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Integrating culturally informed approaches into physiotherapy assessment and treatment of chronic pain: a pilot randomised controlled trial

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Abstract

Objective: To evaluate patient engagement with, and the feasibility of, a novel, culturally adapted physiotherapy pain management approach

Design: A participant- and assessor-blinded pilot randomised controlled trial

Setting: Outpatient physiotherapy departments at two public hospitals and one district Pain Clinic.

Participants: Adults (*n*=48) with chronic musculoskeletal pain (daily pain >3-months), who self-identified as Mandaean, Assyrian or Vietnamese, were randomised to one of two physiotherapy treatment conditions.

Interventions: Twenty-four participants underwent combined group and individualised treatment described as 'culturally adapted physiotherapy', while 24 underwent evidence-informed 'usual physiotherapy care'. Both treatment arms consisted of up to 10 sessions over a 3-month period.

Outcome Measures: Patient engagement was measured via participant attendance, adherence, and satisfaction data. Secondary outcomes included clinical measures of

pain severity, interference and suffering; physical function, and negative emotional state.

Results: Ninety-six percent of participants undergoing culturally adapted physiotherapy completed treatment, compared with 58% of the usual physiotherapy group. Attendance and adherence were significantly higher in the culturally adapted group (p=0.013 and p=0.008). There was no difference for satisfaction between groups. 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 η^2 0.086, p=0.043).

Conclusion(s): Aligning treatment with the beliefs and values of CALD communities enhances patient engagement with physiotherapy. These results support the feasibility of a larger, multisite trial to determine if improved engagement with culturally adapted physiotherapy translates to improved clinical outcomes.

Trial Registration: This study was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12616000857404).

Strengths and limitations of this study

- This was a randomised, assessor- and participant- blind controlled trial
- It provides evidence of feasibility of culturally adapted physiotherapy approaches for pain management as explored with three culturally and linguistically diverse communities
- Observed recruitment rates, follow-up rates and preliminary data can inform a future fully powered RCT
- As a pilot study, analysis of clinical outcomes are exploratory.

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Conflict of interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare no conflicts of interest.

Ethical Approval

The study was approved by the South West Sydney Local Health District (SWSLHD) Human Research Ethics Committee (HREC/16/LPOOL/194) and Western Sydney University Human Research Ethics Committee (RH11741).

Original protocol for the study

Brady B, Veljanova I, Schabrun S, et al. Integrating culturally informed approaches into the physiotherapy assessment and treatment of chronic pain: protocol for a pilot randomised controlled trial. *BMJ Open* 2017;7(5): http://bmjopen.bmj.com/content/7/5/e014449.

Introduction

Patient engagement is paramount for the delivery of efficient and effective healthcare, reflecting a patients' relationship with the health encounter, such that they participate (attends and adheres) and recognise value in their treatment (satisfaction and treatment completion).[1 2] Research that has evaluated interventions and models of care to enhance patient engagement has provided evidence of success.[2] Whether this is true for culturally and linguistically diverse (CALD) communities remains uncertain.[1] This is problematic because healthcare must be responsive to the comparatively poorer health status observed in many CALD communities.[3] Further, strategies promoting engagement tailored to the needs of CALD communities is vital, particularly given that many countries around the world are now culturally plural societies.

Culturally adapted approaches have been suggested to be an effective strategy to enhance patient engagement and reduce health disparities in CALD communities.[1,4] Systematic reviews and meta-analyses support the use of culturally adapted treatment for mental health conditions, chronic disease management, cancer screening, and health promotion.[4-8] For example, meta-analyses of mental health interventions demonstrated small to large pooled effect sizes in favour of culturally adapted treatments, compared to usual care.[5-6,9] Despite evidence supporting the use of culturally-adaptive approaches, research is still lacking for many prominent, debilitating conditions, including for chronic pain.[10] As such, suboptimal health outcomes continue to be observed in patients from CALD communities with chronic pain.

Chronic pain disorders contribute to considerable societal burden and personal suffering.[11] Many physiotherapy interventions for chronic pain, particularly exercise based approaches, are safe and effective.[12-13] Current evidenced based recommendations suggest that exercise, when combined with cognitive behavioural and psychosocial treatments, reduces pain, improves quality of life, and reduces long term disability.[12,14] However, the efficacy of these approaches has been established in general populations, with few studies including CALD and migrant communities.[10] The limited research inclusive of CALD communities suggests limited efficacy for pain, quality of life and psychological health outcomes.[10] Such uncertainty supports investigation of sociocultural factors that could influence implementation of pain management approaches within CALD communities.[15]

Successful management of chronic pain requires a strong therapeutic alliance and patient acceptance of, and engagement with, treatment concepts.[16-17] Unfortunately, engagement with activity based treatments is often suboptimal in CALD communities, evidenced by lower attendance, reduced acceptance, and premature drop-out from treatment.[10,18] Discordant expectations, low patient-provider alliance, cultural-spiritual factors and communication problems have been cited as contributors to suboptimal engagement for CALD communities.[19,20]. Since engagement with treatment underpins improved patient outcomes[21], it is imperative that strategies are implemented to optimise engagement by CALD populations for costly and debilitating conditions, such as chronic pain.

Thus, the aim of this pilot study was to determine the feasibility, patient engagement, and trends of clinical effectiveness of a culturally adapted physiotherapy assessment and treatment approach compared with evidence informed 'usual physiotherapy care'. Thus, the research questions for this pilot randomised trial were:

1. Is a 12 week culturally adapted treatment approach superior to 'usual physiotherapy care', in terms of patient engagement (adherence, attendance, and satisfaction)?
2. Is it feasible to deliver and evaluate culturally adapted physiotherapy assessment and treatment approaches across three CALD communities using a randomised controlled trial design?

Methods

Design

This was a prospective, multi-centre pilot randomized controlled trial with concealed allocation, and participant and assessor blinding, using a patient sample with chronic pain drawn from 3 CALD communities (Mandaean, Assyrian and Vietnamese). The trial was conducted across 2 hospital-based physiotherapy departments and one district Pain Clinic, between July 2016 and June 2017. A study protocol with eligibility criteria and intervention descriptions was published previously.[22] The study was approved by the South West Sydney Local Health District (SWSLHD) Human Research Ethics Committee (HREC/16/LPOOL/194), Western Sydney University Human Research Ethics Committee (RH11741) and was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12616000857404).

Participants and Recruitment

A total of 94 participants were assessed for eligibility with 48 randomised into the study. Inclusion criteria were: adult (≥18 years), non-specific musculoskeletal pain, daily pain of greater than three months' duration, self-identification as a member of the Mandaean, Assyrian or Vietnamese ethnocultural communities, and ability to provide written informed consent in their own language or English. Exclusion criteria were: specific diagnoses necessitating other treatment (i.e. complex regional pain syndrome), surgery within the last 3-months, and assistance for mobility other than a walking stick, to ensure safety during a group or home-based exercise program.

Sixteen participants from each community were allocated randomly to the experimental or control group after baseline assessment (Figure 1). Group allocation was determined by a computer-generated sequence with a 1:1 allocation ratio, with each ethnocultural community randomised separately. This was prepared by an independent investigator and concealed until assignment to ensure investigators and assessors were blind to therapy allocation. Participants were blind to treatment allocation and were told the trial was comparing two physiotherapy approaches for chronic pain and it was unknown which was more effective. Thus, participants were unaware they were receiving culturally adapted treatment approaches for the experimental groups. The success of blinding was assessed at the 3-month re-assessment with the question; "Do you think your physiotherapist has been trained in culturally responsive treatments for chronic pain?".

Intervention

Participants from Intervention and Control groups attended for a maximum of 10 sessions of physiotherapy over a 3-month treatment period. A maximum of '10' sessions was selected to enable the treating physiotherapist to tailor interventions to the individual needs of participants, and was consistent with the average number of physiotherapy sessions reported in clinical trials for the management of chronic pain.[13-14] All participants were given a home exercise program designed by their physiotherapist, and they were provided with translated log-books to facilitate recording of exercise adherence. A professional health interpreter was available for all treatment sessions (group and individual), if required, in accordance with best practice.

i. Culturally adapted physiotherapy assessment and treatment

Participants received a combination of group and individual physiotherapy sessions, adapted to reflect the ethnocultural beliefs and values of the community to which the participant identified. Three ethnocultural-specific group programs were designed by the research team, informed by qualitative research involving each community and guided by two adaptation frameworks.[15,22] Sessions were delivered once per week for 6-weeks, included a combination of education and exercise, and were conducted in groups of 8 participants from the same ethnocultural community. Sessions were run by a physiotherapist at a local community facility, and facilitated by a bilingual educator in the language of participants. In addition to an initial physiotherapy assessment, group sessions were supplemented by up to 3 individual sessions tailored to the participant according to the culturally-informed initial assessment to ensure consistency with the dose of the control group. Components of the cultural

adaptation for each ethnocultural community have been previously published and a summary is presented in Appendix 1.[22]

ii. Evidence informed 'usual physiotherapy care'

Participants allocated to this condition attended physiotherapy in the outpatient department where they were referred, for treatment informed by evidence based recommendations for chronic pain. All treating physiotherapists underwent a training session to familiarise them with evidence-based management of chronic pain. Treatment adherence to these guidelines was monitored by review of therapist treatment logs. Treating physiotherapists used their clinical judgement to guide the specifics of treatment according to principles of patient-centred care.[23] Following the initial assessment, physiotherapists worked with patients to select the treatment mode (individual or group based), frequency and dose (to a maximum of 10 sessions) tailored to the patient's needs and goals, consistent with best available evidence.[13,24]

Outcomes

Trained assessors, not involved in the recruitment or treatment of participants and unaware of group assignment, performed assessments according to standardised instructions at baseline (Month 0), and 3-month reassessment). Success of assessor blinding was determined with the question; "Did you know to which treatment arm the participant belonged?" If an assessor responded "yes", they were asked to nominate; "to which group?".

