Author's response to reviews

Title: Nurse clinic versus home delivery of evidence-based community leg ulcer care: A randomized health services trial

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Author's response to reviews: see over
Dear Dr. Todd:

Thank you for the feedback of our manuscript “Nurse clinic versus home delivery of evidence-based community leg ulcer care: a randomized health services trial.” The reviewers have made some very good points to help us improve our paper. Unfortunately the issue of the “question posed” and economic analyses is something we cannot change at this point but I hope to explain more explicitly the context under which the study was conceived and initiated. In early 2000, the trial was reviewed and funded by our Medical Research Council (now Canadian Institutes of Health Research) and was considered by the reviewers as “highly original”, “will be largest and most scientifically rigorous yet taken …promises to be more informative than those that have gone before” and, from an international reviewer, “…rather sad that such a high calibre team has never been interested in leg ulcers in the UK!”

The question at the time was effectiveness as Canadian home care authorities were beginning to seriously consider alternatives to home visiting. Community nurse clinics for those with problems such as chronic wounds seemed an appealing option. There were a few UK effectiveness studies as well as weaker evidence and anecdotal reports that highly supported clinics because of perceived improvement in mobility and social support. Some Canadian authorities wanted to accept and move in this direction, using the UK studies for support. However solid evidence was required, particularly given the limitations with the previous leg ulcer studies outlined in the manuscript and further noted by the reviewers.

Economic analyses (or lack of) - both reviewers raised questions in this regard. Nurse travel time would be a factor favouring clinics and we could have used an average distance/cost factor. However, we are mindful that expenditures would differ greatly depending on the setting of care for both the system and the patients/families. Advice was that an appropriate, comprehensive economic analysis would require a societal, rather than sector, perspective. In such an analyses, ALL expenditures such as travel time to provide or receive care (nurse and patient), vehicle allowances for nurses, overhead of the community located leg ulcer community clinic settings (rent, utilities, reception, etc.), as well as family expenditures related to leg ulcer care (time off work, travel, out-of-pocket expenses etc.) would be required. It was beyond the scope of this trial to assess all the direct and indirect expenditures related to home and clinic care. Basic resource data collected in this trial may provide the basis in planning for a full economic analysis or modeling study.
Our research team decided it would be strategic to conduct a health services trial, integrating both a quality and clinical outcome. In Canada, healing is a health services quality decision factor i.e. once healed individuals are off service and return to follow-up care with their primary physician. At the time of starting the trial, 3-month healing was the most commonly reported healing outcome and from our administrative databases we knew the vast majority were still on service at 3 months. Thus, we believed this primary outcome would be clinically and administratively meaningful. Importantly, it would also be reasonable to track in both the home and clinic settings.

Since then research outcomes have shifted. In our most current studies we use the more sensitive ‘time to healing’ outcome. Notwithstanding, this RCT was built on the 3-month healing rate as the primary outcome and for sample size calculation, thus we are bound to report it as such. The reviewers note that the trial was well conducted and reported following CONSORT standards. As this question has still not been conclusively answered from an effectiveness viewpoint, we believe it makes an important contribution to the existing evidence and syntheses housed at Cochrane.

Hopefully this explains the conditions and context upon which this trial was planned and conducted. Below is the point-by-point response to each reviewer’s comments with our response underlined and in the revised manuscript, highlighted for ease of review. A statement on the ethics status has been added to the methods section (last para pg. 7) as per your request.

**Reviewer 1 (Dr. Andrew Jull)**

**Compulsory Minor Revisions**

1. pg. 8 para 2 – more information on the HRQL instrument. Thanks for pointing this out! We have done substantive work assessing the feasibility of available pain and HRQL measures for use with this community based wound population. More information added on the HRQL instrument (SF-12) on pg. 8 2nd para to pg. 9.

2. pg. 8 para 5 Analyses. This was an oversight on our part with a previous version being included. Updated and corrected analyses section added pg. 11, 1st para.

