. Can't tell

The following are examples of confounders:
   1. Race
   2. Sex
   3. Marital status/family
   4. Age
   5. SES (Income or class)
   6. Education
   7. Health status
   8. Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)
   1. 0 – 25% (none)
   2. 25 – 50% (some)
   3. Less than 25% (few or none)
   4. Can't tell

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D) BLINDING

(Q1) Were (were) the outcome assessor(s) aware of the intervention or exposure status of participants?
   1. Yes
   2. No
   3. Can't tell

(Q2) Were the study participants aware of the research question?
   1. Yes
   2. No
   3. Can't tell

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E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?
   1. Yes
   2. No
   3. Can't tell

(Q2) Were data collection tools shown to be reliable?
   1. Yes
   2. No
   3. Can't tell

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F) **WITHDRAWALS AND DROP-OUTS**

(01) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?
1. Yes
2. No
3. Can’t tell
4. Not Applicable (e.g., one-time surveys or interviews)

(02) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).
1. 100%
2. 79%
3. Less than 60%
4. Can’t tell
5. Not Applicable (e.g., Retrospective case-control)

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G) **INTERVENTION INTEGRITY**

(01) What percentage of participants received the allocated intervention or exposure of interest?
1. 100%
2. 79%
3. Less than 60%
4. Can’t tell

(02) Was the consistency of the intervention measured?
1. Yes
2. No
3. Can’t tell

(03) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?
1. Yes
2. No
3. Can’t tell

H) **ANALYSES**

(01) Indicate the unit of allocation (circle one)
1. Community
2. Organisation
3. Institution
4. Practice/Office
5. Individual

(02) Indicate the unit of analysis (circle one)
1. Community
2. Organisation
3. Institution
4. Practice/Office
5. Individual

(03) Are the statistical methods appropriate for the study design?
1. Yes
2. No
3. Can’t tell

(04) Is the analysis performed by intervention allocation status (i.e., intention to treat) rather than the actual intervention received?
1. Yes
2. No
3. Can’t tell
GLOBAL RATING

COMPONENT RATINGS
Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

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GLOBAL RATING FOR THIS PAPER (circle one):

1 STRONG
2 MODERATE
3 WEAK

(no WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No
Yes

If yes, indicate the reason for the discrepancy

1 Oversight
2 Differences in interpretation of criteria
3 Differences in interpretation of study

Final decision of both reviewers (circle one):

1 STRONG
2 MODERATE
3 WEAK
Appendix 5: Contributor guidelines for Qualitative Health Research

QHR
MANUSCRIPT GUIDELINES
SEPTEMBER, 2011

NOTE TO AUTHORS:

If answers to your questions are not found within the Guidelines, please address your inquiries to QHR-Journal@nurs.utah.edu (please do not send inquiries to other/additional QHR email addresses). You may also telephone our office at 801-585-5378. Thank you for your cooperation.

When APA rules and QHR guidelines conflict, follow QHR.
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ABOUT QUALITATIVE HEALTH RESEARCH (QHR)

Editor: JANICE M. MORSE, RN, PhD (ANTHRO), PhD (NURSE), FAAN
University of Utah College of Nursing, Salt Lake City, Utah, USA

QUALITATIVE HEALTH RESEARCH, widely referred to as QHR, is an international, interdisciplinary, refereed journal for the enhancement of health care. Published monthly, it is designed to further the development and understanding of qualitative research methods in health care settings. The journal is an invaluable resource for researchers, practitioners, academics, administrators, and others in the health and social service professions, and graduate students who seek examples of qualitative methods.

COMPREHENSIVE, TIMELY COVERAGE FROM A VARIETY OF PERSPECTIVES

Issues of QHR provide readers with a wealth of information, including articles covering research, theory, and methods in the following areas:

- Description and analysis of the illness experience
- Health and health-seeking behaviors
- The experiences of caregivers
- The sociocultural organization of health care
- Health care policy
- Related topics

Articles in QHR examine an array of timely topics such as chronic illness; risky behaviors; patient-health professional interactions; pregnancy and parenting; substance abuse; food, feeding, and nutrition; living with disabilities; milestones and maturation; monitoring health; children’s perspectives on health and illness, and much more. In addition, the journal addresses a variety of perspectives, including cross-cultural health, family medicine, health psychology, health social work, medical anthropology, sociology, nursing, pediatric health, physical education, public health, and rehabilitation.

We also consider critical reviews; articles addressing qualitative methods; and commentaries on conceptual, theoretical, methodological, and ethical issues pertaining to qualitative inquiry.

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Qualitative Health Research
An International, Interdisciplinary Journal

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http://qhr.sagepub.com/

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- direct all manuscript-related faxes to the attention of Dori Fortune.
- direct all manuscript-related documents to the attention of Dori Fortune.

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- submit manuscripts via email.
- send email messages to two or more addresses simultaneously, doing so will cause a significant delay in the QHR response.
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- send query letters/email messages asking if we would be interested in your manuscript. After ensuring that your manuscript complies fully with these Guidelines, the only way to determine if the manuscript is suitable for QHR is to submit it (online) for consideration.
Reviewers must have a strong background in qualitative health research and/or qualitative methods. They must have a willingness to share their expertise by evaluating manuscripts and providing feedback for authors to assist them in strengthening their articles.

What’s in it for you?
You have the prerogative of reading prepublication articles in your methodological or substantive areas, and assisting in molding the literature in your field. Also, we give you copies of the other reviews received, so you can review the general consensus about the decision, and in doing so improve your own research, reviewing, and writing skills.

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No—but if you are a doctoral student we recommend that you do the first few reviews jointly with your supervisor or some other experienced reviewer, so you can learn the "ins and outs."

Qualitative Health Research (QHR) is an international journal published monthly by Sage Publications. Research articles, developments in qualitative methods, and Pearls, Pith, and Provocation—discussion articles on qualitative ethics and other issues—are reviewed. Keynote addresses, editorials, and book reviews are also published.

If you would like to join the review board for QHR, please email your curriculum vitae (CV) and complete contact information to QHR-Journal@uams.edu

Thank you! We look forward to hearing from you!

Janice M. Morse
Editor
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http://www.sagepub.com/repository/binaries/RequestForPermissionForm.pdf

Once you have obtained written reprint permission, submit it along with the original manuscript submission or, if you have obtained it after submitting the manuscript, submit it to QHR, being sure to refer to your manuscript ID number:

By email: Send it to QHR-TE@nurs.utah.edu
By facsimile: Fax it to 801-587-9838, Attention Dori Fortune

EXCLUSIVE LICENSE TO PUBLISH (AKA CONTRIBUTOR FORM)

Sage Publications requires a completed and signed Exclusive License to Publish (ELP) form from the author(s) of every article, keynote address, book review, letter to the editor, or other material published in QHR. It is to be submitted to QHR when notice is received that the article has been accepted for publication. The ELP, also known as a Contributor Form, is to be completed by the corresponding author on behalf of all authors.

The ScholarOne Manuscripts / SageTrack system will be triggered to automatically send you ELP information (via email), including instructions to access and complete the form, immediately after an “accept” decision is sent to you. The subject line of the email will read: “ACTION NEEDED: Contributor Form.” If you do not receive this notification, or if you accidentally delete it, you may request a blank (.pdf) ELP form by contacting QHR at QHR-Journal@nurs.utah.edu. Under these circumstances, please take the steps listed below to submit your form:

Print the form, complete it (be sure to answer all questions), and sign it. Write your manuscript ID number in the upper right corner of the first page of the form (e.g., QHR-2011-0XXX). Submit the first 2 pages only to QHR by one of the following methods:

By email (preferred): Scan the completed form, save it to your computer, and send it as an attachment to: QHR-Journal@nurs.utah.edu.

By facsimile: If you use this method, please send an email alerting us to the pending arrival of the fax (QHR-Journal@nurs.utah.edu). Fax the completed document to: 801-587-9838, Attention: Dori Fortune
By mail/post: Mail the completed document to:
Dori Fortune
University of Utah College of Nursing
10 S. 2000 E.
Salt Lake City UT 84112-5880 USA

- Note that the corresponding author completes and signs the form on behalf of all coauthors of a particular manuscript; it is not necessary to obtain the signature of each author. Remember that all author names must appear on the first page of the form. Please print legibly!
- Submit only the first 2 pages of the completed form.
- Do not submit a completed Exclusive License to Publish form unless and until you receive word that your manuscript has been accepted for publication.

JOURNAL STYLE

GENERAL INFORMATION

This section of the Guidelines covers matters of QHR journal style, which are not subject to author preference, adherence is required.

Note: If you still have questions after carefully reading these instructions, please refer to the sample manuscripts (there are several types) beginning on page 35 before contacting the QHR office.

IMPORTANT CONSIDERATIONS

- Qualitative Health Research is a peer-reviewed journal. Only complete, finished manuscripts should be submitted for consideration.
- We do not publish stand-alone abstracts, quantitative studies, manuscript outlines, pilot studies, manuscripts-in-progress, letters of inquiry, or literature reviews. Research articles must be pertinent to health.
- Write both the abstract and the text of your manuscript in first-person, active voice.
- For best results, review this entire document prior to preparing and submitting your manuscript.
- Proper manuscript preparation will speed the peer-review process for your manuscript, and will facilitate a smoother production process if it should be selected for publication.
- Improper manuscript preparation could result in burdensome revisions, lengthy delays in the review and production processes, and the possible rejection of your manuscript.

GENERAL STYLE

We ask authors considering submission to QHR to review these guidelines, survey several issues of the journal, and make their own decision regarding the "fit" of their article for QHR's mission. Please refrain from writing or calling to ask if we are interested in your particular manuscript or idea.


Many universities and private organizations have Web sites devoted to APA style. However, when guidelines found on those sites, or in the APA Publication Manual, conflict with QHR Guidelines, you must follow the QHR Guidelines.
CONFIDENTIALITY AND PROTECTION OF IDENTITY

QHR is committed to protecting the identity and confidentiality of research study participants. With the exception of participatory action research (PAR), no information that could potentially allow identification of a participant—or even a specific study site—should be included in a submitted manuscript or, subsequently, included in a published article.

If the use of participant names is absolutely necessary for reader understanding, each study participant referred to in the manuscript should be assigned a pseudonym. Study sites, such as hospitals, clinics, or other organizations, should not be named, but instead should be described; for example: “Study participants were recruited from the coronary care unit of a large metropolitan hospital on the eastern seaboard of the United States.” Authors who include participant names and/or photos/images in which individuals are identifiable must submit written permission from the participants to do so—no exceptions. Permission to use photographs should contain the following verbiage: “Permission is granted to use, reproduce, and distribute the likeness/photograph(s) in all media (print and electronic) throughout the world in all languages.”

To protect author anonymity during the review process, author citations in the text should include only the word “Author” and the year: (Author, 2008). Author references in the reference list should also include only the word “Author” and the year: Author. (2008). (See the section on references for more details.)

WORD CHOICES

It is always best to use the most precise language possible to convey important data, concepts, and findings. Because QHR is an international journal published in U.S. English, there is the added need to avoid commonly used English terms (colloquialisms, slang) that might be misinterpreted by or confusing to readers whose first language is something other than English.

