Author's response to reviews

Title: The association between foot-care self efficacy beliefs and actual foot-care behaviour in people with peripheral neuropathy- a cross sectional study

Authors:

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Author's response to reviews: see over
The authors of the above-titled manuscript thank the reviewers from the *Journal of Foot and Ankle Research* for their comments. Below are the detailed responses to these comments, to be read with the edited version of the manuscript.

**Reviewer 1**

**Major compulsory revision:**

- The use of multiple t-tests for confidence scale and behavior subscales is somewhat problematic and it might be more appropriate to conduct ANOVA as the independent variables are most likely associated with each other...

**Response**

We agree that the use of the multiple t-tests to examine the differences in mean scores of the three variables (the two behaviour subscale scores and the self-efficacy score) in those with and without a history of foot problems may have lead to some problems—both in the increased chance of a type 1 error and the assumption that the variables may be related to each other. To combat this issue, the results of a MANOVA test are now presented and all detail referring to the t-tests has been removed (including table 2):

In methods section:

“A multiple analysis of variance test (with Bonferroni-type adjustment) was used to compare mean FCCS scores and behaviour subscale scores for participants that had a history of diabetes-related pathology with those that did not.”

In results section:

“Multiple analysis of variance was performed to investigate differences in mean FCCS and behaviour subscale scores for those with a history of foot pathology and those without. When considering the FCCS and behaviour subscale scores separately, there was virtually no difference between the mean FCCS scores for those with a history of pathology compared with those with no history of pathology (F = 0.05, p = 0.95). For the preventative behaviour subscale, those that had a history of pathology reported undertaking more preventative behaviours, however this did not reach statistical significance after the Bonferroni-type adjustment (F = 5.62, p = 0.02). However, those that had a history of foot pathology did report undertaking fewer potentially damaging behaviours than those without a history of foot pathology (F = 14.00, p = <0.001).”

- In addition, I understood from page 7 that the foot behavior scale scores were converted to dichotomous variables – which would make the use of a parametric tests unacceptable.

**Response**
On page 7 of version one it is stated that: “Because of the difference in scaling, items were converted to a 0 to 1 scale before summatings scores. After re-coding, higher scores indicate both more preventative and potentially foot-damaging behaviours.” This was not meant to imply that the scores were 0 or 1, but in fact there could be a range of scores from between 0 and 1. To clarify this, the text has now been changed to:

“Because of the difference in scaling, items were converted to a scale that ranged from 0 to 1 before summatings scores. After re-coding, higher scores (i.e. closer to 1) indicated both more preventative and potentially foot-damaging behaviours.”

So parametric testing was used because the data was considered as continuous- after re-coding there could theoretically be any value derived between 0 and 1.

**Major compulsory revision:**

- A major weakness of the article is that there was no mention of power in the study – the potential for being underpowered would affect the findings with a type 2 error – on page 9 authors state: “we found only a weak relationship between FCCS and preventative behaviour scores. While this indicates that the participants who have stronger foot-care self-efficacy beliefs also undertook more preventative behaviours the relationship was unconvincing in its “clinical” significance in practice.”

  The lack of a strong relationship could be explained by the lack of power in the study – a type 2 error. Since the FCCS measured self-efficacy in preventive behaviors, the significant correlation between the preventive behaviors and FCCS scores makes since.

**Response**

In a sense the study is not underpowered because it did detect a relationship between self efficicy and behaviour. So a relationship was detected, but it was not a strong one and not particularly clinically meaningful (essentially the largest Pearson’s r correlation coefficient found was small- 0.2. This small correlation was actually statistically significant using an α value of 0.05). We certainly agree that with a larger sample size this correlation coefficient would be much more statistically significant, but we wonder if this would affect the clinical significance.

To better reflect this, the passage above has been changed to:

“While this indicates that the participants who have stronger foot-care self-efficacy beliefs also undertook more preventative behaviours the relationship was small, and unconvincing in its “clinical” significance in practice- even if statistically the result was significant.

**Discretionary revision:**

- A weakness of the design is the lack of a measurement of foot self-care knowledge. The authors point out on page 11: “Stuart and Wiles seriously doubt the worth of using quantitative tools to assess foot-care “knowledge” in people with diabetes as they found that their
participant’s actual understanding of foot-care practices derived from in-depth qualitative techniques fell well short of their apparent knowledge as investigated using quantitative techniques [39].”

