PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Integrating culturally informed approaches into physiotherapy assessment and treatment of chronic pain: a pilot randomised controlled trial
AUTHORS	Brady, Bernadette; Veljanova, Irena; Schabrun, Siobhan; Chipchase, Lucinda

VERSION 1 – REVIEW

REVIEWER	Dr Deirdre Hurley University College Dublin, Ireland
REVIEW RETURNED	23-Feb-2018

GENERAL COMMENTS	This paper presents a well conducted and written pilot trial demonstrating the feasibility of implementing culturally informed approaches for the physiotherapy assessment and treatment of chronic pain and preliminary effects of the intervention on secondary outcomes compared to usual evidence-based physiotherapy. This pilot trial findings provide some justification for moving to a definitive trial. Additional details concerning some aspects of the study design and some modifications to the reporting of the results are recommended to conform to CONSORT reporting guidelines for pilot trials as detailed below. Methods State how randomisation procedure was implemented and who recruited participants. Give more details of the recruitment strategy and engagement with stakeholders in developing/implementing the strategy. This is important information for other trialists and should be discussed in the paper. There is no reference to how fidelity was assessed in the experimental arm although it is stated in the protocol. There is an inconsistency with the protocol in terms of the number of individual treatments offered in the Intervention arm ie 3 v 4, which may be a typo and needs to be corrected. Justify the method of dealing with missing data by providing a reference. The CONSORT extension for pilot trials advises only the reporting of estimates with 95% confidence intervals for participant outcomes without P values as they are not powered for testing hypotheses of effectiveness. This should be amended in the data analysis section and subsequent results.

	Results Give some specific details of fidelity data for both study arms - how was treatment according to the study protocol assessed and evaluated. Similarly, more details of the specific results related to adherence would be informative, i.e. number of exercises/frequency etc There is extensive reporting of P values in the abstract and results of this paper which should be removed to conform to CONSORT guidelines for pilot trials. Comment on the effect sizes for the secondary outcomes in the text. Figure 1 - for accuracy with the CONSORT statement add the n= for the Total Screening and Analysis sections of the flow chart for the experimental arm. Discussion P18, line 2 - please be more specific in terms of the interpretation of secondary outcome data as the majority of between group differences had small effect sizes. A discussion of these findings compared to the literature is also warranted. Some reference to the cost of the intervention is warranted in relation to moving to a definitive trial. The different settings of both trial arms in the local community and hospital outpatient department should also be discussed as a potential contextual component that may have contributed to the findings. More details of the different settings in the methods and results would also inform this discussion.

REVIEWER	Aimee Stewart University of the Witwatersrand Johannesburg South Africa
REVIEW RETURNED	20-Mar-2018

GENERAL COMMENTS	One of the issues that the authors need to think about is that they also belong to a culture-ie probably an Anglo-Saxon one. So care must be taken in describing other cultures as in the Introduction as if culture only belongs to persons other than Anglo-Saxon ones. The general population for example-what culture does it belong to? Also usual care-which is evidence based has an over-arching cultural component which must be considered. The Introduction should be reworded to include the imposing of one culture ie Anglo Saxon/Western on another culture in healthcare. In the sample size calculation albeit this is a pilot study the actual size effects should be included. A mention of minimal clinical important differences would also be valuable. Define more clearly what is meant by medium and large effect-in which outcome measures was this considered and specifically then what is a medium or large effect?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1: Dr Deirdre Hurley
This paper presents a well conducted and written pilot trial demonstrating the feasibility of implementing culturally informed approaches for the physiotherapy assessment and treatment of chronic pain and preliminary effects of the intervention on secondary outcomes compared to usual evidence-based physiotherapy. This pilot trial findings provide some justification for moving to a

definitive trial. Additional details concerning some aspects of the study design and some modifications to the reporting of the results are recommended to conform to CONSORT reporting guidelines for pilot trials as detailed below.

We thank the reviewer for their considered feedback and have examined each comment below.

