

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	The Development of an Active Behavioural Physiotherapy Intervention (ABPI) for Acute Whiplash Associated Disorder (WAD) II Management: a modified Delphi study
<b>AUTHORS</b>	Wiangkham, Taweewat; Duda, Joan; Haque, Sayeed; Rushton, Alison

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Karen Søgaard University of Southern Denmark, Denmark
<b>REVIEW RETURNED</b>	09-May-2016

<b>GENERAL COMMENTS</b>	<p>Are the authors aware of the intervention mapping as a tool to develop interventions? This may provide a good conceptual framework to their process.</p> <p>Page 5 Line 123: The authors state that they anticipate 3 rounds. Consider to state the criteria in the Delphi process for reaching a final round.</p> <p>Please provide more details regarding the recruitment of 97 participants. Why not include everybody having published studies on WAD? Was West Midlands the only insurance company that was considered? Why only post graduate students from Birmingham? How many were you aiming for as active responders? Why not include chiropractic experts or medical doctors (general practitioners)? This is a limitation that should be stated more explicitly.</p> <p>Page 7, Line 156: Treatment components were included based on systematic literature review. But the amount are comprehensive, were there no criteria for including an item in any of the three components?</p> <p>Provide information on the distribution of the invited 97 compared to the responders. And provide the description of those participating in round 2 and 3 so bias in drop out can be evaluated. Please also consider if you can identify risk of bias due to the low response rate? For instance for researchers on numbers of papers, first authorships, gender etc</p> <p>Table 4: It is not easy to see the systematics behind the order of the treatment items? Could they be sorted so that a clear line is established between the items agreed upon and those that does not pass? So that the result appear more clearly.</p> <p>Page 19 Discussion. The paper ends without a real conclusion on</p>
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	<p>which element to include in a protocol for a rigid RCT on whiplash patients. Since it is obvious that the authors are planning an RCT some consideration could be given on how to restrict elements to include or further criteria on selection, e.g. the highest ranked 2 elements from each recommended component. And some considerations on how to integrate all these different aspects could be relevant (a “burden of treatment” discussion). Further, if the treatment composition should be individualized based on the specifications in the literature review? Add some references on these aspects.</p> <p>How much does the Delphi add to current treatment included in RCT studies? Knowledge on the RCT protocols found in the literature review may be helpful in a discussion on the innovative aspect of a future RCT based on the treatment identified in the presented Delphi. Maybe include some of these protocol papers in the reference list and discuss this aspect.</p> <p>Another issue that should be included in the discussion is how much these components are specific for WAD patients? If compared to recommendations for treatment of chronic neck pain patients without traumatic onset or low back pain patients, how much difference are there? Are these just the physiotherapy general choices of treatment for the musculoskeletal pain patient?</p> <p>The English language reads okay, but the paper would highly benefit from a language editing.</p> <p>Avoid reference to an abstract like reference 14. It seems that reference 1 is the proper reference, but mentioned late in the introduction. Please correct and omit ref 14.</p>
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<b>REVIEWER</b>	Dr. Howard Vernon Canadian Memorial Chiropractic College Toronto, Ontario, Canada
<b>REVIEW RETURNED</b>	13-Jun-2016