While knowledge is necessary it is not sufficient to change behavior but knowledge is a precursor to behavior change. The authors statement on page 10 listed below could be explained in part due to a lack of knowledge of consequences of inconsistent foot prevention techniques and thus the behavior is not taken until the consequence occurs.

“It would be expected that the participants who had suffered a serious problem of a diabetes-related foot problem would undergo more appropriate foot-care behaviours in the future. For these people, adverse outcomes may act as a prompt for preventive behaviour. Unfortunately, it appears that this “prompt” is required first before preventative behaviours are taken place, rather than implementing the preventative behaviours before they get a foot problem.”

Response
We agree with the brief synopsis given about the relationship between knowledge and behaviour. We also agree that not measuring knowledge of consequences is a weakness of the study. However, we raise the conclusions of Stuart and Wiles more to demonstrate the weakness in the design of using a quantitative pen-paper questionnaire to measure self-efficacy beliefs rather than raise the “knowledge” issue. Furthermore, we point out on page 10 that even though this interesting result was found, and we speculate that people undertake better foot-care behaviours after a major foot pathology- as there is such a high recurrence rate of foot pathology that we wonder if this actually matters very much.

So, we would at this stage suggest no changes on this matter.

Minor Essential Revision:
- Finally, it is important to understand that self-efficacy is one construct in Bandura’s social cognitive theory. Self-efficacy is influenced by outcome expectancy and this is an understudied but important link. For those patients who had foot pathology, their outcome expectancy for foot self-care has changed – they now believe that the foot self-care will prevent further problems so their self-efficacy increases and they now undertake more preventive behaviors and fewer damaging behaviors. Thus the statement by the authors on page 10 listed below should be modified to reflect this relationship.
  “It would be expected that those with a history of pathology would report lower self-efficacy.”

Response
We acknowledge that outcome expectancy may be playing a role here. However, we are uncomfortable in asserting the model shown by the reviewer demonstrating the possible influence of outcome expectancy as we are unable to say if indeed the participants that had a history of pathology in fact did “…now believe that the foot
self-care will prevent further problems…” as this was not measured in any way in this study. Therefore, to avoid confusion on the matter the paragraph has been simplified and the problematic sentence above has been removed. The text now states:

“Neither was self-efficacy related to foot pathology outcomes. There was no difference in self-efficacy beliefs between those with a history of foot pathology and those with no history. As with the findings for lack of a relationship between self-efficacy and preventive and damaging behaviours, this result suggests that self-efficacy as measured by the FCCS has limited clinical utility for people with diabetes and loss of protective sensation in their feet. This has implications for health promotion strategies that focus on developing self-efficacy to encourage preventive behaviour.”

**Reviewer 2**

**Major compulsory revision:**

- Methods - This section needs more work as it is not completely described. "Who made the clinical determination of "loss of protective sensation" in the feet.”

**Response**
The principal researcher, using the methods described. The text has been changed to:

“The presence of loss of protective sensation was determined clinically by the principal researcher and defined as an inability to detect…”

- “...is self-reported data or clinical data or what?”

**Response**
Clinically determined- see immediate italic text above

- who interviewed the patients? Did the patients answer a questionnaire?

**Response**
The principal researcher and the participants did answer a questionnaire. The text has been changed a little to clarify this:

“Participants provided informed consent before being interviewed and assessed by the principal researcher to determine the following variables: age, gender, diabetes type, duration of diabetes, education, living arrangements and history of a diabetes-related foot pathology (ulcer, Charcot arthropathy, infection requiring admission to hospital, surgery and amputation). Previous medical records were consulted to confirm details of previous foot pathology.”

“To measure foot-care self-efficacy beliefs each participant completed the self-report “Foot Care Confidence Scale” (FCCS) questionnaire (Figure 1)”

“To measure foot-care behaviour, a self–report questionnaire was used that was derived from a tool developed by Vileikyte and colleagues”

- I do not understand how self-efficacy and foot care behaviour including preventive behaviour was defined or determined.

