

Reducing bias in trials from reactions to measurement: the MERIT study including developmental work and expert workshop

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Scientific summary

The MERIT study

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Scientific summary

Background

Measuring people can affect their behaviour, their emotions and the data they provide about themselves. This phenomenon is known as measurement reactivity. Randomised controlled trials always include measurements of trial outcomes and commonly include further measurements as part of process evaluations. The usual methods of conduct and analysis of trials implicitly assume that the taking of measurements does not affect subsequent outcome measurements or interact with the trial intervention and that any effects of measurement-taking will be the same in each experimental group and, hence, are unlikely to bias treatment comparisons. The present report aims to promote awareness of how and when taking measurements can lead to bias and to provide recommendations to prevent such bias.

There are few areas of research where there is sufficient evidence to be entirely confident that measurement reactivity is present. The most compelling evidence of measurement reactivity is found in two areas: (1) the question-behaviour effect (i.e. when the act of asking questions about behaviour produces small changes in the behaviour being asked about) and (2) the use of pedometers (particularly where step counts can be read by participants) leading to increases in physical activity. Other measurement procedures widely employed for outcome evaluation in randomised controlled trials, such as assessing body weight, are also used as intervention techniques in their own right because they are seen to be effective at producing behaviour change. It is not clear whether the limitations of the evidence base are due to a genuine lack of effect of measurement on outcomes or a lack of research to examine the effects of measurement on outcomes.

There is little direct evidence regarding how much of a problem measurement reactivity poses for bias in trials. As a consequence, measurement reactivity has generally been ignored in discussions of how to reduce bias in trials. Measurement reactivity is therefore not adequately addressed in existing guidelines for designing, reporting and appraising trials.

Objective

The MEasurement Reactions In Trials (MERIT) study aimed to produce recommendations to minimise risk of bias from measurement in trials of interventions to improve health.

Methods

The MERIT study consisted of (1) a series of systematic and rapid reviews, (2) a Delphi study and (3) an expert workshop to develop recommendations on how to minimise bias in trials due to measurement reactivity.

An updated systematic review examined if measuring participants had an effect on participants' health-related behaviours relative to no-measurement controls. Three new rapid systematic reviews were conducted to identify:

1. existing guidance on measurement reactivity
2. existing systematic reviews of studies that have quantified the effects of measurement on outcomes relating to behaviour and affective outcomes
3. studies that have investigated the effects of objective measurements of behaviour on health-related behaviour.

The views of 40 experts were sought to identify the scope of the recommendations in two rounds of a Delphi consultation. A workshop in October 2018 involved discussion of potential recommendations by 23 experts. Recommendations were formed through discussion in groups, with no formal voting procedure to indicate consensus being required.

Recommendations

The MERIT study has produced recommendations for reducing the risk of bias from measurement, with a focus on balancing measurement reactivity concerns in the context of wider trial design decision-making, including attending to established sources of bias. Development of the recommendations has relied extensively on indirect evidence, which is contingent on reasonable inference regarding the likely consequences of measurement in producing bias. Given the limited direct evidence, many of the recommendations are – in the terminology of the Grading of Recommendations Assessment, Development and Evaluations (GRADE) – ‘motherhood statements’, in that to recommend the opposite would not be reasonable.

We propose that researchers consider the following issues in relation to measurement reactivity as a potential source of bias. The recommendations also includes a list of randomised controlled trial features that should act as ‘red flags’ and indicate when risk of bias due to measurement reactivity may be present. The 14 recommendations are as follows:

1. Consider the potential for measurement reactivity causing bias at the design stage of a trial.
2. Consider the potential for measurement reactivity as a source of bias throughout the research process.
3. Consider specific trial features that may indicate heightened risk of bias due to measurement reactivity.
4. Theorise potential measurement reactions as part of a logic model of how an intervention is intended to work.
5. Consider the burden of measurement procedures and potential impact on participants in comparison with the intensity and duration of the studied intervention.
6. Consider how participants may use measurement in trials to meet their own aims.
7. Consider whether or not measurement reactivity concerns for the trial warrant further empirical examination.
8. Examine feedback from research personnel regarding research participants’ reports of changes in their behaviour/thoughts/emotions as a result of measurement.
9. Consider possible measurement reactivity when determining the overall burden of measurement in a trial.
10. Embed measurement procedures onto routine clinical practice when possible.
11. Use identical measurement protocols in all arms of a trial.
12. Avoid overlap between measurement and intervention.
13. Consider the potential benefits of masking measures and/or withholding feedback of measured values against ethical considerations.
14. If measurement reactivity is likely to be present, investigations for measurement reactivity should be included a priori in the statistical analysis plan.

Research priorities

A major limitation of the evidence base used to develop the recommendations is the shortage of good-quality studies that have estimated the extent and magnitude of measurement reactivity in different settings. Accordingly, we identify the following research priorities to develop a

stronger evidence basis for future consideration of the nature and extent of bias in trials due to measurement reactivity:

- more primary research to quantify extent of measurement reactivity
- research priorities for studies within a trial to further understanding of measurement reactivity
 - conduct further empirical studies to provide more compelling evidence on study features that indicate that measurement may be particularly reactive
 - compare traditional, obtrusive research methods with unobtrusive research methods
 - examine effects of measurement on both objective and subjective outcomes
- more systematic reviewing to quantify extent and variability of measurement reactivity
- better theorise when and why measurement reactivity is likely to occur.

We hope that this practical help on measurement reactions in trials will raise awareness of the ways in which trial evidence can be undermined by measurement reactivity and how this can be prevented and advance consideration of how measurement reactivity might be better understood in the future. Our ultimate aim is that these recommendations will be used in designing future trials so that trials are less likely to be at risk of bias.

Study registration

The first systematic review in this study is registered as PROSPERO CRD42018102511.

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The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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