PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for the process and feasibility evaluations of a new model of primary care service delivery for managing pain and function in patients with knee osteoarthritis (PARTNER) using a mixed methods approach
AUTHORS	Bowden, Jocelyn; Egerton, T; Hinman, Rana S.; Bennell, Kim; Briggs, Andrew; Bunker, Stephen; Kasza, Jessica; French, Simon; Pirotta, Marie; Schofield, Deborah; Zwar, Nicholas; Hunter, David

VERSION 1 – REVIEW

REVIEWER	Kelli Allen University of North Carolina, Chapel Hill & Durham VA Healthcare System, NC, USA
REVIEW RETURNED	16-Oct-2019

GENERAL COMMENTS	This is a very well written manuscript and a very detailed plan for the process and feasibilty evaluations of the PARTNER trial. I only have a couple of minor suggestions for the authors to consider: - Page 11, lines 38-41: this states that data will be used to determine "feasibility," but the rest of the sentence sounds more like "acceptability" type data regarding the PARTNER model. - Page 12, 1st paragraph: It is stated that 20 people will be selected with an aim of ensuring maximum heterogenity, and that this will be done after recruitment is finished. The evaluation would include monitoring of intervention phone calls. Based on the timeline of the proposal, wil it really be feasible to end enrollment, then idenetify the 20 patients and still have this evaluation include the initial intervention call?

REVIEWER	Regina Wing Shan Sit Jockey Club School of Public Health and Primary Care, the Chinese University of Hong Kong.
REVIEW RETURNED	26-Nov-2019

GENERAL COMMENTS	I have reviewed this protocol together with the other published one in reference 7. Overall the protocol is comprehensive and the 2 figures are very useful to illustrate the study plan. The mixed-method is a wonderful approach. Just minor comments here: Since the checking of fidelity is one the study goal, the assessment criteria may need to be clarified. Fidelity of behavioral interventions is crucial for preserving the validity of conclusions and for future dissemination. Authors may consider to follow NIH Behavior Change Consortium-issued guidelines to ensure integrity of intervention

	delivery, especially consider if Adherence & Competence Scale would be capable, also any criteria of success? Besides, I am not so sure about the Table 1 point 1.5 "Were the primary and secondary outcome effects due to the nature of the implementation or to the intervention". How is this exactly done and measured?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Comment 1: Page 11, lines 38-41: this states that data will be used to determine "feasibility," but the rest of the sentence sounds more like "acceptability" type data regarding the PARTNER model.

Response: Thank you for this comment, we agree with the reviewer's thoughts. We have amended both this sentence (page 11) and also aim 2 to include both the feasibility and acceptability of the intervention.

Aim 2 is now worded as "Feasibility and acceptability of scaling the intervention in Australia."

The paragraph on page 11 has been amended to:

"We will also use the quantitative data sets to determine the feasibility and acceptability of having the model adopted broadly in an Australian healthcare context. We will explore health care providers' and patients' experience of the intervention and its perceived impact (Aim 2.3) and examine any issues that arose during the trial that would affect broader implementation (Aim 2.1)."

Comment 2: Page 12, 1st paragraph: It is stated that 20 people will be selected with an aim of ensuring maximum heterogeneity, and that this will be done after recruitment is finished. The evaluation would include monitoring of intervention phone calls. Based on the timeline of the proposal, will it really be feasible to end enrollment, then identify the 20 patients and still have this evaluation include the initial intervention call?

Response: We apologise for the ambiguity of this sentence. We are recording all of the consultation calls between the Care Support Team and the participants in the intervention group patients regardless. This includes the initial consultation call. We will select 20 patients to undertake this more detailed analysis with. This final selection of patients will be undertaken once recruitment is completed so we have a complete picture of our cohort. We have amended the wording of this sentence to clarify this point (p. 12), specifically:

"Firstly, we will analyse a sample of the telephone interactions that have been recorded between the patients in the intervention group and the CST. After the final patient is recruited, we will purposely select 20 patients to conduct a detailed analysis of their telephone consultations."

Reviewer 2

Comment 1: Since the checking of fidelity is one the study goal, the assessment criteria may need to be clarified. Fidelity of behavioral interventions is crucial for preserving the validity of conclusions and for future dissemination. Authors may consider to follow NIH Behavior Change Consortium-issued guidelines to ensure integrity of intervention delivery, especially consider if Adherence & Competence

Scale would be capable, also any criteria of success?

Response 1: Thank you for this helpful suggestion. We have a checklist developed by our collaborating partner “HealthChange Australia” who helped develop the behaviour change component of our CST intervention. The checklist was developed to assist with the CST’s initial training and covers most of the aspects described in the Bellg paper (2004) on enhancing treatment fidelity in behaviour change studies. We will change the protocol to include this checklist to assess the fidelity and identify any changes from the initial training when assessing a selection of the consultation phone calls made by the CST.

To address this point we have amended the manuscript to include the following (p.12):

We will use a checklist based on the methodology developed by our partner “HealthChange Australia” to train the CST in behaviour change techniques to examine the fidelity of the delivery of the behaviour change component of the intervention.

Comment 2: Besides, I am not so sure about the Table 1 point 1.5 "Were the primary and secondary outcome effects due to the nature of the implementation or to the intervention". How is this exactly done and measured?

Response 2: This aim will be addressed by answering the other aims of the process evaluation. If the intervention is determined to be delivered as per protocol, we can more confident that our findings (positive or negative) were due to the effectiveness or ineffectiveness of the intervention. Similarly, if there is significant variation in the implementation of the intervention, our findings may be due to other factors identified through the evaluation (e.g. intervention components, contextual factors, reach of the intervention). This approach is advocated by the OARSI Clinical Trial Recommendations (Allen et al 2015).

VERSION 2 – REVIEW

REVIEWER	Kelli Allen University of North Carolina, Chapel Hill & Durham VA Health Care System US
REVIEW RETURNED	12-Dec-2019

GENERAL COMMENTS	No additional comments.

REVIEWER	Regina Wing Shan Sit The JC School of Public Health and Primary Care, The Chinese University of Hong Kong, Hong Kong
REVIEW RETURNED	13-Dec-2019

GENERAL COMMENTS	Thanks for addressing the comment.