**Response**
For self-efficacy, the text has been changed:
“To measure foot-care self-efficacy beliefs each participant completed the self-report “Foot Care Confidence Scale” (FCCS) questionnaire (Figure 1) [34]. The development of the FCCS was guided by self-efficacy theory and was designed to combine the three dimensions of self-efficacy: magnitude, strength and generality. The FCCS consists of twelve statements about the “confidence” people have in undertaking various foot-care activities using a five-point Likert scale response. In response to a statement about undertaking foot-care behaviour (e.g. “I can protect my feet”), the participant could respond with the following Likert responses: “strongly not confident”, “moderately not confident”, “confident”, “moderately confident” and “strongly confident”. The FCCS has been shown to be internally consistent (Cronbach’s α = 0.92), has a strong nursing content validity and has a one-dimensional construct; however criterion validity has yet to be demonstrated [34]. Higher scores indicate a higher level of self-efficacy beliefs.”

For the behaviour scale see below.

- I do not either understand what "a maximum score of sixty is possible, indicating a higher level of self-efficacy beliefs" or...

Response
The text has been changed to:
“A maximum score of sixty is possible, with higher scores indicating a higher level of self-efficacy beliefs.”

- "...it has strong content validity based on established "diabetic foot guidelines" but a stringent validation process has yet to be published".

Response
The addition of new references (37, 38) more accurately describe where the conceptual basis of the behaviour scale came from. Unfortunately, there is no other information about the development of the questionnaire, nor has a detailed examination of the instrument been undertaken. This is reflected in the following textual changes:
“To measure foot-care behaviour, a self–report questionnaire was used that was derived from a tool developed by Vileikyte and colleagues [24]. The content of the tool was based on international “diabetic foot care guidelines” [37, 38]. However, a stringent validation process has yet to be published.”

Major compulsory revision:
- Results - Table 1 - what does some secondary, some university, postgraduate mean and how does it differ from the other alternatives of education? For eg university could be defined as <2> yrs.

Response
The term “some” pertaining to the education levels denotes that the period of time of the education was not completed. Therefore, “some secondary” indicates that secondary school was not completed- that is, the participants did not complete the equivalent of 6 years of secondary education which generally occurs when people are 18 years old. To better clarify this, the table has been changed:

Table 1 - Characteristics of study population

<table>
<thead>
<tr>
<th>Variable</th>
<th>n = 96</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex (%)</td>
<td>76</td>
</tr>
</tbody>
</table>
### Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>64.49 (+ 10.73)</td>
</tr>
<tr>
<td>Diabetes type (type 2 %)</td>
<td>90</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>15.89 (+ 11.54)</td>
</tr>
<tr>
<td>Education (%)</td>
<td></td>
</tr>
<tr>
<td>Completed primary school</td>
<td>6.3</td>
</tr>
<tr>
<td>Undertook some secondary school</td>
<td>80.1</td>
</tr>
<tr>
<td>Completed secondary school*</td>
<td>6.3</td>
</tr>
<tr>
<td>Undertook some university</td>
<td>2.1</td>
</tr>
<tr>
<td>Completed undergraduate university degree</td>
<td>3.1</td>
</tr>
<tr>
<td>Completed postgraduate university degree</td>
<td>2.1</td>
</tr>
<tr>
<td>Living arrangement (%)</td>
<td></td>
</tr>
<tr>
<td>Spouse/partner/friends</td>
<td>72</td>
</tr>
<tr>
<td>Alone</td>
<td>28</td>
</tr>
<tr>
<td>History of foot pathology (%)</td>
<td>70</td>
</tr>
<tr>
<td>FCCS score</td>
<td>41.13 (+ 10.71)</td>
</tr>
<tr>
<td>Preventative behaviour score</td>
<td>0.57 (+ 0.14)</td>
</tr>
<tr>
<td>Potentially damaging behaviour score</td>
<td>0.20 (+ 0.09)</td>
</tr>
</tbody>
</table>

Data are means (± standard deviations), unless otherwise stated.

*In Australia, secondary school is generally completed at around 18 years of age, after 12 years of schooling.

- Isn't this a sample of mainly low educated men with type 2 DM?

**Response**

Yes. Text has been changed slightly to make this clearer:

"Characteristics of the participants are reported in Table 1. A high percentage of the participants were male and were diagnosed with type 2 diabetes, and there were a high proportion of participants that did not complete secondary school. There were a high proportion of participants who had a history of foot pathology."

- In this section you are talking about "patients who had a history of foot pathology" wasn't it self-reported data or?!

**Response**

No- this is clarified above. Medical records were also used.

- Further, in the Discussion you are talking about "actual foot-care behaviour"! This need to be changed.

