Do negative screening test results cause false reassurance? A systematic review

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Do negative screening test results cause false reassurance? A systematic review --Manuscript Draft--

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Manuscript Classifications:	Meta analyses/systematic reviews; Behaviour change; Health-related behaviours; Screening
Abstract:	<p>Purpose: It has been suggested that receiving a negative screening test result may cause false reassurance or have a 'certificate of health effect'. False reassurance in those receiving a negative screening test result may result in them wrongly believing themselves to be at lower risk of the disease, and consequently less likely to engage in health-related behaviours that would lower their risk.</p> <p>Methods: The present systematic review aimed to identify the evidence regarding false reassurance effects due to negative screening test results in adults (over 18yrs) screened for presence of a disease or its precursor, where disease or precursor are linked to lifestyle behaviors. MEDLINE and PsycINFO were searched for trials which compared a group who had received a negative screening results to an unscreened control group. The following outcomes were considered as markers of false reassurance: Perceived risk of disease; anxiety and worry about disease; health-related behaviours or intention to change health-related behaviours (i.e. smoking, diet, physical activity, and alcohol consumption); self-rated health status.</p> <p>Results: Nine unique studies were identified, reporting 55 measures in relation to the outcomes considered. Outcomes were measured at various time points from immediately following screening to up to 11 years after screening. Despite considerable variation in outcome measures used and timing of measurements, effect sizes for comparisons between participants who received negative screening test results and control participants were typically small with few statistically significant differences. There was evidence of high risk of bias, and measures of behaviours employed were often not valid.</p> <p>Conclusions: The limited evidence base provided little evidence of false reassurance following a negative screening test results on any of four outcomes examined. False reassurance should not be considered a significant harm of screening, but further research is warranted</p>
Additional Information:	
Question	Response

<p>If you have any potentially competing interests to declare, please enter them in the box below. If you have no interests to declare, please enter 'none'. Please declare any financial relationships (such as employment, consultancies, stock ownership or options, honoraria, patents, paid expert testimony) or any personal relationships which could be perceived to undermine the credibility of your research. By conflict of interest, we are referring to cases where professional judgment in relation to the research, or the welfare of research participants, may be influenced by another interest, such as financial gain or personal relationships.</p>	none
<p>Does this submission have any links or overlap with any other submitted or published manuscripts, for this or any other publication? (For example; as part of a long-term project, using a shared data set, a response to, or extension of, earlier work.) If yes, please give brief details. If no, please enter 'none'. Any overlap not declared and later discovered will result in the manuscript being withdrawn from consideration.</p>	none
<p>Please specify the word count of your manuscript (excluding the abstract, tables, figures and references).</p>	3044
<p>Do you use Twitter for academic purposes? (If you do and your paper is accepted, we will 'mention' you when we share a link to the online article.)</p>	yes
<p>What is your Twitter handle? as follow-up to "Do you use Twitter for academic purposes? (If you do and your paper is accepted, we will 'mention' you when we share a link to the online article.)"</p>	bc_lifestyle

Response to reviewers

Thank you for these reviews which have raised important issues. We have addressed these comments and feel it has improved the paper considerably.

Reviewer #1:

In 'statement of contribution' - first bullet point: either remove '(erroneously)' or change to 'negative test result, erroneously' as at present the sentence could be misinterpreted as an erroneous test result.

The word erroneously has been removed.

lines 64-66: this appears to be the conclusion to this review - if know prior to review, then why is the review necessary?

This has been reworded, to make it clearer and to avoid prejudging the results of the review. Prior reviews have only considered screening group as a whole and have not considered the negatively screened group separately (lines 69-77)

lines 104-105: how often did you contact the authors and find the detail was not available?

This information has been added to text and PRISMA flowchart. The authors of two studies which met the inclusion criteria but did not report the specified outcomes were contacted. One author provides additional information and this study was included in the review the second author failed to respond (Lines 114-117).

line 106: how was the data extracted and how many researchers extracted the data?

This information has been added. The data needed to calculate effect sizes were extracted and analysed by one author before being independently review by a second author (lines118-119).

line 86: typo? Negative rather than negatively?

This has been corrected (line 98)

line 209: add reference - Collins et al 2011?

This reference has been added (line 223)

lines 222-225 seems repetitive of lines 156-158

Details have been removed in lines 156-158 and included more appropriately in the discussion section (now lines 223-230).

Reviewer #2:

Introduction:

The introduction reads well. The authors provide a clear overview of screening and the potential implications of receiving a negative screen result. I have some minor comments:

1. Page 3, line 46: 'the majority of people will screen negative...' If data is available, could the authors provide a percentage figure for the number of people who screen negative?

The following text has been added in lines 46-50 to demonstrate this; For example in the NHS breast screening programme, one of the most well established screening programmes in the UK 96% of participants receive a negative screening test result. Thought the exact number of negative results varies depending on various factors such as; the population being screened, the disease being screened for and the chosen screening procedure

2. Page 3, lines 61: 'has been indicated' is this a typo?

This has been changed to 'has been demonstrated' to make the statement clearer. (Line 64)

3. Page 3, lines 64-66: Could this sentence be rephrased so 'false reassurance' is not repeated? Please could the authors also provide a reference for this statement?

This has been rephrased and appropriate references added (lines 69-77).

4. In the Discussion (page 8-10, lines 185-226), the authors discuss and cite numerous reviews of false reassurance, but do not mention these in the introduction. I think the introduction could be strengthened with a short summary of these reviews, followed by a line which identifies the gap and reason for conducting this review.