Data to assess feasibility were collected throughout the trial period regarding recruitment rates, treatment withdrawals, therapist fidelity to evidence-based guidelines, success of participant and assessor blinding, and trial drop-outs. Primary outcome measures were: measures of patient engagement, defined by attendance; and adherence to, and satisfaction with treatment. Attendance was measured as the proportion of sessions attended, relative to the number of sessions scheduled. Adherence was calculated as a percentage of the average number of home exercise sessions completed each week, relative to the number of sessions prescribed, determined from participant log-books or self-report (where the participant was unable or did not complete the log-book).[25] Patient satisfaction with treatment was evaluated using the Client Satisfaction Questionnaire (CSQ-8)[26], which evaluates satisfaction with treatment generally, and was selected because it validated in Arabic and Vietnamese.

Secondary outcomes included core measures recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).[27] This included measures for pain severity and interference (Brief Pain Inventory: BPI)[28], pain-related suffering (Pictorial Representation of Illness and Self Measure: PRISM)[29], physical function (6-minute walk test: 6MWT, and 1 minute sit to stand test: STS test)[30 31] and severity of symptoms for Depression, Anxiety, and Stress (DASS-21).[32] The reliability and validity of these measures, including for Arabic and Vietnamese translations, has been reported previously and was documented in the trial protocol.[22]

Patient involvement

The research questions were developed following qualitative enquiry into the experience of chronic pain among CALD communities.[15] Specifically, challenges raised by participants accessing and participating in pain management in South-West Sydney were incorporated in the study design. As such, participant engagement was considered a primary outcome measure. While patients were not involved in the recruitment and conduct of the study, all participants were given the opportunity to attend a feedback session following trial completion, held in local community venues.

Sample Size and Statistical Analysis

A total sample of 48 participants was deemed appropriate to allow the piloting of a novel culturally adapted program with three communities (8 participants per program), while ensuring equal numbers in both treatment arms (24 culturally adapted and 24 usual care) and allowing for the detection of medium to large effects, should they exist.[33-34]

Descriptive statistics were used to report the characteristics of participants, including means and standard deviations (SDs) for continuous variables, and frequencies and proportions (%) for categorical variables. Between-group differences for baseline characteristics of participants were analysed using independent *t* test for continuous variables, and chi-square test for categorical variables. Primary outcome measures (attendance, adherence and satisfaction) were evaluated using descriptive statistics and Mann-Whitney U tests, because data were not normally distributed and transformations did not achieve normality.

Exploratory examination for group differences in secondary outcome measures was undertaken using a repeated-measures analysis of variance (ANOVA), with the treatment condition (usual care/culturally adapted intervention) as the between-group factor, and time of assessment (pre-intervention or re-assessment) as the repeated, within-group factor. One-way repeated measures ANOVAs compared within-group main effects at each time point. Effect sizes were classified as small, medium or large (partial η^2 0.01, 0.06, 0.14, respectively).[35] If the assumptions of ANOVA were violated, data were transformed to achieve a normal distribution[36] before repeating the ANOVA. Intention-to treat analyses were performed for all participants and missing data were addressed by carrying the last data point forward. Statistical significance was set at 0.05. Analyses were performed using the Statistical Package for the Social Sciences, Version 24.

Results

Feasibility and treatment characteristics

Forty-eight participants, 16 from each ethnocultural community, were randomised within 4 months (Figure 1). For the culturally adapted treatment arm, treatment was delivered according to the protocol for 23/24 participants. On average, two individual sessions (excluding initial assessment) were recommended to supplement the six group sessions (range 0-3). One participant discontinued treatment prematurely, citing illness. For the usual care arm, 14 participants completed the treatment they were allocated. Ten participants withdrew from treatment citing reasons that included illness (*n*=1), treatment not helping (*n*=4), lack of time (*n*=1), and changed mind/ sought care elsewhere (*n*=4). Treating physiotherapists in the usual care arm utilised both group and individual modes of delivery for 8/24 participants, while individual

therapy alone was recommended for 16 participants. Therapist fidelity to evidence based principles was confirmed for all participants, except for the two participants who withdrew following their initial assessment.

Blinded re-assessment data were available for 45 participants, with 3 participants (usual care group) withdrawing from the trial and declining final assessment for similar reasons: “treatment has not helped me”, “treatment has not done anything to help my leg pain at all”, and “treatment has been a waste of time”. As such, the last data point for each was carried forward for all outcomes except satisfaction, for which an initial data point was not available. Success rates for assessor blinding was 91%, while 44% of participants correctly answered the blinding question regarding their therapists’ cultural responsiveness. No participant experienced an adverse event due to participation in the trial.

Demographic and baseline symptom characteristics of participants are displayed in Table 1. There were no significant differences between the groups for baseline characteristics.

Primary outcomes

Attendance

Overall mean (±SD) attendance at physiotherapy was 8.0 ±3.1 visits. The culturally adapted treatment group attended a significantly higher number of scheduled sessions compared to ‘usual physiotherapy care’ (mean difference = 4.0 sessions, 95%CI 2.6 to 5.3, p <0.001). There was an 87% (±18) attendance rate in the

culturally adapted program, compared to 68% (±32) in the usual care group (*U*=170, *p*=0.013, *Z*=-2.473, r=0.36).

Home Exercise Adherence

Home exercise adherence data was available for all participants in the culturally adapted program (*n*=24) and 22 participants from the usual care group. Data were absent for 2 participants who dropped out after their initial visit. Overall, adherence varied from 0% to 100%. The culturally adapted group had a significantly higher adherence rate (88% ±15) compared to usual physiotherapy care (55% ±43) (*U*=145, *p*=0.008, *Z*=-2.659, r=0.39).

Satisfaction

Satisfaction data were available for all participants who attended the 3-month blinded assessment (*n*=45). Overall, 93% of participants were satisfied with treatment, and 71% were highly satisfied, evaluated by a score of greater than 50% and 75%, respectively for the CSQ-8. Satisfaction between the two groups did not differ (*U*=235, *z*=-0.388, *p*=0.698). Mean CSQ-8 scores for the culturally adapted and usual physiotherapy care groups were 82.7 (±13.4) and 79.3 (±17.3).

Secondary Outcomes

Culturally adapted treatment resulted in greater improvements in pain related suffering than 'usual physiotherapy care', while no other significant between-group

differences were observed. Between-group comparisons and associated effect sizes are presented in Table 2.

Sample size estimates

With respect to feasibility for a larger trial based on trial data, for power of 80%, alpha of 5%, and a drop-out rate of 20%, a sample size of 124 in each group would be required to detect a clinically significant difference of 50m for walking distance[37] for the intervention group, based on the SD observed in our study of 128m. This sample size would also be sufficient to identify between-group differences for the BPI Severity (2.2-point difference, SD 2.51) and Interference subscales (2.2-point difference, SD 2.55), the PRISM suffering score (3.3 cm difference, SD 8.46) and the DASS total score (13-point difference, SD 31.88). A sample size of 300 would also allow for clinically important between-group differences to be detected for the 1-minute STS test (3 repetition difference, SD 8.46).

Discussion

The culturally adapted program was designed to target specific language, cultural, and access barriers faced by CALD communities that participate in pain management treatments. Results from this pilot study suggest there is an advantage in favour of a culturally adapted physiotherapy program relative to usual physiotherapy care for addressing barriers to optimal patient engagement. The culturally adapted programs were well-received by all 3 communities, demonstrated by significantly higher patient engagement (attendance, completion of treatment, and adherence) compared to the usual care group. While specific conclusions regarding

the efficacy of treatment for clinical outcomes cannot be made, the findings observed for secondary outcome measures provide support for further investigating culturally adapted treatments in CALD communities using a randomised controlled trial design.

Attendance and treatment retention is an important aspect of patient engagement essential to ensure positive outcomes from cognitive behavioural and exercise treatments for chronic pain are realised.[16-17] Despite this, drop-out from pain management programs has been reported to be as high as 40%[38], while for exercise-based physiotherapy, drop-out rates of 30-40% are common[39-40]. In the current study, drop-out rates in the 'usual physiotherapy care' group (42%) were consistent with rates observed in the literature[18,39,40], while for the 'culturally adapted' group, drop-out was less (4%). Further, attendance at scheduled sessions was significantly higher in the 'culturally adapted' group, and participants were willing to attend for a greater number of sessions. In combination, such findings suggest that attention to social and ethnocultural dimensions unique to CALD migrant communities successfully engaged participants. For the culturally adapted group, a combination of both surface- (language, food, music, group interaction and environment) 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.[22] Based on the primary outcomes from the current study, such adaptations should be important considerations for future research.