Methods
State how randomisation procedure was implemented and who recruited participants.
We have included the following in the manuscript to provide detail of the randomisation procedure and recruitment processes:
"A total of 94 participants were assessed for eligibility by a physiotherapist not involved in the delivery of interventions and who was bilingual or used the services of an accredited health language interpreter." [page 9, lines 22-24].

"Group allocation was determined by a computer-generated sequence with a 1:1 allocation ratio, with each ethnocultural community randomised separately. An independent person prepared sealed opaque envelopes containing the intervention arm, labelled with a participant number according to their entrance sequence. These envelopes were managed securely by a central administrative officer responsible for randomising participants and arranging relevant appointments once a participant had been consented." [page 10, lines 13-21].

Give more details of the recruitment strategy and engagement with stakeholders in developing/implementing the strategy. This is important information for other trialists and should be discussed in the paper.

Thank you for this feedback. We have included reference to stakeholders engaged as part of the RCT development and trial process and elaborated on the recruitment strategy:
"This pilot RCT was the culmination of three years of engagement with local Assyrian, Mandaean and Vietnamese communities, facilitated by the multicultural health unit in SWSLHD. Bilingual community educators and multicultural health workers informed the development of the intervention in earlier qualitative phases15 and guided processes in this RCT ensuring the research team were cognisant of the community needs and vulnerabilities.

Following consultation with multicultural representatives, it was evident that a broad recruitment strategy was required to be inclusive. This included: a) recognising the complexity of chronic pain in each community by not excluding participants based on pain location (such as only including low back pain) or psychological comorbidity; b) considering patients from multiple countries of birth (Iraq, Iran, Syria, Turkey, Jordan and Vietnam) and anyone speaking Arabic, Assyrian or Vietnamese as potentially eligible, especially where data on ethnocultural identification was not available. Ethnocultural identification was then established according to self-identification by the participant at the screening assessment. A total of 94 participants were assessed for eligibility by a physiotherapist not involved in the delivery of interventions. While a multicultural community representative was not present during recruitment, participants were offered the opportunity to consult community representatives and family members before consenting to participation". [page 9, lines 7-25]

There is no reference to how fidelity was assessed in the experimental arm although it is stated in the protocol.
We recognise the need for further clarification of fidelity and have incorporated greater detail of average adherence to core elements for both groups.
For the usual care group:
"Fidelity was evaluated from logbooks completed by each therapist as the percentage of core treatment components included. The components included pain education, goal setting, activity

pacing, active coping strategies, flare-up management and a tailored home exercise program. For the 14 participants who completed treatment, there was 100% therapist fidelity to 6 core treatment components while for the other participants, an average of 4 of the 6 core components were included prior to drop-out, with flare-up management and active coping strategies the most commonly omitted elements" [page 16, lines 12-19]

For the culturally adapted group:

"For the culturally adapted treatment arm, all group sessions were delivered by the physiotherapist who developed the culturally adapted treatment protocols, according to the session manual and verified by review of the therapist logbook" [page 16, lines 1-4].

There is an inconsistency with the protocol in terms of the number of individual treatments offered in the Intervention arm ie 3 v 4, which may be a typo and needs to be corrected.
We thank the reviewer for alerting us to the different descriptions of the number of individual sessions. To clarify, the four individual sessions described in the protocol included the physiotherapists initial assessment, while in the manuscript we referred to this as initial assessment plus three sessions. For consistency, we have amended as follows:
1. In the methods: "In addition, group sessions were supplemented by up to 4 individual sessions" [page 12, lines 2-3]
2. In the results: On average, 3 individual sessions were recommended to supplement the 6 group sessions (range 1-4)" [page 16, lines 4-5].

Justify the method of dealing with missing data by providing a reference.
Thank you for this feedback. We have included a relevant reference for this method:
"Intention-to treat analyses were performed for all participants and missing data were addressed by carrying the last data point forward.41" [page 15, lines 17-18].