More details of these reviews have been added to the introduction (lines 69-84), and the discussion has been shortened by removing these details.

Methods:

5. Page 4, line 86: Should this read '...those receiving a negative screen test'?

Yes as indicated this now read 'those receiving a negative screen test' (lines 97-98)

6. Page 4, line 87: Do the authors mean controls who were not screened? If so, please could this be clarified?

This has reworded to make it clear that controls had not received screening (line 98).

7. Page 4, lines 87-90: I assume this list of reported measures were selected as they can be used as proxy measures for false reassurance. Please could the authors provide a statement to clarify this for the reader either in the methods section or in the final paragraph of the introduction?

More detail has been added to introduction to make this clearer (lines 64-67 and lines 99-103)

8. Analysis section is missing

Analysis heading has been added, and the relevant text from the results moved to this section (lines 130 -137)

Results:

9. Page 5, lines 111-114: Please could the authors precede all the numbers in brackets with 'n=' e.g. 'studies screened for diabetes (n=3)'.

These have been added (123-125).

10. Page 5, line 117: If all studies had high risk of bias, why were they included in the review?

In line with Cochrane guidance, all studies should be included in systematic reviews, and not omitted on basis of study quality. Risk of bias was mostly unavoidable due to a lack of blinding which would not be possible in these studies. Bias was also due to self-reported measures such as questionnaires which were usually appropriate for the measurements being taken. By highlighting these sources of bias, we flag up where future research in this area could be improved.

11. Page 6, lines 119-125: This section would be better placed in the 'analysis section' of the Methods

This is now included in the analysis section (lines 130 -137).

12. Page 6, line 127: Could the authors replace the word 'overwhelming' with a numerical figure?

The word overwhelming has been removed and the number given under each outcome heading

13. Page 6, lines 127-140: This section would benefit from being broken down into four sub-sections in line with each of the four outcome measures. This results section also seems fairly brief and in places I found it difficult to understand the direction or effect of a negative screening result on each outcome. For instance on lines 132-134, two studies found a significant difference in terms of anxiety or worry- so did a negative screening test result in this case mean that p's were more anxious/worried or less anxious/worried after the negative screen result? Please could this be clarified with some additional text for this statement and all other statements in this section to provide some level of interpretation?

Heading for each outcome have been added and the direction of significances clarified (lines 104-163).

14. References for the studies discussed in this section are missing

References have been added as foot notes to the tables to clarify which results are from which study. The references are also included in the reference list

Discussion:

I found the discussion difficult to follow in places. I think the Discussion would benefit from some revision, restructuring and perhaps shortening so the key messages stand out to the reader. I have a few suggestions for how this could be done:

15. Page 7, lines 146-149: Could this sentence be rephrased to focus on the key headline finding?

This sentence has been rephrased (lines 169-170)

16. Page 7, lines 151-155: This study should be discussed in the results section

This has been moved to the results section (Lines 156-163).

17. Page 7, lines 155-158: 'a larger proportion of screening participants were screen positive for at least one the conditions'- this is interesting but I'm not sure how relevant it is to the review as the review was about impact of negative screening results on self-rated health.

As described above in response to reviewer 1s comment this has been removed and explained more clearly in lines 222-225 (now lines 323-330).

18. Page 8-10, lines 185-226: Please see my comment in the Introduction section (comment 4). I think this section would benefit from shortening. If the authors provide a brief overview of previous reviews in the Introduction, they can draw on these in the Discussion to briefly explain which findings were in line with their review and which were not. This can be followed by discussion around why their findings were/were not in line with previous review studies.

Details of previous reviews have been moved from the discussion to the introduction. Making the discussion clearer and more concise (lines 64-84).

19. Page 8-10, lines 185-226: Findings appear to be reported in the Discussion which were not reported in such depth in the Results section (see my comment number 13).

Findings moved to results section (Lines 156-163).

20. Page 9, line 207: Please could the authors reflect on what they think is atypical about this study?

The following information has been added as a possible explanation for this difference (lines 218-221);

It's not clear why this study follows a different trend to all the other studies included in this review. One possible explanation for this could be related to the screening procedure itself. The NORCCAP study utilised flexible sigmoidoscopy as a means of screening for colorectal cancer, it is possible that the more invasive nature of this test could influences people belief in the reliability and validity of the outcome.

21. Page 10, lines 228-230: I wonder if the conclusion is slightly overstated considering all studies included were of high risk of bias?

The wording has been changed to avoid overstating the conclusion (lines 263-264).

22. Page 11, line 252: '...done at low cost and with validated measures'?

With validated measures has been added (line 266)

Table 2: Numbered referencing with references in a footnote of the table would be useful to direct the reader to which study the outcome was measured and which study the figures have been extracted from.

An additional footnote has been added with references, which are also included in reference list at the end of the document.

Do negative screening test results cause false reassurance? A systematic review

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Word count (exc. figures/tables): 3044

Statement of contribution

What is already known on this subject?

- It has been argued that screening for disease may cause 'false reassurance' whereby those who receive a negative screening test result wrongly interpret their result as indicating they are less likely to develop the disease in the future.
- There is some evidence for false reassurance, but the relevant studies consider a range of diseases and possible indicators of false reassurance (i.e. risk perceptions, lifestyle behaviours, emotional outcomes and quality of life).
- For these reasons, it is currently unclear the extent to which receiving negative screening test results is likely to impact on participants' lifestyle behaviours, or other possible indicators of false reassurance.

