

## Survey: methods to minimise missing data in randomised trials

**Overview:** We are contacting you as the Chief Investigator of a HTA funded trial to seek your opinion on effective strategies to minimise missing data in randomised trials. We are also looking at the association between missing data, monitoring approach, trial design characteristics and how outcomes are measured to help inform the development of effective solutions. The results will contribute towards a wider MRC MRP funded project aiming to identify which strategies and practices used to minimise missing data should be assessed in further research.

**Definition of missing data:** Missing data occurs when randomised participants are not included in the trial analysis for a particular outcome. Missing data may arise due to participant loss to follow up, withdrawal from follow up, failure to measure a particular outcome for a participant or the exclusion of a participant's measured outcome from the analysis.

**Confidentiality:** Your responses will be treated confidentially. Overall responses and associations will be reported in an anonymous manner.

**Completion:** The survey takes around 5-10mins to complete. This can be done electronically within this Word document or on paper, depending on your preference. If you are unsure of any trial practice, you could ask your trial manager or supporting CTU to help answer the relevant questions. If your version of Word has problems with the checkboxes, please let us know and we can send an alternate version to you.

**Return to:** [a.kearney@liv.ac.uk](mailto:a.kearney@liv.ac.uk) by 23<sup>rd</sup> January 2015

Paper copies can be posted to: Anna Kearney, Clinical Trials Research Centre, University of Liverpool, Institute of Child Health, Alder Hey Children's NHS Foundation Trust, Liverpool, L12 2AP

<b>HTA reference:</b>
<b>Trial title:</b>

1. When did the above trial open to recruiting and randomising patients? \_\_\_\_\_
2. If applicable, when did the trial close to recruiting and randomising patients? \_\_\_\_\_
3. Would the primary outcome have been routinely measured for patients with the relevant condition regardless of their participation in the trial?

<input type="checkbox"/>	Yes, is a routine care measurement
<input type="checkbox"/>	Is likely to be measured in routine care, but might not be measured depending on local practice
<input type="checkbox"/>	Is unlikely to be measured in routine care, but might be measured depending on local practice
<input type="checkbox"/>	Would not be measured in routine care

Optional comments (for example, if you had more than one primary outcome, or to expand on your answer):

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**4. Is the measurement of the primary outcome taken during an appointment that coincides with routine care visits, or is it collected during a trial specific visit?**

<input type="checkbox"/>	Yes, measured during routine care visit
<input type="checkbox"/>	No, measured during a trial specific visit
<input type="checkbox"/>	Varies depending on whether the trial specific visit coincides with routine care visit
<input type="checkbox"/>	Not applicable (primary outcome is not measured at a visit)
<input type="checkbox"/>	Other, specify

**5. When designing the trial were you aware of any factors which made your trial at increased risk of missing data e.g. patient population, technical issues, response rates to surveys etc.?**

<input type="checkbox"/>	Yes (see below)
<input type="checkbox"/>	No (go to Q6)

**If yes, what were the factors you were aware of (in particular for your primary outcome) and what did you do to mitigate the risk?**

Factor	Strategies used to mitigate the risk of missing data

**6. In addition to any listed above, what strategies have you used to minimise missing data, either to avoid patients withdrawing from the study, or to maximise data collection for patients retained in the trial? This may include strategies you are planning to implement.**

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**7. Where are levels of missing data reviewed within your trial and how frequently?**

	<p><b>How frequently is missing data reviewed? (e.g. never, monthly, 6 monthly, annually)</b>  <i>Please note we are not interested in the frequency of the meetings or reports, but the frequency with which missing data is reviewed within them.</i></p>
Trial Steering Committee meetings	
Independent Data Monitoring Committee meetings	
Trial Management Group meetings	
Internal CTU meetings	
During statistical analysis (e.g. interim reports, periodic monitoring, final report)	
For periodic reports to the sponsor or the funder	
Other, Specify	

**8. How do the observed levels of missing primary outcome data compare with the levels you anticipated at the trial design stage, for example when calculating your original sample size?**

<input type="checkbox"/>	Much higher than expected
<input type="checkbox"/>	Higher than expected
<input type="checkbox"/>	As expected
<input type="checkbox"/>	Lower than expected
<input type="checkbox"/>	Much lower than expected
<input type="checkbox"/>	Other, specify

**9. If you are willing to say, what percentage of missing primary outcome data are you currently observing?**  
*Please note this answer will not be linked to your trial and will remain confidential.*

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**What proportion of this missing data do you think may be obtainable?**

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**10. In your opinion why do you think the observed levels of missing data are different to the levels of missing data you predicted at the start of the trial? In your response consider that levels may be higher or lower than expected e.g. a higher or lower questionnaire return rate than anticipated.**

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**11. Which of the following reasons for missing primary outcome data have occurred in your trial? (tick all that apply)**

<input type="checkbox"/>	Clinicians have withdrawn patients from treatment and follow-up
<input type="checkbox"/>	Patients have withdrawn from follow up
<input type="checkbox"/>	Losing contact with patients
<input type="checkbox"/>	Patient deaths (unrelated to primary outcome)
<input type="checkbox"/>	Patient outcomes (other than death) which prevent the measurement of the primary outcome
<input type="checkbox"/>	Missed measurements by clinical staff
<input type="checkbox"/>	Data not provided by clinical staff
<input type="checkbox"/>	Failure of patient to return a questionnaire or the material to measure the primary outcome
<input type="checkbox"/>	Failure of patient to attend a visit for the measurement of the primary outcome
<input type="checkbox"/>	Problems with laboratory measurements
<input type="checkbox"/>	Problems with data measured using technology e.g. pedometer, accelerometer, insulin pump etc.
<input type="checkbox"/>	Other, Specify

**12. Within your HTA funded trial do you attempt to collect reasons why patients withdraw from trial follow up?**

<input type="checkbox"/>	Yes - If so have you had any problems trying to collect reasons (e.g. most patients not willing to say, sites not willing to ask)
<input type="checkbox"/>	No – If so, was there a reason why you have not attempted to collect this information?

**13. In your opinion what are the three most effective strategies for minimising missing data that you have used within the trial?**

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**14. If you have any further insights from any trials you have been involved in about effective or ineffective strategies to minimise missing data, please share your thoughts here:**

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**15. Patient information sheet included:**

Lack of patient retention through withdrawal of consent or loss to follow up are key causes of missing data within trials. As part of our work identifying strategies that might mitigate missing data we are interested to understand how withdrawal, outcome data collection and patient retention are communicated to participants. To do this we would like to review the content of patient information sheets from a number of trials, including your HTA funded trial (listed above).

It would be of great help to our research if you (or a colleague) could send us a copy of the trial’s Patient Information sheet and consent forms. (For trials recruiting children, please include both the parental and patient information sheets and consent/assent forms)

<input type="checkbox"/>	Yes attached with the completed survey
<input type="checkbox"/>	Please email _____ to obtain a copy.

**Many thanks for taking the time to complete this survey.**

It would be very helpful to know who completed the survey and if you would be willing to be contacted if we have any further questions about any of the information supplied.

<b>Name:</b>	<b>Date:</b>
<b>Role:</b>	
<input type="checkbox"/>	I am happy to be contacted if you have any further questions about the information I have supplied
<input type="checkbox"/>	I would like a copy of the results when available