<table>
<thead>
<tr>
<th>Word or Phrase</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>amongst</td>
<td>Use among instead.</td>
</tr>
<tr>
<td>as</td>
<td>Do not use this word when your meaning is because.</td>
</tr>
<tr>
<td>as regards</td>
<td>Use with regard to, or regarding instead.</td>
</tr>
<tr>
<td>can’t, don’t, and so</td>
<td>Use cannot, do not, and so forth. Do not use contractions unless they are</td>
</tr>
<tr>
<td>forth</td>
<td>part of a quotation.</td>
</tr>
<tr>
<td>Caucasian</td>
<td>Use White instead, capitalized.</td>
</tr>
<tr>
<td>due to</td>
<td>Use because of instead.</td>
</tr>
<tr>
<td>etc.</td>
<td>Use and so forth instead.</td>
</tr>
<tr>
<td>feel</td>
<td>It is appropriate to use this word when referring to a physical sense or state of mind; do not use it when your intent is think or believe.</td>
</tr>
<tr>
<td>female(s)</td>
<td>Please use woman or women instead, whenever possible and appropriate.</td>
</tr>
<tr>
<td>firstly, secondly,</td>
<td>Use first, second, and third instead.</td>
</tr>
<tr>
<td>thirdy</td>
<td></td>
</tr>
<tr>
<td>further</td>
<td>This word is appropriately used when referring to distance, or perhaps with respect to “furthering” something. At the beginning of a new sentence, when writing of something in addition to something already stated, it is more appropriate to use furthermore, moreover, in addition, or additionally.</td>
</tr>
<tr>
<td>Importantly</td>
<td>Do not use this word unless it is part of a quotation.</td>
</tr>
<tr>
<td>in order to</td>
<td>Use to instead.</td>
</tr>
<tr>
<td>Interestingly</td>
<td>Do not use this word unless it is part of a quotation.</td>
</tr>
<tr>
<td>lasty</td>
<td>Use last or finally instead.</td>
</tr>
<tr>
<td>male(s)</td>
<td>Please use man or men instead, whenever possible and appropriate.</td>
</tr>
<tr>
<td>may</td>
<td>Do not use this word in place of might. Use may for permission, might for possibility, and can for ability.</td>
</tr>
</tbody>
</table>
on the one hand / on the other hand

over

paper

since

towards

upon

U.S./United States

while/whilst

Do not use these terms in your writing.

Do not use this word when the intended meaning is more than.

Use article instead.

Since is the appropriate word to use when referring to the passage of time; do not use it when your intended meaning is because.

Use toward instead.

Use on instead

Use U.S. only as an adjective; in all other instances, spell out United States.
The same rule applies to UK/United Kingdom.

Use while when referring to concurrent events; do not use it when your intent is whereas, although, or even though. Do not use whilst.

COMMON PROBLEMS

Acronyms

The full spelling of the related words must precede the first usage of an acronym (even if you think everyone knows what the acronym stands for), followed by the acronym in parentheses; e.g., World Health Organization (WHO). Thereafter you may use the acronym alone: WHO. Avoid the overuse of multiple acronyms.

Anthropomorphism

Anthropomorphism occurs when human characteristics are attributed to things not human. For example: This study used a grounded theory approach... Obviously, a study cannot “use” anything. It would be more appropriate to write, In this study we used a grounded theory approach... Eliminate anthropomorphism from your manuscript.

Back-to-back parentheses

Incorrect: (xxx) (yyy) / Correct: (xxx; yyy)

Bad beginnings

Do not begin sentences—and especially paragraphs—with and, yet, or but. Use caution when beginning a sentence, and do not begin a paragraph, with however.

Capitalization

Capitalize proper names. Do not capitalize words unnecessarily, such as titles and ranks (e.g., director, professor, doctor, chairperson), or themes, categories, concepts, and so forth. (See also Title Case, below)

Ellipses

Ellipses ( . . . ) are to be used only to represent words missing from quotations. Do not use them to represent pauses in speech.

Hyphenation

Refer to the APA Publication Manual, 6th edition, for an excellent explanation of the proper use of hyphens and dashes; do not depend on Word’s “Spell Checker” feature for decisions on hyphenation. With few exceptions (see APA), words beginning with co, non, pre, post, re, semi, socio, and sub do not require hyphenation.

Horizontal lines

Do not place horizontal lines in your manuscript. If footnote separator lines appear, remove them.

Inconsistent writing style

When reviewing your manuscript prior to submission, watch for inconsistent writing style. This is especially important for manuscripts having two or more authors.

Irrelevant data

Page space in the journal is precious. Refrain from including interesting but irrelevant data or commentary.

Jargon

QHR readers come from a wide variety of disciplines and backgrounds, and therefore might not be familiar with the terminology related to your particular field or discipline. If you must include jargon, be sure to explain it clearly the first time a discipline-specific word is used. Avoid the overuse of jargon.
Non-English words

The first time a non-English word is used, italicize it. Thereafter, use only Roman font. All non-English words must be explained or defined in the text. Include English translations of all non-English titles in the reference list (refer to APA for instruction on how to do this).

Paragraph length

To facilitate ease of reading, paragraphs should be no longer than one half of a double-spaced, 8.5 x 11-inch page. Avoid paragraphs of only two or three sentences in length; combine them as necessary to make paragraphs of more appropriate length.

Participant characteristics

Under no circumstances should you include individual participant characteristics in your manuscript. Group participant characteristics. In most cases it is best to write group characteristics into the text rather than placing them in a table (use whichever format takes the least amount of page space).

Repetition

Avoid it! Make your writing as "right," precise, and concise as possible. Avoid including the same facts, conclusions, or information in multiple places in the text (this does not mean you cannot summarize, of course). Avoid overuse of the same phrases, and avoid repeating certain characteristics of your sample: for example: Twelve-year-old boys are perceived as ... This is often a problem for 12-year-old boys. Also, 12-year-old boys are ... .

Run-on sentences

Avoid long, wordy, complex sentences.

Spacing

Use no spaces before, and only a single space after periods (.), commas (,), colons (:), semicolons (;), question marks (?), and closing quotation marks ("). All line spacing (except for text within figures) should be set at exactly double, with 0" before and 0" after.

Special formatting

Never use any coding or formatting in your manuscript that is not called for in these Guidelines.

Spelling

QHRI is published in U.S. English. For best results, set the language of your document to U.S. English when you are establishing all other document setup requirements. Note the correct spelling of a few commonly misspelled words: health care (two words); keywords (one word); semistructured (one word, no hyphen). Also, refer to the section on hyphenation, above. QHRI uses Merriam-Webster’s Collegiate Dictionary (2005) as our spelling reference.

Title Case

Title case is properly created by capitalizing:
- the first letter of the first word
- the first letter of the first word after a colon (:), period (.), or em dash (——)
- all important words, and
- all words containing four or more letters

Verb tense

Things that happened, were said, or were written in the past should be written in the past tense. When writing about what is included in your article, use the present tense rather than the future tense (e.g., in this article we present, rather than in this article we will present).

Voice

Write in the first-person, active voice (use of third-person passive voice is not acceptable). When there are two or more authors, avoid the use of "I" statements.

Word confusion and substitution

Research studies and articles about research studies are two separate things. Do not confuse the meaning of these words in your writing.
BASIC DOCUMENT PREPARATION

See also a variety of sample manuscripts beginning on page 35.

Note: Do not use any coding or formatting that is not described within these Guidelines!

DOCUMENT SETUP AND FORMATTING

Document file type Submit only documents created in Microsoft Word, and only with the regular file extension .doc or .docx (do not submit documents with .docm, .rtf, .pdf or other extensions).

Paper size Letter, 8.5 x 11 inches, with portrait orientation

Margins 1 inch (1"; approximately 2.5 cm.) on all sides

Line numbers None

Line spacing Exactly “double,” with 0” before and 0” after

ORDER OF MANUSCRIPT ELEMENTS

Compile the elements of your manuscript in the following order:

Document 1:
- Title page (required)

Document 2:
- Abstract and keywords (required)
- Main manuscript text (required)
- Notes (if any)
- References (required)
- Appendices (if any)
- Tables (if any)

Document 3:
- Figure 1 (if any)

Document 4:
- Figure 2 (if any; and so forth, with each subsequent figure in a separate document)

FORMATTING OF MANUSCRIPT ELEMENTS

Note: For ease in locating needed information, the various elements are listed below in alphabetical order, and not in the order of anticipated use.

Dialogue Presentation of participant dialogue (i.e., two or more “speakers”) should be set as block quotes/excerpts, indented by ½ inch (approximately 1.3 cm.) from the left margin. Do not use bullets or hanging paragraphs. Begin the narrative of each speaker on a new line. The first time a speaker name is used, type it in full, followed by an appropriate abbreviation in parentheses prior to the colon; thereafter, use only the abbreviation for the speaker name. Refer to the sample manuscripts for an example of dialogue presentation.

Ellipses / ellipsis points Almost every manuscript contains ellipses. They are used to indicate words missing from quotations, and are to be created in a very specific manner. The proper way to create ellipsis points is as follows:

Three (3) dots, preceded, divided, and followed by spaces (i.e., .SPACE.SPACE.SPACE.SPACE), like . . . .

If it is necessary to indicate missing words between sentences (instead of in mid-sentence):

Place a period (full stop) at the end of the first sentence, then format the ellipsis points as noted, and begin the next sentence (with a capital letter) immediately after the last space (i.e., .SPACE.SPACE.SPACE.SPACE). . . .

Like this.
Font size: text  Use 12-point font for everything except text in tables, figures, and (if applicable) conversation analysis.

Font size: tables and figures  Use only 8-point font in tables and figures.

Font style: headings, title page, abstract, keywords, tables, and figures  Use Gill Sans font style for all of these. This includes figure/table numbers, titles, text within the figures/tables, and citations or explanatory notes below the figures/tables (if any). Note: If you do not have Gill Sans font on your computer, please use Arial instead.

Font style: main manuscript  Use Times New Roman font for the main body text. Also, use Times New Roman font for the text (not the headings) of author’s notes, acknowledgments, declarations of conflicting interests, funding statements, footnotes, and bios. Italicics should be used only
- as appropriate in the reference list (see APA);
- as appropriate in level-2, -3, and -4 headings; and
- to introduce non-English words, or unusual new concepts (2 to 3 words), and then only when the new word or concept is first introduced in the manuscript; subsequent use of the same word(s) should be in regular Roman font.

Headings  All headings, without exception, are to be set in Gill Sans, 12-point font. (Use Arial if you do not have Gill Sans on your computer.) QHR uses 4 distinct levels of headings (H = Heading), including:

H Level  Formatting (Note: All headings should be double-spaced, just like the regular text)

H1  Flush Left, Bold Text, in Title Case

H2  Flush Left, Italicized Text, in Title Case

H3  Flush left, italicized text, in sentence case, ending with a period. At this level, the paragraph text begins immediately after the heading, instead of on the next line. The heading is part of the paragraph. Use this heading only if you have a total of four (4) heading levels. Note: Try to avoid the use of H3 if possible, and use only H1, H2, and H4 (see below).

H4  Indented (5" or 1.3 cm.), italicized text, in sentence case, and ending with a period. At this level, the paragraph text begins immediately after the heading, instead of on the next line. The heading is part of the paragraph.

Use at least two heading levels:
- For manuscripts with 2 heading levels, use H1 and H2
- For manuscripts with 3 heading levels, use H1, H2, and H4  (not H3)
- For manuscripts with 4 heading levels, use H1, H2, H3, and H4

Be aware of limitations on the use of heading levels H2, H3, and H4: You are not required to use an H2 heading below any given H1 heading, but if you do, you must use two or more H2 headings; you cannot use just one. The same is true for H3 headings below any given H2 heading, and for H4 headings below any H2 or H3 heading.

Justification of margins  All text should be left justified.

Length of manuscript  There is no predetermined word or page limit. Provided they are “tight” and concise, without unnecessary repetition and/or irrelevant data, manuscripts should be as long as they need to be.

The editor might require a reduction in length if the manuscript contains material that does not add anything useful to the topic being discussed. Limits might be imposed on the number/size/length of tables, figures, reference lists, and appendices.

Line spacing  Everything in all elements of the manuscript (from the title page through the references and tables (if any), must be exactly double spaced. The only exception: Text within a figure should be single spaced.
Lists
Vertical lists (i.e., listed down the length of the page) should be either simple dot bullets or bullets numbered 1., 2., 3., and so forth. Leave a blank, double-spaced line after all lists.

Paragraphs
Paragraphs are to flow, one after the other, without additional line breaks (with few exceptions; see below), and with no extra space between paragraphs.

Leave a blank (double-spaced) line between the abstract and the keywords.