The CONSORT extension for pilot trials advises only the reporting of estimates with 95% confidence intervals for participant outcomes without P values as they are not powered for testing hypotheses of effectiveness. This should be amended in the data analysis section and subsequent results.

We acknowledge the recommendations by the CONSORT extension and the feedback of the reviewer. We have omitted discussion of statistical comparisons between groups using p values and report only on effect sizes for descriptive purposes, consistent with our published protocol. This has been amended using track changes in the following sections:

1. The abstract [page 3, lines 6-14]
"For the culturally adapted group attendance (87% ± 18) and adherence (68% ± 32) were higher relative to usual care (68% ± 32 and 55% ± 43). Satisfaction was similar for the culturally adapted (82.7 ± 13.4) and usual care groups (79.3 ± 17.3). For secondary outcomes, a significant between-group effect for pain-related suffering in favour of the culturally adapted group was observed with a medium effect size (partial η2 0.086, mean 3.56, 95% CI 0.11 to 7), while results for pain severity, interference, physical function and negative emotional state were similar."

2. The methods
The omission of:
"Between-group differences for baseline characteristics of participants were analysed using independent t test for continuous variables, and chi-square test for categorical variables" [page 15, lines 1-3].

"Statistical significance was set at 0.05" [page 15, line 18-19].

The inclusion of:
“Effect sizes for non-parametric tests were reported using r and interpreted as large (0.5), medium (0.3) or small (0.1)38” [page 15, lines 6-7].

3. The results
The omission of reference to ‘significant’ on pages 17 (line 15) and page 18 (lines 3, 21-22).

The omission of p values from Table 2 and text on pages 17 (line 17), page 18 (lines 5 and 12).

Results
Give some specific details of fidelity data for both study arms - how was treatment according to the study protocol assessed and evaluated. Similarly, more details of the specific results related to adherence would be informative, i.e. number of exercises/frequency et

As discussed above, we have amended discussion of fidelity on page 16 lines 1-4:
“For the culturally adapted treatment arm, all group sessions were delivered by the physiotherapist who developed the culturally adapted treatment protocols, according to the session manual and verified by review of the therapist logbook”.

And page 16, lines 12-19:
“Fidelity was evaluated from logbooks completed by each therapist as the percentage of core treatment components included. The components included pain education, goal setting, activity pacing, active coping strategies, flare-up management and a tailored home exercise program. For the 14 participants who completed treatment, there was 100% therapist fidelity to 6 core treatment components while for the other participants, an average of 4 of the 6 core components were included prior to drop-out, with flare-up management and active coping strategies the most commonly omitted elements”.

We have also expanded on the reporting of home exercise program adherence:
The average number of home exercises prescribed was similar for the culturally adapted (n=7, range 2-10) and usual care group (n=6, range 3-11). Overall, the culturally adapted group had a higher adherence rate (88% ±15) relative to usual physiotherapy care (55% ±43)….” [page 18, lines 1-4].

There is extensive reporting of P values in the abstract and results of this paper which should be removed to conform to CONSORT guidelines for pilot trials. Comment on the effect sizes for the secondary outcomes in the text.

We have omitted p values from the abstract (page 3), statistical analysis (page 14-15), results (pages 17-18) and Table 2. We have expanded on the text discussion of the secondary outcomes, referring to the effect sizes more specifically:
“Culturally adapted treatment resulted in greater improvement in pain related suffering than ‘usual physiotherapy care’, with a medium effect size observed (partial η2 0.086) (Table 2). A small effect size was observed for between group difference in favour of the culturally adapted group for BPI pain interference (partial η2 0.02) and 6MWT (partial η2 0.053), while no effect was observed for BPI pain severity, STS test or the DASS-21 (Table 2)” [page 18, lines 16-23].

Figure 1 - for accuracy with the CONSORT statement add the n= for the Total Screening and Analysis sections of the flow chart for the experimental arm.
We have amended figure 1 to include the total screened prior to eligibility assessment and have specified the analysis section for the culturally adapted group.