What does this study add?

- Current available evidence shows that negative screening test results are unlikely to cause false reassurance, and in particular are unlikely to have a negative impact on lifestyle behaviours.
- Given the limitations of the current evidence base in terms of number of studies and study quality, future research should continue to explore this issue, where this can be done at low cost.

Do negative screening test results cause false reassurance? A systematic review

Abstract

Purpose: It has been suggested that receiving a negative screening test result may cause false reassurance or have a ‘certificate of health effect’. False reassurance in those receiving a negative screening test result may result in them wrongly believing themselves to be at lower risk of the disease, and consequently less likely to engage in health-related behaviours that would lower their risk.

Methods: The present systematic review aimed to identify the evidence regarding false reassurance effects due to negative screening test results in adults (over 18yrs) screened for presence of a disease or its precursor, where disease or precursor are linked to lifestyle behaviors. MEDLINE and PsycINFO were searched for trials which compared a group who had received a negative screening results to an unscreened control group. The following outcomes were considered as markers of false reassurance: Perceived risk of disease; anxiety and worry about disease; health-related behaviours or intention to change health-related behaviours (i.e. smoking, diet, physical activity, and alcohol consumption); self-rated health status.

Results: Nine unique studies were identified, reporting 55 measures in relation to the outcomes considered. Outcomes were measured at various time points from immediately following screening to up to 11 years after screening. Despite considerable variation in outcome measures used and timing of measurements, effect sizes for comparisons between participants who received negative screening test results and control participants were

typically small with few statistically significant differences. There was evidence of high risk of bias, and measures of behaviours employed were often not valid.

Conclusions: The limited evidence base provided little evidence of false reassurance following a negative screening test results on any of four outcomes examined. False reassurance should not be considered a significant harm of screening, but further research is warranted.

Keywords

False reassurance, certificate of health effect, screening, negative screening test result, systematic review

Introduction

Screening programmes aim to find a disease or precursors to a disease early before overt symptoms develop. This allows early treatment and improves outcomes. However, there are potential harms of screening which should be taken into account when assessing the net benefit of screening. These include over-diagnosis leading to unnecessary treatment, false positives or false negatives, and discomfort or risk associated with the screening procedure (Raftery & Chorooglou, 2011). Screening programmes are also very costly, and some argue that money used to fund screening could reduce the burden of disease more if it was used for to fund primary prevention and treatment (Sackett & Holland, 1975). The potential harms of screening should be assessed as well as the potential benefits when evaluating whether a screening programme is warranted. For example, in the UK the National Screening Committee (NSC) considers the likely balance of harms and benefits of potential screening programmes before they are recommended and implemented (Public Health England, 2015).

In any screening program the majority of people will screen negative (Wilson & Jungner, 1968). For example in the NHS breast screening programme, one of the most well established

screening programmes in the UK 96% of participants receive a negative screening test result (Marmot et al., 2013). Though the exact number of negative results varies depending on various factors such as; the population being screened, the disease being screened for and the chosen screening procedure. It has been proposed that some people who receive negative screening test results will interpret their result as indicating they are less likely to develop the disease (Marteau, Kinmonth, Thompson, & Pyke, 1996). This is a misconception as screening only identifies if a person currently has the condition or marker for the condition at the time of screening and does not provide information about a person's future risk of developing the disease. This interpretation of negative screening test results as being informative about future disease risk has been described as "false reassurance" or a "certificate of health effect" (Larsen, Grotmol, Almendingen, & Hoff, 2007; Marteau et al., 1996). The main practical implication of false reassurance is that this misconception may result in people who receive negative screening test results being less likely to engage in behaviours to reduce their risk of disease (Larsen et al., 2007; Marteau et al., 1996). This is highly relevant to most screening programme which mainly screen for diseases which are strongly linked to lifestyle factors, such as smoking and lack of physical activity.

It has also been argued that false reassurance has been demonstrated in, reports of lower anxiety or worry about the disease screened for (Marteau et al., 1996; van der Aalst, van den Bergh, Willemsen, de Koning, & van Klaveren, 2010) and higher self-rated health (Eborall et al., 2007) in those receiving negative screening test results.

Previous systematic reviews have compared differences in health-related behaviours between participants who had been offered screening with control participants (Deutekom et al., 2010). However, authors were unable to draw conclusion due to a lack of studies. A separate

systematic review by Collins, Lopez and Marteau (2011) compared emotional outcomes in participants who had been offered screening with control participants and concluded that screening had no impact on anxiety, depression and quality of life beyond four weeks after screening. These previous reviews have focussed only on the effects of all screening attendees, to be able to draw conclusions about the overall net effect of screening, and have not consider the negatively screened group separately to the whole screening population.

Given this, we conducted a systematic review to assess whether receiving a negative screening test result causes false reassurance. We specifically examined the available evidence of the impact of receiving a negative screening result on: Perceived risk of disease; Anxiety and worry about disease; Lifestyle behaviours or intention to change lifestyle behaviours including smoking, diet, weight, physical activity, and alcohol consumption; Self-rated health.

Methods

Search strategy. MEDLINE and PsycINFO, were searched up to May 2016, with a search strategy based on key review papers (Collins, Lopez, & Marteau, 2011; Deutekom et al., 2010) (see appendix 1) and adjusted for each database. Forward and backward citation searches from included articles and the key review papers (Collins et al., 2011; Deutekom et al., 2010) were conducted.

