PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial
AUTHORS	Abbott, Allan; Schröder, Karin; Enthoven, Paul; Nilsen, Per; Öberg, Birgitta

VERSION 1 – REVIEW

REVIEWER	Chris Maher The University of Sydney, Australia
REVIEW RETURNED	07-Oct-2017

GENERAL COMMENTS	I am sorry but I was completely lost after reading the manuscript a couple of times. I think there are a few reasons for this. Firstly the manuscript seems to describe multiple studies (pilot trial, main trial, process evaluation, cost-effectiveness analysis, mediation analyses) but each is briefly and confusingly described. I think it would have been better to split up the manuscript into separate papers. Secondly I was unfamiliar with many terms (eg dog leg wth two assessments) and I suspect many readers will be as well. When I considered the main trial it seems like a stepped wedge RCT but this more familiar term is not used. Some attention to terminology could resolve a lot of the lack of clarity. Thirdly each study of the suite of studies was incompletely described. For example I did not get a clear understanding of the objectives of the pilot study, the justification for the mediation analyses, or the components of the BetterBack model of care in the main trial. With regard to the main trial I think you could have spent less time describing the development of the BetterBack model of care and more time describing its components using a checklist such as TIDieR to guide you. I would have liked a better justification for each facet of the multifaceted implementation strategy. I was also underwhelmed by the clinician outcomes. I think when you implement a model of care you are primarily trying to change the care the clinician provides to patients rather than the clinicians confidence/attitudes/beliefs.

REVIEWER	Annette Becker Department of General Practice, Preventive and Rehabilitative Medicine University of Marburg Germany
REVIEW RETURNED	30-Oct-2017

GENERAL COMMENTS	Thank you, this is definitely an interesting study and a detailled and thorough presentation of its design! A few remarks: - Could you please comment in what way and if true, why patients with subacute and chronic pain are excluded. - Please give details concerning the target patient sample in the abstract. - Is the baseline data collection done prior to or after group allocation of clusters? - It would be helpful to have some clarification on the mode of data collection. I think most is done via questionnaires, but as for HCP inteviews seem to be performed as well. - I am wondering whether oucome description and data collection can be summarized.

REVIEWER	Simon French Queen's University
REVIEW RETURNED	21-Nov-2017

GENERAL COMMENTS	Carefully designed and described protocol for a complex implementation trial. Overall well written and described. Nice to see a detailed justification and development of a theory-informed implementation intervention. My comments will hopefully help to improve the quality of the manuscript: 1. The term “user pull” is used in the abstract and the main manuscript text. Suggest replace this with a plain language term to better describe this concept. 2. Background: suggest you cite some recently published systematic reviews in this area: Mesner SA, Foster NE, French SD. Implementation interventions to improve the management of non-specific low back pain: a systematic review. BMC Musculoskelet Disord 2016;17:258 Suman A, Dikkers MF, Schaafsma FG, van Tulder MW, Anema JR. Effectiveness of multifaceted implementation strategies for the implementation of back and neck pain guidelines in health care: a systematic review. Implement Sci 2016;11(1):126. 3. The use of innovative study designs (hybrid type 2 trial and dog leg) is welcome, but a protocol publication also gives the authors an opportunity to describe these in detail, especially because these are not well known designs. Provide more information on these designs in the Background for readers who are not familiar with these designs. Also, provide justification for the chosen study designs; why are these the best designs for your intervention and research question/s? 4. Considering the innovative trial design chosen and the somewhat confusing description (p4), please provide a diagram/flow chart of the overall study design. Table 2 is helpful, but a diagram would make this even clearer. 5. A concluding statement is needed summarising the main design of the study and the potential impact this will make. 6. Authors state that the manuscript conforms to the SPIRIT

	guidelines, however the SPIRIT checklist was not available. 7. Numerous typographical errors are present throughout the manuscript. A thorough proof read and correction is needed.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

• Firstly the manuscript seems to describe multiple studies (pilot trial, main trial, process evaluation, cost-effectiveness analysis, mediation analyses) but each is briefly and confusingly described. I think it would have been better to split up the manuscript into separate papers.

Author's response - While developing our protocol, we considered the trade-offs of having several separate or one integrated study protocol for our research aims. We realise that fragmenting into separate study protocols allows more room for rationale but this also leads to substantial overlap and repeated reporting of rationale and methodology between protocols and also would inflate the time lag for publishing protocols. We reason that fragmenting into separate study protocols would be at a cost of reduced validity where we regard the effectiveness of the model of care at the HCP and patient levels to go hand in hand with the implementation processes involved. We see advantages of one concise integrated study protocol using effectiveness-implementation hybrid type 2 trial methodology designed specifically for conditions in line with the context of our study. We have therefore decided to revise the reporting of the protocol to provide more concise rational rather than fragmenting into separate study protocols.