<b>GENERAL COMMENTS</b>	<p>This MS presents the results of a study employing a Delphi approach to obtaining consensus on the development of an optimal treatment approach for acute whiplash which the authors term ABPI. They have developed the foundational elements from their work reviewing the literature (RCT’s) on this topic. This is a well-grounded exercise, and the use of the Delphi approach is to be commended. The Methods used by the authors are high-quality, and the results are of interest to practitioners in this field. The results are displayed effectively.</p> <p>I have several critiques to offer:</p> <p><b>Abstract:</b> 1. The objective stated in the Abstract does not indicate that the actual objective was to use a Delphi method to assist in developing consensus for the basic features of the ABPI.</p> <p><b>Background:</b> 1. The actual objective of this study is left to the last sentence of the Background: “In order to create a confidential intervention, the ABPI was therefore</p>
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	<p>developed using a rigorous method.”</p> <p>This should be elaborated upon in the Background. (I believe the authors have misused the term “confidential” in that they likely mean “in order to have high confidence in the intervention”. I recommend changing “confidential” to “effective”).</p> <p>Methods:</p> <p>1. I take mild issue with some of the items listed as “principles” of the ABPI program:  “The potential underlying principles were explored in the systematic review, clinical guidelines, and recent trials. The proposed underlying principles of the ABPI included return to normal function as soon as possible, return to normal movement as soon as possible, pain management, reduce post-traumatic stress, reduce fear avoidance and anxiety, increase confidence for exercises of the neck and shoulders, prevent future re-current symptoms, encouragement of self-management, return to work and social activities as soon as possible, return to quality of life before pre-injury, and facilitate personal motivation for healthy lifestyle.”</p> <p>Many of these items are actually objectives. The ones that I would regard as “principles” are:  pain management, reduce post-traumatic stress, reduce fear avoidance and anxiety, increase confidence for exercises of the neck and shoulders, encouragement of self-management, facilitate personal motivation for healthy lifestyle.</p> <p>The items that remain in the list are objectives that any management approach should and would have. So, I would recommend separating the list out into principles (first) and objectives (second).</p> <p>Following my recommendation entails dividing up Table 2. I don’t think this is too onerous a request as it would, in my opinion, strengthen the paper.</p> <p>2. The description of the purposes of Rounds 2 and 3 is repetitive and redundant. All that is necessary is something in the text to indicate that a further iteration of the same purposes as Round 1 took place with the aim of adding from Round 1 in Round 2 and from Round 2 in Round 3.</p> <p>Results:</p> <p>1. I note that, in Table 1, the list of professions includes medicine, chiropractic, osteopathy and psychology. All of these are listed as 0. The inclusion of these professions contradicts the Methods, where members from none of these professions appears to have been solicited. As such, it makes it look like people in these professions were unresponsive.</p> <p>If this is actually referring to the “international whiplash experts”, then the authors should indicate in the Methods that these included members of all of these other professions.</p> <p>Discussion:</p> <p>1. Page 18, line 317 indicates that the response rate (75%) from consented respondents was “quite high”. This is not really an</p>
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	<p>accurate description of the overall response rate which the authors themselves indicate was actually quite low (37%). The actual number of participants = 32. What the authors need to do at this point in the Discussion is provide some information from the literature as to whether this number – 32 – is a sufficiently large enough number (by comparison to other studies using the Delphi process) to warrant confidence in the consensus of the recommendations cited in this paper. My sense is that this is a relatively low number from which to obtain and then act on a consensus of experts.</p> <p>The authors do cite this as a limitation later on in the manuscript. In that section, it becomes apparent that a rather low number of actual practicing physiotherapists participated in this study. Again, this calls the generalizability of this study’s findings into question.</p> <p>2. With regard to the statement at line 318, page 18, I have some problem with the notion that open responses contribute to the reliability of the study, as these would have to be interpreted by the authors in order to determine consensus (as opposed to closed responses with numerical answers which require no interpretation). As to the validity, I do agree that open responses contribute to what I call the “ecological validity”, whereby a deeper understanding of the respondents’ answers is afforded, but that may have less generalizability to the whole field of musculoskeletal practitioners.</p>
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### VERSION 1 – AUTHOR RESPONSE

Thank you very much for your consideration of the manuscript entitled ‘**The Development of an Active Behavioural Physiotherapy Intervention (ABPI) for Acute Whiplash Associated Disorder (WAD) II Management: a modified Delphi study**’. Thank you for the opportunity to respond to the reviewers’ comments.

Comments	Responses
<b>Reviewer #1</b>	
Are the authors aware of the intervention mapping as a tool to develop interventions? This may provide a good conceptual framework to their process.	Thank you for your suggestion that we have incorporated. Please see <b>Figure 2</b> for the mapping of the ABPI development.
Page 5 Line 123: The authors state that they anticipate 3 rounds. Consider to state the criteria in the Delphi process for reaching a final round.	Thank you for your suggestion. In line with previous literature, the process of the modified Delphi study can be stopped based on a pre-specified protocol (e.g. number of round, achievement of consensus, stability of results) (Diamond et al., 2014). In our protocol, we stated that it was anticipated for 3 rounds. At the end of round 3 consensus had been achieved and all objectives addressed.
Please provide more details regarding the recruitment of 97 participants. Why not include everybody having published studies on WAD? Was West Midlands the only insurance company that was considered? Why only post graduate students from Birmingham? How many were you aiming for as active responders? Why not include chiropractic experts or medical doctors (general practitioners)? This is a limitation that should be stated more explicitly.	<p>The 3 groups of participants were included to represent all stakeholders in the management of WAD i.e. WAD experts in terms of research, private physiotherapy and postgraduate clinical perspectives (<b>please see the yellow highlight on p.6</b>). The private practitioners and postgraduate students represent key clinical groups in the UK.</p> <p>To ensure currency of participants, we recruited researchers who have published at least 2 articles within the last 10 years, and active</p>