Inclusion and exclusion criteria. Randomised controlled trials which compared population based screening of asymptomatic adults (over 18 years) with no screening controls were eligible. Screening programmes were included if they screened for diseases linked to lifestyle behaviours such as type 2 diabetes, cancer (breast, bowel, cervical, lung), or

abdominal aortic aneurysm. We included only studies which reported results for those receiving a negative screen test versus a control group who did not undergo screening. Included papers reported on one or more of the following markers of false reassurance: Perceived risk of disease; Anxiety and worry about disease; Lifestyle behaviours or intention to change lifestyle behaviours including smoking, diet, weight, physical activity, and alcohol consumption; Self-rated health. For the lifestyle behaviour outcome we also included weight and BMI, due to the poor quality of many self-report diet measures .

We excluded unpublished literature and papers not available in English, as well as papers which communicated disease risk assessment i.e. where there is no negative test result for a condition but participants were told their future risk of developing a disease, e.g. Q Risk for cardiovascular disease (Hippisley-Cox, Coupland, & Brindle, 2017).

Identification of relevant studies. Electronic searching identified 347 unique results. Titles and abstracts of the papers were assessed for potential eligibility by two researchers independently, with a satisfactory level of agreement ($\kappa=0.7$). Discrepancies were settled by discussion and consensus amongst all three study authors. The full text papers were obtained for all papers deemed potentially relevant. The authors of two studies which met the inclusion criteria but did not report the specified outcomes were contacted. One author provides additional information and this study was included in the review the second author failed to respond. The final set of studies to be included was agreed following discussion by all three authors. The data needed to calculate effect sizes were extracted and analysed by one author before being independently review by a second author. We assessed risk of bias amongst the selected studies using the Cochrane Risk of Bias Tool (Higgins & Green, 2011).

Figure 1. PRISMA Flow Diagram

Ten papers were identified, describing eight unique studies (see table 1 for a summary of study characteristics). Studies screened for diabetes (n=3), abdominal aortic aneurysm (n=1), and cancer (lung cancer [n=2] colorectal [n=1] and multiple cancers [n=1]). Studies were based in the UK (n=3), Netherlands (n=2), USA (n=2), Norway (n=1) and Denmark (n=1). Study sample sizes were typically large, varying from N=278 to N=14012. Outcomes were measured at various time points from immediately following screening to up to 11 years after screening. All the included studies had high risk of bias from a number of sources (see appendix 2).

Analysis. Difference in how outcomes were measured and the time points at which they were measured between the studies meant that meta-analysis was not appropriate. For example, there were 10 different measures of diet quality, and six each for smoking status or physical activity. (for full details see appendix 3). Given this heterogeneity, results were tabulated to show the effect sizes and results of statistical significance tests for comparisons between participants who received negative screening test results compared with control participants across the studies (see table 2).

Results

Perceived risk of disease. Of the seven measures of disease risk perception, only two were statistically significant. In both these cases the effect size was small ($-0.16 < \text{Standardised mean difference (SMD)} < -0.01$), indicating that only in these two cases did a negative screening test results result in a small decrease in perceived risk of the disease screened for.

Anxiety and worry about disease. There were nine tests assessing if participants who received negative screening test results or control participants differed in terms of anxiety or worry. Only two of these nine were statistically significant indicating lower levels of anxiety or worry in the screen negative group however both were of small effect ($-0.22 < \text{SMD} < 0.06$).

Lifestyle behaviours or intention to change lifestyle behaviours. Of 28 tests of whether participants who received negative screening test results or control participants differed in reports of health-related behaviours or intention to change behaviour only five showed a statistically significant unfavourable change in the negatively screened groups health related behaviours or intention to change their behaviour. The NORCCAP (Berstad et al., 2014) study of colorectal screening was responsible for all of these significant results suggesting that in this trial, negative screening test results had a detrimental effect on lifestyle behaviours that were apparent at three years post-screening. As observed with all outcomes, the effect sizes were consistently small ($-0.11 < \text{SMD} < 0.17$; $0.74 < \text{OR} < 1.1$). The largest effects came in relation to self-reported health ($-0.55 < \text{SMD} < 0.14$; $\text{OR}=1.1$), but even there, none of 11 tests comparing those received negative screening test results with control participants were statistically significant.

Table 1 about here

Table 2 about here

Discussion

Across a variety of diseases screened for, countries, measures of false reassurance and duration of measurement since screening, there was little evidence of false reassurance or a negative impact on lifestyle behaviours. Effect sizes for comparisons between participants who received negative screening test results and control participants were typically small with few statistically significant differences. This lack of statistical significance is notable because of the very large sample sizes employed in these studies. There were two studies which deviated from this otherwise consistent pattern of results. The NORCCAP (Berstad et al., 2014; Larsen et al., 2007) study of colorectal screening was responsible for all five of the significant results obtained. The largest effect sizes in the review were found in the PLCO trial (Taylor, Shelby, Gelmann, & McGuire, 2004).

The present systematic review aimed to provide a comprehensive assessment of false reassurance by including four indicators of false reassurance. To achieve this aim, we searched using multiple databases and used forward and backward citation searching to identify relevant literature. However, we did not include unpublished literature or studies published in languages other than English. Further, given that the studies included in this review were not specifically design to examine false reassurance, it is possible that other eligible studies may have been missed due to searches being unlikely to pick up all such studies. It is also likely that other studies collected data that would have been eligible for the present review, and may even have been analysed, but not published due to the general tendency of non-significant result to not be reported (Hopewell, Loudon, Clarke, Oxman, & Dickersin, 2009).

