Author's response to reviews

Title: The use of global positional system location in dementia: A feasibility study for a randomised controlled trial.

Authors:

Heather Milne (H.Milne@student.liverpool.ac.uk)
Marjon van der Pol (m.vanderpol@abdn.ac.uk)
Lucy McCloughan (lucy.mccloughan@ed.ac.uk)
Janet Hanley (j.hanley@napier.ac.uk)
Gillian Mead (Gillian.E.Mead@ed.ac.uk)
John Starr (jstarr@staffmail.ed.ac.uk)
Aziz Sheikh (aziz.sheikh@ed.ac.uk)
Brian McKinstry (brian.mckinstry@ed.ac.uk)

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Author's response to reviews: see over
Dear Colleagues,

*The use of global positional system location in dementia: A feasibility study for a randomised controlled trial.*

Thank you for sending us the reviewers’ comments on our paper which we found very helpful. We have extensively revised the manuscript in the light of these suggestions. Below we have annotated how we have addressed these in each case. We have submitted a revised paper along with a highlighted copy which shows the alterations we have made.

We hope that you find our revisions satisfactory and look forward to hearing from you in due course.

Yours faithfully

Brian McKinstry

**Reviewer: David Renauld**

- The overall length of the manuscript should be reduced especially the method

We accept the need for succinctness in journal articles. We have attempted to summarise the method, but we are aware that two other reviewers have asked for more detail in different sections of the paper.

- The method, especially participants’ inclusion criteria, lacks of accuracy for a preliminary study designed to investigate the feasibility of a RCT (criteria for the AD diagnosis, severity of the demented syndrom,...).

We have clarified the text with respect to the inclusion criteria. However, this was a pragmatic study set within an existing care-management pathway and effectively we considered most patients who were assessed by the local authority to be suitable for GPS location based on their criteria. We did not restrict the study to people with AD or to people with a pre-defined level of severity. Restricting the inclusion criteria further would have implications for the generalizability of findings.

- The use of different GPS devices would probably increase the risk of confounding factors, considering the fact that GPS devices already have technical issues (battery duration,...)

We accept this and address this now in the discussion section. Some devices suit some types of people better than others (e.g. some women did not want to wear a bulky watch) and it is important to use the device that is most appropriate for the person. The study was primarily around
recruitment and retention feasibility as the technology is rapidly developing. In any future trial the intervention equipment will be chosen on the basis of reliability and acceptability.

- there are probably too many outcome measures to conduct a RCT with a limited numbers of participants.

The study was an observational study and was partly about the acceptability and utility of the outcome measures. For that reason we employed rather more than we would normally in definitive RCT. The research showed that some were clearly unacceptable and would not be used in the future

- the preliminary study does not clearly provide information explaining how the authors will conduct the coming RCT (outcome measures, statistical analyses).

We have added some lines to the discussion about this. We have been persuaded by the referee’s comments and are more circumspect about the feasibility of an RCT in this area.

**Reviewer Eleanor Bantry White**

*Major compulsory revisions:*

1. Greater clarity required about the number of participants, length of follow-up, rounds of data collection that actually occurred (rather than what was planned) and consistency in reporting this between the abstract and methods section.

   We have provided more detail in the text which we believe clarifies these issues and additional detail to table 1.

2. Methods section: Provide a basis for the decision to follow up for 6 months and a reference that indicates that this is a sufficient time-frame for observing long-term care as an end-point.

   We aimed to evaluate the intervention over around six months to allow a sufficient number of wandering events (as identified by the caregiver) and possibly some admissions to hospital or care homes or both to occur while keeping within the timescale of a feasibility study and to give an indication of the likely retention of these devices. A previous local audit suggested around 20% of those meeting the inclusion criteria would have at least one admission during this period and previous research suggested that the median length of time between first wandering and institutionalisation was 8 months [1]. We have now included this and also refer to it in the discussion.

3. Methods section and Discussion section: be far more critical about use of carer report to measure time spent searching in the baseline measurement. The accuracy of this approach is questionable when seeking information about remote events. Caution is needed if making conclusions about a subsequent reduction in the time spent searching for the person using this form of measurement.

   We accept this and draw attention to this in the methods and discussion

4. Methods section: Pay more attention to critically examining why it’s useful to report health and social care utilisation when unable to distinguish whether utilisation results from getting lost or from other case characteristics.
This is an important point and we have now included the particular challenges in deciding what resource use may or may not be as a result of wandering/dementia and the utility of global measure of health service use in the discussion. However, within the context of a substantive randomised controlled trial as patients are randomised, any differences in utilisation can be attributed to the intervention. This is now mentioned in the paper.

5. Results: Qualitative data should be supported with reference to the data i.e. quotations.

We initially decided to remove the quotations in order to save space, but we completely accept that their inclusion improves the paper. We have compromised by adding a few pertinent quotations to illustrate the points made.