• Secondly I was unfamiliar with many terms (eg dog leg wth two assessments) and I suspect many readers will be as well. When I considered the main trial it seems like a stepped wedge RCT but this more familiar term is not used. Some attention to terminology could resolve a lot of the lack of clarity.

Author's response - We have now revised reporting of the first 3 paragraphs of the study design section to provide more clarity of the design and use of terminology for the following: 1) effectiveness-implementation hybrid type 2 trial methodology, 2) the design on the HCP level involves data collection in the cohort before and prospectively after implementation of the BetterBack model of care. On a patient level, data is collected in a blinded pragmatic randomized controlled stepped cluster format with longitudinal follow up at 3, 6 and 12 months post baseline, 3) The form of stepped cluster structure applied in this study has been described by methodologists to resemble the form of a dog hind leg [32]. The optimal stepped structure applied in the context of our study is classified as a dog leg with 2 assessments in routine care [32,33].

• Thirdly each study of the suite of studies was incompletely described. For example I did not get a clear understanding of the objectives of the pilot study, the justification for the mediation analyses, or the components of the BetterBack model of care in the main trial.

Author's response - We have now revised reporting in paragraphs 4 & 5 of the study design section to better clarify objectives of the internal pilot phase of our study. We reason that an internal pilot phase integrated in the main trial is the most efficient design for the context of our trial design and the time and financial constraints.
Regarding the justification of the mediation analyses, we have now provided a more clear rationale in paragraph 1&2 on page 7 explaining the potential TDF determinants mediation of the MOC effect on implementation process related HCP behaviours leading to implementation outcomes. In paragraph 2 on page 8 we also explain the potential mediating effect of illness behaviour and self-care enablement of the MOC effect on patient behaviour. We have added a new figure (figure 1) to display how the mediation analyses are a part of the process evaluation logic model in a Hybrid type 2 trial.

Regarding the justification of the components of the BetterBack model of care, we have now provided more clear explanation for the support tool's coherence with the Swedish adaptation of best practice clinical guidelines.

- With regard to the main trial I think you could have spent less time describing the development of the BetterBack model of care and more time describing its components using a checklist such as TIDieR to guide you. I would have liked a better justification for each facet of the multifaceted implementation strategy. I was also underwhelmed by the clinician outcomes. I think when you implement a model of care you are primarily trying to change the care the clinician provides to patients rather than the clinicians confidence/attitudes/beliefs.

Author's response – We have now applied the TIDieR checklist to help describe the BetterBack MOC components. We have provided new references in the second last paragraph of the introduction to support multifaceted and sustained strategy. We have rearranged in the intervention section so that the MOC and it's implementation strategy is described in line with the new Figure 1 to more easily understand the intervention. After your comment regarding clinician outcomes we come to realise that the STaRI recommends using the term "Implementation Process" instead for clinician outcomes and "implementation outcomes" instead for process measures (ex. Referrals to specialist care, clinical intervention coherent with best practice recommendations…). We have now adjusted terminology and in figure 1 it is now more clearly reported that implementation processes aim to change in confidence/attitudees/beliefs that then result in clinical care outcomes.

Reviewer 2 –
Thank you, this is definitely an interesting study and a detailed and thorough presentation of its design!

- Could you please comment in what way and if true, why patients with subacute and chronic pain are excluded.

Author's response: Thank you for this comment. We realise now that the wording "first time or recurrent debut of LBP" in our inclusion criteria is ambiguous. We do indeed include patients with first-time or recurrent episode of acute, subacute or chronic phase LBP but exclude patients with who fulfil criteria for multimodal/multidisciplinary pain rehabilitation team interventions. We have now revised this wording to provide more clarity in the manuscript.

- Please give details concerning the target patient sample in the abstract.

Author's response: Details concerning the target patient sample has now been added to the abstract.

- Is the baseline data collection done prior to or after group allocation of clusters?

Author's response: Cluster randomisation was performed before we started recruitment of patients. We have now provided clarification in paragraph 2 in the study design section.

- It would be helpful to have some clarification on the mode of data collection. I think most is done via questionnaires, but as for HCP interviews seem to be performed as well.

Author's response: We have now added the following text under the Data Collection subheading on page 11 "Data will be collected through quantitative questionnaires and qualitative focus group and semi-structured interviews".