Leave a blank line after (not before) each block quote, numbered list, or bulleted list.

Leave a blank line between block quotes if you have placed two or more in succession.

Indent the first line of every new paragraph by 1/2 (.5) inch (approximately 1.3 cm.), except:

- the first line of the abstract or the keywords,
- the first (opening) paragraph of the manuscript text,
- paragraphs immediately after level-1 and level-2 headings,
- paragraphs beginning with level-3 headings.

Use Word's Format > Paragraph function to set paragraph first-line indentations, but apply this paragraph by paragraph, and not to the entire document.

Use Word's Format > Paragraph function to set block quote/excerpt and bulleted/numbered list indentations. Note that block quotes/excerpts and lists are to be completely indented (not just the first line) by 5 inches (approximately 1.3 cm.) from the left margin only; do not indent from the right side.

Quotation marks
In general, use double quotation marks (e.g., "Xxx.") to set off quotations appearing within regular paragraphs, and to set off words being used with "special" meaning (or unusual spelling to convey special meanings within the text; e.g., "bus-ness"). Do not use quotation marks around quotations presented as block quotes/excerpts.

In regular paragraphs, use single quotation marks to set off a quote within a quote (e.g., "Xxx, "Yyy," xx.xx.").

Note that when closing quotation marks coincide with a comma or period (full stop), the quotation marks go outside (after) the comma or period: "Quotation... last word."

Quotations
Quotations of fewer than 40 words should be surrounded by double quotation marks (") and included within the regular sentences of a paragraph. Internal quotations within quotations of fewer than 40 words should be set apart with single quotation marks (').

Quotations of 40 or more words should be set as separate paragraphs, with the entire quotation indented .5 inches (approximately 1.3 cm.) from the left margin (this is also referred to as a "block quote" or "excerpt"). Do not use quotation marks for block quotes unless there is a separate, internal quotation within the larger quotation; in that case, use double quotation marks (") for the internal quotation only. Make sure all quotations are properly capitalized and punctuated.

Format the indentation for block quotes with Word’s Format > Paragraph feature.

See the special section, below, for instructions on formatting conversation analysis.

Seriation
Seriation refers to "numbered" lists appearing in sentences of regular text (in other words, across the page rather than in a vertical list). The proper seriation style for manuscripts submitted to QHR is (a), (b), (c), and so forth (lowercase letters, enclosed in parentheses).

Spelling
See "Common Problems," above. Exceptions to the use of U.S. English include (a) direct quotes from written, published material, and (b) titles in the reference list (which should be spelled exactly as published).
CONVERSATION ANALYSIS

Note: This specific instruction does not pertain to "regular" quotations, excerpts, or block quotes. If you have not conducted conversation analysis in your study, do not use this formatting for your quotations.

For your excerpts of conversation analysis, you will need to create tables with very specific formatting. Use a level-2 heading, but bolded, with the word "Extract" and the extract number. You may also use a colon with a subheading, if you wish. Use the following steps to format your sections of conversation analysis.

Create a table with the left border of the table aligning with the left margin of the page. Set only two columns. Highlight the entire table and set the font for Courier style, 9-point font (this is critical). In column 1, number the lines, beginning with "1." When you have numbered as many lines as you think you will need, drag the column separator as far to the left as it will go without forcing double-digit numbers onto two lines (i.e., make the first column as narrow as possible). Then, drag the far right border of the table to the left, narrowing the table so that the entire width of the table is exactly 3 3/4 inches (approximately 8 cm.) wide.

Begin typing the excerpt on line 1 of column 2. If you need to use speaker names, place them in this same space, followed by a colon and a single space, before the quotation begins. Use abbreviations for speaker identification as much as possible, to conserve space (see the sample, below). Type across the line, ending as close to the right edge as possible, then drop down to the next line and continue typing. Do not allow the typing to "wrap" within the same row. After typing the entire excerpt, you might need to go back and manually change the first letter of some rows (if your computer automatically capitalized it) to lowercase letters (see below).

Manipulate the text within the rows of column 2 to achieve your desired alignment. Place the symbols for your chosen transcription conventions in the type as you go.

To delete rows, highlight the selected row(s), and then go Table > Delete rows. To add rows, place your cursor in the last line of the table, and hit the tab key until you have as many rows as you need. "Hide" the lines of the table. Format the entire table for double line spacing (do not use hard returns).

Sample excerpt of conversation analysis:

Excerpt 1: Emile

1 Interviewer (I): What happened after
2 that?
3 Emile (E): Well, after that I
4 walked to the corner without my
5 friend, because he took too long
6 getting ready to go.
7 I: How did you feel walking there
8 by yourself?
9 E: I was a little bit nervous.
10 'cause I'm not used to going places
11 by myself.

Note that the sample does not contain transcription symbols. When these symbols are used, cite and reference the transcription style, add a note explaining the symbols if only a few are used, or add a note advising the reader to contact the corresponding author for a key to the symbols.

WHAT YOU SHOULD NOT DO

Conversation analysis  ▪ Do not include a list of the transcription conventions in the manuscript if more than 5
symbols have been used.
Ellipses  
- Do not use the "Insert > Symbol" function in Word to enter ellipses.
- Do not use ellipses to indicate pauses in speech.
- Do not place ellipses within parentheses ( . . . ) or brackets [ . . . ]; the only exception to this is in conversation analysis, as appropriate for the conventions used.

Emphasis  
- Do not use italics, bolding, underlining, or ALL CAPITAL LETTERS for emphasis.
- Do not use italics for quotations (long or short).
- Do not use bolding except for level-1 headings, as appropriate (see below).

General formatting  
- Do not add any special formatting to the document, such as increased line space before and/or after headings.

Headings  
- Do not follow APA guidelines for headings; format your headings only as described in these QHR Guidelines.
- Do not use any headings (such as Introduction or Background) at the beginning of the manuscript.

Line spacing  
- Do not create double spacing with hard returns (by striking the "enter" key twice).
- Do not leave blank lines between paragraphs (with the exceptions of after block quotes/excerpts, bulleted or numbered lists, or sections of conversation analysis; see below).

Margins and indentations  
- Do not use full justification for any portion of your manuscript. The text at the right-hand margin should be uneven (irregular).
- Do not make indentations using tabs, or by using two, .25" indentations to achieve a .5-inch (approximately 1.3 cm.) indentation.
- Do not change margins to create indentations.
- Do not change the margins for block quotes (margins should remain at 1", or approximately 2.5 cm., on all sides).

Quotations  
- Do not use quotation marks for block quotes unless there is a separate, shorter quote contained within the larger quote; in such a case, use double quotation marks (e.g., "YYYY, "YYYY" XXXX ) only for the "inner" quote.

Seriation  
- Do not use numbers of any type for in-text seriation; use only (a), (b), (c), and so forth.

"Review" Your Manuscript

One common reason for " revise" decisions is that authors are sometimes so immersed in their data and findings that they lose track of
- whether the information presented contributes new knowledge
- whether the appropriate method and design have been used
- whether ethical standards have been met
- whether the information is presented in a complete, concise, and logical manner, with attention to writing style, and
- what the reader needs/wants to know (remember that QHR readers have expertise in diverse areas, and therefore many will not be familiar with concepts and terminology common to your research area)

Before submission, we recommend an informal peer review of your article, using the criteria shown on page 55.

Prior to Submission

- Make sure your entire manuscript is prepared in accordance with these Guidelines in every respect.
- Have your manuscript professionally edited by an expert in the English language. This is especially important if English is not your first language. Remember to inform your editor of the need to use U.S.-English spelling, and provide him or her with a copy of these Guidelines.
- Proofread your manuscript siously; doing so will help you identify awkward phrasing, run-on sentences, incomplete sentences, improper punctuation, missing text, and much more. We
recommend that the corresponding author and all coauthors proofread the entire manuscript (including abstract and references) from a paper copy rather than a computer screen.

**KEYWORDS**

Your keywords are words related to the article topics that readers or researchers could search on to find your published article. They are also used to assist QHR in selecting appropriate reviewers for your manuscript during the review process.

Keywords should follow on the same page as the abstract. Leave a blank, double-spaced line between the abstract and the keywords (see the sample manuscripts beginning on page 35).

Include keywords selected only from the QHR Keyword List, below. List them exactly as they are shown in the keyword list, in lowercase letters (except for proper names), horizontally across the page, in the order in which they appear on the keyword list. Try to select at least five keywords. Use the most specific keywords possible from the list provided.

Individual keywords should be separated by semicolons; note that some keywords are actually two or more words, and might include commas. Do not capitalize the first keyword unless it is a proper name (i.e., Africa), and do not add a period (full stop) at the end of the keywords.

You may request that new keywords be added to the list, but the words should be general in nature, and not specific to a narrow topic. New keywords will be added at the editor’s discretion.

**QHR KEYWORD LIST**

*Note: We recommend reading the entire list to identify the most relevant keywords.*

*Remember that the keywords might not be listed exactly the way you think of them (the specific words and the order of words might be different).*

- Aboriginal people, Australia
- Aboriginal people, North America
- abortion
- abuse, child
- abuse, domestic
- abuse, emotional
- abuse, physical
- abuse, sexual
- addiction / substance use
- adherence / compliance
- adolescents / youth
- adolescents / youth, at-risk
- adolescents, pregnancy / parenting
- Africa
- Africa, North
- Africa, South
- Africa, sub-Saharan
- Africa, West
- African Americans
- aging
- alcohol / alcoholism
- altruism
- Alzheimer's disease
- America, Central
- America, North
- America, South
- anesthesia
- animal-human interactions
- anorexia / bulimia
- anthropology
- art
- arthritis
- Asia
- Asia, Central
- Asia, Eastern
- Asian people / cultures
- asthma
- attachment / bonding
- attention-deficit hyperactivity disorder (ADHD)
- autism
- autoethnography
- behavior change
- bereavement / grief
- biographical analysis
- bipolar disorder
- bisexuals
- blood
- body image
- boundaries
- brain injury
- breastfeeding
- burn injury, burns
- burnout
cancer
cancer, breast
cancer, genetics
cancer, psychosocial aspects
cancer, screening and prevention
caregivers / caregiving
Caribbean peoples / cultures
case studies
cerebral palsy
childbirth
child
children, disability
children, growth and development
children, illness and disease
China, Chinese culture
clinical supervision
CNAs
coding
cognition
cognitive
comfort / comforting
communication
communication, medical
community and public health
community capacity and development
community-based programs
comparative analysis
complexity
concept analysis
concept development
concept mapping
confidentiality / privacy
constant comparison
constructivism
consumerism / marketing
content analysis
contraception
conversation analysis
coping and adaptation
crisis management
critical incident technique
critical methods
culture / cultural competence
cystic fibrosis
data collection and management
death and dying
decision making
delirium
Delphi technique
dementia
depression
descriptive methods
developing countries
diabetes
diaries / journals
dignity
dimensional analysis
disability / disabled persons
disability, developmental
disability, learning
discharge planning
discipline / subdiscipline
disclosure
discourse analysis
disfigurement
Down syndrome
dramaturgical analysis
eating disorders
education, patient
education, professional
embodiment / bodily experiences
emergency care
emotions / emotion work
empathy
end-of-life issues
enduring
environment
epidemiology
epilepsy
epistemology
ethics / moral perspectives
ethnicity
ethnography
ethnomethodology
ethnoscience
ethnosemantics
ethology
Europe, Eastern
Europe / Europeans
Europe, Western
euthanasia
event analysis
evidence-based practice
exercise / physical activity
exercise / physical activity, older people
experiential methods
exploratory methods
falsely
falling
families
families, caregiving
families, high-risk
fathers, fathering
fatigue / exhaustion
feminism
fertility / infertility
fibromyalgia
focus groups
Gadamer
gays and lesbians
gender
geriatrics
Giorgi
grounded theory
group interaction
healing
health and well-being
health behavior
health care
health care administration
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nursing, cross-cultural
nursing, maternity
nursing, palliative care
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participatory action research (PAR)
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pharmacology
phenomenography
phenomenology
philosophy
photography / photovoice
physical therapy
politics
postpartum care
posttraumatic stress disorder (PTSD)
poverty
power / empowerment
practice guidelines
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prisons, prisoners
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research participation
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research, clinical
research, collaborative
research, cross-cultural
research, cross-language
research, dissemination and utilization
research, interdisciplinary
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research, qualitative
research, quantitative
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review
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ritual
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SARS
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self
self-care
self-efficacy
self-harm
self-help
sensitive topics
sex workers
sexual harassment
sexuality / sexual health
situational analysis
sleep / sleep disorders
smoking cessation
social constructionism
social development
social equality / inequality
social identity
social issues
social services
social support
social work
sociology
sorrow
spinal cord injury
statistics
stigma
stories / storytelling
stress / distress
stroke
ELEMENTS OF A MANUSCRIPT

Note: Some instructions differ for accepted manuscripts; please refer to page 28.

