

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Evidence-based development of a post-surgical lumbar discectomy leaflet intervention: a Delphi consensus study
<b>AUTHORS</b>	Goodwin, Peter; Wright, Chris; Allan, Carol; Crowther, Lisa; Darley, Catherine; Heap, Alison; Paul, Emma; White, Louise; Rushton, Alison

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Tasha Stanton The University of South Australia Australia
<b>REVIEW RETURNED</b>	25-Nov-2014

<b>GENERAL COMMENTS</b>	<p>This study aimed to develop an educational leaflet for patients that are undergoing lumbar discectomy to assist them with recovery post-surgery. This leaflet was developed using a combination of Delphi survey methods and focus groups. A major strength of this study is the use of various stakeholders including patients, physiotherapists and surgeons. I think this study would be of interest to the readership of BMJ Open and it does provide new, relevant information that may be able to assist care of lumbar discectomy patients.</p> <p>Revisions:</p> <p>1. Methods (page 5): Currently there is not adequate description of the scales and methods used. For example, please define what CV refers to (is it coefficient of variation?) because currently there is no definition for it. Further, it is stated that 80% of responses had to be 'agree' or 'strongly agree' but there is no information provided on what scale was used to determine agreement. You mentioned a Likert scale was used to evaluate the 'importance' of each item, but was there also a Likert scale for agreement?</p> <p>2. Results: There is currently a lot of confusion regarding what scales were performed in what Round as the methods and the results section are not consistent. For example, in the methods section, it says that Round 1 involved whether the content of the leaflet should be based around the four headings in the Selkowitz et al leaflet and that this involved a yes or no response. However, in Table 1 which presents the results of Round 1, you are presenting the mean importance score, CV and agreement. These scales, based on the methods description, were not completed until Round 2. Conversely, Table 3, which provides the results of Round 2, only provides agreement – (which I presume comes from the yes/no answers?) – but CV and mean importance are not provided. Either the tables for each Round are presently in the wrong order in the results or the methods are in the wrong order.</p>
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	<p>3. In Table 1, there is a mistake in the Likert scale anchors that you present – i.e. 1 = not important, 5 = strongly agree – I assume 5 is meant to be ‘very important’?</p> <p>4. In Table 3, can you explain what the agreement column is referring to? Is this the average agreement for all items under that heading? Or is it what I raised in Comment #2?</p> <p>5. Currently, this paper does not provide enough information about the final leaflet. It seems relevant to provide the final product as an Appendix or at least a comprehensive summary. Right now all we are provided with are the general headings, but no information is given regarding the specific items under the headings that achieved consensus and were included in this leaflet. Further, the focus groups appeared to give specific content on the leaflet’s appearance and wording that would be helpful information to have.</p> <p>6. Please comment how the relevant scientific literature informed creation of this leaflet. For example, many Delphi studies involve a review of the relevant literature to generate Delphi items. It appears that the main topic headings (and possibly items under the topic heading) were based on Selkowitz, therefore there needs to be a greater description of where Selkowitz et al sourced their items from, because at the present time, it appears that this leaflet has been created based on participant’s opinions, not on the relevant scientific literature. For example, a main strength of this study is identified as providing information on when to start activities because other educational leaflets have not addressed this issue; however, what is the information based on? However, it may be that there is not sufficient scientific literature - you actually touch on this issue in the discussion section (i.e., lack of evidence for the effectiveness of physiotherapy post-surgery); I think this information needs to be included in the introduction section and highlighted throughout the paper. If there is no evidence to guide post-discectomy care, this makes your methodology incredibly important as you are getting input from numerous relevant stakeholders.</p>
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<b>REVIEWER</b>	José Cid Pain Unit, Anesthesiology and Reanimation Department Toledo Hospital Complex Toledo Spain
<b>REVIEW RETURNED</b>	26-Nov-2014

<b>GENERAL COMMENTS</b>	<p>This is an interesting work and the method used is adequate and correctly performed. The structure of the consensuated final leaflet, well described in the manuscript, may satisfy stakeholders, yet it is more important the content of the information itself. This is not provided by the authors, but interestingly they reached early consensus about the inclusion of specific types of exercises, although there is lack of evidence of their effectiveness. In this sense a recent Cochrane review support the use of exercise programmes in postsurgical discectomy patients.(1)</p> <p>(1) Cochrane Database Syst Rev. 2014 Mar 14;3:CD003007. doi: 10.1002/14651858.CD003007.pub3</p>
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## VERSION 1 – AUTHOR RESPONSE

Reviewer 1: Tasha Stanton - The University of South Australia

Reviewer item 1. Methods (page 5): Currently there is not adequate description of the scales and methods used.

a. For example, please define what CV refers to (is it coefficient of variation?) because currently there is no definition for it.

Response: CV is Coefficient of Variation and has now been defined in page 4, paragraph 5.

b. Further, it is stated that 80% of responses had to be 'agree' or 'strongly agree' but there is no information provided on what scale was used to determine agreement.

