Author's response to reviews

Title: Tailored educational intervention for primary care to improve the management of dementia: The EVIDEM-ED cluster Randomised Controlled Trial

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Version: 4 Date: 2 October 2013

Author's response to reviews: see over
Dear Editor(s)

Thank you for the opportunity to respond to the reviewers comments for the below named manuscript which we resubmit for your consideration for publication to TRIALS.

**Tailored educational intervention for primary care to improve the management of dementia: The EVIDEM-ED cluster Randomised Controlled Trial.**

The responses to the comments and associated page numbers where changes have been made are shown in the tables below.

I hereby certify that this paper consists of original, unpublished work which is not under consideration for publication elsewhere.

The authors have no conflict of interests to declare.

The manuscript with track changes turned on has been re-submitted via the online system.

Yours Faithfully,

Jane Wilcock (Corresponding Author) with

Steve Iliffe, Mark Griffin, Priya Jain, Ingela Thuné-Boyle, Frances Lefford & David Rapp

<table>
<thead>
<tr>
<th>Reviewer 1 points addressed:</th>
<th>Pages</th>
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<tbody>
<tr>
<td><strong>Major compulsory revisions:</strong></td>
<td></td>
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<tr>
<td>Detail has been added about the intervention development and delivery</td>
<td>7 &amp; 12 &amp; box 1</td>
</tr>
<tr>
<td>The following questions have been addressed:</td>
<td></td>
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### Reviewer 1 points addressed:

<table>
<thead>
<tr>
<th>Question</th>
<th>Pages</th>
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<tbody>
<tr>
<td>1 What findings from the pilot led to decisions about the nature and duration of the intervention and who would be able to deliver it in practice?</td>
<td>14²</td>
</tr>
<tr>
<td>2 Who actually delivered the intervention at each participating site and to what extent did this differ across sites?</td>
<td>14²</td>
</tr>
<tr>
<td>3 To what extent did those who received the intervention vary across sites as well as the proportion of clinicians that were trained and those that opted out?</td>
<td>14³</td>
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### Minor essential revisions:

<table>
<thead>
<tr>
<th>Revision</th>
<th>Pages</th>
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<tbody>
<tr>
<td>More clarification about the limitations of intervention development and how these could be ameliorated.</td>
<td>16⁴</td>
</tr>
<tr>
<td>Clarification regarding use of co-design and/or nominal group techniques.</td>
<td>20, additional references added⁵</td>
</tr>
<tr>
<td>Misquote reference 15 amended.</td>
<td>32</td>
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</table>

### Reviewer 2 points addressed:

<table>
<thead>
<tr>
<th>Question</th>
<th>Pages</th>
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<tbody>
<tr>
<td>The order of methods could be clarified.</td>
<td></td>
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<tr>
<td>Was other data collected?</td>
<td>Page 21⁵ and within fig. 1</td>
</tr>
<tr>
<td>How was the education monitored?</td>
<td>16⁷</td>
</tr>
<tr>
<td>Did all practices attend all sessions?</td>
<td>16⁸</td>
</tr>
<tr>
<td>The audit if medical records and main outcome seems difficult to replicate, perhaps the audit instrument could be included in an appendix?</td>
<td>The audit instrument is not included as a separate appendix as these are defined in Table 1 and on page 9, 10 &amp; as bullet points on page 11 within the article⁹</td>
</tr>
<tr>
<td>The method of collecting practice level data should be included</td>
<td>12¹⁰</td>
</tr>
<tr>
<td>The method of collecting patient level data should be included (age &amp; gender)</td>
<td>13¹¹</td>
</tr>
<tr>
<td>Suggestions for discussion:</td>
<td></td>
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<tr>
<td>One could add that the payment incentives and roll out of dementia guidelines may well have caused change in both arms</td>
<td>Already noted page 21¹²</td>
</tr>
<tr>
<td>Possibility of being underpowered, a 50% change is a lot to ask</td>
<td>21¹³</td>
</tr>
<tr>
<td>Greater discussion of what other changes and outcomes may have been impacted but were not measured, i.e. staff and patient satisfaction with care</td>
<td>21¹³</td>
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¹ Experienced general practitioners with a background in postgraduate education facilitated the small group workshops with the practice teams. This comprised of an initial needs assessment group discussion which was guided
by a set series of questions. The questions were designed to elicit information about what systems were already in place for the diagnosis of and care for dementia patients, but also to encourage all staff to reflect on what they were already doing, whether they were doing that well, what they still need to be doing, and how to fill the gaps in knowledge and service (see Box 1).