**Response**

We believe that we did, in fact measure actual behaviour (a self-report instrument-Figure 2). Although the way this was measured is one-dimensional and not as robust as other behavioural measurement techniques (as we discuss) we believe that in some sense we did, in fact, measure actual foot-care behaviour.

### Major compulsory revision:

- In the Discussion I do lack reflection on what the sample characteristics mean for the results. Is this a representative sample as it includes mainly men (76%), being old (64.49 yrs) and having type 2 DM (90%)?

**Response**

We would suggest that the sample is reasonably reflective of the population of people with peripheral neuropathy and at high risk of diabetes-related foot problems—particularly a population that has a history of diabetes-related foot problems. This is clarified in the additional text in the discussion (with additional references):
“This sample has a preponderance of older males with type 2 diabetes that have low levels of education. These demographics are consistent with other populations of people with diabetes, peripheral neuropathy and who are at high risk of future diabetes-related foot problems [39-42]. These characteristics may influence the results of this study. For example, older people have been shown to have difficulty in undertaking basic foot-care behaviours such as inspection and appropriate nail care [43]. Males generally are less likely to rest or seek medical advice during an illness and engage in fewer health promoting activities [44]. Interestingly, with respect to diabetes care, males have been shown to have higher self-efficacy beliefs in managing their diabetes than females [45].”

- What does the sampling procedure with inclusion of persons (and set inclusion criterias) with self-reported data mean to the results?

**Response**
The main inclusion criteria is that participants had to have clinically diagnosed loss of protective sensation in their feet. The ramifications of this with respect to behaviour forms a fundamental part of the research question and still needs to be determined by further research, including this research. As demonstrated above, with respect to variables such as “history of pathology” medical records were used.

- Would the results have been different with persons being clinically investigated and the use of medical record data?

**Response**
Medical records were used. See above for clarification

- What does gender, type of DM and perceived seriousness of DM imply on foot self-care behaviour? (See eg studies by Hjelm et al).

**Response**
See above

- I do also lack discussion of what the instruments actually measure. Is it really self-efficacy? This again need to be related back to definitions and determinations of levels defined mentioned above.

We believe that the two questionaries do measure what is required- that is foot-care self-efficacy beliefs and actual foot-care. As clarified above and in the original text, the development of the self efficacy scale was undertaken using a sound conceptual basis and underwent appropriate psychometric testing. The behaviour questionnaire is less robust, but has sound content validity, as has been clarified above. The weaknesses of the behaviour tool and indeed the method of measuring behaviour is discussed in the discussion.

- I would also like the authors to refer to the literature when talking about “the apparent inconsistency in the literature”.

**Response**
This comment pertained to the introduction- where is was demonstrated that the previous research using self-efficacy has shown that people with diabetes have high levels of foot-care self-efficacy (Sloan 2002, Perrin and Snow 2006) but the evidence suggest that people do not actually employ these foot-care behaviours. This has been clarified by a sight change in the text in the discussion:
“These findings explain the apparent inconsistency in the literature that people with diabetes score highly on their self-efficacy for conducting appropriate foot-care and yet display low levels of actual preventive behaviour (as discussed above).”

- The most important critique in here is what are the instruments really measuring?

**Response**
We are hoping this is now better explained

**Major compulsory revision:**

- Abstract does not adhere to the content in the paper as concerns methods used. Is it an interview study or a self-report pen-paper questionnaire? What instruments were used in the study to measure self-efficacy and foot-care behaviour?

**Response**
The text of the abstract has been changed to clarify this:
“All participants had diabetes and clinically diagnosed loss of protective sensation in their feet. The participants completed a self-report pen-paper questionnaire regarding foot-care self-efficacy beliefs (the “Foot Care Confidence Scale”) and actual foot-care behaviour.”

We hope that this statement makes it clear that loss of protective sensation of the feet was clinically determined and that the self-efficacy and behaviour measurements were undertaken using a “self-report” questionnaire approach.

- Conclusion is not in agreement with aim of the paper.

**Response**
The conclusion in the abstract has been changed:
“There is little association between foot-care self-efficacy beliefs and actual foot-care behaviour. The usefulness of measuring foot-care self-efficacy beliefs using currently available instruments is limited in people with diabetes and loss of protective sensation.”

- Need to be clear that it is self-reported data.

**Response**
We are hoping this is clearer now.