The following elements are required for each manuscript, and should be compiled in the following order:

Title page
Submit the title page as a separate document.

Abstract
The abstract is placed on page 1 of the main document.

Keywords
Place the keywords below the abstract, on the same page. Leave a (double-spaced) blank line between the abstract and the keywords.

Main manuscript
The main text of the manuscript begins on page 2 of the main document.

References
References begin on a new page, after the end of the manuscript text, or after the notes, if any (do not submit references in a separate document).

The following elements are optional, and may be included in your submission:

Notes
Place notes (also known as endnotes) after the main text, before the first page of references.

Tables
Place tables, one per page, at the end of the main manuscript document, after the references (do not submit tables as separate documents).

Figures
Submit each figure in a separate document, in order, by number.

Appendices
Appendices are published only at the editor’s discretion. Place any appendices after the reference list, and before any tables (place them before the bios in accepted manuscripts).
PREPARATION OF MANUSCRIPT ELEMENTS

A maximum of four (4) types of documents should be submitted: (a) title page; (b) main manuscript; (c) figures (if any); and (d) permissions (if needed). Despite what the online submission system (ScholarOne Manuscripts / SageTrack) might allow, do not submit such elements as abstracts, references, and tables in separate documents. Be sure to refer to the sample manuscripts, beginning on page 35.

TITLE PAGE

The title “page” may be longer than one page. To maintain author anonymity during peer review, it is submitted as a separate document. Title page information should not be included in the main manuscript document. Do not format a running header. The title page should include the following, in this order:

Article title
A title should convey, as clearly and succinctly as possible, the main idea, focus, or content of a manuscript. It should be clear in meaning even when standing alone.

Make your title 10 to 12 words (or fewer) in length; avoid long, “wordy” titles.

Avoid titles with colons or quotations unless they are necessary to convey an important concept or idea in the article.

Type your title in Title Case; this means you should:
- capitalize the first letter of the first word
- capitalize all important words
- capitalize all words that have four (4) or more letters
- capitalize the first word after a colon (:), period (.), or em dash (—)

Author names
List the name (not just initials) of each author, without credentials, in order, horizontally across the page.

If there are two authors, list them as follows: Janice M. Morse and Author Two

If there are three or more authors, list them as follows: Janice M. Morse, Author N. Two, Writer Three, and Fourth Author (and so forth)

After each name (or after the comma following a name, if applicable), use a superscript number to link that particular author with his or her primary affiliation (see the section on author affiliations, below).

Author affiliations
Using the same superscript numbers as used with the authors’ names (see above), list only the primary affiliation of each author, not multiple affiliations (see the sample manuscripts).

Spell out all city, state, and country names (exception: use USA instead of United States). Spell out any organization or institution names (for example, University of Utah instead of U of UT, or World Health Organization instead of WHO).  

Corresponding author information
Use only the following format for the corresponding author information, and do not include any information that is not listed below. List information only for the individual who should be contacted by readers after (if) the article is published.

Note that this should be a complete mailing/postal address. Example:
Janice M. Morse, University of Utah College of Nursing, 10 S. 2000 E., Salt Lake City, UT 84112-5980, USA
Email: QRH.Editor@nurs.utah.edu

Author’s / Authors’ Note
This is optional. This is the place to mention, perhaps, that portions of the article were presented at a professional meeting, or other information of that sort.

Acknowledgments
This is optional. The section is limited to two (2) or three (3) brief sentences.

Overtong acknowledgments will be reduced at the copyeditor’s discretion. Do not include long descriptions of persons being acknowledged, and do not include roles, titles, or credentials.
Avoid phrases such as We wish to thank, We would like to thank, and We want to thank; just use a simple, We thank, or We acknowledge.

Declaration of conflicting interests

You must use one of the following statements, in the exact words shown below.

If you have no conflicts of interest (or potential conflicts of interest):

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

If you have conflicts of interest:

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: [Then, in sentence form, list all specific author relationships with organizations and/or products that were declared].

Funding

You must use one of the following statements, in the exact words shown below.

If you did not have financial support:

The author(s) received no financial support for the research, authorship, and/or publication of this article.

If you did have financial support:

The author(s) disclosed receipt of the following financial support for the research, authorship, and or publication of this article: [Then list, in sentence form, all entities/organizations that funded the research and/or authorship].

Bios

Bios are simple and concise, 1-sentence statements about each author. Long bios will be reduced by the copyeditor. In this space you may include department or division names, and secondary affiliations (if any). Use only the format shown below for your bios. Note that primary credentials (the most important only, with a limit of three per person; QHR does not publish long credential strings) and current positions (or affiliations or professional pursuits) are required.

Janice M. Morse, PhD, FAAN, is a professor and presidential endowed chair at the University of Utah College of Nursing in Salt Lake City, Utah, USA.

[Template: Name, bolded, credentials, role or title, affiliation (here you may include department, school, division, and so forth), city, state or province (if any), country.]

ABSTRACT AND KEYWORDS

The abstract should be placed at the top of page 1 of the main manuscript document. It should be a single paragraph, no more than 150 words in length, and briefly describe your article. It should not contain headings or citations, and should not be divided into sections. Place your keywords below the abstract, on the same page (see “Keywords,” above).

Double space the entire abstract page (including the keywords). Briefly state the purpose of your research, the main findings, and your primary conclusions. Make sure the abstract is written in the first-person, active voice.

MAIN MANUSCRIPT

Note that the sample manuscripts beginning on page 35 are abbreviated for illustration purposes, and might not contain all optional elements that could be included in an actual manuscript. The sample articles contain all four heading levels.

The main text of the manuscript begins at the top of page 2 of the document, immediately after the abstract page. Write your article in the first-person, active voice.

The main text of the manuscript should be broken into appropriate sections by the use of section headings. Sections should flow in a logical sequence, and include, at a minimum, Methods, Results, and Discussion (these are all level-1 headings); other level-1 headings and subheadings may be used at the author’s discretion. The author may choose to use different names for the three main sections, but the basic content should be that which would appropriately fall under the headings of Methods, Results, and Discussion.
There are very specific requirements for the preparation of in-text citations; refer to the APA Publication Manual, 6th edition, for details. Every in-text citation should have a corresponding reference in the reference list—no exceptions.

During the review process, author citations should include only the word Author and the year: (Author, 2008). If and when the manuscript is accepted for publication, the missing information can be restored.

Double space the entire manuscript document, except for text contained in figures. Use only U.S.-English spelling (except in the references, as appropriate, and for direct quotations from published written sources). Use U.S.-English translations of non-English quotations or excerpts. Use a minimum of two (2) heading levels.

Attend to copyright regulations and permission requirements (required). Submit, at the time of manuscript submission, written permission for the use of any names, photographs, or copyrighted tables, figures, and/or text; written permission must come from the person(s) depicted in the photographs, or in the case of copyrighted work, from the copyright holder (which is not necessarily the author or the journal in which it is published; see page 7).

REFERENCES

Note: Proper formatting of the reference list is the responsibility of the author, NOT journal personnel.

The reference list (also known as a bibliography) should include complete references for the sources used in the preparation of your manuscript. Every reference must be cited in the text.

The reference list should begin on a separate page (not in a separate document) following the last page of manuscript text (or after the notes, if any). Each type of reference (journal article, book, chapter in edited book, newspaper, online reference, and so forth) must be formatted in accordance with the precise guidelines contained in APA, 6th edition.

Elements such as listing order, spelling, punctuation, spacing, capitalization, and the use of italics or Roman (regular) font are as important as the content of the reference. Note that if an author has two or more initials, there should be spaces between the initials; incorrect = X.Y.Z.; correct = X. Y. Z.

References should be listed in hanging paragraph format (with indentations at ½ inch or 1.3 cm.), in alphabetical order by the last name of the first author; additional considerations might apply (see APA). The hanging paragraphs should be created by using Word’s Format > Paragraph feature.

During the review process, author references in the reference list should include only the word “Author” and the year; Author, (2008). To prevent author identification during the review process, do not include the article title, journal name, or any other part of the reference. Do not place these references in alphabetical order in the reference list; place them at the very beginning or very end of the list. If and when the manuscript is accepted for publication, the missing information can be restored and properly placed.

Avoid the use of unnecessary references and lengthy reference lists. Extensive bibliographies will not be published; articles should include only the “essential” or key references. If the author wishes to offer a secondary reference list (for example, references used in meta-analysis), it should be so stated in a note, and made available to readers by contacting the author directly. Do not include such a list in the manuscript document, but it may be submitted separately for purposes of review.

Use only the 6th edition of the Publication Manual of the American Psychological Association (APA) as your source of instruction for references (this is critically important). Translate non-English titles into English (see APA for instruction on how to do this). Reference and cite all other studies mentioned in the article. Test all Internet URLs (Web addresses) immediately before submission to ensure that they are accurate, and that the sites are still accessible; do this prior to submission of all revisions and accepted manuscripts, as well.

APPENDICES

Appendices are not encouraged, and are published only at the editor’s discretion. If included, appendices should be placed in the main manuscript document following the reference list, and before any tables (place them before the bios in an accepted manuscript). Appendices must be referred to in the text.
WHAT YOU SHOULD NOT DO

Title page
- Do not type your title in ALL CAPITAL letters (this is especially important when entering the article title in the ScholarOne Manuscripts / SageTrack system).
- Do not place a period (full stop) at the end of your title.
- Do not include unnecessary words, such as A Qualitative Study, A Doctoral Student's Investigation of, An Ethnographic Study, and so forth.
- Do not list secondary or additional author affiliations (departments, divisions, hospital units, and so forth).
- Do not use abbreviations (except USA).
- Do not include department or division names, or secondary unit names.

Abstract
- Do not include the manuscript title on the abstract page.
- Do not indent the first line of the abstract.
- Do not include citations.
- Do not show the word count.
- Do not repeat text from the manuscript in the abstract.

Main document
- Do not include the manuscript title.
- Do not include any author-identifying information.
- Do not include participant identifiers (name, pseudonym, age, and so forth) except to identify a particular category of respondent (e.g., men aged 18 to 24; community professional; psychologist; and so forth), and even then, include identifiers only when necessary for reader understanding.
- Do not include names of specific study sites (hospitals, organizations, small towns or villages).
- Do not use any headings (such as "Introduction" or "Background") at the beginning of the manuscript.

References
- Do not format the hanging paragraphs with hard returns ("enter") and tabs.
- Do not submit the reference list as a separate document (except for lists such as meta-analysis references, as noted above).

FINAL CHECKLIST FOR SUBMISSION

GOAL: To submit the perfect manuscript. This checklist is intended to facilitate the swift internal review of your manuscript prior to submission.

GENERAL MANUSCRIPT PREPARATION

Refer to the instructions contained in the QHR Manuscript Guidelines. Review the section addressing QHR style, beginning on page 8.

AVOID COMMON PROBLEMS:
- Refer to your article as an article, not as a paper or a study.
- Avoid anthropomorphism. Neither your study nor your article conducted the research; you did. Neither your study nor your article considered, chose, utilized, explored, selected, or took any other type of action; you did.