Treatment adherence is an aspect of patient engagement that has been positively related to patient outcomes in rehabilitation programs.[17] Nevertheless, adherence to

exercise interventions for chronic pain conditions is suboptimal.[41] For example, adherence rates for osteoarthritis exercise programs can be as low as 50%[42], and varies between 64% and 71% respectively, for neck pain and low back pain.[41,43] For the current study, there was wide variation in adherence rates for the 'usual care' group with a mean of 55% (±43), while for the 'culturally adapted' group, adherence was significantly higher and less variable (88% ±15). Low adherence rates in the 'usual care' group could have been due to suboptimal communication, patient-provider interactions, and failure to adequately tailor interventions to the sociocultural needs of the individual patient.[44] Further, a systematic review[25] cited the association between anxiety and depression, highly prominent symptoms in our sample, with reduced adherence to physiotherapy. However, since both treatment arms experienced similar symptoms, this association alone, does not account for the different adherence rates observed. Similarly, the low adherence rate for the 'usual care' group could not be ascribed to language barriers, since both groups had similar access to professional interpreting services and translated exercise diaries. Instead, the current findings emphasise a potential role for physiotherapists to optimise the inter-cultural therapeutic interaction by attending to a patient's beliefs and values, and aligning treatment components accordingly.

Baseline outcome data from the three CALD communities highlighted participants' severe pain and psychological symptoms. Participants had higher mean pain duration, and average pain severity scores, than those observed in cohorts attending multidisciplinary pain clinics.[45] Similarly, average scores for depression, anxiety, and stress according to the DASS, were all in the 'severe' range, and higher than mean scores observed in a large Australian pain clinic cohort.[45] Potentially, such

observations were not surprising given 71% of our sample identified as refugees. However, in the context of severe depression, the efficacy of rehabilitation programs for chronic pain programs is known to be reduced.[46] As such, the physiotherapy approaches employed in our study might be insufficient to induce meaningful changes in pain and psychosocial functioning. While the individualised design of both treatment arms allowed for the involvement of other specialities, such as psychology, participants did not pursue this recommendation in 85% of cases. Such low uptake, in combination with high pain and psychological symptom scores, emphasises a need for treatment adaptations to engage other disciplines and align comprehensive multidisciplinary approaches with the beliefs, values, and unique needs of diverse ethnocultural communities. However, the maintained high adherence and attendance data for the culturally adapted group in the presence of high pain scores and psychological symptoms was a positive finding.

Feasibility

Previous research involving CALD communities has identified significant challenges in engagement and retention in clinical research.[47] Williams et al[48] enrolled and randomised 78 participants from 3 CALD backgrounds (Greek, Italian, and Vietnamese) living with chronic disease to a medication self-management program and found less than half completed the post-treatment reassessment (3-months). Similarly, Swerissen et al[49] found a 35% drop-out rate among CALD communities in Australia enrolled to a chronic disease self-management program. Despite this, our experience supports research inclusive of, and specifically targeted towards, CALD communities. Our high recruitment rates, short recruitment time, absence of adverse outcomes, and low trial drop-out rate of 6%, supports the feasibility of implementing

randomised controlled research trial designs within CALD communities. Specific attention should be given towards involvement of bilingual support workers, professional translation and interpreting services, and engagement of ethnocultural community members in trial design and implementation, to optimise the prospects of the success of our pilot study.[10] Finally, sample size estimates using our pilot data inform the feasibility of a fully powered RCT to evaluate the clinical effectiveness of culturally adapted approaches, with the potential to maintain participant engagement.

Study Limitations

While the 'culturally adapted' program was successfully piloted across the 3 ethnocultural communities, it is important to note the study's limitations. First, participant adherence data relied on self-report. A log book was developed to facilitate recording of adherence, but many participants (15/48) had difficulty completing and/or did not complete the log-book. As such self-report during sessions was used, and therefore data could have been compromised by recall error, or desire to please the treatment provider.[50] This is a challenge for researchers working with CALD communities who have linguistic limitations, with a need for find reliable, valid measures for recording patient adherence to address such issues. Second, some participants with low education and literacy levels (33% of the sample had either no or primary level schooling) were challenged by the log book and scale outcome measures, potentially compromising results. However, the challenge of literacy was similar for both groups and is unlikely to explain any between-group differences because all participants were provided with assistance from the bilingual blinded assessor to interpret and complete outcome measures. Third, 44% of participants were potentially unblinded, based on their responses to the participant

blinding question. However, since the difference between the two treatment arms ('culturally adapted' versus 'usual physiotherapy') and study hypothesis was not disclosed to participants, it is unlikely that this substantially influenced their treatment outcomes. Fourth, since there was no follow-up beyond treatment conclusion, we cannot report the sustainability of treatment gains. Thus, there is a need for longer-term outcomes. Finally, current results only relate to the 3 ethnocultural communities of interest and are not generalizable to broader CALD communities within Australia or internationally. Nonetheless, improved engagement by all 3 communities highlights that treatment approaches can be effectively adapted to suit individual communities, using a structured adaptation framework[22].

Conclusions

To meet the needs of multicultural populations, interventions should be tailored to the individual, social, and ethnocultural factors that influence health. Novel interventions, such as the culturally adapted physiotherapy approaches documented in this study, are likely to be critical for the development of effective pain management approaches that fully engage CALD patients with chronic pain.

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Author contribution

All authors have made a substantial contribution to this work. Conception, design, analysis and interpretation of data were completed by BB under the supervision of IV, SS and LC. All authors were involved in interpretation of the data, writing and editing of the manuscript. All authors have read and approved the final manuscript.

Data Sharing

Data are available by contacting the corresponding author at Bernadette.brady@health.nsw.gov.au.

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Figure 1 Flow diagram of the study following Consolidated Standards of Reporting Trial guidelines.

Table 1 Participant Baseline Demographic and Symptom Characteristics

	Culturally adapted (n = 24)	Usual Care (n = 24)
Age (years)	55 (10.0)	54 (10.9)
Sex, (n) Male: Female	5:19	4:20
Length of time in Australia, years	15.5 (12.9)	14.0 (10.1)
Migration circumstances		
Voluntary migrant, n (%)	6 (25%)	8 (33%)
Refugee, n (%)	18 (75%)	16 (67%)
Marital status - Married n (%)	16 (67%)	18 (75%)
Level of education		
No school or primary, n	9 (38%)	7 (29%)
Secondary, n	13 (54%)	13 (54%)
Tertiary, n	2 (8%)	4 (17%)
Duration of Pain (years)	10.0 (7.9)	8.5 (7.3)
Work status		
Full or part-time work, n	1 (4%)	2 (8.3%)
Unemployed due to pain, n	18 (75%)	18 (75%)
Retired, n	2 (8%)	2 (8.3%)
Other, n	3 (13%)	2 (8.3%)
Receiving pension or benefit, n (%)	23 (96%)	22 (92%)
Mean classes of pain medication[#] /5	2.08 (0.78)	2.08 (0.72)
BPI (Pain Severity) /10	7.3 (1.8)	7.4 (1.3)
BPI (Pain Interference) /10	7.7 (1.6)	7.1 (1.3)
DASS Sub-scores /42		
Depression	27.6 (12.2)	26.0 (9.8)
Anxiety	23.9 (12.4)	23.5 (10.2)
Stress	26.8 (11.4)	28.8 (8.3)

Pain Suffering (PRISM) /27	3.4 (5.0)	5.2 (6.4)
6MWT	266.8 (142.3)	265.3 (108.7)
1 min STS test	9.6 (6.5)	9.4 (6.9)

Data are presented as mean (±SD) unless otherwise indicated

n = Number of participants % = Percentage within the group

BPI = Brief Pain Inventory DASS = Depression, Anxiety and Stress Scale

6MWT = Six-minute walk test 1 min STS test = 1-minute sit to stand test

PRISM = Pictorial Representation of Illness and Self Measure Separation

[#]Classes included simple analgesics, compound analgesics, anti-inflammatory, anti-convulsant and opioids.