6. Results/Discussion: Some discussion required about the length of follow-up and impact, if any, of missing data on results relating to Carer QOL.

We have added some discussion about this

Minor essential revisions:
1. Methods section: State reason for why you sought to recruit 20 participants
   As above

2. Discussion: There could be some discussion as to the value of measuring health care utilisation when the sample size is small.
   As above

Discretionary revisions:
1. Generally, the standard of English is good with a few minor typos. Consistency is recommended in the use of the term 'people with dementia' and removal of the term 'dementia sufferer' in the Discussion
   This has been changed.

Reviewer: James Tung

While the relevance of the topic is important in the field of dementia care, the manuscript lacks key points that limit its clarity and impact. A stronger summary of literature examining the key issues regarding GPS localization, including observational, ethical, and technology studies, would improve the reader’s understanding of the issues and need for in-depth evaluation.
We have added to the literature review partly in the introduction and partly in the discussion and now refer to the ethical dimension.

To support their main conclusion that an RCT is feasible, the authors could improve the impact of the study by providing deeper interpretation of the data. In particular, recommendations on dealing with variability in devices, geofence settings, and wandering behavior would be important to audiences investing in RCT studies.

We accept this and have added this to the discussion. Different devices were used, but all used more or less the same technology with some slight variation in service provision. Differences were mainly due to personal choice (e.g. pendant rather than watch) and how the device was employed e.g. some caregivers and people with dementia chose to have a geo-fence and others didn’t.

**Major Compulsory Revisions**

Background, third paragraph: The authors describe the potential benefits of GPS location systems well, but a fuller description of the drawbacks is needed to provide a clearer introductory framework. While there have been no high-quality RCT studies, there have been a number of qualitative and observational studies related to the use of GPS use that need to be appraised. The key findings and concerns arising from a number of cited work (e.g., [21-24]), along with related literature, would help frame the issue and clarify the questions to be addressed in an RCT (e.g., Are GPS systems worth the cost?).

See above


Thank you for suggesting these very helpful papers which we have now included.

Discussion, paragraph 2: The findings from the qualitative analysis are interesting, and warrant the mentioned in-depth analysis in a separate paper. For the current manuscript, I advise interpreting these findings in the context of designing future trials.

We have added more detail to the qualitative report as mentioned above. We focussed on issue so acceptability/practicality of the equipment and on the acceptability of some of the outcome-measures, and the likely willingness of social services to become involved in future randomised trials.
Discussion, paragraph 3: Some clarification on the impact of growing proliferation of smartphones on contamination of control groups is recommended. While smartphones have localization sensors, the use of a geo-tracking and alerting function needs to be installed and set up by the user. Could a control group include smartphone users that do not apply geo-tracking alerting functions?

The problem with this is the potential for contamination. It would be relatively easy for a family member to switch this on. Given that people interested in a trial are already interested in the technology the temptation to use geolocation when randomised to control would be strong and contamination difficult to measure. Leaving it switched on but not using it as has been suggested would be quite unethical if a control patient became lost. We have extended our comments on this.

Discussion, paragraph 3: Some greater depth of discussion on the advantages and disadvantages of interrupted time series design would be appropriate to guide future studies.

We have added to this

Discussion, paragraph 4 and Table 7: If time spent searching is a key outcome, the large variation in time spent searching may limit the feasibility of an RCT. Was the data in Table 7 used to estimate sample sizes for future trials? Please report means and standard deviations for time and frequency estimates, if available.

Thank you. We have been persuaded by the reviewers’ comments here. We are now more circumspect in the discussion about the utility of this measure in terms of its variability and reliability. We conclude that a more robust method of estimating this is required before it could be used as an outcome in a trial.

Conclusion: The authors conclude that designing an RCT is feasible despite the challenges encountered. However, the discussion produces few suggestions on how to overcome the described challenges, including recruitment, homogeneity (i.e., devices, geofence settings, and wandering behavior), and technical (i.e., equipment failures, difficulty in use). As written, I did not agree with the authors’ main conclusion considering the long list of challenges and lack of solutions. This section could better highlight the key arguments supporting the feasibility of an RCT.

We address this now in the discussion and as previously mentioned are more circumspect about the ability to manage run a high quality quantitative study in this area.

Minor Essential Revisions

Abstract, Background, last sentence: the comma between ‘informing’ and ‘deliberations’ is unnecessary.

Removed

Results, Results from qualitative interviews, Perceived utility and acceptability, second sentence: The term ‘inappropriate walking’ needs to be clarified.

We have substituted ‘unscheduled’ for this
Table 8: I recommend a brief explanation of the 48 events recorded by P10 in the last month. How might such behavior be handled/processed in an RCT

P10’s partner worked full time he liked walk everyday and was getting increasingly frequently lost. This is now referred to in the text