- I am wondering whether outcome description and data collection can be summarized.

Author's response: We have considered this but the SPIRIT checklist requests outcome description and data collection to have separate headings and to be fully described including reliability and validity of measures.

Reviewer 3 –
Carefully designed and described protocol for a complex implementation trial. Overall well written and described. Nice to see a detailed justification and development of a theory-informed implementation intervention. My comments will hopefully help to improve the quality of the manuscript:

- The term "user pull" is used in the abstract and the main manuscript text. Suggest replace this with a plain language term to better describe this concept.

Author's response: We have now replaced the term "user pull" with plain language terms.

- Background: suggest you cite some recently published systematic reviews in this area: Mesner SA, Foster NE, French SD. Implementation interventions to improve the management of non-specific low back pain: a systematic review. BMC Musculoskelet Disord 2016;17:258 Suman A, Dikkers MF, Schaafsma FG, van Tulder MW, Anema JR. Effectiveness of multifaceted implementation strategies for the implementation of back and neck pain guidelines in health care: a systematic review. Implement Sci 2016;11(1):126.

Author's response: Thank you for these references. We have now integrated them into the background to better describe evidence for implementation strategies.

- The use of innovative study designs (hybrid type 2 trial and dog leg) is welcome, but a protocol publication also gives the authors an opportunity to describe these in detail, especially because these are not well known designs. Provide more information on these designs in the Background for readers who are not familiar with these designs. Also, provide justification for the chosen study designs; why are these the best designs for your intervention and research question/s?

Author's response: We have now added more detailed description and rational for hybrid type 2 trial and dog leg design in the study design section. We considered to place this information in the introduction but we consider it better placed in the study design section.

- Considering the innovative trial design chosen and the somewhat confusing description (p4), please provide a diagram/flow chart of the overall study design. Table 2 is helpful, but a diagram would make this even clearer.

Author's response: We have now included a new diagram as figure 1 to help reporting. The flow chart is similar to the example from the STaRI reporting standards.

- A concluding statement is needed summarising the main design of the study and the potential impact this will make.

Author's response: We have now provided a concluding statement in the manuscript.

- Authors state that the manuscript conforms to the SPIRIT guidelines, however the SPIRIT checklist was not available.

Author's response: We have now added the SPIRIT checklist as a supplementary file 1.

• Numerous typographical errors are present throughout the manuscript. A thorough proof read and correction is needed.

Author's response: We have now edited the manuscript for typographical errors.

VERSION 2 – REVIEW

REVIEWER	Simon French Queen's University
REVIEW RETURNED	29-Dec-2017

GENERAL COMMENTS	I am satisfied that the authors have adequately responded to my concerns

REVIEWER	Annette Becker Department of General Practice, Preventive and Rehabilitative Medicine Philipps University Marburg Germany
REVIEW RETURNED	19-Jan-2018

GENERAL COMMENTS	This is an extremely complex trial design. The manuscript has gained a lot from its last revision with respect to understanding. Still, I would like to suggest only one thing - to change figure 1 in an even more simplified figure of the trial design including the sketched chronological sequence of the intervention in different centers. I would like to get (at one glance) a clear idea of the sequence of pilot study, interventions and process evaluation - the respective table is not really helpfull. Thank you

VERSION 2 – AUTHOR RESPONSE

Editors comments

1) We noted an inconsistency with the name of your intervention throughout your manuscript. In many cases the intervention name is followed by a smiley face (BetterBack☺) whereas in other cases it is not. Please clarify the intervention name throughout the manuscript.

Authors response: We have now corrected inconsistencies where the MOC name has not had a smiley face at the end. When typing the study title in Scholar one though, we are unable to put the smiley face in. However in our manuscript file title the smiley face is present in the title.

2) Please revise the 'Strengths and limitations' section of your manuscript (after the abstract). This section should relate specifically to the methods of the study. For example, receipt of funding is not a direct strength of your study methodology.

Authors response: We have deleted mention of study funding in the strengths and weaknesses section after the abstract.

Reviewer 2 comments

1) This is an extremely complex trial design. The manuscript has gained a lot from its last revision with respect to understanding.

Still, I would like to suggest only one thing - to change figure 1 in an even more simplified figure of the trial design including the sketched chronological sequence of the intervention in different centers. I would like to get (at one glance) a clear idea of the sequence of pilot study, interventions and process evaluation - the respective table is not really helpfull. Thank you.

Author response: We have now amended figure 1 to also show chronological sequence of the intervention in different centres to support the trial sequence described in table 2.

-The Author also provided a marked copy with additional comments. Please contact the publisher for full details.