Discussion
P18, line 2 - please be more specific in terms of the interpretation of secondary outcome data as the majority of between group differences had small effect sizes. A discussion of these findings compared to the literature is also warranted.

We thank the reviewer for their comment and acknowledge the need for caution interpreting the secondary outcome measures. We have clarified this statement and have included discussion of the secondary outcomes relative to the literature:
"While specific conclusions regarding the efficacy of treatment for clinical outcomes cannot be made, the moderate to small effect sizes observed for the secondary outcomes of pain-related suffering, pain interference and physical function warrant further investigation. Recent systematic reviews of multidisciplinary and exercise-based treatments for chronic pain have revealed pooled effect sizes that were small for function and disability, while pain and psychological health were associated with small effect sizes or no effect depending on whether care was inter- or single-disciplinary43-45. In the context of such evidence, the results of this trial support further research into cultural adaptation to maximise the effect on pain and psychological outcomes" [page 19 lines 23-25, and page 20, lines 1-8].

Some reference to the cost of the intervention is warranted in relation to moving to a definitive trial. While cost-effectiveness was not a specific outcome of the study, we recognise that information on the direct costs would facilitate interpretation. We have therefore amended the manuscript to reflect this:

"Further, while cost-effectiveness was not a specific outcome, there were no substantial cost disadvantages of delivering culturally adapted treatment. Both treatment arms were delivered by public health outpatient services. While the cost of hire of community venues was greater ($1595 AUD), this cost was offset by delivering 67% of culturally adapted treatment in groups. Similarly, there were no cost disadvantages of engaging a bilingual support worker in lieu of a health language interpreter, both of which are funded by different sectors of the public health service. This provides further support for feasibly" [page 23, lines 15-22].

The different settings of both trial arms in the local community and hospital outpatient department should also be discussed as a potential contextual component that may have contributed to the findings. More details of the different settings in the methods and results would also inform this discussion.
We acknowledge that the setting is likely to play a significant factor but was a deliberate component based on the cultural adaptation framework. This framework and rationale for the choice of setting was described in the protocol paper. However, we acknowledge reference would be of value to aid interpretation of our findings. Thus, we have included the following in the discussion:
For the culturally adapted group, a combination of both surface- (language, food, music, group interaction and setting) and deep-level (reframing content to align with explanatory models of pain and ethnocultural values) adaptations were included to enhance the cultural relevance of program content and facilitate patient engagement.25 While programs were conducted in a similar geographic location (i.e. suburb) to the usual care group in the hospital outpatient service, the use of a community venue was an important technique for balancing power differentials in therapeutic relationships and reducing access barriers, thereby contributing to engagement outcome".49-50 [page 20, lines 21-25 and page 21, lines 1-4].

Reviewer: 2: Aimee Stewart
One of the issues that the authors need to think about is that they also belong to a culture-ie probably an Anglo-Saxon one. So care must be taken in describing other cultures as in the Introduction as if culture only belongs to persons other than Anglo-Saxon ones. The general population for example-

what culture does it belong to? Also usual care-which is evidence based has an over-arching cultural component which must be considered. The Introduction should be reworded to include the imposing of one culture ie Anglo Saxon/Western on another culture in healthcare.

We acknowledge the complexities of operating in inter-cultural contexts raised by Reviewer 2. We have made amendments to the manuscript to reflect clarification of the cultural context within which the study was conducted and references to both healthcare provider and health system (including evidence based treatment culture) throughout. These amendments include:

Introduction: page 6 [lines 15-19]:
"Culturally adapted approaches have been suggested to be an effective strategy to enhance patient engagement and reduce health disparities in CALD communities.1,4 Such approaches speak to more equitable health outcomes for diverse cultures by minimising the risk of a model that results in more favourable outcomes for the dominant, hegemonic culture.4"

page 7 [lines 9-10]:
"However, the efficacy of these approaches has been established in populations speaking the same language, with few studies including CALD and migrant communities".10

Page 7 [lines 23-25]:
"This is perhaps not surprising in the context of intercultural encounters where there is evidence of healthcare provider ethnocentrism, implicit and explicit bias towards patients from CALD backgrounds21-23."

