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: Andrew Jull

Reviewer's report:

Thank you for the opportunity to review this paper. The study is a randomized controlled trial of two methods of delivering organized nursing care for patients with venous and mixed aetiology leg ulcers to determine effects on healing rates and acceptability of the models. An additional group who were eligible but not randomized were followed, but these results are not included in this report. There was no significant difference between two randomized methods of care, although the trial did not meet its recruitment target. However, even if the recruitment target had been met, the difference between the groups was likely to have been much lower than anticipated in the sample size calculation and the result would still have been non-significant. Generally speaking, this paper is well written, follows the CONSORT standard for reporting RCTs and is appropriately interpreted. I have requested a number of minor revisions

Minor essential revisions

1. Page 8, paragraph 2: a health-related quality of life instrument is referred to without identifying the instrument. It is later revealed to be the SF12 with PCS and MCS scores reported. The SF12 needs describing in a similar manner to the explanations given for SF-MCQ.

2. Page 8, paragraph 5, analyses: reference is made to changes in leg ulcer being analysed, but these data are not presented. Similarly it is reported that changes in ulcer size were analysed using Chi-squared test, although the data is continuous and should probably be analysed t-test (assuming normality) or similar non-parametric test of significance. Recurrence rates were to be analysed using Student’s t test, but the data were presented as proportions (table 3), so presumably were analysed using Chi squared test or similar.

3. There is no diagram of participant flow through the study (approached, registered, randomised, followed up, analysed) as required by the CONSORT statement.

4. There is no description of the analyses undertaken for the resource use. More importantly, there is no explanation as to why the costs for the home care group did not incorporate travel time, which surely would be useful in deciding which model of care to employ given the choice.

5. Page 10, paragraph 2, Healing: absolute differences and 95% confidence intervals (95%CIs) for the difference need to be reported in addition to the significance tests.
6. Page 10, paragraph 3, Pain and HRQoL: between-group mean difference of change from baseline needs to be reported, along with the 95% CIs.

7. This trial employed the same group of specially trained nurses to undertake protocol guided care in either the participant’s home or a clinic setting. The healing rates were the same, as one would expect if the same treatment protocol were used for both groups. The authors quote three previous studies (Moffat et al, Simon et al, Morrell et al) which found differences in healing rates based on the different settings, with healing rates in clinic-based care being higher than home care healing rates (incidentally, the reference for the study by Morrell et al is incorrect). However, the three studies were not really evaluations of settings, but rather tests of organised care versus non-organised care with organisation resulting in increases in compressed patients. For instance, in the Stockport study (Simon et al) 81% in the organised care (clinic-based) area received compression compared to 52% in the non-organised care area. Similarly, in Morrell et al – the only RCT, usual care patients (usual nurse, no protocol, home-based care) received compression during just 42% of visits, whereas the organised care group (clinics, trained nurses and protocol guided care) would probably have been compressed more frequently if the protocol was effective (although the actual number of not reported). Moffat et al similarly reported increases in healing rates in an audit after care was organised. The key point is that the organisation of care is more important than the setting and this is likely to be the explanation for the difference Harrison et al’s study and that of previous studies. This issue requires exploration in the discussion.

Discretionary revisions

1. Page 8, paragraph 4, sample size calculation: The control group event rate was assumed to be 20%, when the baseline healing rate reported in a pre-post intervention audit by the same team was 23%. The anticipated difference between groups was 20%. The rationale for both these assumptions could be detailed further.

2. Perhaps the authors could consider incorporating the cost information in a separate paper using a cost minimisation approach so that the input costs and the modelling used could be properly assessed.

3. It is unnecessary to report significance tests for the differences between groups at baseline - the p values are tests of whether the results will have occurred by chance, when we already know that to be the case as the groups were randomly assigned.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

I have no competing interests to declare.