Table 2 Between-group comparison

		ANOVA Time x Group		
	Between-group comparison of change scores Culture – Usual Mean (95% CI)	F (1,46) value	*p value*	partial η^2
BPI Pain Severity	-0.14 (-1.25 to 0.97)^	0.063	0.803	0.001
BPI Pain Interference‡	-0.57 (-1.73 to 0.60)^	0.962	0.332	0.020
Pain-Self Separation‡	3.56 (0.11 to 7.0)	4.322	0.043*	0.086
6MWT (m)	28.44 (-7.40 to 64.28)	2.551	0.117	0.053
STS test (reps)	1.13 (-2.44 to 4.69)	0.405	0.528	0.009
DASS Depression	-2.67 (-9.03 to 3.69)^	0.712	0.403	0.015
DASS Anxiety	-2.0 (-8.28 to 4.28)^	0.411	0.524	0.009
DASS Stress	0.58 (-4.80 to 5.97)^	0.048	0.828	0.001

^Minus score in favour of experimental group **p* is significant at the 0.05 level ‡ Transformed data

BPI: Brief Pain Inventory 6MWT: Six-minute walk test STS test: 1 minute sit to stand test reps: repetitions

DASS: Depression, Anxiety and Stress Scale

Figure 1

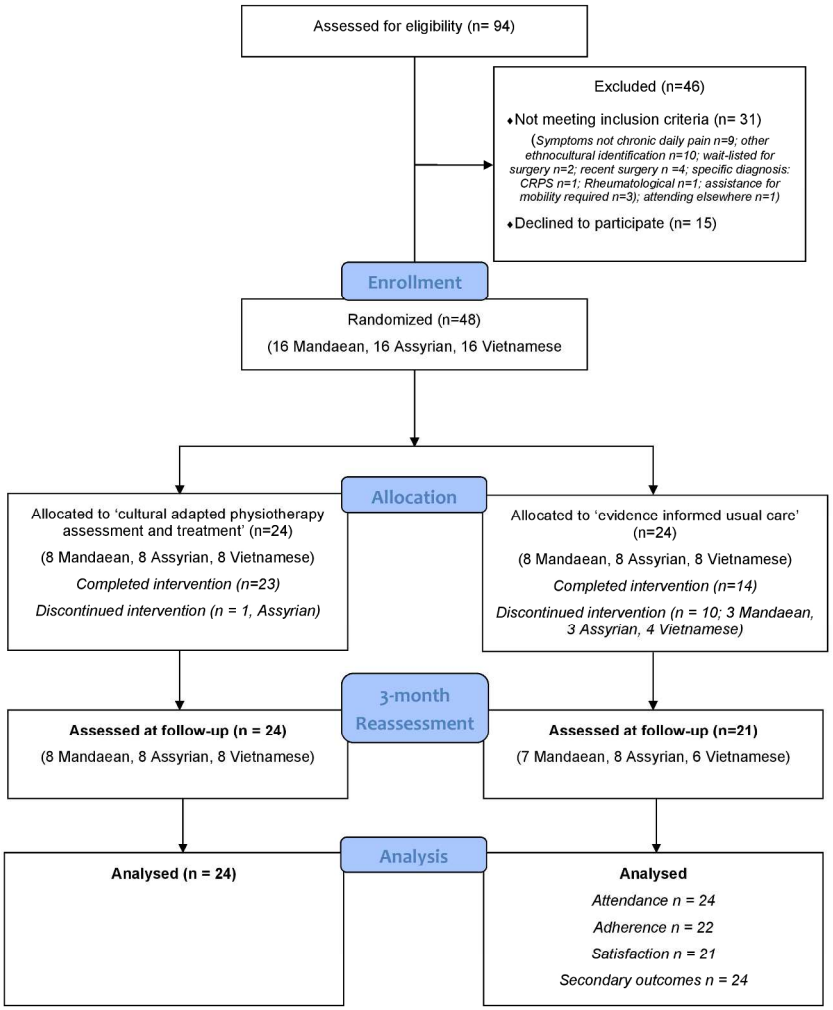

Figure 1 Flow diagram of the study following Consolidated Standards of Reporting Trial guidelines.

215x279mm (300 x 300 DPI)

Appendix One Examples of culturally adapted elements

	Mandaean	Assyrian	Vietnamese
Language	Program content to be delivered in Iraqi Arabic and program materials translated into Arabic and reviewed by a Mandaean community member and health worker.	Program content to be delivered in Assyrian language. Materials translated into Arabic (reflective of the reading/writing language of the Iraqi Assyrian community) and reviewed by an Assyrian community member and health worker.	Program content and materials to be delivered and translated into Vietnamese and reviewed by a Vietnamese community member and health worker.
Persons	Delivered by an Arabic multicultural health worker* and the physiotherapist who developed the culturally adapted approaches, with guest speakers from the Mandaean community.	Delivered by an Assyrian multicultural health worker* and the physiotherapist who developed the culturally adapted approaches with guest speakers from the Assyrian community.	Delivered by a Vietnamese multicultural health worker* and the physiotherapist who developed the culturally adapted approaches with input from the Vietnamese community in traditional health practices.
Metaphors	Water, an important ethnoreligious symbol for Mandaeans, utilised as a metaphor and tool in sessions for rejuvenation of the self and a means of connecting with spiritual supports.	The giving and sharing of food will be integrated into sessions as a metaphor and means for community connectedness and support.	Traditional Vietnamese proverbs incorporated as “take home messages” for each session, providing a means for the sharing of advice in non-confrontational ways.
Content	Culturally specific case examples will be used to communicate concepts such as pacing and graded exposure. Spiritual relaxation methods will be incorporated as part of physical and emotional pain coping strategies. Culturally specific music will be	Culturally specific case examples will be used to communicate concepts of pacing and graded exposure. Traditional Assyrian dance will form the basis for exercise components.	Traditional medicine components will be incorporated into pain reliving strategies. Exercise, activity and pacing will be framed with an emphasis of Am-Duong Harmony. Exercises will be categorised for participants as either Am or Duong and participants

	used to facilitate exercise sessions.		encouraged to focus on achieving balance/harmony with their programs.
Concepts	Biopsychosocial-spiritual theoretical construct underpins the program content, as informed by focus group findings	Biomedical theoretic construct underpins the adaptation of the program content and its delivery to participants, according to the focus group findings.	Traditional Am-Duong Medicine construct underpins the adaptation of the program content and its delivery to participants, according to the focus group findings.
Goals	Focused on fulfilment of traditional cultural roles and expectations. For example, goals for women will focus around ability to fulfil the role of carer and adhere to the Mandaean customs (such as prayer and food preparation customs).	Focused on fulfilment of traditional cultural roles and expectations. For example, goals for women will focus on ability to prepare and share traditional Assyrian food with family, relatives and friends.	Focused on fulfilment of traditional cultural roles and expectations. For example, goals for men will focus on setting an example for the children, building self-management strategies in order to avoid burdening the family or displaying pain.
Methods	Drawing on the strength of the three collectivist communities by encouraging group sharing, bringing family/friends along to the sessions and inviting community members to share their experiences and knowledge. The programs are designed to be delivered in a large community hall or group room that is located central to each community.		
Context	Recognising the social, environmental, political and economic context this community experienced their pain as refugees. Links and references to community support structures such as migrant resource centres, community social programs and other health services.	Recognising the social, environmental, political and economic context this community experienced their pain. Links and references the Assyrian Resource Centre, community social and religious activities and other health services.	Recognising the social, environmental, political and economic context this community experienced their pain. Links to community supports and facilitative programs such as meditation classes and public accessible exercise programs (eg. tai chi).

Table reproduced with permission from Brady et al 2017[22]

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	Page 1, line 2
Authors *	Contact details for the corresponding author	Page 1, lines 17-21
Trial design	Description of pilot trial design (eg, parallel, cluster)	Page 3, line 9
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	Page 3 lines 11-12 and 14-16
Interventions	Interventions intended for each group	Page 3, lines 18-21
Objective	Specific objectives of the pilot trial	Page 3, lines 6-7
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	Page 3, lines 23-24 and page 4, lines 1-2
Randomization	How participants were allocated to interventions	Page 9, lines 11-16
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page 3, line 9
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	Page 3, lines 14; 18-19
Recruitment	Trial status†	N/A
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	Figure 1, Page 14, lines 15-20
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	Page 3, lines 4-10
Harms	Important adverse events or side effects	Page 15, lines 12-13
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	Page 3, lines 12-15
Trial registration	Registration number for pilot trial and name of trial register	Page 3, lines 17-18
Funding	Source of funding for pilot trial	Page 4, lines 10-173

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*
†For conference abstracts.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Page 2, lines 1-2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Page 2-3 and attached checklist
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pages 6-8
	2b	Specific objectives or research questions for pilot trial	Page 8, lines 1-10
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Page 8, lines 14-17 and page 9, lines 12-14
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Page 14, lines 9-20
Participants	4a	Eligibility criteria for participants	Page 9, lines 1-9
	4b	Settings and locations where the data were collected	Page 8, lines 17-19
	4c	How participants were identified and consented	Page 9, lines 2-9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 10-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Page 11, lines 17-23 and

			page 12.
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Page 12, lines 1-13
Sample size	7a	Rationale for numbers in the pilot trial	Page 13, lines 10-15
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 9, lines 12-16
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	Page 9, lines 13
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 9, line 15
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 9, lines 14-16
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 9, lines 15-22
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Page 13 and 14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 1 and page 14-15
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 15, lines 5-13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 14, lines 15-18
	14b	Why the pilot trial ended or was stopped	Page 14-15
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Page 15-16 and Table 1,

			Table 2
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 2
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Page 17, lines 4-14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 15, line 12-13
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Page 21-22
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Page 20-21
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Page 17-21
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Page 20, lines 3-11 Page 21, lines 1-5 Page 21, lines 16-18 Page 22, lines 5-8
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Page 3, lines 17-18
Protocol	24	Where the pilot trial protocol can be accessed, if available	Page 5, lines 5-9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 4, lines 10-17
	26	Ethical approval or approval by research review committee, confirmed with reference number	Page 5, lines 1-3

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Integrating culturally informed approaches into physiotherapy assessment and treatment of chronic pain: a pilot randomised controlled trial

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Keywords:	Cultural diversity, chronic pain, Physical Therapy Speciality, Cultural competency

Title: Integrating culturally informed approaches into physiotherapy assessment and treatment of chronic pain: a pilot randomised controlled trial

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Title: Integrating culturally informed approaches into physiotherapy assessment and treatment of chronic pain: a pilot randomised controlled trial

Abstract

Objective: To evaluate patient engagement with, and the feasibility of, a novel, culturally adapted physiotherapy pain management approach

Design: A participant- and assessor-blinded pilot randomised controlled trial

Setting: Outpatient physiotherapy departments at two public hospitals and one district Pain Clinic.