	<p>postgraduate students from University of Birmingham - a UK University with a specialist musculoskeletal programme, for convenience.</p> <p>We recruited private physiotherapists via the Physio 1st company, in which WAD patients are referred from a large number of UK insurance companies. All of them have substantial experience for treating WAD. It was difficult to collaborate with several private physiotherapy companies owing to competitive business reasons.</p> <p>Actually, we were planning to recruit 30 participants with around 10 participants from each group to enable equal representation of the three groups within participants and a feasible number of participants (<b>please see the yellow highlight on p.6 line 147-149</b>).</p> <p>We did not recruit chiropractic experts or general medicine practitioners for clinical opinions because the WADII patients are commonly managed by physiotherapists in the UK context, and this is the focus of the intervention. However, we added these points in the limitation section (<b>please see the yellow highlight on p.21 line 409-410</b>). Thank you for your suggestion.</p>
<p>Page 7, Line 156: Treatment components were included based on systematic literature review. But the amount are comprehensive, were there no criteria for including an item in any of the three components?</p>	<p>The potential components, derived from the systematic review, clinical guidelines and recent trials, were allocated to one of the categories of treatment components (behavioural, physiotherapy or other treatment components) based on their focus/emphasis. All were included in round 1 to seek the level of agreement for each component prior to making any decisions about removal (<b>please see the yellow highlight on p.7 line 162-163</b>).</p>
<p>Provide information on the distribution of the invited 97 compared to the responders. And provide the description of those participating in round 2 and 3 so bias in drop out can be evaluated. Please also consider if you can identify risk of bias due to the low response rate? For instance for researchers on numbers of papers, first authorships, gender etc</p>	<p>The comparison of the potential participants with respondents was discussed in the limitation part of the discussion section to inform analysis of potential bias. We have added some points based on your suggestions to enable greater clarity (<b>please see on p. 21</b>). However, we do not know who dropped out from the study as participants were anonymised and IP addresses were not saved. There were very few drop outs in each round.</p>
<p>Table 4: It is not easy to see the systematics behind the order of the treatment items? Could they be sorted so that a clear line is established between the items agreed upon and those that does not pass? So that the result appear more clearly.</p>	<p>Thank you for your suggestion. We have placed interventions which did not achieve the consensus at the end of each treatment component. Furthermore, an italic font was used to make them clearer (<b>please see Table 4 on p. 17-18</b>).</p>
<p>Page 19 Discussion. The paper ends without a real conclusion on which element to include in a protocol for a rigid RCT on whiplash patients. Since it is obvious that the authors are planning an RCT some consideration could be given on how to restrict elements to include or further criteria on selection,</p>	<p>Thank you for your suggestion. The aim of publishing this manuscript is to show the results of the modified Delphi study. However, the results of the study lacked any theory to underpin the ABPI and deliver to physiotherapy practice. From the literature, social cognitive theory focusing on</p>

