Questions

1. To what extent are missing data reported in accordance with current reporting guidance?

2. Does the quality of reporting differ between missing data reporting criteria specified by CONSORT vs. those not specified by CONSORT?

3. Are journal impact factor and CONSORT endorsement status associated with the quality of missing data reporting?

Method: Reporting criteria

1. Proportion of missing data
2. Reasons for missing data
3. Minimising missing data
4. Risk of bias posed by missing data
5. Justification of missing data analytical approach
6. Statistical methods to handle missing data
7. Impact of missing data on trial findings

Method: Systematic review

- P = advanced life-limiting disease
- I = palliative
- C = palliative / usual care / placebo
- O = Patient reported / dependent
- S = RCTs

Information specialist searched: CENTRAL, OVID Medline, EMBASE (Jan 2009-April 2014)

Random selection / no language restrictions / double screening, selection, extraction

Search: PRISMA Flow diagram

Records identified through database searching: 1936
Additional records identified through other sources: 0
Records excluded: N = 1745
Records included: N = 1923

Numbers after duplicates removed: N = 1923

Full-text articles assessed for eligibility: N = 179
Studies included in synthesis: N = 108

Reasons for exclusion: Participant = 13
Intervention = 12
Outcome = 12
Study design = 75
Duplicate data = 12
Other = 10
Q1. To what extent are missing data reported in accordance with current reporting guidance?

<table>
<thead>
<tr>
<th>Missing data reporting criterion</th>
<th>Proportion of trials reporting the criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account for all participants who enter the study</td>
<td>6% (66/108)</td>
</tr>
<tr>
<td>Report number of participants not included in the primary outcome analysis</td>
<td>0% (0/108)</td>
</tr>
<tr>
<td>Report number of participants with missing data at each arm in the primary outcome analysis (non-cross-over trials)</td>
<td>0% (0/108)</td>
</tr>
<tr>
<td>Report number of non-level missing data in the primary outcome analysis (if primary outcome was a scale summary)</td>
<td>0% (0/108)</td>
</tr>
<tr>
<td>Report missing data trend over time for primary outcomes measured repeatedly</td>
<td>All time points: 7% (7/93) Some time-points: 48% (48/93)</td>
</tr>
<tr>
<td>Report amount of missing data for secondary outcomes if measured</td>
<td>For all: 9% (9/93) For some: 18% (18/93)</td>
</tr>
</tbody>
</table>

* Fifteen trials reported no missing data.
For ≤0% of participants with missing data the reason was described as ‘LTFU’ or ‘withdrawal’ only.

2. Reason for missing data

<table>
<thead>
<tr>
<th>Missing data reporting criterion</th>
<th>Proportion of trials reporting the criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report reason for missing data</td>
<td>71% (66/93)</td>
</tr>
<tr>
<td>Report amount of missing data due to death</td>
<td>63% (60/93)</td>
</tr>
<tr>
<td>Report amount of missing data due to illness/disease progression</td>
<td>46% (43/93)</td>
</tr>
</tbody>
</table>

3. Minimising & 4. Risk of bias

<table>
<thead>
<tr>
<th>Missing data reporting criterion</th>
<th>Proportion of trials reporting the criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report plans to minimise missing data</td>
<td>27% (29/108)</td>
</tr>
<tr>
<td>Report comparison of baseline characteristics of those with observed data</td>
<td>6% (6/93)</td>
</tr>
<tr>
<td>Report comparison of baseline characteristics of those with missing data</td>
<td>0%</td>
</tr>
</tbody>
</table>

5. Justification of missing data analytical approach

<table>
<thead>
<tr>
<th>Missing data reporting criterion</th>
<th>Proportion of trials reporting the criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report assumed mechanism of missing data</td>
<td>37% (37/108)</td>
</tr>
<tr>
<td>Report criteria for missing not at random (informative missing data)</td>
<td>1% (1/108)</td>
</tr>
<tr>
<td>Report pattern of missingness</td>
<td>0%</td>
</tr>
<tr>
<td>Compare baseline characteristics of those with and without missing data</td>
<td>13% (13/93)</td>
</tr>
</tbody>
</table>

6. Statistical methods to handle missing data

<table>
<thead>
<tr>
<th>Missing data reporting criterion</th>
<th>Proportion of trials reporting the criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report methods used to handle missing data</td>
<td>48% (48/93)</td>
</tr>
<tr>
<td>Report missing data sensitivity analyses</td>
<td>16% (15/93)</td>
</tr>
<tr>
<td>Report any changes to the planned missing data analysis</td>
<td>0%</td>
</tr>
</tbody>
</table>
7. Impact of missing data on the trial findings

- 46% (43/93)
- Limitations section
- 23 discussed potential for missing data to bias the treatment effect estimate

Q2. Does the quality of reporting differ between criteria specified by CONSORT vs. those not specified by CONSORT?

Q3. Are journal impact factor and CONSORT endorsement status associated with the quality of missing data reporting?

So what?

- Q1. The reporting of missing data in palliative care trials does not comply fully with current reporting guidance
- Q2. Criteria specified by CONSORT were better reported
- Q3. The odds of reporting the majority of the MD criteria increased as journal impact factor increased and in journals that endorsed the CONSORT statement
Methods section:
1. Report the justification of the missing data analytical approach including all of the following:
   a. Any assumptions about the missing data mechanism with justification.
   b. What analyses will be performed to support assumptions about the missingness mechanism. For example, comparison of outcome according to whether the partially observed outcomes are missing may shed light on the validity of the MAR assumption.
   c. How the assumed missingness mechanism and any relevant features of the data and patterns of missingness would influence the choice of method(s) to handle missing data and the need for sensitivity analyses.
   d. Details of the statistical methods used to handle missing data.
   e. How truncated data due to death will be handled and justification of method(s) if applicable.

Results section:
2. Report the following measures of amount of missing data:
   a. For each outcome: number of participants in each arm with missing data (unit-level missing data).
   b. For outcomes that are scale summaries: amount of item-level missing data, for example the number of participants in each arm with some items reported and some items missing.
   c. For repeated outcomes: number of participants in each arm with missing data at each time-point.

3. Reasons for missing data in each arm, with enough detail that the reported reason can be used to reduce the uncertainty about the potential underlying mechanism of missing data — although this will not be verifiable using the partially observed data. If terms such as lost to follow-up or withdrawal are used, these must be defined.

4. Comparison of the baseline characteristics of those included in the analysis (if participants are excluded from the analysis post-randomisation).

5. *Results of investigations of the missingness mechanism and/or pattern, and whether these led to changes to the choice of the primary method to handle missing data.

6. *Missing data sensitivity analyses results including analyses based on plausible missing not at random assumptions if appropriate.

Discussion section:
7. Impact of missing data on the interpretation of findings, including effect on validity and generalisability.