Reviewer's report

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

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Reviewer: Nicky Cullum

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The paper describes a randomised controlled trial comparing clinic- and home-based care for the management of people with venous and mixed aetiology leg ulcers. The trial seems well conducted, though there are areas where the reporting could be improved and I will proceed to indicate these. The report is very well written.

QUESTION POSED:

I am not really sure why the authors chose this question. As the authors outline in the Introduction, there have been some studies comparing home based and clinic based care of people with leg ulcers in the UK however the major distinction between the UK evidence and this Canadian study is that in the UK studies the setting was NOT the only systematic difference in treatments. The treatment arms in the one UK RCT (Morrell et al, refs 13 and 14) differed in setting (home vs clinic), treatment (best evidence based compression vs. treatment as usual), and the skill and knowledge of the personnel (leg ulcer trained vs usual community nurses). It was completely unsurprising then that clinic managed patients had better clinical outcomes.

I am not clear then why setting up an RCT in Canada that compared clinical outcomes in the face of all other things apart from setting being equal was the way to go - there is no obvious reason why two patient groups for whom clinical management and personnel were identical with the only difference being setting should differ in clinical outcome. The more interesting question would be whether clinic or home care is more COST EFFECTIVE but the team does not seem to have undertaken an economic evaluation. I would have thought the cost-effectiveness could have been modelled using existing information supplemented by more detailed cost data acquired outside of an RCT. Whilst some cost data does seem to have been collected, there is little detail re. this or the analysis and this is not an economic evaluation as such. The perspective of the economic study is not clear but surely the clinics must have been more efficient than home care (with the service being able to see more patients per unit time?). However the analysis described here does not seem to have accounted for throughput or travel time. I think these issues need to be addressed as a MAJOR COMPULSORY REVISION.

METHODS:
I think fundamentally this is an economic, rather than clinical question so I am not sure why this RCT design has been chosen (see above) - in this report clinical outcomes have been privileged over economic ones but one wouldn't have expected the clinical outcomes to be different (or if the applicants did it is not clear why, since the existing UK studies are not a suitable comparison).

That said the paper still contributes interesting information but more detail is required regarding:

a) how outcomes were collected - blinded photographs are first mentioned in the discussion. How was time to healing data collected/validated? Should be in the methods. MAJOR COMPULSORY REVISION.

b) how were resource use data collected? Analysed? Why was a formal economic evaluation not undertaken? MAJOR COMPULSORY REVISION.

c) The choice of primary outcome is not a good choice despite its use elsewhere (the 3 month point is arbitrary; time to healing is FAR more informative and a more efficient use of data). DISCRETIONARY REVISION.

d) that there was a preference element to this study is only revealed in the results on page 9 - this is interesting and should be in the methods. DISCRETIONARY REVISION.

I think the Discussion should shed more light on why this RCT was undertaken rather than an economic modelling exercise. The Discussion and Conclusions need to more accurately reflect the major differences between the design of this study and the ones it is being compared with: the Moffatt studies were not RCTs, but historically controlled (thus open to many biases and explicitly the care was better in the clinics than the home setting); the Morrell study was an RCT but again, care was explicitly better in the clinic than the home. MAJOR COMPULSORY REVISION.

Finally the paper needs to give more detail regarding the nature of the localities in which the study was undertaken (urban, rural etc) since this is likely to impact on the findings (clinics may be more or less efficient depending on travel times - this could be modelled in future studies). MAJOR COMPULSORY REVISION.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.