Response: More detail describing the scale has been included on page 4, paragraphs 4 and 5: "Round 1 asked whether the content of a leaflet should be based around the four headings identified by Selkowitz et al (2006). The inclusion of each heading required a response on a 5 point Likert scale [1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree]. Open questions requested suggested content under each heading. Data from open questions were analysed for emerging themes."

In each round, consensus was established by: mean rating  $\geq 3.5$  on the 5 point Likert scale; Coefficient of Variation (CV)  $\leq 30\%$ ; and  $\geq 80\%$  of responses scoring 4 or 5 [i.e. round 1 = agree or strongly agree; round 2 & 3 = important or very important].

c. You mentioned a Likert scale was used to evaluate the 'importance' of each item, but was there also a Likert scale for agreement?

Response: More detail has been added on page 4, paragraph 5 to clarify this [see above].

Reviewer item 2. Results: There is currently a lot of confusion regarding what scales were performed in what Round as the methods and the results section are not consistent. For example, in the methods section, it says that Round 1 involved whether the content of the leaflet should be based around the four headings in the Selkowitz et al leaflet and that this involved a yes or no response. However, in Table 1 which presents the results of Round 1, you are presenting the mean importance score, CV and agreement. These scales, based on the methods description, were not completed until Round 2. Conversely, Table 3, which provides the results of Round 2, only provides agreement – (which I presume comes from the yes/no answers?) – but CV and mean importance are not provided.

a. Either the tables for each Round are presently in the wrong order in the results or the methods are in the wrong order.

Response: Thank you for pointing this out. This was an error. As well as the descriptions of analysis on page 4, paragraph 4, clarity has been added to the results section of round 1, page 6 paragraph 1.

"Table 1 shows the mean rating, SD, CV, and percentage of those who 'agree or 'strongly agree' with the inclusion of each heading."

Table 1 title has also been amended for clarity.

Reviewer item 3. In Table 1, there is a mistake in the Likert scale anchors that you present – i.e. 1 = not important, 5 = strongly agree – I assume 5 is meant to be 'very important'?

Response: Thank you, this has been corrected to say [1=strongly disagree, 5=strongly agree].

Reviewer item 4. In Table 3, can you explain what the agreement column is referring to? Is this the average agreement for all items under that heading? Or is it what I raised in Comment #2?

Response: I agree this was confusing. It has now been changed to 'consensus'. Consensus = N(%) of items under the heading that met the criteria for consensus from the previous round. The definition of consensus is described above in item 1b, and on in the article on page 4, paragraph 5.

Reviewer item 5. Currently, this paper does not provide enough information about the final leaflet. It seems relevant to provide the final product as an Appendix or at least a comprehensive summary. Right now all we are provided with are the general headings, but no information is given regarding the specific items under the headings that achieved consensus and were included in this leaflet. Further, the focus groups appeared to give specific content on the leaflet's appearance and wording that would be helpful information to have.

Response: The content of the final leaflet has now been provided. The previous Table 4 has been removed and replaced with a section "The final Leaflet" on page 8 and 9. It includes a description and Table 5: Sections and sub-sections of final leaflet.

Reviewer item 6. Please comment how the relevant scientific literature informed creation of this leaflet. For example, many Delphi studies involve a review of the relevant literature to generate Delphi items. It appears that the main topic headings (and possibly items under the topic heading) were based on Selkowitz, therefore there needs to be a greater description of where Selkowitz et al sourced their items from, because at the present time, it appears that this leaflet has been created based on participant's opinions, not on the relevant scientific literature. For example, a main strength of this study is identified as providing information on when to start activities because other educational leaflets have not addressed this issue; however, what is the information based on? However, it may be that there is not sufficient scientific literature - you actually touch on this issue in the discussion section (i.e., lack of evidence for the effectiveness of physiotherapy post-surgery); I think this information needs to be included in the introduction section and highlighted throughout the paper. If there is no evidence to guide post-discectomy care, this makes your methodology incredibly important as you are getting input from numerous relevant stakeholders.

Response: Three comments have been included in the introduction to strengthen this part of the paper:

Page 3, paragraph 3: "Traditionally, in the UK, patient information is developed locally by physiotherapists and/or surgeons without any scientific method or evidence base."

Page 3, paragraph 4: "Following a literature review[10] it was concluded that the type of exercise and effectiveness of other physiotherapy interventions most beneficial to this population remains unclear."