CHECKLIST:
- Consistently use the first-person, active voice in your writing.
- Be accurate and consistent with verb tense: things that happened, were written, or were said in the past should be written about in the past tense.
Submit the title page as a separate document.

Obtain (and submit) any needed permissions for use of copyrighted work and/or for the use of photographs/images.

Obtain an informal peer review of your manuscript prior to submission (see the review criteria on page 55).

Have your manuscript professionally edited prior to submission. If English is not your first language, make certain your editor is an expert in the English language.

**QUOTATIONS**

Read the instructions regarding quotations on page 14 of the QHR Manuscript Guidelines.

**AVOID COMMON PROBLEMS:**

- Participant identifiers and/or codes included with quotations pose a potential threat to participant confidentiality; do not use them. Even pseudonyms should be used with caution, especially if it is possible for the reader to “track” multiple comments presented from a particular participant.

- Ellipses/ellipsis points ( . . . ) are to be used only to represent deleted words or phrases, and not pauses in speech.

**CHECKLIST:**

- Set quotations of fewer than 40 words within regular sentences. Set quotations of 40 or more words as block quotes. (Use Word’s “Word Count” feature.)

- Indent block quotes by ½ inch (approximately 1.3 cm.) from the left margin only. (Use Word’s “Format > Paragraph” feature to create the indentation.)

- Type your quotations in 12-point Times New Roman font, double spaced. Do not use italics.

- Cite and reference all quotations taken from sources other than research participants, and include page numbers in the citations.

- If you add words of explanation or comment within quotations, place those words in brackets rather than (parentheses).

- Properly capitalize and punctuate all participant quotations.

**REFERENCES & CITATIONS**


**AVOID COMMON PROBLEMS:**

- APA has stipulated a particular format for each specific reference type; be sure to use the correct format. Note that not all types of periodicals are referenced in the same manner as journal articles.

- References and citations should be prepared with exactness and attention to detail. The order of listing, spelling, punctuation, spacing, capitalization, and use of italic or Roman font are all important.

**CHECKLIST:**

- Spell out all journal names, and provide complete page numbers (e.g., 172-185 rather than 172-85).

- "Blind" your personal (author) references and citations as noted in the Guidelines.

- Double check the spelling of all reference author names, and ensure that both spelling and years of publication are consistent between the reference list and the in-text citations.

- Provide English translations for all non-English titles (retain the original titles).
☐ Format your references in hanging-paragraph style and double line spacing. Indent the “hanging” text by ½ inch (approximately 1.3 cm.), using Word’s “Format > Paragraph” feature.

**Tables**

**Goal:** To organize and present relevant data that would be too cumbersome or complex to write into the text. Our standard is space. If your material can be more efficiently presented as text, do not make a table. A table must not duplicate material already appearing in the text.

Read the instructions for table preparation on page 29 of the *QHR Manuscript Guidelines*. Place each table on a separate page at the end of your manuscript document.

**Avoid Common Problems:**
- The typesetting process removes all bullets from tables (whether numerals, letters, or dingbats); do not use them.
- The use of underlining, all uppercase (capital) letters, and italics can make a table look busy and cluttered, and can obscure important data. Use these features sparingly or not at all. Use bold font sparingly.

**Checklist:**
- To maintain anonymity, present participant characteristics in aggregate (group) form, and refrain from listing individual participant characteristics.
- Make sure your table has a minimum of two (2) columns, a minimum of two (2) rows, and a clear and concise heading for every column. Double space the table.
- Create your table in “portrait” orientation on the page, within the regular 1-(approximately 2.5 cm.) margins of the document.
- Give your table a clear, descriptive, and concise title.
- Place individual data items or grouped data in separate rows of the table, rather than placing multiple items in a single row.

**Figures**

**Goal:** To create useful and coherent figures that clarify complex concepts or accurately illustrate models and/or processes.

See the instructions for preparing figures on page 31 of the *QHR Manuscript Guidelines*. Make your figure simple, clear, and easy to read and understand.

**Avoid Common Problems:**
- Put your efforts into presenting clear, meaningful data rather than “fancy” or artistic creations. Achieving simplicity, accuracy, and clarity should be your goals.
- Do not use shading, color, or bolded font.
- Too many lines and arrows, and especially lines and arrows that cross each other or cross text boxes, can lead to confusion and make a “muddle” of a figure, obscuring rather than revealing intended meaning. Do not use “heavy” or “bolded” lines and arrows.

**Checklist:**
- Prepare and submit each figure in a separate document.
- Create your figure to be read from left to right and from top to bottom.
- Arrange text boxes in an orderly fashion, making them no larger than necessary to contain your text.
- Make your lines and arrows the proper length, so their beginnings and endings join the cells and clearly indicate direction.
- Use single line spacing for the text, and place the text in a horizontal orientation so it is not necessary to turn the document to read the figure.
Appendix 6: National Research Ethics Service Approval Letter

28 May 2014

Mrs Gabriella Le Geyt, Trainee Clinical Psychologist
School of Psychological Sciences
The University of Manchester
2nd Floor, Zochonis Building
Oxford Road
Manchester
M13 9PL

Dear Mrs Le Geyt

Study title: Personal accounts of the decisions and processes involved in making choices about antipsychotic medication
REC reference: 14/NW/0306
IRAS project ID: 143440

The Research Ethics Committee reviewed the above application at the meeting held on 20 May 2014. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager, Elaine Hutchings, nrescommittee.northwest-gmeast@nhs.net.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study:

- Please provide a copy of the review of the study by the University Research Sub-Committee.
Information sheet

a. The sheet should give more information about where the interviews could be held.

b. It should say that the study is being conducted for the purposes of achieving a PhD qualification.

c. The reference to Yvonne Awenat should be removed if she is no longer to be involved with the study.

d. It should say what will happen to study data already collected if a participant withdraws from the study.

e. The reference to ‘payment’ should be reworded ‘compensation’ for time spent in taking part in the study.

f. As discussed at the meeting, consideration should be given to replacing the cash payment with a shopping voucher to avoid any impact on benefits; please confirm your decision on this matter and ensure that the information sheet is accurate on this point.

g. The correct name of the reviewing REC needs to be inserted.

Consent form

- This needs to refer to the correct version of the information sheet.

Letter to professional contacts

a. The second sentence beginning ‘Your involvement….. ‘ is considered to overstate the benefits and should be removed.

b. It should say that the study is being conducted for the purposes of achieving a PhD qualification.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.
For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on question 2 of the IRAS filter page) must be registered on a publicly accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Summary of discussion at the meeting

Your application was considered in conjunction with application 14/NW/0307. These were found to be well presented applications giving rise to minimal issues of concern.

Social or scientific value; scientific design and conduct of the study

The studies were considered to be worthwhile qualitative research which had the potential to help prevent relapse and to add to the literature in this field. The grounded theory to be used was found to be appropriate for the projects. The studies would focus on patient participants’ perspectives and this was to be commended, as was the inclusion of feedback from a service user Community Liaison Group in the design of the study.

Recruitment arrangements and access to health information, and fair participant selection

The recruitment procedures were well thought out and described. It was commented that the applications listed a large number of study sites. You explained that staged recruitment would be carried out, starting with three Trusts and extending the number of sites if this proves necessary. This was considered to be a well-planned approach.
Favourable risk benefit ratio: anticipated benefit/risks for research participants (present and future)

The risks to participants and the researchers themselves had been carefully considered, described and addressed. It was pleasing to see that a distress protocol was in place. The Committee concluded that the risk/benefit ratio was favourable. The Committee was satisfied with the compensation for participants as the amount was small and should cover any expenses incurred. However, the point was made that the payment to be made to participants could impact on benefits and it might be preferable to offer a high street shopping voucher instead. The wording about the payment would then need to be worded in the information sheet.

The possibility was raised of participation having the effect of suggesting the idea of reducing or stopping medication. The researchers assured the Committee that the studies would recruit patients who had already tried to reduce or stop medication.

It was confirmed that the interviews would take place at a location of the participant's choosing, which could include their home. The researchers confirmed that they would abide by an appropriate lone worker policy in this regard.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
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</tr>
</thead>
<tbody>
<tr>
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<td>23 April 2014</td>
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<td>8</td>
<td>23 April 2014</td>
</tr>
</tbody>
</table>

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

14/NW/0306 Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee’s best wishes for the success of this project.

Yours sincerely

Mr Francis Chan  
Chair

Enclosures: List of names and professions of members who were present at the meeting

“After ethical review – guidance for researchers”

Copy to: Ms Lynne MacRae, University of Manchester

Jennifer Higham, Greater Manchester West Mental Health NHS Foundation Trust
NRES Committee North West - Greater Manchester East

Attendance at Committee meeting on 20 May 2014

Committee Members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present</th>
<th>Notes</th>
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</thead>
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<tr>
<td>Mr David Asher</td>
<td>Retired Pharmacist</td>
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<td></td>
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<tr>
<td>Mr R Trevor Benn</td>
<td>Retired Statistician</td>
<td>No</td>
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<tr>
<td>Mr James Burns</td>
<td>Retired</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mr Francis Chan</td>
<td>Consultant Orthopaedic Surgeon</td>
<td>Yes</td>
<td>Chair</td>
</tr>
<tr>
<td>Dr Jacqueline Crowther</td>
<td>Research Associate</td>
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<td></td>
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<tr>
<td>Dr Mary Dolan</td>
<td>Retired Nurse Lecturer</td>
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<td></td>
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<tr>
<td>Dr Michael Hollingsworth</td>
<td>Retired Senior Lecturer in Pharmacology</td>
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<td></td>
</tr>
<tr>
<td>Mr Christopher Houston</td>
<td>Lay Member</td>
<td>No</td>
<td></td>
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<tr>
<td>Mr Richard Hovey</td>
<td>Lay member</td>
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<tr>
<td>Mr Simon Jones</td>
<td>Specialist Podiatrist - Paediatrics</td>
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<tr>
<td>Dr Philip Lewis</td>
<td>Consultant Cardiologist</td>
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<tr>
<td>Dr Charles D King</td>
<td>Lay Member</td>
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<tr>
<td>Professor Janet Maraden</td>
<td>Professor of Ophthalmology and Emergency Care</td>
<td>No</td>
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</tr>
<tr>
<td>Mrs Mary Spoke</td>
<td>Clinical Research Practice Educator</td>
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</table>

Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elaine Hutchings</td>
<td>Committee Co-ordinator</td>
</tr>
</tbody>
</table>
10 June 2014

Mrs Gabrielle Le Geyt, Trainee Clinical Psychologist
School of Psychological Sciences
2nd Floor, Zochonis Building
The University of Manchester
Oxford Road
Manchester
M13 9PL

Dear Mrs Le Geyt

Study title: Personal accounts of the decisions and processes involved in making choices about antipsychotic medication
REC reference: 14/NW/0306
IRAS project ID: 143440

Thank you for your letter of 4 June 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 23 May 2014.

Documents received

The documents received were as follows:

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<thead>
<tr>
<th>Document</th>
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</tr>
</thead>
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<td>30 May 2014</td>
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Approved documents

The final list of approved documentation for the study is therefore as follows:

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You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor’s responsibility to ensure that the documentation is made available to R&D offices at all participating sites.
Yours sincerely

Elaine Hutchings
REC Manager
E-mail: nrescommittee.northwest-gmeast@nhs.net

Copy to: Ms Lynne MacRae, University of Manchester
Jennifer Higham, Greater Manchester West Mental Health NHS Foundation Trust
Appendix 7: Local research and development ethical approval letters
Standardised Process for Electronic Approval of Research

10 June 2014

Mrs Gabrielle Le Geyt
University of Manchester
2nd Floor, Zochonis Building
Brunswick Street
Manchester
M13 9PL

Dear Mrs Le Geyt

Re: NHS Permission for Research

Project Reference: 831
REC Reference Number: 14/NW/0306
Sponsor: University of Manchester
Project Title: Personal accounts of the decisions and processes involved in making choices about antipsychotic medication
Date of Permission: 10 June 2014

Further to your request for permission to conduct the above research study at this Trust, we are pleased to inform you that this Trust has given NHS permission for the research. Your NHS permission to conduct research at this site is only valid upon receipt of a signed 'Conditions for NHS Permission Reply Slip' which is enclosed.

