Characterising ‘standard care’ in randomised controlled trials of complex interventions: Using a novel multi-methods approach

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Background
- Standard care provided in the control arm is rarely described in palliative care trials. End-of-life care provided to different patient populations varies. 1,2
- Several attempts have been made to measure standard care, including open-ended questions to gauge health professionals’ understandings of care provided to a specific patient population. 3,4
- Examining standard care is essential to determine intervention benefits and assess concurrent changes in standard care during trials. 5

Aim
To examine the use of multiple methods for characterising standard care in a cluster randomised controlled trial (RCT) of a complex intervention for patients with clinical uncertainty.

Methods
- Design Prospective multi-methods embedded within a cluster RCT, using standard care questionnaires, case note reviews, and focus groups with ward staff. Descriptive statistics and thematic analysis, followed with triangulation.
- Setting/participants Four wards in four hospitals. Purposive sample of health professionals, and review of case notes of 20 patients per ward who died during their admission or within 100 days of discharge.

Take-home message
Similarities and significant variations identified in the standard care could impact the interpretation of the intervention, and trial results.

Results
23 standard care questionnaires (94.3% completion) were obtained at baseline. 2 focus groups comprising 20 professionals (15 women, 5 men) and 80 cases notes reviews (55.0% older than 71 years, had a cancer, or respiratory disease diagnosis) were completed at the end of the trial. Standard care provided to patients with clinical uncertainty was classified as:

<table>
<thead>
<tr>
<th>Similarities and embedded practices</th>
<th>Variations within, and across study sites</th>
<th>Changes in the control arm during the study</th>
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<tbody>
<tr>
<td>Admission and current care planning</td>
<td>Timely recognition of deterioration and specialist involvement</td>
<td>Majority of care unchanged</td>
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<tr>
<td>Communication with the patient and family</td>
<td>Advance care planning</td>
<td>Referral practices to the palliative care team</td>
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<td>Escalation decisions</td>
<td>Decision-making and communication between ward staff</td>
<td>Confidence in communication</td>
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<tr>
<td>Recognising clinical uncertainty</td>
<td>Competence and confidence in communication</td>
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<td>Emotional support</td>
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Conclusions
By using multiple methods at different time points within the RCT, we were able to characterise standard care. While standard care is often assumed to be already understood and similar across all sites of a research study, major variations were identified.

References

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