Participants: Adults (*n*=48) with chronic musculoskeletal pain (daily pain >3-months), who self-identified as Mandaean, Assyrian or Vietnamese, were randomised to one of two physiotherapy treatment conditions.

Interventions: Twenty-four participants underwent combined group and individualised treatment described as 'culturally adapted physiotherapy', while 24 underwent evidence-informed 'usual physiotherapy care'. Both treatment arms consisted of up to 10 sessions over a 3-month period.

Outcome Measures: Patient engagement was measured via participant attendance, adherence, and satisfaction data. Secondary outcomes included clinical measures of

pain severity, interference and suffering; physical function, and negative emotional state.

Results: Ninety-six percent of participants undergoing culturally adapted physiotherapy completed treatment, compared with 58% of the usual physiotherapy group. 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 (79.3 ± 17.3) groups. 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 η^2 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.

Conclusion(s): Aligning treatment with the beliefs and values of CALD communities enhances patient engagement with physiotherapy. These results support the feasibility of a larger, multisite trial to determine if improved engagement with culturally adapted physiotherapy translates to improved clinical outcomes.

Trial Registration: This study was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12616000857404).

Strengths and limitations of this study

- This was a randomised, assessor- and participant- blind controlled trial
- It provides evidence of feasibility of culturally adapted physiotherapy approaches for pain management as explored with three culturally and linguistically diverse communities
- Observed recruitment rates, follow-up rates and preliminary data can inform a future fully powered RCT
- As a pilot study, analysis of clinical outcomes are exploratory.

Funding

This work was supported by the Physiotherapy Research Foundation grant number S16-005. The development of the culturally adapted assessment protocols used in this trial was supported by a South West Sydney Local Health District and Ingham Institute Research Scholarship. BB is the recipient of a Sir Robert Menzies Memorial Research Scholarship in the Allied Health Sciences, from the Menzies Foundation, while SS receives salary support from the National Health and Medical Research Council of Australia (1105040).

Conflict of interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare no conflicts of interest.

Ethical Approval

The study was approved by the South West Sydney Local Health District (SWSLHD) Human Research Ethics Committee (HREC/16/LPOOL/194) and Western Sydney University Human Research Ethics Committee (RH11741).

Original protocol for the study

Brady B, Veljanova I, Schabrun S, et al. Integrating culturally informed approaches into the physiotherapy assessment and treatment of chronic pain: protocol for a pilot randomised controlled trial. *BMJ Open* 2017;7(5): http://bmjopen.bmj.com/content/7/5/e014449.

Introduction

Patient engagement is paramount for the delivery of efficient and effective healthcare, reflecting a patients' relationship with the health encounter, such that they participate (attends and adheres) and recognise value in their treatment (satisfaction and treatment completion).[1 2] Research that has evaluated interventions and models of care to enhance patient engagement has provided evidence of success.[2] Whether this is true for culturally and linguistically diverse (CALD) communities remains uncertain.[1] This is problematic because healthcare must be responsive to the comparatively poorer health status observed in many CALD communities.[3] Further, strategies promoting engagement tailored to the needs of CALD communities is vital, particularly given that many countries around the world are now culturally plural societies.

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] Systematic reviews and meta-analyses support the use of culturally adapted treatment for mental health conditions, chronic disease management, cancer screening, and health promotion.[4-8] For example, meta-analyses of mental health interventions demonstrated small to large pooled effect sizes in favour of culturally adapted treatments, compared to usual care.[5 6 9] Despite evidence supporting the use of culturally-adaptive approaches, research is still lacking for many prominent, debilitating conditions, including for chronic pain.[10] As

such, suboptimal health outcomes continue to be observed in patients from CALD communities with chronic pain.

Chronic pain disorders contribute to considerable societal burden and personal suffering.[11] Many physiotherapy interventions for chronic pain, particularly exercise based approaches, are safe and effective.[12 13] Current evidenced based recommendations suggest that exercise, when combined with cognitive behavioural and psychosocial treatments, reduces pain, improves quality of life, and reduces long term disability.[12 14] However, the efficacy of these approaches has been established in populations speaking the same language, with few studies including CALD and migrant communities.[10] The limited research inclusive of CALD communities suggests limited efficacy for pain, quality of life and psychological health outcomes.[10] Such uncertainty supports investigation of sociocultural factors that could influence implementation of pain management approaches within CALD communities.[15]

Successful management of chronic pain requires a strong therapeutic alliance and patient acceptance of, and engagement with, treatment concepts.[16 17] Unfortunately, engagement with activity based treatments is often suboptimal in CALD communities, evidenced by lower attendance, reduced acceptance, and premature drop-out from treatment.[10 18] Discordant expectations, low patient-provider alliance, cultural-spiritual factors and communication problems have been cited as contributors to suboptimal engagement for CALD communities.[19 20] 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 backgrounds.[21-23] Since engagement with treatment underpins improved patient outcomes,[24] it is imperative that strategies are implemented to optimise engagement by CALD populations for costly and debilitating conditions, such as chronic pain.

Thus, the aim of this pilot study was to determine the feasibility, patient engagement, and trends of clinical effectiveness of a culturally adapted physiotherapy assessment and treatment approach compared with evidence informed 'usual physiotherapy care'. Thus, the research questions for this pilot randomised trial were:

1. Is a 12 week culturally adapted treatment approach superior to 'usual physiotherapy care', in terms of patient engagement (adherence, attendance, and satisfaction)?
2. Is it feasible to deliver and evaluate culturally adapted physiotherapy assessment and treatment approaches across three CALD communities using a randomised controlled trial design?

Methods

Design

This was a prospective, multi-centre pilot randomized controlled trial with concealed allocation, and participant and assessor blinding, using a patient sample with chronic pain drawn from 3 CALD communities (Mandaean, Assyrian and Vietnamese). The trial was conducted across 2 hospital-based physiotherapy departments and one district Pain Clinic, between July 2016 and June 2017. A study protocol with eligibility criteria and intervention descriptions was published previously.[22] The study was

approved by the South West Sydney Local Health District (SWSLHD) Human Research Ethics Committee (HREC/16/LPOOL/194), Western Sydney University Human Research Ethics Committee (RH11741) and was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12616000857404).

Participants and Recruitment

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 phases[15] and guided processes in this RCT, ensuring the research team were cognisant of the communities 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 and who was bilingual or used the services of an accredited health language interpreter. 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. This resulted in 48 participants randomised into the study. Inclusion criteria were: adult (≥18 years), non-specific musculoskeletal pain, daily pain of greater than three months' duration, self-identification as a member of the Mandaean, Assyrian or Vietnamese ethnocultural communities, and ability to provide written informed consent in their own language or English. Exclusion criteria were: specific diagnoses necessitating other treatment (i.e. complex regional pain syndrome), surgery within the last 3-months, and assistance for mobility other than a walking stick, to ensure safety during a group or home-based exercise program.

Sixteen participants from each community were allocated randomly to the experimental or control group after baseline assessment (Figure 1). 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 sequences. These envelopes were managed securely by a central administrative officer responsible for randomising participants and arranging relevant appointments once a participant had been consented. Participants were blind to treatment allocation and were told the trial was comparing two physiotherapy approaches for chronic pain and it was unknown which was more effective. Thus, participants were unaware they were receiving culturally adapted treatment approaches for the experimental groups. The success of blinding was assessed at the 3-month re-assessment with the question; "Do you think your

physiotherapist has been trained in culturally responsive treatments for chronic pain?".