Page 3, paragraph 5: "All centres used in-house leaflets. They were agreed by the physiotherapists and surgeons, but based on clinical experience because of the lack of an evidence base. "

Reviewer 2: José Cid - Pain Unit, Anesthesiology and Reanimation Department, Toledo Hospital Complex, Spain

Reviewer item 1. This is an interesting work and the method used is adequate and correctly performed. The structure of the consensuated final leaflet, well described in the manuscript, may satisfy stakeholders, yet it is more important the content of the information itself. This is not provided

by the authors, but interestingly they reached early consensus about the inclusion of specific types of exercises, although there is lack of evidence of their effectiveness. In this sense a recent Cochrane review support the use of exercise programmes in postsurgical discectomy patients.(1)

(1) Cochrane Database Syst Rev. 2014 Mar 14;3:CD003007. doi: 10.1002/14651858.CD003007.pub3

Response: The content of the final leaflet has now been provided. The previous Table 4 has been removed and replaced with section "The final Leaflet"; page 8 and 9. It includes a description and Table 5: Sections and sub-sections of final leaflet.

We think that the latest Cochrane review on rehabilitation after lumbar discectomy offers little extra information for the clinician than the previous. The evidence comparing home exercises, education, or leaflets with supervised rehabilitation is inadequately described and classed as low or very low quality evidence; hence the need for an evidence-based leaflet incorporated into a well-designed and conducted trial.

### VERSION 2 – REVIEW

<b>REVIEWER</b>	Tasha Stanton The University of South Australia, Australia
<b>REVIEW RETURNED</b>	02-Feb-2015

<b>GENERAL COMMENTS</b>	<p>The authors have done an excellent job in making both the methods and results section clearer to the reader. I only have very minor comments.</p> <ol style="list-style-type: none"> <li>1. Introduction: Please clarify that the outcome assessed in the McGregor study was function. For example: "no effect of the leaflet or rehabilitation and the leaflet combined on patient function post-surgery." Also, McGregor's study findings suggest that leaflets might not be important for outcome following surgery; I would include a short sentence to express why it is still then important for you to create a patient information leaflet.</li> <li>2. It is not intuitively clear in paragraph 5 what Selkowitz's et al leaflets are and if you've already discussed them in the introduction - perhaps include the name Selkowitz in the paragraph above so that we know that this was the leaflet used in a trial post lumbar microdiscectomy in the USA (you only cite this as reference 11 in paragraph 4 and in paragraph 5 only cite it as Selkowitz). This comment is incredibly pedantic but I did have to look back to figure it out!</li> <li>3. Methods: Round 1 - please provide more information regarding how you analysed data from open questions for emerging themes. How did you actually do this?</li> <li>4. Methods: Round 2 - please provide the scale labels for all the values for importance (instead of only 1 and 5).</li> <li>5. Methods: Round 3 - I assume that the open question answers from Round 2 were also provided in Round 3? If yes, please add this into the methods section as it is currently missing. Q</li> </ol>
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## VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Please leave your comments for the authors below

The authors have done an excellent job in making both the methods and results section clearer to the reader. I only have very minor comments.

1. Introduction: Please clarify that the outcome assessed in the McGregor study was function. For example: "no effect of the leaflet or rehabilitation and the leaflet combined on patient function post-surgery." Also, McGregor's study findings suggest that leaflets might not be important for outcome following surgery; I would include a short sentence to express why it is still then important for you to create a patient information leaflet.

Response: We have added "on patient function post-surgery". We have also added the sentence: "Despite this, they found that providing the leaflet to discectomy patients achieved modest gains at a low cost, but acknowledged this requires further investigation."; Page 3 para 3.

2. It is not intuitively clear in paragraph 5 what Selkowitz's et al leaflets are and if you've already discussed them in the introduction - perhaps include the name Selkowitz in the paragraph above so that we know that this was the leaflet used in a trial post lumbar microdiscectomy in the USA (you only cite this as reference 11 in paragraph 4 and in paragraph 5 only cite it as Selkowitz). This comment is incredibly pedantic but I did have to look back to figure it out!

Response: We have changed the sentence in paragraph to read: "Selkowitz et al (2006) created a leaflet for use in a trial post lumbar microdiscectomy in the USA[11]".

3. Methods: Round 1 - please provide more information regarding how you analysed data from open questions for emerging themes. How did you actually do this?

Response: The sentence on Page 5, Para 4 has been removed because it is repeated again in in the same section on Page 6, Para 2. This second sentence has been strengthened to say, "Data from open questions requesting suggested content under each heading were collated and analysed for emerging themes/sub-themes by two authors [PCG, AR] independently. Agreed themes/sub-themes comprised the topics for round 2."

4. Methods: Round 2 - please provide the scale labels for all the values for importance (instead of only 1 and 5).

Response: The Likert scale did not include scale labels for all numbers. We provided anchors for 1 and 5. We have included the following on Page 6, Para 3, "Panel members responded to closed questions using a 1-5 Likert scale with the anchors, 1=not important, 5=very important."

5. Methods: Round 3 - I assume that the open question answers from Round 2 were also provided in Round 3? If yes, please add this into the methods section as it is currently missing.

Response: We have included the following sentence, "Any answers from open questions in round 2 were also included for consideration."