<p>e.g. the highest ranked 2 elements from each recommended component. And some considerations on how to integrate all these different aspects could be relevant (a “burden of treatment” discussion). Further, if the treatment composition should be individualized based on the specifications in the literature review? Add some references on these aspects.</p>	<p>self-efficacy enhancement seems to be suitable as a part of the ABPI for the management of acute WADII patients. Therefore, the ABPI was developed further using the results of this study and self-efficacy theoretical concept to create the definitive ABPI as a complex intervention in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008) prior to conducting a pilot and feasibility trial.</p> <p>We have added some information in the discussion and conclusion in this manuscript (<b>please see the yellow highlight on p. 19-22</b>) to reflect this further development. Unfortunately, we cannot include all information on the development of the ABPI using the self-efficacy theory in create a concept and intervention framework of the ABPI for acute WADII management owing to the word limit.</p>
<p>How much does the Delphi add to current treatment included in RCT studies? Knowledge on the RCT protocols found in the literature review may be helpful in a discussion on the innovative aspect of a future RCT based on the treatment identified in the presented Delphi. Maybe include some of these protocol papers in the reference list and discuss this aspect.</p>	<p>Currently, the literature has minimal detail regarding a behavioural approach. Our systematic review found adding behavioural approach as a part of active physiotherapy may be a potential effective intervention to prevent acute WADII patients progressing to chronicity. This was based on 4 trials that investigated a behavioural but not combined intervention. We have added some points in the background (<b>please see the yellow highlight on p.5 line 102-105</b>).</p> <p>Findings from this study provided a range of both behavioural and active physiotherapy components which have been agreed by the experts as potentially effective interventions for acute WADII management. We have highlighted that these findings provide more variety of behavioural components than current guidelines and RCTs (<b>please see on p. 18-19 line 339-342</b>)</p>
<p>Another issue that should be included in the discussion is how much these components are specific for WAD patients? If compared to recommendations for treatment of chronic neck pain patients without traumatic onset or low back pain patients, how much difference are there? Are these just the physiotherapy general choices of treatment for the musculoskeletal pain patient?</p>	<p>Thank you for your suggestion. For the literature, WADII patients commonly faced both physical (e.g. pain and disability) and psychological (e.g. fear of movement, anxiety and depression) problem. The results of this study address both perspectives (<b>please see the yellow highlight on p. 19</b>). However, as you identify many of these components may also be used in a wider population of musculoskeletal pain patients as there may also be a combination of physical and psychological dimensions to address, but we feel that it is beyond the scope of this paper (and its word limit) to address this point specifically.</p>
<p>Avoid reference to an abstract like reference 14. It seems that reference 1 is the proper reference, but mentioned late in the introduction. Please correct and omit ref 14.</p>	<p>Thank you for your suggestion. We have omitted the ref 14.</p>
<b>Reviewer #2</b>	
<p>Abstract: The objective stated in the Abstract does not indicate</p>	<p>Thank you for your comment and suggestion. We have added ‘....using a modified Delphi method to</p>

<p>that the actual objective was to use a Delphi method to assist in developing consensus for the basic features of the ABPI.</p>	<p><i>develop consensus for the basic features of the ABPI</i> in the abstract (<b>please see the yellow highlight on p.2 line 35-36</b>).</p>
<p>Background: The actual objective of this study is left to the last sentence of the Background: "In order to create a confidential intervention, the ABPI was therefore developed using a rigorous method."  This should be elaborated upon in the Background. (I believe the authors have misused the term "confidential" in that they likely mean "in order to have high confidence in the intervention". I recommend changing "confidential" to "effective").</p>	<p>Thank you for your suggestion. We added some point in the background (<b>please see the yellow highlight on p. 5 line 102-105</b>).</p>
<p>Methods: 1. I take mild issue with some of the items listed as "principles" of the ABPI program: "The potential underlying principles were explored in the systematic review, clinical guidelines, and recent trials. The proposed underlying principles of the ABPI included return to normal function as soon as possible, return to normal movement as soon as possible, pain management, reduce post-traumatic stress, reduce fear avoidance and anxiety, increase confidence for exercises of the neck and shoulders, prevent future re-current symptoms, encouragement of self-management, return to work and social activities as soon as possible, return to quality of life before pre-injury, and facilitate personal motivation for healthy lifestyle."  Many of these items are actually objectives. The ones that I would regard as "principles" are: pain management, reduce post-traumatic stress, reduce fear avoidance and anxiety, increase confidence for exercises of the neck and shoulders, encouragement of self-management, facilitate personal motivation for healthy lifestyle.  The items that remain in the list are objectives that any management approach should and would have. So, I would recommend separating the list out into principles (first) and objectives (second).  Following my recommendation entails dividing up Table 2. I don't think this is too onerous a request as it would, in my opinion, strengthen the paper.  2. The description of the purposes of Rounds 2 and 3 is repetitive and redundant. All that is necessary is something in the text to indicate that a further iteration of the same purposes as Round 1 took place with the aim of adding from Round 1 in Round 2 and from Round 2 in Round 3.</p>	<p>Thank you for your comment and suggestion. The term 'underlying principles' in this study can be used as objectives or goals in treating WADII (<b>please see on p.18 line 333-334</b>). The APBI was developed further to be a complex intervention using social cognitive theory focusing on self-efficacy enhancement to underpin the ABPI and deliver the ABPI to physiotherapy practice in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008) prior to conducting a pilot and feasibility trial. At this stage the underlying principles were grouped and combined with the self-efficacy theoretical concept to create the concept of the ABPI for the management in patients with acute WADII (<b>please see Figure 3 and yellow highlight on p.20 line 372-373</b>). We have now included further detail to explain this.  Thank you for your comment and suggestion. Although the purposes in each round look similar and redundant, writing clearly in each round will hopefully prevent readers' confusion, as some purposes of round 3 were different from rounds 1 and 2.</p>
<p>Results: I note that, in Table 1, the list of professions includes medicine, chiropractic, osteopathy and psychology. All of these are listed as 0. The inclusion of these professions contradicts the Methods, where</p>	<p>The list of professions was used in the online questionnaire because we thought that some researchers may have a different background e.g. medicine, chiropractic, and osteopathy</p>