Intervention

Participants from Intervention and Control groups attended for a maximum of 10 sessions of physiotherapy over a 3-month treatment period. A maximum of '10' sessions was selected to enable the treating physiotherapist to tailor interventions to the individual needs of participants, and was consistent with the average number of physiotherapy sessions reported in clinical trials for the management of chronic pain.[13 14] All participants were given a home exercise program designed by their physiotherapist, and they were provided with translated log-books to facilitate recording of exercise adherence. A professional health interpreter was available for all treatment sessions (group and individual), if required, in accordance with best practice.

i. Culturally adapted physiotherapy assessment and treatment

Participants received a combination of group and individual physiotherapy sessions, adapted to reflect the ethnocultural beliefs and values of the community to which the participant identified. Three ethnocultural-specific group programs were designed by the research team, informed by qualitative research involving each community and guided by two adaptation frameworks.[15 25] Sessions were delivered once per week for 6-weeks, included a combination of education and exercise, and were conducted in groups of 8 participants from the same ethnocultural community. Sessions were run by a physiotherapist at a local community facility, and facilitated by a bilingual

educator in the language of participants. In addition, group sessions were supplemented by up to 4 individual sessions tailored to the participant according to the culturally-informed initial assessment to ensure consistency with the dose of the control group. Components of the cultural adaptation for each ethnocultural community have been previously published and a summary is presented in Appendix 1.[25]

ii. Evidence informed 'usual physiotherapy care'

Participants allocated to this condition attended physiotherapy in the outpatient department where they were referred, for treatment informed by evidence based recommendations for chronic pain. All treating physiotherapists underwent a training session to familiarise them with evidence-based management of chronic pain. Treatment adherence to these guidelines was monitored by review of therapist treatment logs. Treating physiotherapists used their clinical judgement to guide the specifics of treatment according to principles of patient-centred care.[26] Following the initial assessment, physiotherapists worked with patients to select the treatment mode (individual or group based), frequency and dose (to a maximum of 10 sessions) tailored to the patient's needs and goals, consistent with best available evidence.[13 27] 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]

Outcomes

Trained assessors, not involved in the recruitment or treatment of participants and unaware of group assignment, performed assessments according to standardised

instructions at baseline (Month 0), and 3-month reassessment). Success of assessor blinding was determined with the question; “Did you know to which treatment arm the participant belonged?” If an assessor responded “yes”, they were asked to nominate; “to which group?”.

Data to assess feasibility were collected throughout the trial period regarding recruitment rates, treatment withdrawals, therapist fidelity to evidence-based guidelines, success of participant and assessor blinding, and trial drop-outs. Primary outcome measures were: measures of patient engagement, defined by attendance; and adherence to, and satisfaction with treatment. Attendance was measured as the proportion of sessions attended, relative to the number of sessions scheduled. Adherence was calculated as a percentage of the average number of home exercise sessions completed each week, relative to the number of sessions prescribed, determined from participant log-books or self-report (where the participant was unable or did not complete the log-book).[28] Patient satisfaction with treatment was evaluated using the Client Satisfaction Questionnaire (CSQ-8),[29] which evaluates satisfaction with treatment generally, and was selected because it validated in Arabic and Vietnamese.

Secondary outcomes included core measures recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).[30] This included measures for pain severity and interference (Brief Pain Inventory: BPI),[31] pain-related suffering (Pictorial Representation of Illness and Self Measure: PRISM),[32] physical function (6-minute walk test: 6MWT, and 1 minute sit to stand test: STS test)[33 34] and severity of symptoms for Depression, Anxiety, and Stress

(DASS-21).[35] The reliability and validity of these measures, including for Arabic and Vietnamese translations, has been reported previously and was documented in the trial protocol.[25]

Patient involvement

The research questions were developed following qualitative enquiry into the experience of chronic pain among CALD communities.[15] Specifically, challenges raised by participants accessing and participating in pain management in South-West Sydney were incorporated in the study design. As such, participant engagement was considered a primary outcome measure. While patients were not involved in the recruitment and conduct of the study, all participants were given the opportunity to attend a feedback session following trial completion, held in local community venues.

Sample Size and Statistical Analysis

A total sample of 48 participants was deemed appropriate to allow the piloting of a novel culturally adapted program with 3 communities (8 participants per program), while ensuring equal numbers in both treatment arms (24 culturally adapted and 24 usual care) and allowing for the detection of medium to large effects (effect sizes of 0.5-0.8), should they exist.[36 37]

Descriptive statistics were used to report the characteristics of participants, including means and standard deviations (SDs) for continuous variables, and frequencies and proportions (%) for categorical variables. Primary outcome measures (attendance, adherence and satisfaction) were evaluated using descriptive statistics and Mann-

Whitney U tests, because data were not normally distributed and transformations did not achieve normality. Effect sizes for non-parametric tests were reported using *r* and interpreted as large (0.5), medium (0.3) and small (0.1).[38]

Exploratory examination for group differences in secondary outcome measures was undertaken using a repeated-measures analysis of variance (ANOVA), with the treatment condition (usual care/culturally adapted intervention) as the between-group factor, and time of assessment (pre-intervention or re-assessment) as the repeated, within-group factor. One-way repeated measures ANOVAs compared within-group main effects at each time point. Effect sizes were classified as small, medium or large (partial η^2 0.01, 0.06, 0.14, respectively).[39] If the assumptions of ANOVA were violated, data were transformed to achieve a normal distribution[40] before repeating the ANOVA. Intention-to treat analyses were performed for all participants and missing data were addressed by carrying the last data point forward.[41] Analyses were performed using the Statistical Package for the Social Sciences, Version 24.

Results

Feasibility and treatment characteristics

Forty-eight participants, 16 from each ethnocultural community, were randomised within 4 months (Figure 1). 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 log-book. On average, 3 individual sessions were recommended to supplement the 6 group sessions (range 1-4). One participant discontinued treatment prematurely, citing illness. For the usual care arm, 14 participants

completed the treatment they were allocated. Ten participants withdrew from treatment citing reasons that included illness (*n*=1), treatment not helping (*n*=4), lack of time (*n*=1), and changed mind/ sought care elsewhere (*n*=4). Treating physiotherapists in the usual care arm utilised both group and individual modes of delivery for 8/24 participants, while individual therapy alone was recommended for 16 participants. 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. Therapist fidelity to evidence based principles was confirmed for all participants, except for the two participants who withdrew following their initial assessment.

Blinded re-assessment data were available for 45 participants, with 3 participants (usual care group) withdrawing from the trial and declining final assessment for similar reasons: “treatment has not helped me”, “treatment has not done anything to help my leg pain at all”, and “treatment has been a waste of time”. As such, the last data point for each was carried forward for all outcomes except satisfaction, for which an initial data point was not available. Success rates for assessor blinding was 91%, while 44% of participants correctly answered the blinding question regarding their therapists’ cultural responsiveness. No participant experienced an adverse event due to participation in the trial.

Demographic and baseline symptom characteristics of participants are displayed in Table 1. There were no significant differences between the groups for baseline characteristics.

Primary outcomes

Attendance

Overall mean (±SD) attendance at physiotherapy was 8.0 ±3.1 visits. The culturally adapted treatment group attended a higher number of scheduled sessions compared to 'usual physiotherapy care' (mean difference = 4.0 sessions, 95%CI 2.6 to 5.3). 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).

Home Exercise Adherence

Home exercise adherence data was available for all participants in the culturally adapted program (n=24) and 22 participants from the usual care group. Data were absent for 2 participants who dropped out after their initial visit. Overall, adherence varied from 0% to 100%. 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), consistent with a moderate between group effect size (U=145, r=0.39).

Satisfaction

Satisfaction data were available for all participants who attended the 3-month blinded assessment (*n*=45). Overall, 93% of participants were satisfied with treatment, and 71% were highly satisfied, evaluated by a score of greater than 50% and 75%, respectively for the CSQ-8. Satisfaction between the two groups did not differ. Mean CSQ-8 scores for the culturally adapted and usual physiotherapy care groups were 82.7 (±13.4) and 79.3 (±17.3).

Secondary Outcomes

Culturally adapted treatment resulted in greater improvements in pain related suffering than 'usual physiotherapy care', with a medium effect size observed (partial η^2 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 η^2 0.02) and 6MWT (partial η^2 0.053), while no effect was observed for BPI pain severity, STS test or the DASS-21 (Table 2).

Sample size estimates

With respect to feasibility for a larger trial based on trial data, for power of 80%, alpha of 5%, and a drop-out rate of 20%, a sample size of 124 in each group would be required to detect a clinically significant difference of 50m for walking distance [42] for the intervention group, based on the SD observed in our study of 128m. This sample size would also be sufficient to identify between-group differences for the BPI Severity (2.2-point difference, SD 2.51) and Interference subscales (2.2-point difference, SD 2.55), the PRISM suffering score (3.3 cm difference, SD 8.46) and the DASS total score (13-point difference, SD 31.88). A sample size of 300 would also

allow for clinically important between-group differences to be detected for the 1-minute STS test (3 repetition difference, SD 8.46).

Discussion

The culturally adapted program was designed to target specific language, cultural, and access barriers faced by CALD communities that participate in pain management treatments. Results from this pilot study suggest there is an advantage in favour of a culturally adapted physiotherapy program relative to usual physiotherapy care for addressing barriers to optimal patient engagement. The culturally adapted programs were well-received by all 3 communities, demonstrated by significantly higher patient engagement (attendance, completion of treatment, and adherence) compared to the usual care group. 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 are 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-disciplinary.[43-45] 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.

Attendance and treatment retention is an important aspect of patient engagement essential to ensure positive outcomes from cognitive behavioural and exercise

treatments for chronic pain are realised.[16 17] Despite this, drop-out from pain management programs has been reported to be as high as 40%[46], while for exercise-based physiotherapy, drop-out rates of 30-40% are common.[47 48] In the current study, drop-out rates in the 'usual physiotherapy care' group (42%) were consistent with rates observed in the literature[18 47 48], while for the 'culturally adapted' group, drop-out was less (4%). Further, attendance at scheduled sessions was higher in the 'culturally adapted' group, and participants were willing to attend for a greater number of sessions. In combination, such findings suggest that attention to social and ethnocultural dimensions unique to CALD migrant communities successfully engaged participants. 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 outcomes.[49 50] As such broad multidimensional adaptations should be considered in future research.