3. Inclusion of a CONSORT participant flow diagram. A schema has been added and referred to in the Results pg. 10, 1st para (Figure 1: Flow of population with leg ulcers and eligible pool for Clinic vs Home Trial).

4. Add description of the Resource Use analyses and explanation about travel time not being included. A paragraph (top pg. 10) has been added to address travel time issue and on the top of pg. 11, a sentence about resource use analysis.

5. Add in Discussion more on the comparison with previous UK studies, and importance of the organization of care. A section has been added in the discussion (pg. 14) to highlight this point.
Discretionary revisions

1. pg. 8, para 4 sample size calculation – rationale for assumptions. We based this on available local data and what was being reported in the literature. If I understand the question it is about why 20% improvement – it was a conservative estimate of the improvement drawn from studies available at the time.

2. Consider incorporating cost info in another paper using cost minimization approach. We hope the basic resource information (visits, supplies for episode of care) for clinic and home presented in this paper will provide the basis for a full economic evaluation or modeling study.

3. Unnecessary to report differences between groups at baseline. We would prefer to leave this information in to demonstrate the similarities of the 2 groups for readers particularly as the planned sample size was not achieved.

Reviewer 2 (Dr. Nicky Cullum)

Compulsory Major Revisions

1. Choice of the question, economic analyses: the primary question for providers and health care planners at the time that this study was conceived, funded, and initiated was effectiveness of clinic vs home delivery. It should be noted that we housed this RCT within a larger pre-post evidence-based practice effort in order to tease out the evidence for clinic vs home for mobile individuals. In a real world, pragmatic approach we controlled for the quality of provider, protocol, and patient population, in order to understand if there were differences. Setting of care in itself remains important in many spheres as it is thought that getting out to clinics is better for healing (e.g. mobility and social factors). Thus taking a reasonably mobile cohort and randomizing them would help discover if there were any advantages to clinics that should be further explored. For Canadian home care authorities, this evidence on effectiveness was (and still is) crucial as this community option remains under scrutiny.

From our data we do not know if clinics are more “cost effective”. We undertook a limited resource data collection for an episode of care that could be largely done from administrative databases. Travel time for nurses would be an important factor in favour of clinics but there would be many additional differences between delivering clinic or home depending on ones perspective (sector, patient/family). Thus a societal perspective would be required for a full and proper economic study capturing real expenditures related to setting up and maintaining clinics (rent at convenient locales, overhead, reception etc.), car allowances for nurses, travel time for both nurses and family members, and as well as out-of-pocket expenses with each setting option.

A paragraph has been added to address the economic approach and its limitations upfront and in the methods (pg. 4, last para; pg. 10 1st para) and in the Conclusions about future research (pg. 17 last para).
2. Methods

a. Describe how healing outcomes were collected. Additional information has been added pg. 8, 1st para.

b. How were resource data collected? Why not an economic analyses? A section has been added pg. 10, para 1st para describing the resource data collection. The issue of the economic analyses, addressed in #1 response to Dr. Cullum above.

c. Discussion – add more about why an RCT was undertaken rather than an economic modeling exercise. An additional para in the discussion pg. 14, 1st para addresses the explicit nature of the care organization and how that differentiated this study form the previous ones.

d. More detail on the nature of the localities (urban, rural), efficiency of clinics depending on travel times. The urban-rural mix is added to the discussion pg. 16, last para. As we do not have travel time or distances travelled we cannot comment on the relative efficiency.

Discretionary Revisions

1. Methods

a. Choice of primary outcome not a food one. Agree but at the time of RCT development (early 2000) it was primarily the outcome of choice in trials and as you can appreciate we cannot change the primary outcome.

b. Preference element should be in methods. The study was not planned as a preference trial. This aspect was revealed after the RCT was underway when a sizable proportion of those approached expressed willingness but only if they received their choice. Thus not included in the methods but noted in Results for transparency that we followed them. In hindsight it would have been a better approach!

Thank you for the opportunity to revise the manuscript and I trust we have been able to respond to reviewers’ questions and concerns. We look forward to your reply.

Sincerely,

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