The primary studies included in this review had complete data and good follow-up, even many years following screening which further adds strength to these findings (see table one). However, all the included studies had high risk of bias from several sources (see appendix 2). Blinding of participants to the intervention was not possible resulting in a high risk of performance bias, and most of the outcome data was collected via a participant completed questionnaire resulting in a high risk of detection bias. Response rates in the control group were generally lower than in the screening groups, leading to a high risk of attrition bias. In addition, although anxiety and worry and self-rated health were assessed using validated scales, behavioural outcomes were typically measured using unvalidated scales, often with self-reported measures. Further, the wide variety of scales across all outcomes made it difficult to synthesise results across studies, as did the variety of assessment time points.

The present results are broadly in agreement with previous systematic reviews which compared participants who had been offered screening with control participants (Collins et al., 2011; Deutekom et al., 2010) his agreement is notable given that both previous reviews focussed on the effects of all screening attendees,. The similarity of the results of the previous reviews and the present review probably reflects the fact that in most screening programmes, most people receive negative screening test results.

The review by Deutekom et al., 2010 found two eligible RCTs of the effects of screening on health behaviours, only one of which is included in the present review as the other study was concerned with screening for hearing loss. In the present review, five studies provided 28 tests of whether participants who received negative screening test results or control participants differed in reports of health-related behaviours or intention to change behaviour only five were statistically significant, with consistently small effect sizes. It is notable that

the five significant results all came from the NORCCAP (Berstad et al., 2014; Larsen et al., 2007) study of colorectal screening. It's not clear why this study follows a different trend to all the other studies included in this review. One possible explanation for this could be related to the screening procedure itself. The NORCCAP study utilised flexible sigmoidoscopy as a means of screening for colorectal cancer, it is possible that the more invasive nature of this test could influence people's belief in the reliability and validity of the outcome.

The previous review of emotional outcomes (Collins et al., 2011) identified 12 eligible studies, and concluded that screening had no impact on anxiety, depression and quality of life beyond four weeks after screening. In the present review, two out of nine tests showed statistically significant differences in anxiety or worry in participants who received negative screening test results compared to control participants with consistently small effect sizes. This provides some support for the idea that receiving negative screening test results may reduce anxiety or worry, a result that is in line with the common finding that people attend screening in order to receive reassurance (Saidi, Sutton, & Bickler, 1998). In the present review, the largest effects came in relation to self-reported health, but even there, none of 11 tests comparing those who received negative screening test results with control participants were statistically significant. The largest effect sizes for self-rated health in the present review were found for the PLCO (Taylor et al., 2004) study of screening for four conditions (prostate, lung, colorectal and ovarian cancers), in contrast to all other studies in the present review, which screened for a single condition. In the PLCO (Taylor et al., 2004) study, a high proportion of screening participants were screen positive for at least one of the conditions, which may indicate why those who screened negative for all conditions showed a comparatively large effect on self-rated health, with the caveat that the effects were not significant as the sample size was small for this study.

The available evidence in the present review suggests that concerns about false reassurance with negative screening test results appear overstated and is unlikely to be a major harm of screening for any of the four outcomes examined. Across a range of conditions screened for in a variety of countries and populations overwhelmingly the studies contained in this review do not find evidence of false reassurance.

It should be noted that there remains considerable uncertainty around the conclusion that false reassurance is not a major harm of screening. There are several limitations of the present evidence base: few studies, which lack a priori planned analyses in relation to false reassurance, which have high risk of bias, which use often unvalidated single item measures, and which employ different measures in each study, making it problematic to aggregate findings.

Given this, future studies to examine the effects of screening programmes should include a priori planned analyses of false reassurance. This could be most suitable for studies assessing the effectiveness and cost effectiveness of either new screening programs or when existing ones are introduced into new populations. Such studies should use validated measures of false reassurance and lifestyle behaviour change and should aim to use the same measures as those employed in studies in this review, where possible, to allow accumulation of knowledge.

Conclusion

Current available evidence shows that negative screening results are unlikely to cause false reassurance, and in particular are unlikely to have a negative impact on lifestyle behaviours. However, given the numerous limitations of the current evidence base future research should

265 continue to explore this issue, where this can be done at low cost and with validated
266 measures.