Please take the time to read the attached conditions for NHS permission. Please contact the R&D Office should you require any further information. You will need this letter as proof of NHS permission. Please note when contacting the R&D office about your study you must always provide the project reference numbers provided above.

NHS permission for the above research has been granted on the basis described in the IRAS application form, Protocol and supporting documentation.

The documents reviewed were:

Protocol, Version 8, dated 23/04/2014
Topic Guide, Version 3, dated 01/03/2014
Distress and Risk Protocol, Version 3, dated 02/01/2014
Participant Information Sheet, Version 5, dated 30/05/2014
Participant Consent Form, Version 5, dated 30/05/2014
Advertising poster, Version 3, dated 01/03/2014
Demographic Questionnaire, Version 3, dated 01/03/2014

Greater Manchester West Mental Health NHS Foundation Trust, Trust HQ, Bury New Road, Prestwich, Manchester M25 3BL  Tel 0161 773 9121
Chair: Alan Maden  Chief Executive: Bev Humphrey
Additional information for participants, Version 3, dated 05/03/2014
Letter to professional contacts, Version 4, dated 30/05/2014
Letter for establishments, Version 3, dated 05/03/2014
REC letter giving favourable ethical opinion, dated 10/06/2014

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP (if applicable), and NHS Trust policies and procedures. Permission is only granted for the activities for which a favourable opinion has been given by the Ethics Committee.

Permission covers all locations within the Trust, however, you should ensure you have liaised with and obtained the agreement of individual service/ward managers before commencing your research.

We would like to point out that hosting research studies incurs costs for the Trust such as: staff time, usage of rooms, arrangements for governance of research. We can confirm that in this instance we will not charge for these. However, we would like to remind you that Trust costs should be considered and costed at the earliest stage in the development of any future proposals.

May I wish you every success with your research.

Yours sincerely

Dr Stephen Colgan
Medical Director and R&D Lead

cc : Sponsor: University of Manchester

Enc: Approval Conditions Leaflet
     Induction & ID Badge Information
10th June 2014

Mrs Gabrielle Le Geyt
University of Manchester
2nd Floor Zochonis Building
Brunswick Street
Manchester
M13 9PL

Dear Gabrielle,

Re: Research Governance Decision Letter

SPEAR/Trust Project Reference: 1326
Project Title: Personal accounts of the decisions and processes involved in making choices about antipsychotic medication.
REC No.: 14/NW/0306

Further to your request for research governance approval, we are pleased to inform you that this Trust has approved the study. Please note when contacting the R&I office about your study you must always provide the project reference numbers provided above.

Trust R&I approval covers all locations within the Trust, however, you should ensure you have liaised with and obtained the agreement of individual service/ward managers before commencing your research. This letter also gives NHS permission, on behalf of Rotherham Doncaster and South Humber NHS Foundation Trust, to undertake the protocol specified research activities within the Early Intervention Service.

Please take the time to read the attached ‘Information for Researchers – Conditions of Research Governance Approval’ leaflet, which give the conditions that apply when research governance approval has been granted. Please contact the R&I Office should you require any further information. You may need this letter as proof of your approval.

A partnership between the NHS and Manchester City Council
We would like to point out that hosting research studies incurs costs for the Trust such as: staff time, usage of rooms, arrangements for governance of research. These are demonstrated in the enclosed proforma invoice. We can confirm that in this instance we will not charge for these. However, we would like to remind you that Trust costs should be considered and costed at the earliest stage in the development of any future proposals.

You will need to contact us before any new researchers join your team as they will need Trust permission before they start work on the project.

It is your responsibility to contact us a week prior to the expiry date we have recorded for this project to let us know if you wish to extend it, as we will need to send a new approval letter. You will also need to let us know immediately if for any reason the project finishes earlier.

It is a condition of our Trust approval that on completion of this study we are in receipt of an end of study report summary and a copy of the Ethics letter confirming that they have closed the study, we will remind you of this nearer the time. You will also be asked to complete an audit form for each year your study is supported by this Trust (including the year of its completion) this approval requirement and failure or refusal to complete it may result in Trust approval being withdrawn.

By beginning your research you are agreeing to all the terms and conditions as stated within this letter.

May I wish you every success with your research and if you have any queries do not hesitate to contact the R&I Team.

Yours sincerely

[Signature]

Dr. Andy Mee
Research & Innovation Manager

cc: Research Governance Sponsor: University of Manchester
    Academic supervisor(s): Prof. Gillian Haddock
    Dr. Sara Tai

Enc: Approval Conditions Leaflet
     Induction & ID Badge Information, TrustTECH Leaflet
     Invoice
Standardised Process for Electronic Approval of Research

16th June, 2014

Gabrielle Le Geyt
School of Psychological Sciences
Division of Clinical Psychology
2nd Floor, Zochonis Building
The University of Manchester
Brunswick Street,
Manchester,
M13 9PL

Dear Gabrielle,

Re: NHS Permission for Research

Project Title: Personal accounts of making choices about antipsychotic medication
Unique SPEAR Identifier: 1326
Sponsor: University of Manchester

Further to your request for permission to conduct the above research study at this Trust, we are pleased to inform you that this Trust has given NHS permission for the research. Your NHS permission to conduct research at this site is only valid upon receipt of a signed ‘Conditions for NHS Permission Reply Slip’ which is enclosed.

Please take the time to read the attached conditions for NHS permission. Please contact the Research Office should you require any further information. You will need this letter as proof of NHS permission.

NHS permission for the above research has been granted on the basis described in your university application form and supporting documentation.

The documents reviewed were:
- NHS ethics application and approval
- Participant information sheet, version 5, dated 30/05/2014
- Consent forms, version 5, dated 30/05/2014
- Protocol, version 8, dated 23/04/2014

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP (if applicable), and NHS Trust policies.
and procedures. Permission is only granted for the activities for which a favourable
opinion has been given by the Ethics Committee (where appropriate).

May I wish you every success with your research.

Yours sincerely,

Phil Elliott
Senior Research Facilitator on Behalf of:

Dr Pat Mottram
Research and Effectiveness Manager

Enc:  Approval Conditions Leaflet
Appendix 8: Letters to professionals

Letter for establishments: Version 3, 05/03/2014

SCHOOL OF PSYCHOLOGICAL SCIENCES
Zochonis Building, Oxford Road, Manchester, M13 9PL
Telephone: 0161 306 0400
Email: gabrielle.legeyt@postgrad.manchester.ac.uk
Mobile: 07770129703

Dear Sir/Madam,

Re: ‘Personal accounts of making choices about antipsychotic medication’ research study

My name is Gabrielle Le Geyt and I am a Trainee Clinical Psychologist at the University of Manchester, where we are conducting research to better understand the choices people make about the use of antipsychotic medication. In particular, we would like to understand what happens when people with psychosis choose to reduce or discontinue their antipsychotic medication. Previous research indicates that many people prescribed antipsychotic medication choose to withdraw from it, and often do so without informing a healthcare professional. Obviously this can be dangerous for patients and can lead to many unpleasant withdrawal effects, which can be difficult to manage. I would like to talk to people about their experiences of discontinuing antipsychotic medication in the hope that this will allow for a better understanding of the support needs of this group. This may in turn influence service development, which seeks to support people who are making treatment decisions in relation to the use of antipsychotics.

I am currently recruiting people for the study from the Greater Manchester area and I wondered if it is possible for you to display the enclosed advertisement poster in your surgery/pharmacy/establishment so that potential participants can learn about the study and contact me for further information if they are interested?

I am enclosing a copy of the Participant Information Sheet, which will provide you with information on what participants recruited into the study would be required to do to assist you in deciding whether you feel that it would be appropriate to display the study poster in your surgery/pharmacy/establishment.

If you would like to discuss the research further, please do not hesitate to contact me at: gabrielle.legeyt@postgrad.manchester.ac.uk

Thank you in advance,

Gabrielle Le Geyt
Trainee Clinical Psychologist.
Personal accounts of making choices about antipsychotic medication.

Dear Sir or Madam:

Thank you for agreeing to support this piece of research, which is being conducted as part of my doctoral training and for the purposes of achieving a ClinPsyD qualification.

Overview of study
The study seeks to explore personal accounts of making choices about using antipsychotic medication from the perspective of the client. Specifically, this study will consider the experiences of people with psychosis who choose to reduce or discontinue their antipsychotic medication.

Rationale for the study
The research is being conducted as literature has suggested that many people who are prescribed antipsychotic medication choose to withdraw from it, and often do so without informing a healthcare professional. Obviously this can be dangerous for people and can lead to many unpleasant withdrawal effects, which can be difficult to manage. I am interested in talking to people about their experiences of discontinuing antipsychotic medication in the hope that this will allow for a better understanding of the support needs of this group. This knowledge, in turn may inform service development, which seeks to support people who are making treatment decisions in relation to the use of antipsychotics.

Your involvement
I am hoping to recruit between 12 – 14 participants to this study from the Greater Manchester area. To support recruitment, I am asking professionals who are either involved in the care of people who have experienced psychosis or who work in organisations that support people with psychosis to act as the initial contact for the study.

This will involve identifying potential participants and discussing the study with them. Individuals who express an interest in learning more about the study can then be provided with some brief study information and invited to discuss the study with me in more detail. This will require potential participants to provide you with consent for me to contact them and their contact details.

The reasons for this approach are twofold. Firstly, the likelihood that individuals who are invited to participate in the study meet the inclusion criteria (see below), is increased and hence this limits the number who may be interested but unfortunately
not eligible to participate. Secondly, this approach will protect potential participants from experiencing undue influence, which may lead to them feeling obliged to be involved in the study, as they will be invited by an impartial contact.

Once consent to contact has been agreed with interested individuals, I will contact them, provide detailed information about the study and offer the opportunity for questions. I will request consent to contact their GP or care coordinator at this point to establish their suitability for the study. Once suitability has been established, I’ll screen for eligibility and provide further information. If the inclusion criteria are satisfied, I will arrange an interview to take place in a mutually convenient location.

**Inclusion Criteria**

**Participants must have:**

- Experienced psychotic symptoms for a minimum period of 3 months, which is not explained by organic causes (e.g. a brain tumour)
- Taken antipsychotic medication for a minimum of 3 months
- Engaged in reduction or discontinuation of antipsychotics at some point (complete or partial/successful or unsuccessful)
- Mental capacity to consent

N.B. if an individual’s capacity to consent to participation is in doubt, please do not invite the individual to the study.

**Participants must be:**

- 18 years old or over
- Proficient in spoken English
- Community based and not subject to Community Treatment Order
- Free from organic cognitive impairment

N.B This inclusion criteria is provided as a guide for you to identify potential participants. I will complete a full inclusion screen with all interested potential participants before including them in the study to ensure they satisfy the criteria.

I have enclosed a copy of the Participant Information Sheet, which provides you with further information on what participants recruited into the study would be required to do.

If you have any queries or would like to discuss the research further, please do not hesitate to contact me on: gabrielle.legeyt@postgrad.manchester.ac.uk or telephone: 07770129703.

Yours sincerely,

Gabrielle Le Geyt

Trainee Clinical Psychologist.
Appendix 9: Study advert

Do you take antipsychotic medication?
Have you ever taken antipsychotic medication in the past?
Have you ever tried to reduce or stop taking your antipsychotic medication?

The University of Manchester are currently researching people’s experiences of stopping or reducing antipsychotic medication. We would like to talk to you if you have ever tried to reduce or stop taking your antipsychotic medication.

We’re interested in hearing about:

- Your hopes and expectations of stopping/reducing your medication
- The ways you made decisions
- How you put decisions into action
- The things that informed your choice to come off
- The outcome of cutting down or coming off

We hope this information will help Mental Health Services understand what support people need when they make the choice to reduce or stop their antipsychotic medication.

