Author’s response to reviews

Title: Pilot Parallel Randomised Controlled Trial of Protective Socks against Usual Care to Reduce Skin Tears in High Risk People: 'STOCPUTS'.

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Author’s response to reviews:

Reviewer #1: Thank you for your paper which addresses an issue that requires investigation - I enjoyed reading it.

Skin tears are often overlooked in research studies and there is little information regarding the prevalence and cost of these.

Thank you.
Please note that slow recruitment is repeated several times in the manuscript - this may require attention.

I have removed the second mention of this issue which was in para 1 of the original Results section.

Please do not shorten words e.g. didn't this is better written as did not; wasn't - was not

I have changed all occurrences of these words to their correct form.

Please review this sentence as I find it difficult to understand: Recruitment to the pilot study was easier from GP practices than from volunteers or care homes, having a conversion of approached to consented of 1 in 2 potential participants.

I have removed this sentence and replaced it with:

"However, it was easier to recruit participants for the trial from the community because consenting one person only required two people to be invited. In care homes, it required six residents to be invited. Running clinics in GP surgeries was also less costly on travel and research nurse time where they could see five patients in a single morning."

I also moved a short paragraph in front of this to make it flow more easily, in my opinion, as follows:

"Working in geographical cohorts proved to be efficient for research nurses but recruitment from care homes was slow due to mental capacity issues among residents and some reluctance to take part in research. Once recruited, however, residents enjoyed the weekly contact with the research nurses by phone and in person. In order to reach our target sample, participants were recruited from the community (GP practices) but they were on average 10 years younger than those from care homes (median 80 versus 90 years respectively)."
Reviewer #2: Thank you for asking me to review this valuable study.

I have several issues I would like you to address:

1) In the abstract you state that skin tears are the most common reason for attention from a community nurse and in care homes they are the second most common wound after pressure ulcers. Do you have a reference to support this in your region?

I have changed the wording to say that they are "among the commonest reasons for attention from a community nurse".

Regarding the second part of the question, in care homes they are the second most common wound after pressure ulcers. There is already a reference to this [15]. This was based on the work of one of my co-authors, Andrew Kingsley who had conducted a point prevalence study of care homes in North Devon (he was based at North Devon District hospital at the time and eventually became the Tissue Viability Champion for Devon. The reference is already in the paper [15]. In paragraph 1 on page 4 we stated: “A recent wound point prevalence audit undertaken in North Devon [15] in 16 care homes revealed 195 wounds among 115 of 458 residents (25%). Traumatic injuries (skin tears) were the second most common wound type (37, 19%) after pressure ulcers (87, 45%).” I don't think I am allowed put the reference in the abstract.

2) You state that the Payne and Martin definition is the most frequently used definition in the literature. While I agree that this is true for the literature published prior to 2011, after 2011 the ISTAP skin tear definition is the most frequently quoted in the literature. I have just completed an extensive systematic review on this subject.

Thank you. I have changed the wording accordingly, as follows:

"Until 2011, the most commonly cited definition of a skin tear was that of Payne and Martin: ‘‘A skin tear is a traumatic injury occurring principally on the extremities of older adults as a result of shearing or friction forces which separate the epidermis from the dermis (partial thickness wound) or which separate both the epidermis and the dermis from underlying structures (full-
thickness wound)” [1]. This was superseded in 2011 [2] by the iSTap (International Skin Tears Advisory Panel) definition “A skin tear is a wound caused by shear, friction, and/or blunt force resulting in separation of skin layers. A skin tear can be partial-thickness (separation of the epidermis from the dermis) or full-thickness (separation of both the epidermis and dermis from underlying structures).”

3) on page 5 you state that skin tears are predominately treated in the community. Can you reference this statement?

I have changed the wording of this based on wording found in our reference 37:

"Skin tears are often treated in the community [37], however for more severe tears and if a patient develops complications such as an infection, or is in need of surgical debridement, they will need to be referred to secondary care."

4) your study population was community patients and residents in care homes, can you please define the differences between the 2 populations?

The differences between them are summarised in Table 1 - Baseline Characteristics. The main difference was that the community patients were younger than the care home residents by an average of 10 years. Care home residents were mostly in their 80s and 90s. Being younger, the community participants were mostly independent and displayed more activities of daily living such as shopping, household chores and hobbies such as gardening. In our sample, the care home group had slightly more females (48%) than the community group (44%). These features have been described and discussed on the paper.

5) I would like to see a short summary of the methods for those who did not read your first paper. If I had not read the first paper I would have had many questions. For example, how were the participants randomised?

Pages 6 to 9 already describe the Methods and these have been extracted from our protocol paper. There is a heading for Randomisation on page 7. I thought that part of the reason for
publishing a protocol paper was that one would not have to repeat a lot of the detail when publishing the results - especially as these are open access papers and are readily available on the internet.

Did you include individuals with cognitive impairment and if so how did you obtain consent?

Due to our interpretation of the Mental Capacity Act, the study did not include individuals with cognitive impairment. This was based on the principle that if a trial can be done involving ‘healthy people’ (with regard to mental capacity), then this should be done instead of involving ‘people lacking capacity’. We would have liked to have included them and in our qualitative work, managers of care homes asked us why we didn’t because in their view, people lacking capacity were more at risk.

6) You have stated that the Payne Martin is a validated tool, Payne and Martin have claimed validation however they did not publish their results. The STAR and ISTAP classification systems are the only systems with published validation.

I have added some wording to this effect on p19:

"Although the Payne-Martin classification system [1] has been validated both internally and externally, the results were not published (K. LeBlanc, pers. comm) and this may be why it has not been widely used in clinical practice [56, 57]."

I hope that this is satisfactory (to quote you as an authority in this).

7) THANK YOU for including patient stakeholders!!!!!

We did our best but it was very difficult. Considering the age group and their health status, very few were available to help and were fit enough to attend meetings. Not many used computers for communication either.
8) Did you assess causal associations? In Table 3 you have listed reported causes, did you place them into themes? Were there differences between those in care homes and the community?

I have now put them into themes, as follows:

"Causes of the skin tears differed between the care home and community participants. In care homes, the 12 tears were caused by falls (4) including falling out of bed and in transferring from bed to chair; knocks against objects (4) such as walking aids, bathroom furniture and blunt or sharp edges and ‘unknown’ (4) where the participants could not recall the cause. In the community, the 19 tears were caused by gardening activities (7) including two falls in the garden; knocks against objects (4) such as a door, a door frame, wine rack and recycling bin; overnight in bed (3) on the bed frame and simply by dragging bed sheets over their legs; dropping objects being carried (2) - a full cardboard box and a heavy crate that scraped the legs; and ‘other’ (3) such as putting ordinary socks on in the morning (from fingernails), a penetrating injury of unknown origin and a fall indoors."

9) You have used brand names in the body of the paper, can you use a generic name?

It is hard to come up with a generic name which has some meaning but isn't overly long - unlike the situation with drugs where a single word is suitable as the generic name e.g. paracetamol instead of the brand name Tylenol. We came up with 'thin skin protection socks' but this is still a bit of a mouthful to keep repeating in a paper. I am now using 'protective socks' throughout the paper but there is still a reference to Dermatuff in the Abstract, as a keyword and in the description of the socks themselves.