Treatment adherence is an aspect of patient engagement that has been positively related to patient outcomes in rehabilitation programs.[17] Nevertheless, adherence to exercise interventions for chronic pain conditions is suboptimal.[51] For example, adherence rates for osteoarthritis exercise programs can be as low as 50%[52], and varies between 64% and 71% respectively, for neck pain and low back pain.[51 53] For

the current study, there was wide variation in adherence rates for the 'usual care' group with a mean of 55% (±43), while for the 'culturally adapted' group, adherence was significantly higher and less variable (88% ±15). Low adherence rates in the 'usual care' group could have been due to suboptimal communication, patient-provider interactions, and failure to adequately tailor interventions to the sociocultural needs of the individual patient.[54] Further, a systematic review[28] cited the association between anxiety and depression, highly prominent symptoms in our sample, with reduced adherence to physiotherapy. However, since both treatment arms experienced similar symptoms, this association alone, does not account for the different adherence rates observed. Similarly, the low adherence rate for the 'usual care' group could not be ascribed to language barriers, since both groups had similar access to professional interpreting services and translated exercise diaries. Instead, the current findings emphasise a potential role for physiotherapists to optimise the inter-cultural therapeutic interaction by attending to a patient's beliefs and values, and aligning treatment components accordingly.

Baseline outcome data from the three CALD communities highlighted participants' severe pain and psychological symptoms. Participants had higher mean pain duration, and average pain severity scores, than those observed in cohorts attending multidisciplinary pain clinics.[55] Similarly, average scores for depression, anxiety, and stress according to the DASS, were all in the 'severe' range, and higher than mean scores observed in a large Australian pain clinic cohort.[55] Potentially, such observations were not surprising given 71% of our sample identified as refugees. However, in the context of severe depression, the efficacy of rehabilitation programs for chronic pain programs is known to be reduced.[56] As such, the physiotherapy

approaches employed in our study might be insufficient to induce meaningful changes in pain and psychosocial functioning. While the individualised design of both treatment arms allowed for the involvement of other specialities, such as psychology, participants did not pursue this recommendation in 85% of cases. Such low uptake, in combination with high pain and psychological symptom scores, emphasises a need for treatment adaptations to engage other disciplines and align comprehensive multidisciplinary approaches with the beliefs, values, and unique needs of diverse ethnocultural communities. However, the maintained high adherence and attendance data for the culturally adapted group in the presence of high pain scores and psychological symptoms was a positive finding.

Feasibility

Previous research involving CALD communities has identified significant challenges in engagement and retention in clinical research.[57] Williams et al[58] enrolled and randomised 78 participants from 3 CALD backgrounds (Greek, Italian, and Vietnamese) living with chronic disease to a medication self-management program and found less than half completed the post-treatment reassessment (3-months). Similarly, Swerissen et al[59] found a 35% drop-out rate among CALD communities in Australia enrolled to a chronic disease self-management program. Despite this, our experience supports research inclusive of, and specifically targeted towards, CALD communities. Our high recruitment rates, short recruitment time, absence of adverse outcomes, and low trial drop-out rate of 6%, supports the feasibility of implementing randomised controlled research trial designs within CALD communities. Specific attention should be given towards involvement of bilingual support workers, professional translation and interpreting services, and engagement of ethnocultural

community members in trial design and implementation, to optimise the prospects of the success of our pilot study.[10] 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 feasibility. Finally, sample size estimates using our pilot data inform the feasibility of a fully powered RCT to evaluate the clinical effectiveness of culturally adapted approaches, with the potential to maintain participant engagement.

Study Limitations

While the 'culturally adapted' program was successfully piloted across the 3 ethnocultural communities, it is important to note the study's limitations. First, participant adherence data relied on self-report. A log book was developed to facilitate recording of adherence, but many participants (15/48) had difficulty completing and/or did not complete the log-book. As such self-report during sessions was used, and therefore data could have been compromised by recall error, or desire to please the treatment provider.[60] This is a challenge for researchers working with CALD communities who have linguistic limitations, with a need for reliable, valid measures for recording patient adherence to address such issues. Second, some participants with low education and literacy levels (33% of the sample had either no or primary level schooling) were challenged by the log book and scale outcome

measures, potentially compromising results. However, the challenge of literacy was similar for both groups and is unlikely to explain any between-group differences because all participants were provided with assistance from the bilingual blinded assessor to interpret and complete outcome measures. Third, 44% of participants were potentially unblinded, based on their responses to the participant blinding question. However, since the difference between the two treatment arms ('culturally adapted' versus 'usual physiotherapy') and study hypothesis was not disclosed to participants, it is unlikely that this substantially influenced their treatment outcomes. Fourth, since there was no follow-up beyond treatment conclusion, we cannot report the sustainability of treatment gains. Thus, there is a need for longer-term outcomes. Finally, current results only relate to the 3 ethnocultural communities of interest and are not generalizable to broader CALD communities within Australia or internationally. Nonetheless, improved engagement by all 3 communities highlights that treatment approaches can be effectively adapted to suit individual communities, using a structured adaptation framework.[25]

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 relationship.[61 62] As such, cultural concordance and healthcare provider cultural responsiveness are factors that may have influenced treatment outcomes.[63] 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 outcomes.[64]

Conclusions

To meet the needs of multicultural populations, interventions should be tailored to the individual, social, and ethnocultural factors that influence health. Novel interventions, such as the culturally adapted physiotherapy approaches documented in this study, are likely to be critical for the development of effective pain management approaches that fully engage CALD patients with chronic pain.

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Author contribution

All authors have made a substantial contribution to this work. Conception, design, analysis and interpretation of data were completed by BB under the supervision of IV, SS and LC. All authors were involved in interpretation of the data, writing and editing of the manuscript. All authors have read and approved the final manuscript.

Data Sharing

Data are available by contacting the corresponding author at Bernadette.brady@health.nsw.gov.au.

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Figure 1 Flow diagram of the study following Consolidated Standards of Reporting Trial guidelines.

Table 1 Participant Baseline Demographic and Symptom Characteristics

	Culturally adapted (n = 24)	Usual Care (n = 24)
Age (years)	55 (10.0)	54 (10.9)
Sex, (n) Male: Female	5:19	4:20
Length of time in Australia, years	15.5 (12.9)	14.0 (10.1)
Migration circumstances		
Voluntary migrant, n (%)	6 (25%)	8 (33%)
Refugee, n (%)	18 (75%)	16 (67%)
Marital status - Married n (%)	16 (67%)	18 (75%)
Level of education		
No school or primary, n	9 (38%)	7 (29%)
Secondary, n	13 (54%)	13 (54%)
Tertiary, n	2 (8%)	4 (17%)
Duration of Pain (years)	10.0 (7.9)	8.5 (7.3)
Work status		
Full or part-time work, n	1 (4%)	2 (8.3%)
Unemployed due to pain, n	18 (75%)	18 (75%)
Retired, n	2 (8%)	2 (8.3%)
Other, n	3 (13%)	2 (8.3%)
Receiving pension or benefit, n (%)	23 (96%)	22 (92%)
Mean classes of pain medication[#] /5	2.08 (0.78)	2.08 (0.72)
BPI (Pain Severity) /10	7.3 (1.8)	7.4 (1.3)
BPI (Pain Interference) /10	7.7 (1.6)	7.1 (1.3)
DASS Sub-scores /42		
Depression	27.6 (12.2)	26.0 (9.8)
Anxiety	23.9 (12.4)	23.5 (10.2)
Stress	26.8 (11.4)	28.8 (8.3)
Pain Suffering (PRISM) /27	3.4 (5.0)	5.2 (6.4)
6MWT	266.8 (142.3)	265.3 (108.7)

1 min STS test	9.6 (6.5)	9.4 (6.9)

Data are presented as mean (±SD) unless otherwise indicated

n = Number of participants % = Percentage within the group

BPI = Brief Pain Inventory DASS = Depression, Anxiety and Stress Scale

6MWT = Six-minute walk test 1 min STS test = 1-minute sit to stand test

PRISM = Pictorial Representation of Illness and Self Measure Separation

[#]Classes included simple analgesics, compound analgesics, anti-inflammatory, anti-convulsant and opioids.