If you would like to take part in the study, a researcher will arrange to talk with you for about one hour about your experiences. You will be reimbursed £10 for taking part in the research.

If you are interested in taking part, or if you would like some more information about the study, please contact Gabrielle Le Geyt using the email address or phone number detailed below:

SCHOOL OF PSYCHOLOGICAL SCIENCES
Zochonis Building, Oxford Road, Manchester, M13 9PL
Telephone: 07770129703
Email: gabrielle.legeyt@postgrad.manchester.ac.uk
Appendix 10: Participant Information Sheet

SCHOOL OF PSYCHOLOGICAL SCIENCES
Zochonis Building, Oxford Road, Manchester, M13 9PL

Study: Personal accounts of making choices about antipsychotic medication.

We would like to invite you to take part in an interview research study. Before you decide whether to take part, please read why the research is being done and what it would involve for you. Please take time to read this information carefully and to speak to others about the study. The study aims to talk to people about their experiences of making choices about antipsychotic medication, particularly people who have tried to come off medication, to allow us to understand the support that people might need when they go through this process.

What does the study involve?
The study involves talking to a researcher for about 1 hour about your experiences of coming off antipsychotic drugs. It does not matter if you are taking antipsychotics now, we want to talk to anyone who has ever tried to cut down or stop their antipsychotics. We would like to talk to you about how you made decisions about this process and how you put these decisions into action. For example, we would like to hear about the factors influencing your choice to come off, your hopes and expectations, and the outcomes of cutting down or coming off. This information will help us understand what support people need when they cut down or stop their antipsychotics.

Who is carrying out the research?
This research is being conducted by Gabrielle Le Geyt, who is a Trainee Clinical Psychologist at the University of Manchester. The project will be supervised by Dr Sara Tai and Professor Gillian Haddock, who are both qualified Clinical Psychologists working at the University of Manchester. The study is being conducted for the purposes of achieving a doctorate qualification in Clinical Psychology (a ClinPsyD qualification).

What happens if I take part? If you are interested in taking part, this is what will happen:

1. With your permission, we will contact your GP or care coordinator to check that it is suitable for you to take part. If you do take part in the study, we will also write a very brief letter to your G.P or care coordinator afterwards to let them know of this. We will be happy to show you this letter so that you can see what has been written. However, please be reassured that if you do take part, the information that you discuss in your interview will not be shared unless we become concerned about your safety.

2. We will arrange to talk to you about the research and check that you are suitable for the study. This gives you the chance to find out more and ask any questions. We can have this talk over the telephone or face-to-face in a room that the team can book out (for example in a GP surgery, a university building or a local charity).

3. You will be given some time to think about whether you want to take part in the study. If you decide that you do want to take part we will ask you to sign a consent form stating that you want to be involved.
4. We would then come and see you to do the interview. The interview will take place in a booked out room at a location convenient to you (for example in a GP surgery, a university building or a local charity) or if preferred, at your home. The interview will be recorded on an audio recorder so that we can listen back to it and type up what was said. We would like to hear your experiences so we will ask some general questions that should help us focus on the parts of your experiences that you feel are most important. We will also ask you to fill out a short questionnaire asking for information like your age and gender, how long you have been taking antipsychotics and which ones you take.

5. When the research is finished we will send you a summary sheet of the findings (if you would like us to do so).

Payment and expenses
You will be compensated £10 for the time you spend taking part in the study and to cover any travel expenses. You will be given the option of receiving this as a high street voucher or as cash. Please be aware that if you receive benefits and choose to receive cash compensation for your involvement, your benefits may be affected. You will receive the £10 at the end of the interview.

Participation in this study is entirely voluntary
You are free to withdraw from the study at any point without giving a reason. Any data collected before your withdrawal will be kept securely, but not used, until the end of the study and then destroyed. If you do not take part in this study it will not affect your care or treatment.

Will my information be kept confidential?
The questionnaire from the study and the typed-up version of your interview will not have your name or personal details on. Instead they will have a number on. Any names that you mention in the interview will be changed so they cannot be identified. All paperwork and recordings will be kept confidential. Only the research team will be able to see/hear them. To ensure the study is being carried out properly, individuals from the University, Trust or regulatory authorities may access study data. With your permission, the information they look at may include personal data but the individuals accessing the data will have a duty of confidentiality to all research participants. Once the study is finished, the audio-recording of your interview will be destroyed. The results of this project will be written in a research report, which may be published in a scientific journal. We may use quotes from what you say in this report, but your details will be removed so nobody will know your identity. The study information might also be used in future research studies but would still remain anonymous.

We will not pass on anything that you talk about to your care coordinator, psychiatrist or anyone else involved in your care.

The only exception to this would be if you told us something that made us think that you or someone else could be at risk of harm. In this case, we would have to share that information with other relevant professionals such as your G.P. in order to keep you and others safe. However, we would talk to you about this first so that you knew who we would be sharing the information with and why.
Will the researcher be able to provide me with advice on my treatment?
No. Although the researcher is training to be a Clinical Psychologist, she will not be involved in your usual care for mental health difficulties and would therefore not be able to provide any advice or guidance on your treatment. However, she will be able to advise you on who you should speak to should you wish to discuss your treatment.

Are there any potential benefits to taking part?
It is hoped that the study will allow you an opportunity to share your experiences, and that in doing so, you will feel that you are part of a piece of research which aims to improve support for people with psychosis.

Are there any potential risks?
It is hoped that the research will not lead to any risks for participants; however, some people may find it upsetting to talk about their experiences. The researcher will regularly check your distress and you will be able to stop the interview at any point or take a break if you need to. The researcher will also be able to guide you to further support if you feel that this would be helpful.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk.

Who has reviewed the study? All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the National Research Ethics Service Committee North West – Greater Manchester East.

Who do I contact?
If you have any questions about the study or would like to take part please contact the researcher, Gabrielle Le Geyt on the details below.

Many thanks for your interest.
With best wishes,

Gabrielle Le Geyt

Telephone: 07770129703
Email: gabrielle.legeyt@postgrad.manchester.ac.uk
Appendix 11: Consent form to complete risk assessment

SCHOOL OF PSYCHOLOGICAL SCIENCES
Zochonis Building, Oxford Road, Manchester, M13 9PL
Telephone: 0161 306 0400
Email: gabrielle.legeyt@postgrad.manchester.ac.uk

Study: Personal accounts of making choices about antipsychotic medication.

The project is being sponsored by the University of Manchester.

Thank you for your interest in this study. To ensure your suitability for this study, we would like to contact your GP or care coordinator, with your permission. We do this as a matter of course for everyone who is interested in research studies of this kind that are being sponsored by the University of Manchester and we would like to reassure you that this is to complete routine suitability checks and not to share your information (for example your reasons for wanting to be in the study). If you have any questions about this, please discuss these with Gabrielle Le Geyt on the number above before you sign this consent form.

Signing this form does not sign you up to the study. Your consent to participate in the study will be requested following contact being made with your GP/care coordinator.

Please initial in the box to agree

1. I give my consent for the researcher, Gabrielle Le Geyt, to contact my GP to check my suitability for involvement in this study

2. I give my consent for the researcher, Gabrielle Le Geyt, to contact my care coordinator to check my suitability for involvement in this study.

I would be grateful if you would sign this form to show that you have read, or have had read to you the contents of this consent form and that you consent for the researcher to contact your GP or care coordinator.

Name of participant       Date       Signature
Appendix 12: Participant Consent Form

**Study: Personal accounts of making choices about antipsychotic medication.**

The project is being sponsored by the University of Manchester.

Please read the information sheet before you sign the consent form.

Thank you for your willingness to take part in this research project. Your involvement is very much appreciated. We would like to reassure and remind you that as a participant in this project you have several very definite rights.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Please initial if answering ‘yes’ to the statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I confirm that I have read and understand the information sheet (Version 5, 30/05/14) for the above study and have had the opportunity to ask questions.</td>
<td></td>
</tr>
<tr>
<td>2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.</td>
<td></td>
</tr>
<tr>
<td>3. I understand that quotes from interviews and details from the questionnaire may be part of the final research report and used in research publications, but under no circumstances will names or identifying characteristics be included.</td>
<td></td>
</tr>
<tr>
<td>4. I agree to the researcher contacting my care coordinator and/or my GP prior to my involvement in the study to check my suitability to take part in the research.</td>
<td></td>
</tr>
<tr>
<td>5. I give my consent for the interview to be audio recorded and typed up in full. I understand that only the researcher will use this material.</td>
<td></td>
</tr>
<tr>
<td>6. I give consent for the researchers to send me a summary of the study results via post or e-mail (please delete as appropriate).</td>
<td></td>
</tr>
<tr>
<td>7. I understand that there is a possibility that the information from the interview and questionnaire may be used in future research studies, however this information will remain confidential and anonymous.</td>
<td></td>
</tr>
<tr>
<td>8. I understand that data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data from this study.</td>
<td></td>
</tr>
<tr>
<td>9. I agree to take part in the above study.</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 13: Participant Demographics Questionnaire

**Title of Project:** Personal accounts of making choices about anti-psychotic medication.

This questionnaire is designed to gather some more information about you. Please ask the researcher if you would like any thing explained further or if you would like someone helping to fill it out.

**Age:**
- Male 
- Female 

<table>
<thead>
<tr>
<th>Ethnicity: with which ethnic group do you identify?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>White!</td>
<td></td>
</tr>
<tr>
<td>White - British!</td>
<td></td>
</tr>
<tr>
<td>White - Irish!</td>
<td></td>
</tr>
<tr>
<td>White - Any other white background!</td>
<td></td>
</tr>
<tr>
<td>Mixed!</td>
<td></td>
</tr>
<tr>
<td>Mixed - White and Black Caribbean!</td>
<td></td>
</tr>
<tr>
<td>Mixed - White and Black African!</td>
<td></td>
</tr>
<tr>
<td>Mixed - White and Asian!</td>
<td></td>
</tr>
<tr>
<td>Mixed - Any other mixed background!</td>
<td></td>
</tr>
<tr>
<td>Asian or Asian/British!</td>
<td></td>
</tr>
<tr>
<td>Asian or Asian/British - Indian!</td>
<td></td>
</tr>
<tr>
<td>Asian or Asian/British - Pakistani!</td>
<td></td>
</tr>
<tr>
<td>Asian or Asian/British - Bangladeshi!</td>
<td></td>
</tr>
<tr>
<td>Asian or Asian/British - Any other!</td>
<td></td>
</tr>
<tr>
<td>Asian Background!</td>
<td></td>
</tr>
<tr>
<td>Black or Black British!</td>
<td></td>
</tr>
<tr>
<td>Black or Black British - Caribbean!</td>
<td></td>
</tr>
<tr>
<td>Black or Black British - African!</td>
<td></td>
</tr>
<tr>
<td>Black or Black British - Any other Black!</td>
<td></td>
</tr>
<tr>
<td>Other ethnic group!</td>
<td></td>
</tr>
</tbody>
</table>
Demographic Questionnaire: Version 3: 01.03.2014

Title of Project: Personal accounts of making choices about antipsychotic medication.

This questionnaire is designed to gather some information about you. Please ask the researcher if you would like anything explained further or if you would like some help filling it out.