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Appendix 1-Search strategy

1. Medline; *MASS SCREENING/; 45220 results.
2. Medline; *RISK ASSESSMENT/; 20729 results.
3. Medline; screen*.ti,ab; 527649 results.
4. Medline; 1 OR 2 OR 3; 527649 results.
5. Medline; (cancer OR diabetes OR aneurysm).ti,ab; 1618415 results.
6. Medline; ((self ADJ rated) AND health).ti,ab; 6084 results.
7. Medline; (Intention* AND change).ti,ab; 4886 results.
8. Medline; ((reassured OR reassurance)).ti,ab; 5137 results.
9. Medline; (percived OR perception).ti,ab; 114308 results.
10. Medline; SMOKING/; 127301 results.
11. Medline; DIET/; 127085 results.
12. Medline; BODY WEIGHT/; 168969 results.
13. Medline; (BMI OR "Body mass index").ti,ab; 158109 results.
14. Medline; ALCOHOL DRINKING/; 55163 results.
15. Medline; ("Physical activity" OR exersice).ti,ab; 67383 results.
16. Medline; 6 or 7 or 8 or 9 or 10 or 11 or 12 or14 or 14 or 15; 195309 results.
17. PsycInfo; SCREENING/; 9072 results.
18. PsycInfo; RISK ASSESSMENT/; 11216 results.
19. PsycInfo; screen*.ti,ab; 72746 results.
20. PsycInfo; 17 or 18 or 19; 72746 results.
21. PsycInfo; (cancer OR diabetes OR aneurysm).ti,ab; 66681 results.
22. PsycInfo; 20 AND 21; 7041 results.
23. PsycInfo; ((self ADJ rated) AND health).ti,ab; 3677 results.
24. PsycInfo; (Intention* AND change).ti,ab; 4811 results.
25. PsycInfo; ((reassured OR reassurance)).ti,ab; 2402 results.
26. PsycInfo; (percived OR perception).ti,ab; 129372 results.
27. PsycInfo; TOBACCO SMOKING/; 25892 results.
28. PsycInfo; DIETS/; 10581 results.
29. PsycInfo; BODY MASS INDEX/; 4415 results.
30. PsycInfo; ALCOHOLIC BEVERAGES/; 1716 results.
31. PsycInfo; PHYSICAL ACTIVITY/; 14642 results.
32. PsycInfo; CLINICAL TRIALS/; 10155 results.
33. PsycInfo; (random* OR trial* OR group* OR placebo*).ti,ab; 905046 results.
34. PsycInfo; 22 and (26 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 34); 350 results.
35. PsycInfo; 34 [Limit to: (Language English) and (Age group Adulthood 18 Yrs & Older) and (Population Human)];
36. Medline; PREGNANCY/; 766255 results.
37. Medline; 4 not 36; 502765 results.
38. Medline; 5 AND 37; 95039 results.
39. Medline; 16 AND 38; 1877 results.
40. Medline; 39 [Limit to: (Document type Randomized Controlled Trial) and (Language English) and (Age group Adult) and Humans]; 92 results.
41. PsycInfo; 35 [Limit to: (Language English) and (Age group Adulthood 18 Yrs & Older) and (Population Human)]; 24 results.
42. Medline; 40 [Limit to: (Document type Randomized Controlled Trial) and (Language English) and (Age group Adult) and Humans]; 7 results.

Appendix 2 Risk of bias table using the Cochrane Collaboration's tool for assessing risk of bias

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
(Andersen et al., 2007)			—	—	—		+
(Ashraf et al., 2008)	+	+	—	—	—		+
(Berstad et al., 2014)		+	—	—	—		
(Eborall et al., 2007)		+	—	—	—		+
(Larsen et al., 2007)		+	—	—	—		
(Paddison et al., 2009)	+	+	—	—	—	+	+
(Park et al., 2008)	+	+	—	—	—	+	+
(Scott, 2002)	+	+	—	—	—		+
(Taylor et al., 2004)	+	+	—	—	—	+	
(van der Aalst et al., 2010)	+	+	—	—	—		+
(Willems et al., 2013)		+	—	—	—	+	+

Blank indicates, unclear risk

Appendix 3 Full break down of results from each study and calculated effect sizes or odds ratio

Perceived risk of disease screened for

Measure	Description of measure	Condition and population	Study	Time frame after screening	Effect size
Personal risk	Percentage risk of developing diabetes in lifetime	Diabetes Screening Cambridge, east England, UK	ADDITION (Paddison et al., 2009)	Immediate 3-6months 12-15months	-0.08 -0.01 -0.3
Comparative risk	Risk of developing diabetes compare to other the same age: Much more likely/Much less likely scale	Diabetes Screening Cambridge, east England, UK	ADDITION (Paddison et al., 2009)	Immediate 3-6months 12-15months	-0.16* -0.02 -0.1
Perceived risk	Risk of developing diabetes compare to other the same age: Much more likely/Much less likely scale	Diabetes screening Netherlands	(Willems et al., 2013)	4 yrs	-0.14*

**Indicates $p < 0.05$*

Positive effect size indicates negative screen group > control (unscreened group)

Self-rated health

Measure	Description of measure	Condition and population	Study	Time frame	Effect size (Or odds ratio where appropriate)
Self-rated health	Excellent to poor scale	Diabetes Screening Cambridge, east England, UK	ADDITION (Paddison et al., 2009) and (Eborall et al., 2007)	Immediate 3-6months 12-15months	0.04 0 -0.06
Self reported health	Scale improved or not on follow up	Diabetes screening Netherlands	(Willems et al., 2013)	4yrs	Odds ratio 1.1
EuroQol visual acuity score	Self rated health scale 0-100	Aneurysm screening Portsmouth, Southampton, Winchester, and Oxford, South England, UK	MASS (Scott, 2002)	6 week	0.05
Mental health summary score	SF-12	Prostate, lung, colorectal , ovarian cancers screening. Georgetown, Washington, USA	PLCO (Taylor et al., 2004)	Immediate	-0.55
Mental health summary score	SF-36	Aneurysm screening Portsmouth, Southampton, Winchester, and Oxford, South England, UK	MASS (Scott, 2002)	6 week	0.04
mental health summary score	SF-12	Prostate, lung, colorectal , ovarian cancers screening. Georgetown, Washington, USA	PLCO (Taylor et al., 2004)	1year	-0.24
Physical health	SF-36	Prostate, lung, colorectal , ovarian cancers screening. Georgetown, Washington, USA	PLCO (Taylor et al., 2004)	Immediate	-0.27
Physical health	SF-36	Aneurysm screening Portsmouth, Southampton, Winchester, and Oxford, South England, UK	MASS (Scott, 2002)	6 week	0.07
Physical health	SF-36	Prostate, lung, colorectal , ovarian cancers screening. Georgetown, Washington USA	PLCO (Taylor et al., 2004)	1year	0.14