Table 2 Between-group comparison

	ANOVA Time x Group	
	Between-group comparison of change scores Culture – Usual Mean (95% CI)	F (1,46) value	partial η^2
BPI Pain Severity	-0.14 (-1.25 to 0.97)^	0.063	0.001
BPI Pain Interference‡	-0.57 (-1.73 to 0.60)^	0.962	0.020
Pain-Self Separation‡	3.56 (0.11 to 7.0)	4.322	0.086
6MWT (m)	28.44 (-7.40 to 64.28)	2.551	0.053
STS test (reps)	1.13 (-2.44 to 4.69)	0.405	0.009
DASS Depression	-2.67 (-9.03 to 3.69)^	0.712	0.015
DASS Anxiety	-2.0 (-8.28 to 4.28)^	0.411	0.009
DASS Stress	0.58 (-4.80 to 5.97)^	0.048	0.001

^Minus score in favour of experimental group

‡ Transformed data

BPI: Brief Pain Inventory

6MWT: Six-minute walk test

STS test: 1 minute sit to stand test reps: repetitions

DASS: Depression, Anxiety and Stress Scale

Figure 1

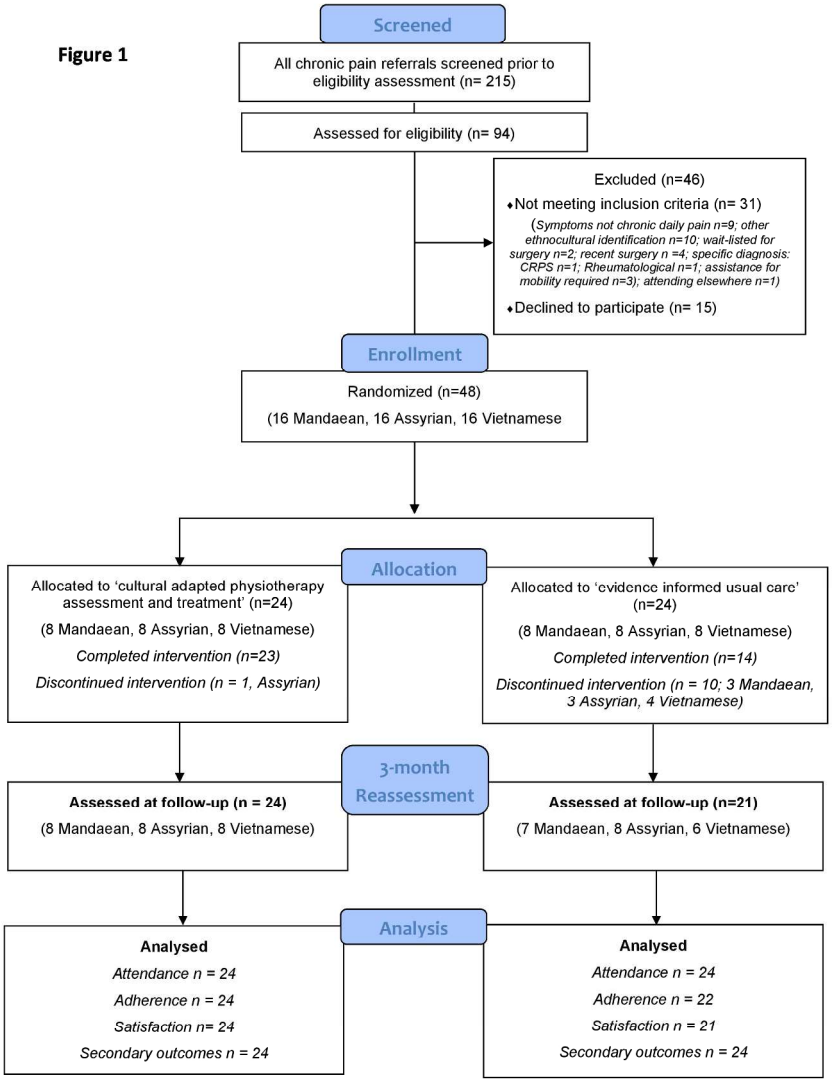

Figure 1 Flow diagram of the study following Consolidated Standards of Reporting Trial guidelines.

215x279mm (300 x 300 DPI)

Appendix One Examples of culturally adapted elements

	Mandaean	Assyrian	Vietnamese
Language	Program content to be delivered in Iraqi Arabic and program materials translated into Arabic and reviewed by a Mandaean community member and health worker.	Program content to be delivered in Assyrian language. Materials translated into Arabic (reflective of the reading/writing language of the Iraqi Assyrian community) and reviewed by an Assyrian community member and health worker.	Program content and materials to be delivered and translated into Vietnamese and reviewed by a Vietnamese community member and health worker.
Persons	Delivered by an Arabic multicultural health worker* and the physiotherapist who developed the culturally adapted approaches, with guest speakers from the Mandaean community.	Delivered by an Assyrian multicultural health worker* and the physiotherapist who developed the culturally adapted approaches with guest speakers from the Assyrian community.	Delivered by a Vietnamese multicultural health worker* and the physiotherapist who developed the culturally adapted approaches with input from the Vietnamese community in traditional health practices.
Metaphors	Water, an important ethnoreligious symbol for Mandaeans, utilised as a metaphor and tool in sessions for rejuvenation of the self and a means of connecting with spiritual supports.	The giving and sharing of food will be integrated into sessions as a metaphor and means for community connectedness and support.	Traditional Vietnamese proverbs incorporated as “take home messages” for each session, providing a means for the sharing of advice in non-confrontational ways.
Content	Culturally specific case examples will be used to communicate concepts such as pacing and graded exposure. Spiritual relaxation methods will be incorporated as part of physical and emotional pain coping	Culturally specific case examples will be used to communicate concepts of pacing and graded exposure. Traditional Assyrian dance will form the basis for exercise components.	Traditional medicine components will be incorporated into pain reliving strategies. Exercise, activity and pacing will be framed with an emphasis of Am-Duong Harmony. Exercises will be categorised for participants as either Am or Duong and participants

	strategies. Culturally specific music will be used to facilitate exercise sessions.		encouraged to focus on achieving balance/harmony with their programs.
Concepts	Biopsychosocial-spiritual theoretical construct underpins the program content, as informed by focus group findings	Biomedical theoretic construct underpins the adaptation of the program content and its delivery to participants, according to the focus group findings.	Traditional Am-Duong Medicine construct underpins the adaptation of the program content and its delivery to participants, according to the focus group findings.
Goals	Focused on fulfilment of traditional cultural roles and expectations. For example, goals for women will focus around ability to fulfil the role of carer and adhere to the Mandaean customs (such as prayer and food preparation customs).	Focused on fulfilment of traditional cultural roles and expectations. For example, goals for women will focus on ability to prepare and share traditional Assyrian food with family, relatives and friends.	Focused on fulfilment of traditional cultural roles and expectations. For example, goals for men will focus on setting an example for the children, building self-management strategies in order to avoid burdening the family or displaying pain.
Methods	Drawing on the strength of the three collectivist communities by encouraging group sharing, bringing family/friends along to the sessions and inviting community members to share their experiences and knowledge. The programs are designed to be delivered in a large community hall or group room that is located central to each community.		
Context	Recognising the social, environmental, political and economic context this community experienced their pain as refugees. Links and references to community support structures such as migrant resource centres, community social programs and other health services.	Recognising the social, environmental, political and economic context this community experienced their pain. Links and references the Assyrian Resource Centre, community social and religious activities and other health services.	Recognising the social, environmental, political and economic context this community experienced their pain. Links to community supports and facilitative programs such as meditation classes and public accessible exercise programs (eg. tai chi).

Table reproduced with permission from Brady et al 2017[22]

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Page 2, lines 1-2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Page 2-3 and attached checklist
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pages 6-8
	2b	Specific objectives or research questions for pilot trial	Page 8, lines 1-10
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Page 8, lines 14-17 and page 9, lines 12-14
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Page 14, lines 9-20
Participants	4a	Eligibility criteria for participants	Page 9, lines 1-9
	4b	Settings and locations where the data were collected	Page 8, lines 17-19
	4c	How participants were identified and consented	Page 9, lines 2-9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 10-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Page 11, lines 17-23 and

			page 12.
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Page 12, lines 1-13
Sample size	7a	Rationale for numbers in the pilot trial	Page 13, lines 10-15
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 9, lines 12-16
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	Page 9, lines 13
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 9, line 15
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 9, lines 14-16
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 9, lines 15-22
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Page 13 and 14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 1 and page 14-15
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 15, lines 5-13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 14, lines 15-18
	14b	Why the pilot trial ended or was stopped	Page 14-15
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Page 15-16 and Table 1,

			Table 2
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 2
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Page 17, lines 4-14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 15, line 12-13
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Page 21-22
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Page 20-21
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Page 17-21
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Page 20, lines 3-11 Page 21, lines 1-5 Page 21, lines 16-18 Page 22, lines 5-8
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Page 3, lines 17-18
Protocol	24	Where the pilot trial protocol can be accessed, if available	Page 5, lines 5-9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 4, lines 10-17
	26	Ethical approval or approval by research review committee, confirmed with reference number	Page 5, lines 1-3

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	Page 1, line 2
Authors *	Contact details for the corresponding author	Page 1, lines 17-21
Trial design	Description of pilot trial design (eg, parallel, cluster)	Page 3, line 9
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	Page 3 lines 11-12 and 14-16
Interventions	Interventions intended for each group	Page 3, lines 18-21
Objective	Specific objectives of the pilot trial	Page 3, lines 6-7
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	Page 3, lines 23-24 and page 4, lines 1-2
Randomization	How participants were allocated to interventions	Page 9, lines 11-16
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page 3, line 9
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	Page 3, lines 14; 18-19
Recruitment	Trial status†	N/A
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	Figure 1, Page 14, lines 15-20
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	Page 3, lines 4-10
Harms	Important adverse events or side effects	Page 15, lines 12-13
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	Page 3, lines 12-15
Trial registration	Registration number for pilot trial and name of trial register	Page 3, lines 17-18
Funding	Source of funding for pilot trial	Page 4, lines 10-173

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.