Methods, page 12 [lines 20-22] describing usual care:
"It is of note that a substantial proportion of research examining the impact of interventions on chronic pain had excluded patients from CALD backgrounds.10"

Discussion, page 25 [lines 5-15]:
"A final consideration is the healthcare context within which this study was conducted. Australia is a multicultural society and healthcare providers, including participating physiotherapists, comprise a multitude of ethnocultural, religious and professional identities, that influence their provision of healthcare and the inter-cultural relationship61-62. As such, cultural concordance and healthcare provider cultural responsiveness are factors that may have influenced treatment outcomes63. Future studies may wish to consider the assessment of healthcare provider cultural competence to allow treatment effects to be delineated between adaption elements and therapist characteristics. Culture is a highly complex construct and it must be considered that the culture of healthcare providers, along with the health system itself, will influence treatment outcomes64"

In the sample size calculation albeit this is a pilot study the actual size effects should be included.
We recognise the importance of justifying sample size and have provided additional clarification of effect sizes, consistent with the additional information provided in our protocol paper and the examples in the CONSORT extension for pilot studies:
"…ensuring equal numbers in both treatment arms (24 culturally adapted and 24 usual care) and allowing for the detection of medium to large effects (effects sizes of 0.5-0.8), should they exist.36-37 [page 14, lines 20-22].

A mention of minimal clinical important differences would also be valuable.
Thank you for this feedback. The MCIDs are discussed with respect to sample size calculation in a future RCT on page 19, lines 2-11. However, as this was a pilot study, our aim was not to investigate between group differences for secondary outcomes. Thus, we have made no reference to the size of the sample required to detect a MCID in our pilot study sample size calculation.

Define more clearly what is meant by medium and large effect-in which outcome measures was this considered and specifically then what is a medium or large effect?
We thank the reviewer for their comment. We have referred to effect sizes and their interpretation more specifically in the results and discussion sections:
Results
"There was an 87% (±18) attendance rate in the culturally adapted program, compared to 68% (±32) in the usual care group with a medium between group effect size (U=170, r=0.36)" [page 17, lines 17-19].

"the culturally adapted group had a higher adherence rate (88% ±15) relative to usual physiotherapy care (55% ±43), consistent with a moderate between group effect size (U=145, r=0.39)". [page 18, lines 3-5]

"Culturally adapted treatment resulted in greater improvement in pain related suffering than 'usual physiotherapy care', with a medium effect size observed (partial η2 0.086) (Table 2). A small effect size was observed for between group difference in favour of the culturally adapted group for BPI pain interference (partial η2 0.02) and 6MWT (partial η2 0.053), while no effect was observed for BPI pain severity, STS test or the DASS-21 (Table 2)" [page 18, lines 16-23].

Discussion:
"While specific conclusions regarding the efficacy of treatment for clinical outcomes cannot be made, the moderate to small effect sizes observed for secondary outcomes of pain-related suffering, pain interference and physical function…." [page 19, lines 22-25].

FORMATTING AMENDMENTS (if any)
Required amendments will be listed here; please include these changes in your revised version:
- Kindly re-upload APPENDIX in PDF format
We have uploaded the appendix in PDF format.

VERSION 2 – REVIEW

REVIEWER	Dr Deirdre Hurley University College Dublin, Ireland
REVIEW RETURNED	02-May-2018

GENERAL COMMENTS	The authors have comprehensively addressed all my comments and i would recommend acceptance of this manuscript for publication.

REVIEWER	Prof Aimee Stewart University of the Witwatersrand, Johannesburg, South Africa
REVIEW RETURNED	07-May-2018

GENERAL COMMENTS	The comments of the reviewers have been addressed. There are a couple of minor issues that can be addressed. - The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.