<p>members from none of these professions appears to have been solicited. As such, it makes it look like people in these professions were unresponsive.</p> <p>If this is actually referring to the “international whiplash experts”, then the authors should indicate in the Methods that these included members of all of these other professions.</p>	<p>(researchers were recruited across the world). However, we have omitted other professional backgrounds from the table to avoid confusion.</p> <p>In this study, those professionals were not targeted for recruitment as clinicians. This is because WADII patients in the UK are commonly managed by physiotherapists and we are planning to conduct a pilot and feasibility trial in the UK. Hence, we recruited only physiotherapists (<b>please see the yellow highlight on p. 21 line 409-410</b>).</p> <p>We actually used ‘international research and local clinical whiplash experts’ to define our participants and this has been corrected (<b>please see on p. 19 line 389</b>).</p>
<p>Discussion:</p> <p>1. Page 18, line 317 indicates that the response rate (75%) from consented respondents was “quite high”. This is not really an accurate description of the overall response rate which the authors themselves indicate was actually quite low (37%). The actual number of participants = 32. What the authors need to do at this point in the Discussion is provide some information from the literature as to whether this number – 32 – is a sufficiently large enough number (by comparison to other studies using the Delphi process) to warrant confidence in the consensus of the recommendations cited in this paper. My sense is that this is a relatively low number from which to obtain and then act on a consensus of experts.</p> <p>The authors do cite this as a limitation later on in the manuscript. In that section, it becomes apparent that a rather low number of actual practicing physiotherapists participated in this study. Again, this calls the generalizability of this study’s findings into question.</p> <p>2. With regard to the statement at line 318, page 18, I have some problem with the notion that open responses contribute to the reliability of the study, as these would have to be interpreted by the authors in order to determine consensus (as opposed to closed responses with numerical answers which require no interpretation). As to the validity, I do agree that open responses contribute to what I call the “ecological validity”, whereby a deeper understanding of the respondents’ answers is afforded, but that may have less generalizability to the whole field of musculoskeletal practitioners.</p>	<p>Thank you for your comments. We have changed ‘An overall response rate..’ to ‘The response rate in the final round..’ (<b>please see the yellow highlight on p.18 line 325</b>).</p> <p>We have also clarified that it was the <b>participation</b> rate that was low at 37% (<b>page 21</b>).</p> <p>Actually, we expected to recruit 30 participants (10 participants in each group). From the literature, approximately 30 experts can make a consensus in a Delphi study. We have added this information in the manuscript (<b>please see the yellow highlight on p. 6 line 147-149</b>).</p> <p>Also, we have explained why some researchers did not participate - because they work with chronic WAD (<b>please see the yellow highlight on p. 21 line 402-403</b>). The main reason for students not participating was that they did not see WAD patients clinically (<b>please see page 21 line 404-405</b>).</p> <p>Thank you for your comments and suggestions. Actually, we mean ‘<i>this study provided open questions in each section and the last section (for general comments or suggestions) in order to allow panellists to comment and express their views, to enable greater ecological validity of the results</i>’ (<b>please see the yellow highlight on p. 18 line 326-328</b>). So, we deleted ‘an increase of reliability of this study’ because it is not relevant. Sorry for making you confused.</p> <p>We have added ‘<i>Using open question in increasing ecological validity may have less generalisability to the whole field of musculoskeletal practitioners</i>’ in the limitation part of discussion section (<b>please see the yellow highlight on p. 21 line 417-418</b>).</p>

We hope that we have fully addressed the feedback from reviewers and thank them for their time in reviewing the manuscript. We feel that the manuscript has been improved as a result of this process.

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Howard Vernon DC, PhD Canadian Memorial Chiropractic College, Toronto, Ontario, Canada
<b>REVIEW RETURNED</b>	19-Jul-2016

<b>GENERAL COMMENTS</b>	I am satisfied with the revisions made by the authors. The MS is now acceptable for publication.
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