**Box 1 near here**

From this discussion an educational prescription tailored to those needs was generated and supported with workshops and electronic information resources.

As a result of the field-testing the variety of learning materials used were broadened to include more reference material given during sessions and available online for instant access. The pacing of delivery for topics was also amended and the expert tutors became more knowledgeable and aware of areas of need that were consistent across individuals and groups. The intervention practice teams were offered flexible delivery of the needs assessment of workshop training and advised that one-hour sessions be the optimal length of each session. Practices had a mean of three educational workshops, including the needs assessment workshop at the beginning of the trial (range 2-4). These were staggered across the practices and took place from 2009-2011. The educational needs assessment generated individual workshop content for each practice. The workshops were delivered by one or two general practitioner dementia experts each working to a tutors manual which included learning objectives and timings. For three of the workshops a single trainer with non-participant observer facilitated the workshops (SI(3); Fl(3)) and in four practices both facilitators were present (SI & FL). A non-participant observer (JW) took notes at all meetings to ensure that all educational needs were met and to check for consistency in delivery of the intervention.

Each practice defined their own team which comprised the core clinical staff but with an extension of the intervention to administrative & support staff, community nursing teams and other professionals linked with the practice. We found this approach to work well with consistent attendance throughout the sessions from the teams. In several practices the support staff attended the sessions and one practice invited community nursing staff and one representatives from the local paramedic team.

The intervention may have been too weak to change practice. More workshops may have been needed, with reinforcement or mentoring of practitioners over longer periods of time. This level of educational input was not practicable in this trial, and we doubt that it would be feasible in real-world primary care organisations. Physicians have a limited ability to accurately self-assess their competence. Although the educational needs assessment was designed as a group process to offset this tendency, more external assessment may have been needed to truly tailor the intervention to needs.
The educational intervention was developed following the Medical Research Council’s recommendations for complex interventions [5], with strong elements of co-design modified by nominal groups to gain the insights and experiences of a range of practitioners [5]. Co-design is a technique adopted from product development which has tangible benefits in developing or redesigning health services [5, 5, 5, 5].

Professional knowledge, confidence and attitudes; Dementia management activity concordant with the NICE guidelines and carers’ satisfaction & unmet need were all measured pre and post intervention and will be reported elsewhere. It is possible that these or other unmeasured outcomes (such as patient satisfaction with care) may have had an impact as a result of the intervention.

A non-participant observer (JW) took notes at all meetings to ensure that all educational needs were met and to check for consistency in delivery of the intervention.

We found this approach to work well with consistent attendance throughout the sessions from the teams.

Practices self-completed a data recording form at randomisation and at follow-up twelve months later. This comprised the following fields:

- Practice list size
- Number of partners (FTE)
- Number of practice nurses (FTE)
- Any other member of staff specific for caring for older people based within the practice? If so please state title
- Do you currently look after residents in a nursing or care home? (if so how many patients have a dementia diagnosis? Do you include this number on your QoF reporting)
- Age/Sex register:
  - Male 0-64 years
  - Female 0-64 years
  - Male 65+ years
  - Female 65+ years
- Practice Deprivation score, (if known)
- Dem 1 QoF (Number of patients on register diagnosed with dementia)
- Dem 2 QoF (The percentage of patients diagnosed with dementia whose care has been reviewed in the previous 15 months)

The following anonymous audit data were collected by independent clinicians:

- Age at randomisation and/or intervention
• Registered with current practice pre or post randomisation and/or intervention
  o (If left) Date left the practice
• Gender
• Living at home
• Diagnosis
• Date of diagnosis
• Number of dementia reviews within twelve months pre/post randomisation and/or intervention
• Number of opportunistic dementia reviews within twelve months pre/post randomisation and/or intervention

The data collection tools are available on request to the authors.

10 Practices self-completed a data recording form at randomisation and at follow-up twelve months later.
11 The following anonymous audit data were collected by independent clinicians:

12 However, the results of this study have wider implications, particularly about the value of tailoring educational interventions. Distribution of newsletters and guidelines to normal care arm practices may have had an effect on their behaviour.

13 It is possible that the trial was underpowered for the 50% expected change. Other changes may be detectable. Professional knowledge, confidence and attitudes; Dementia management activity concordant with the NICE guidelines and carers’ satisfaction & unmet need were all measured pre and post intervention and will be reported elsewhere. It is possible that these or other unmeasured outcomes (such as patient satisfaction with care) may have had an impact as a result of the intervention.