**Indicates $p < 0.05$*

Positive effect size indicates negative screen group > control (unscreened group)

Anxiety and worry

Measure	Description of measure	Condition and population	Study	Time frame	Effect size
Worry about diabetes	Adapted Lerman cancer worry scale (score 6-24)	Diabetes screening Cambridge, East of England, UK	ADDITION(Eborall et al., 2007)	Immediate 3-6ms 12-15months	0.01 -0.09 -0.22*
Anxiety	State trait anxiety	Diabetes screening Cambridge, East of England, UK	ADDITION(Eborall et al., 2007)	Immediate 3-6ms 12-15months	-0.03 0.15* 0.06
Anxiety	State trait anxiety	Diabetes screening Cambridge, East of England, UK (Different GP practises from those in full ADDITION)	ADDITION-Pilot (Park et al., 2008)	6 weeks	-0.06
Anxiety	State trait anxiety	Aneurysm screening Portsmouth, Southampton, Winchester, and Oxford, South England, UK	MASS (Scott, 2002)	6 weeks	-0.09
Worry about getting diabetes	Symptoms risk questionnaire	Diabetes screening Netherlands	(Willems et al., 2013)	4yrs	0

*Indicates $p < 0.05$

Positive effect size indicates negative screen group > control (unscreened group)

Lifestyle behaviour and Intention to change lifestyle behaviour

Smoking

Measure	Description of measure	Condition and population	Study	Time frame	Effect size (Or odds ratio where appropriate)
Smoking status	Smoker or non-smoker	Diabetes screening Netherlands	(Willems et al., 2013)	4yrs	Odds ratio 0.74
Smoking status	1-6 scale: Never(1), former (2), occasional(3), 1-10 day(4), 11-20 day (5) , more than 20/day (6)	Colorectal cancer screening	NORCCAP (Larsen et al.,)	3 yrs	0.07*
Cigarettes per day	Continuous smokers at baseline Recent quitters at baseline	Lung cancer screening Copenhagen, Denmark	DLCST (Ashraf et al., 2008)	1 yr	Odds ratio 1.1 1.00
Prolonged smoking abstinence	Smoked less than 5 cigarettes in 2 weeks after quit date	Lung cancer screening Rotterdam, Netherlands	NELSON (Van der Aalst., 2010)	2 yrs	Odds ratio 0.86
Smoking	Percentage who currently smoke	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Berstard et al 2014)	11years	0.02

**Indicates $p < 0.05$*

Positive effect size indicates negative screen group > control (unscreened group)

Diet

Measure	Description of measure	Condition and population	Study	Time frame	Effect size
Servings of fruit and vegetables/day	1-6 scale: never to more than 3 servings /day	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Larsen et al., 2007)	3 yrs	-0.04*
Servings of fruit and vegetables/day	Number of serving per day.	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Berstard et al 2014)	11years	-0.08
Consumption of meat(not poultry or fish) for dinner	Servings per day	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Berstard et al 2014)	11years	0.04
Consumption of fatty fish	Servings per day	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Berstard et al 2014)	11years	-0.04
Intention to reduce fat intake	5 point Agreement scale 1 strongly disagree - 5 strongly agree	Diabetes Screening	ADDITION (Paddison et al., 2009)	Immediate 3-6months 12-15months	0.05 0.02 0.02
Intention to reduce sugar intake	5 point Agreement scale 1 strongly disagree - 5 strongly agree	Cambridge, East England, UK	ADDITION (Paddison et al., 2009)	Immediate 3-6months 12-15months	0.04 0.02 0.02

*Indicates $p < 0.05$

Positive effect size indicates negative screen group > control (unscreened group)

Weight

Measure	Description of measure	Condition and population	Study	Time frame	Effect size
Weight	Self-reported weight	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Larsen et al., 2007)	3 yrs	0.07*
Weight	Self-reported weight	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Berstard et al 2014)	11years	0.17

*Indicates $p < 0.05$

Positive effect size indicates negative screen group > control (unscreened group)

BMI

Measure	Description of measure	Condition and population	Study	Time frame	Effect size
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Body mass index	Self-reported height and weight	Diabetes screening Netherlands	(Willems et al., 2013)	4 yrs	-0.11
Body mass index	Self-reported height and weight	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Larsen et al., 2007)	3 yrs	0.05*

**Indicates $p < 0.05$, Positive effect size indicates negative screen group > control (unscreened group)*

Waist circumference

Measure	Description of measure	Condition and population	Study	Time frame	Effect size
Waist circumference	self measured	Diabetes screening Netherlands	(Willems et al., 2013)	4 yrs	-0.05 -0.11

**Indicates $p < 0.05$, Positive effect size indicates negative screen group > control (unscreened group)*

Physical activity

Measure	Description of measure	Condition and population	Study	Time frame	Effect size (Or odds ratio where appropriate)
Physical activity	Increased or not since screening	Diabetes screening Netherlands	(Willems et al., 2013)	4 yrs	Odds ratio 0.82
Physical activity	Frequency of physical activity either with or without sweating	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Larsen et al., 2007)	3 yrs	-0.17 *
Physical activity	Undertaking 20 mins or more per day	Colorectal cancer screening Telemark and Oslo, Norway	NORCCAP(Berstard et al 2014)	11years	-0.15
Intention to increase Physical activity	5 point Agreement scale 1 strongly disagree - 5 strongly agree	Diabetes Screening Cambridge, east England, UK	ADDITION (Paddison et al., 2009)	Immediate 3-6months 12-15ms	0.11 -0.05 0.02

