Author's response to reviews

Title: Protocol for a randomised trial on the effect of group education on skin-protective behaviour versus treatment as usual among individuals with newly notified occupational hand eczema - the Prevention of Hand Eczema (PREVEX) Trial

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Version: 2
Date: 8 November 2013

Author's response to reviews: see over
**Consort Checklist**

### Title and abstract
- Identification as a randomised trial in the title
- Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)

### Introduction
- **Background and objectives**
  - Scientific background and explanation of rationale
  - Specific objectives or hypotheses

### Methods
- **Trial design**
  - 3a Description of trial design (such as parallel, factorial) including allocation ratio
  - 3b Important changes to methods after trial commencement (such as eligibility criteria)
- **Participants**
  - 4a Eligibility criteria for participants
  - 4b Settings and locations where the data were collected
- **Interventions**
  - 5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
- **Outcomes**
  - 6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
  - 6b Any changes to trial outcomes after the trial commenced, with reasons
- **Sample size**
  - 7a How sample size was determined
  - 7b When applicable, explanation of any interim analyses and stopping guidelines
- **Randomisation:**
  - **Sequence generation**
    - 8a Method used to generate the random allocation sequence
  - **Allocation concealment mechanism**
    - 8b Type of randomisation; details of any restriction (such as blocking and block size)
  - **Implementation**
    - 9 Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
  - 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
- **Blinding**
  - 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
  - 11b If relevant, description of the similarity of interventions
- **Statistical methods**
  - 12a Statistical methods used to compare groups for primary and secondary outcomes
  - 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses

### Results
- **Participant flow (a diagram is strongly recommended)**
  - 13a For each group, the numbers of participants who were randomly assigned, received intended treatments, and were analysed for the primary outcome
  - 13b For each group, losses and exclusions after randomisation, together with reasons
- **Recruitment**
  - 14a Dates defining the periods of recruitment and follow-up
  - 14b Why the trial ended or was stopped
- **Baseline data**
  - 15 A table showing baseline demographic and clinical characteristics for each group
<table>
<thead>
<tr>
<th>Topic</th>
<th>Section Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numbers analysed</td>
<td>16</td>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>17a</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
</tr>
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<td></td>
<td>17b</td>
<td>For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
</tr>
<tr>
<td>Ancillary analyses</td>
<td>18</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
</tr>
<tr>
<td>Harms</td>
<td>19</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
</tr>
<tr>
<td>Discussion</td>
<td></td>
<td></td>
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<tr>
<td>Limitations</td>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
</tr>
<tr>
<td>Generalisability</td>
<td>21</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
</tr>
<tr>
<td>Interpretation</td>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
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<tr>
<td>Other information</td>
<td></td>
<td></td>
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<tr>
<td>Registration</td>
<td>23</td>
<td>Registration number and name of trial registry</td>
</tr>
<tr>
<td>Protocol</td>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
</tr>
<tr>
<td>Funding</td>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
</tr>
</tbody>
</table>

Indicates that the CONSORT recommendation has been followed. Recommendations related to results are not relevant for this protocol article.