Author’s response to reviews

Title: A protocol for a systematic review of non-randomised evaluations of strategies to increase participant retention to randomised controlled trials

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Author’s response to reviews:

Many thanks for the reviewers’ comments on our review protocol, our point-by-point responses to them are below.

Reviewer #1

Abstract

1-I would suggest to change the imperative statements given by the authors in the discussion section of the abstract and further in the text. (Page 3 line 38-45 and page 7 line 22-29 and page 15 line 9 to 21) ‘If the results of this review signify that evaluating retention strategies in observational studies is worthless, review authors will be in a comfortable position to recommend to funders and trial stakeholders that researchers should not design, conduct and report such studies.’ The expression 'worthless', authors will be in a comfortable position...' seem too extreme and not scientific”.

We agree. We have changed these statements to a more modest text throughout as suggested:

“Should the results of this review suggest that evaluating retention strategies in observational studies provides insufficient evidence to trialists planning their retention strategies, we will be able to say that there is little point in conducting non-randomised studies and that they would do better to invest their time and resources in a randomised evaluation if possible. Where a non-randomised study design is chosen, the review authors will offer recommendations to trialists and others regarding how to ensure that these studies are conducted in a way that can minimise the risk of bias and increase confidence in the findings.”
2- Page 5 line 40-54 two sentences are repetitive (words: potential, problems)

40-54 two sentences Apologies. We have rewritten this sentence. It now reads:

Apologies. The text now reads:

They also did not give much attention to the pre-trial stage, where the likelihood for identifying and addressing future problems is greatest.

The potential contribution that randomised and nonrandomised studies can make to the evaluation of effectiveness has provoked considerable controversy.

3- Page 14 line 53 ‘these rather ignored studies’ is unscientific and not true from a clinical standpoint, should be changed.

Apologies. We have replaced this phrase with ‘these contentious studies’ so that the text becomes:

“Therefore, it is imperative to collect evidence from observational studies to infer whether or not these contentious studies could be considered a practical way to complement or even replace a randomised design in some cases.”

Reviewer #2: Methods

‘Authors should discuss the exclusion criteria after outcome measures; alternatively authors can merge aspects of the inclusion criteria with relevant aspects of the inclusion criteria’

Done. We have moved the exclusion criteria after outcome measures as requested.

‘Authors can move the section ‘search strategy’ to after inclusion/exclusion criteria (but before data management) to allow for smooth flow of thoughts’.

Done. This section has been moved after inclusion/exclusion criteria and before data management.

Data Analysis and Synthesis

‘There appears to be contradiction here: re outcome measures appear to be dichotomous in nature (no. of participants retained/total no. of participants??) but authors are referring to thematic analysis here i.e. qualitative data. Please clarify’. 
Apologies for any confusion. What we mean by using a thematic approach is to identify and categorize retention strategies descriptively by intervention type if pooling results in a meta-analysis is not possible. To avoid this confusion, we have changed the text to the following:

“If the included studies are statistically homogeneous (I²<50%), a meta-analysis using a fixed-effect model will be performed. Otherwise, the random-effect model will be employed. The causes of heterogeneity will be evaluated to supplement choice of model using the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (19).

It is anticipated that there will be much diversity in the included studies. Where it is not appropriate to perform meta-analysis, included studies will be combined in a narrative synthesis. To ensure the synthesis is a rigorous and transparent process, review authors will meet to discuss and categorize different retention strategies from the included studies. Firstly, reviewers will review the strategies independently and assign each retention strategy to the relevant category. The independent results will then be discussed and differences will be reconciled before a final list of major retention categories is provided.”

“Authors should clearly state how the stated outcome measures will be analysed, including measure of effects and unit of analysis”.

We have added two sections for measure of effects and unit of analysis as follows:

“Measures of the effect

For dichotomous outcomes (retention or attrition rates) risk ratios and their 95% confidence intervals will be calculated to determine the effect of strategies on participant retention. It is not clear how participant benefits or difficulties with strategies will be measured, so the data available will be examined and then the most appropriate effect measure will be determined.

Unit of analysis issues

It is anticipated that most of the included studies will be before-and-after studies with the individual participant as the unit of analysis. We will only include clustered studies in the meta-analysis if sufficient data were reported to allow inclusion of analyses that adjusted for clustering; an odds ratio (OR) will be used in the summary effect of the meta-analysis result if the risk difference or risk ratio clustering adjusted analyses were not possible with available data.”

“If data will be combined in a meta-analysis (as authors suggested in line 53) this should be clearly stated with the likely effect model to be employed (fixed or random effect model)”

Done. We have clearly stated the model we will use in the Data Analysis and Synthesis section.

“This section can be titled “Data Analysis and Synthesis (if still applicable)”
Done. This section has been titled as suggested