**Indicates $p < 0.05$, Positive effect size indicates negative screen group > control (unscreened group).*

Appendix 4 PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	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.	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3-4
METHODS			
Protocol and registration	5	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.	No protocol
Eligibility criteria	6	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.	3-4
Information sources	7	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.	3-4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1 (Pg19)
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3-4
Risk of bias in individual studies	12	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.	5

Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2 for each meta-analysis).	5

PRISMA 2009 Flow Diagram

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Table 1. Summary of the eight different studies which were included in the review

Study	Condition screened for	Country	Sample size (Response rate)*	What was measured	How long after screening measurement was taken
ADDITION ^{1,3}	Type 2 diabetes	Cambridge, East of England, UK	6416 (33%) 1366 (At 7yrs) (61%)	Perceived risk Self rated health Anxiety Behaviour/intention to change	3-6 Months 12-15Months 7years
ADDITION pilot ⁶	Type 2 diabetes	Cambridge, East of England, UK	290 (66%)	Anxiety	6 Weeks
DLCST ⁸	Lung cancer	Copenhagen, Denmark	3931 (92%)	Behaviour/Intention to change	1 Year
MASS ⁴	Abdominal aortic aneurysm	Portsmouth, Southampton, Winchester, and Oxford, South England, UK	1644 (82%)	Self rated health Anxiety	6 weeks
NELSON ⁹	Lung cancer	Rotterdam, Netherlands	1284 (84%)	Behaviour/Intention to change	2 years
NORCCAP ^{7,10}	Colorectal cancer	Telemark and Oslo, Norway	7143 (74)	Behaviour/Intention to change	3years 11years
PLCO ⁵	Prostate, lung, Colorectal and Ovarian cancer screening	Nation wide, USA	278 (85%)	Self rated health	1years
Willems et al., (2013) ²	Type 2 diabetes	South west Netherlands	14012 (72%)	Perceived risk Self rated health Anxiety Behaviour/intention to change	4 years

¹(Paddison et al., 2009), ²(Willems, Otto, Klijs, & de Koning, 2013), ³(Eborall et al., 2007), ⁴(Scott, 2002), ⁵(Taylor, Shelby, Gelmann, & McGuire, 2004), ⁶(Park, Simmons, Prevost, & Griffin, 2008), ⁷(Larsen, Grotmol, Almendingen, & Hoff, 2007), ⁸(Ashraf et al., 2008), ⁹(van der Aalst, van den Bergh, Willemsen, de Koning, & van Klaveren, 2010), ¹⁰(Berstad et al., 2014)

*Sample size and response rate calculated from information given in paper, including negative screen and controls only.

Table 2 Summary of number of significance tests, number of significant results and highest and lowest effect sizes or odds ratio for each outcome.

Outcome measured	Number of tests	Number of significant results	Lowest effect size	Highest effect size	Lowest odds ratio	Highest odds ratio
Perceived risk	7	2	-0.16	-0.01	N/A	N/A
Absolute risk ¹	3	0	-0.3	-0.01	N/A	N/A
Comparative risk ^{1,2}	4	2	-0.16	-0.02	N/A	N/A
Self-rated health	11	0	-0.55	0.14	1.1	1.1
Self-rated health scale ^{1,3}	4	0	-0.06	0.04	1.1	1.1
EuroQol visual acuity score ⁴	1	0	N/A	0.05	N/A	N/A
SF-36 Physical health ^{4,5}	3	0	-0.27	0.14	N/A	N/A
SF-36 Mental health ^{4,5}	3	0	-0.55	0.04	N/A	N/A
Anxiety or worry	9	2	-0.22	0.06	N/A	N/A
Worry about disease ^{2,3}	4	1	-0.22	0.01	N/A	N/A
State trait anxiety ^{2,4,6}	5	1	-0.09	0.15	N/A	N/A
Behaviour and intention to change behaviour	28	5	-0.11	0.17	0.74	1.1
Smoking ^{2,7,8,9 10}	6	1	0.02	0.07	0.74	1.1
Physical activity ^{1,2,7,10}	6	1	-0.15	0.11	N/A	0.82
Diet quality ^{1, 7,10}	10	1	-0.08	0.05	N/A	N/A
Weight ^{7,10}	2	1	0.07	0.17	N/A	N/A
BMI ^{2,7}	2	1	-0.11	0.05	N/A	N/A
Waist circumference ²	2 (from same study but men and women reported separately)	0	-0.11	-0.05	N/A	N/A

Bold text indicates a summary of all measurements used to measure each outcome.

Positive effect size indicates negative screening test result group > control group

¹(Paddison et al., 2009), ²(Willems, Otto, Klijs, & de Koning, 2013), ³(Eborall et al., 2007), ⁴(Scott, 2002), ⁵(Taylor, Shelby, Gelmann, & McGuire, 2004), ⁶(Park, Simmons, Prevost, & Griffin, 2008), ⁷(Larsen, Grotmol, Almendingen, & Hoff, 2007), ⁸(Ashraf et al., 2008), ⁹(van der Aalst, van den Bergh, Willemsen, de Koning, & van Klaveren, 2010), ¹⁰(Berstad et al., 2014)