Age:

Male [ ] Female [ ]

Ethnicity: with which ethnic group do you identify? (please tick one)

White [ ]

White- British [ ]

White- Irish [ ]

White- Any other white background [ ]

Mixed [ ]

Mixed- White and Black Caribbean [ ]

Mixed- White and Black African [ ]

Mixed- White and Asian [ ]

Mixed- Any other mixed background [ ]

Asian or Asian British [ ]

Asian or Asian British- Indian [ ]

Asian or Asian British- Pakistani [ ]

Asian or Asian British- Bangladeshi [ ]

Asian or Asian British- Any other Asian background [ ]

Black or Black British [ ]

Black or Black British- Caribbean [ ]

Black or Black British- African [ ]

Black or Black British- Any other black background [ ]

Other ethnic group [ ]
<table>
<thead>
<tr>
<th>Demographic Questionnaire: Version 3: 01.03.2014</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What type of Antipsychotic Medication(s) were you taking when you chose to come off??</th>
<th>How were you taking this medication?? (e.g. tablet, liquid, long lasting depot injection)</th>
<th>How long had you been taking each medication that you ticked above?? (before you chose to come off??)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perphenazine [aka Fentazin®]</td>
<td>!</td>
<td>Years, months, e.g., 2 years, 7 months, 0 years, 9 months</td>
</tr>
<tr>
<td>Pimozide [aka Orap®]</td>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Prochlorperazine</td>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Promazine Hydrochloride [aka Promazine]</td>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Quetiapine [aka Seroquel®]</td>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Risperidone [aka Risperdal®]</td>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Sulpiride [aka Dalmatil®]</td>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Trifluperazine [aka Stelazine®]</td>
<td>!</td>
<td></td>
</tr>
<tr>
<td>Zuclopenthixol [aka Clopixol®]</td>
<td>!</td>
<td></td>
</tr>
</tbody>
</table>

Are you taking any medication now?!!
If so, which one(s)!!

|                                    | 4!                                    |


Appendix 14: Topic guide

Personal accounts of making choices about antipsychotic medication.

What! follows! is! a! guide! to! the! topics! that! are! likely! to! be! covered! in! the! interviews! with! individuals! who! have! experienced! discontinuing! antipsychotic! medication.!! Some! topics! may! emerge! spontaneously! so! the! order! of! the! questions! and! the! exact! content! may! vary! as! the! interview! develops.!! The! questions! may! also! be! influenced! by! the! ongoing! analysis.!!

The following topics stand prompts to elicit an interview guide.!!

1) Starting antipsychotic treatment*
Can! you! tell! me! a! bit! about! the! time! you! were! first! prescribed! antipsychotics?!! (Probe! for! reasons! for! starting! the! decision! making! process?!! who! prescribed! it?!! quality! of! relationship! with! prescriber?!!)
What! were! your! views! about! antipsychotic! medication! at! that! time?!! (Probe! for! beliefs! about! medication;! views! of! positive/negative! toward! taking! medication;! hopes! and! expectations;! concerns?)!!

2) Experiences of taking antipsychotic medication*
Can! you! tell! me! about! your! experiences! of! taking! antipsychotic! medication?!! (Prompt:!! What! was! it! like! to! be! on! this! medication?!! How did! it! feel?!! Benefits! and! problems! most! important! issues.)!!

3) Decision to discontinue or reduce antipsychotics*
When! did! you! first! consider! stopping! or! reducing! antipsychotics?!! (Probe! for! duration! from! starting! if! it! was! a! sudden! decision! or! a! gradual! process! intentional! or! unintentional?!! Discussed! it! with! anyone! else?!! What! was! their! reaction?!! Positive! or! negative?!!
Can! you! tell! me! some! of! the! reasons! for! your! decision?!! (Probe! for! effects! of! medication;! beliefs! about! medication;! including efficacy;! beliefs! about! recovery;! role! of! others!)!!
What! was! it! like! making this decision?!! (Probe! for! decision! made! alone! or! with! others;! easy! or! hard;! straightforward! or! difficult;!! certain! or! uncertain;!! time! spent! thinking! about! it;! impact! on! mood)!!
Can! you! tell! me! if! anything! or! anybody! helped! or! hindered! the! decision! making! process?!! (Probe! for! availability! of! information;!! role! of! others;!! timing! of! decision)!!


Personal accounts of making choices about antipsychotic medication.

What! follows! is! a! guide! to! the! topics! that! are! likely! to! be! covered! in! the! interviews! with! individuals! who! have! experienced! of! discontinuing! antipsychotic! medication. !Some! topics! may! emerge! spontaneously! in the! order! of! the! questions! and! the! exact! content! may! vary! as! the! interview! develops. !The! questions! may! also! be! influenced! by! the! ongoing! analysis!

The following topics and prompts serve as an interview guide!!

1) Starting antipsychotic medication*
   Can! you! tell! me! a! bit! about! the! time! you! were! first! prescribed! antipsychotics? !Probe! for!: when! they! started! them; reasons! for! starting! them;! the! decision! making! process;! who! prescribed! it; quality! of! relationship! with! prescriber!
   What! were! your! views! about! antipsychotic! medication! at! that! time?! (Probe! for!:! prior! beliefs! on! medication;! views! of! positive/negative! toward! taking! medication;! hopes; expectations; concerns)

2) Experiences of taking antipsychotic medication*
   Can! you! tell! me! about! your! experiences! of! taking! antipsychotic! medication? !Prompt:! What! was! it! like! to! be! on! this! medication? !How! did! it! feel?! !Benefits;/problems;/most!important;issues.

3) Decision to discontinue or reduce antipsychotics*
   When! did! you! first! consider! stopping! or! reducing! antipsychotics? !Probe! for!:! duration! from! starting! if! it! was! a! sudden! decision! or! a! gradual! process; intentional! or! unintentional?! !Discussed! it! with! anyone! !who?! What! was! their! reaction! ?Positive!/negative?! Can! you! tell! me! some! of! the! reasons! for! your! decision?! (Probe! for!:! effects! of! medication;! beliefs! about! medication;! including! efficacy;! beliefs! about! recovery; role! of! others)
   What! was! it! like! making! this! decision? ! (Probe! for!:! decision! made! on! down!! or! with! others! !easy! or! hard! !straightforward! or! difficult; certain! or! uncertain! time! spent! thinking! about! it; impact! on! mood)! Can! you! tell! me! anything! or! anybody! helped! or! hindered! the! decision! making! process?! (Probe! for!:! availability! of! information; role! of! others; timing! of! decision)


Topic Guide:  
Version 3, 01/03/2014  

availability of information; support; personal well being; psychological; 
social and physical factors; attitudes of self/ others! 

Do you have any further points that you would like to make? 
Any questions?!! 
Many thanks for your time!
Appendix 15: Participant Debrief sheet

Personal accounts of making choices about antipsychotic medication.

Overview of study
Thank you for taking part in this study by sharing your experiences of reducing or coming off antipsychotic medication. This study is an exploration of the choices that people make about the medication they are prescribed for psychosis. The study seeks to understand what decisions people make, how they make them and the factors involved in making decisions. The study is also looking at how decisions about reducing or stopping medication are put into action and what the outcomes of these decisions are.

What the study involves
In this study, we will interview 12 - 14 people who have made the choice to reduce or discontinue their medication at some point. We will consider the experiences that are unique to individuals and look at themes that might be common to some or all of the people we interview. The study will be written up as a doctoral thesis and submitted to the University of Manchester. Papers from the thesis will also be submitted to research journals and the study may be presented at conferences.

The purpose of the study
It can be difficult to answer the types of questions we asked in this interview, and your generosity and willingness to participate in this study are greatly appreciated. Your input will help contribute to the advancement of the field of psychosis research. We hope that the study will provide the opportunity for the voices of those who experience psychosis and make choices to reduce or stop their medication to be heard. By listening to the voices of those who have this first-hand experience, we hope to provide professionals with information about ways in which they can support people in the choices they make about medication use.

What to do if you were affected by the questions
Sometimes people find the subject matter of these interviews upsetting. If answering any of these questions led you to feel distressed and you would like to speak to someone about your thoughts there are a number of professional and voluntary organisations that you may find helpful. Similarly, if you have been affected in any other way by any of the issues we have discussed as part of this study, you may wish to contact these organisations. We have provided a list of some of these in your area. You may also find that your GP practice has useful suggestions and contact numbers.

Follow up contact
You have the option to receive a summary of the study’s findings and implications. If you would like to receive this information, please indicate your preference to the researcher for
follow up correspondence to be sent either via email or post and provide your email address/postal address. We anticipate that summaries of findings will be available in September 2015. If you need to change your contact details at any point, you can do so by contacting either Gabrielle Le Geyt or Professor Gillian Haddock on the numbers detailed at the top of this page.

**What to do if you have questions or wish to withdraw**

Similarly, if you have any questions regarding the study or you wish at any point to withdraw your involvement in the study, please contact Gabrielle Le Geyt or Professor Gillian Haddock on the numbers detailed at the top of this page.

If you have any concerns about the study that you prefer not to raise with the research team, please contact the University Research Office on 0161 275 7583.

Finally, thank you again for helping us with this research.
Contact list of professional and voluntary organisations

**Samaritans**
*Offering emotional support 24 hours a day*

Tel: 08457 90 90 90  
Email: jo@samaritans.org  
Web: www.samaritans.org

**Manchester and Salford Samaritans day-time drop-in: 9am-8.30pm. No appointment is necessary.**

72-74 Oxford Street  
Address: Manchester  
M1 5NH  
Tel: 0161 236 8000

**Mind Info line**
*For advice about a range of issues relating to mental health and wellbeing*

Tel: 0300 1233393

**Manchester Mind**
*Opening hours: Monday to Friday, 9am - 5pm*

Zion Community Centre  
339 Stretford Road  
Hulme  
Manchester  
M15 4ZY

Tel: 0161 226 9907  
Email: info@manchestermind.org  
Web: www.manchestermind.org

**Sane Line**
*Offering specialist mental health emotional support 6pm -11pm everyday.*

Tel: 0845 767 8000  
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Appendix 16: Distress Protocol

Distress and Risk protocol version 1.0, November 2013.

During the course of the interview, it is possible that participants may become distressed as a result of discussing their treatment decisions. Should this happen, the following action will be taken:

1. If the interview is ongoing, the participant’s distress will be acknowledged and they will be asked if they would like to take a break or end the session. The participant’s decision will be respected and their levels of distress will be monitored throughout the interview.
2. The researcher who is training as a Clinical Psychologist and is therefore experienced in dealing with emotional distress will spend time with the participant and will explore with them what caused the distress.
3. The participant will be encouraged to contact their G.P., care co-ordinator or psychiatrist and will be assisted with this if desired.
4. If the interview is taking place out of hours, the participant will be directed to the emergency G.P. telephone number and will be assisted with this if necessary.
5. Participants will be given contact telephone numbers for various support services, e.g. their local Accident and Emergency department, the Samaritans, Mind, Saneline etc within the Participant debriefing sheet. Participant’s attention will be drawn to these telephone numbers and their use will be explained.
6. Participants will also be provided with the researcher’s telephone number to use should they become distressed after the interview has finished.

The research does not include any intervention component and thus the researcher would not provide any direct input for a participant who becomes distressed as a result of the research. However, as the researcher is a Trainee Clinical Psychologist who receives ongoing clinical supervision, it will be possible for the participant’s acute and chronic emotional distress to be assessed and for the researcher to use her clinical judgement as appropriate to ascertain potential further steps that may need to be considered in ensuring that the participant received appropriate support.

Participants who expressed feelings of distress during the research would be encouraged to contact their G.P or care co-ordinator (as detailed above) and would be assisted with this process if required but the ultimate decision regarding whether or not they access help would remain theirs. However, should a participant show a level of distress which rendered them a potential risk to themselves or others then the researcher would make appropriate contact with the participant’s G.P., care co-ordinator, social services or community mental health team. If immediate risk was apparent, an ambulance and/or the Police would be contacted as appropriate. Furthermore, the researcher would seek guidance on the appropriate course of action to take from her project supervisors, two of
whom are experienced Clinical Psychologists and are trained to deal with risk situations.

Participants who revealed distress at the time of the interview, or who revealed distress following the interview by contacting the researcher and disclosing this would be telephoned 24 hours after revealing their distress by the researcher who would check on whether their distress levels were subsiding or not. Should distress levels remain or have worsened, the participant would be encouraged to seek support from their mental health team or from the support services detailed in their support services sheet. Should issues pertaining to risk be revealed, the appropriate agencies would be contacted (see previous paragraph).