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Clinical and cost-effectiveness of an online-delivered group-based pain management programme in improving pain-related disability for people with persistent pain—protocol for a non-inferiority randomised controlled trial (iSelf-help trial)

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ABSTRACT

Introduction Persistent non-cancer pain affects one in five adults and is more common in Māori—the Indigenous population of New Zealand (NZ), adults over 65 years, and people living in areas of high deprivation. Despite the evidence supporting multidisciplinary pain management programmes (PMPs), access to PMPs is poor due to long waiting lists. Although online-delivered PMPs enhance access, none have been codesigned with patients or compared with group-based, in-person PMPs. This non-inferiority trial aims to evaluate the clinical and cost-effectiveness of a cocreated, culturally appropriate, online-delivered PMP (iSelf-help) compared with in-person PMP in reducing pain-related disability.

Methods and analysis Mixed-methods, using a modified participatory action research (PAR) framework, involving three phases. Phase I involved cocreation and cultural appropriateness of iSelf-help by PAR team members. Phase II: The proposed iSelf-help trial is a pragmatic, multicentred, assessor-blinded, two-arm, parallel group, non-inferiority randomised controlled trial. Adults (n=180, age ≥18 years) with persistent non-cancer pain eligible for a PMP will be recruited and block randomised (with equal probabilities) to intervention (iSelf-help) and control groups (in-person PMP). The iSelf-help participants will participate in two 60-minute video-conferencing sessions weekly for 12 weeks with access to cocreated resources via smartphone application and a password-protected website. The control participants will receive group-based, in-person delivered PMP. Primary outcome is pain-related disability assessed via modified Roland Morris Disability Questionnaire at 6 months post intervention. Secondary outcomes include anxiety, depression, stress, pain severity, quality of life, acceptance, self-efficacy, catastrophising and fear avoidance. Data will be collected at baseline, after the 12-week intervention, and at 3 and 6 months post intervention. We will conduct economic analyses and mixed-method process evaluations (Phase IIA).

Ethics and dissemination The Health and Disability Ethics Committee approved the study protocol (HDEC18/CEN/162). Phase III involves dissemination of findings guided by the PAR team as outcomes become apparent.

Trial registration number ACTRN 12619000771156.

Strengths and limitations of this study

► The iSelf-help (online-delivered pain management programme (PMP)) is a group-based programme cocreated with people with persistent pain and also with committed and ongoing collaboration with Māori whānau (the Indigenous population of New Zealand (NZ)).

► The pragmatic, non-inferiority randomised controlled trial will evaluate both the clinical and cost-effectiveness of iSelf-help when compared with in-person delivered group PMPs (usual care).

► The modified participatory action research framework provides a model for future studies codeveloping online solutions that can be scalable and potentially address the needs of high-risk populations, such as Indigenous and culturally and linguistically diverse communities living with persistent pain.

► The mixed method process evaluation will explore how components of iSelf-help produce change, the delivery of trial processes and the contextual factors influencing future implementation of iSelf-help in tertiary care and other settings (eg, primary care).

► Using only two of the three major tertiary pain services within NZ as trial sites may limit the national generalisability of the findings.

INTRODUCTION

Chronic or persistent, non-cancer pain is a pervasive public health problem[1] and a leading cause of disability worldwide.[2 3] Persistent pain is one of the most common health conditions in New Zealand (NZ), affecting more than 20% of adult New Zealanders.[4] The increase in persistent pain is partly attributable to the fast growing, ageing population in NZ.[5] Māori adults (the Indigenous population) are 20% more likely than non-Māori adults to report persistent pain.[6] Adults living in areas of high socioeconomic deprivation (22%) and aged over 65 years (28%) are also at higher risk.[4 7] Persistent pain severely impairs health-related quality of life[7] and can have major personal and financial costs.[8] The total cost to the NZ economy of all persistent pain conditions is estimated to be $14.8 billion (in 2016) that should project to $24 billion by 2048.[9] Recognising the escalating socioeconomic burden of persistent pain conditions,[2 3] global efforts have been advocating for integrated health policy and system changes.[10]

Multidisciplinary, pain management programmes (PMPs), including group-based PMPs have been found to be more effective in improving pain-related functioning than usual care.[11 12] Such programmes comprise cognitive behavioural therapy (CBT)-based interventions that include mindfulness and acceptance-based approaches[13] to foster development of self-management skills, such as reflection, goal setting and problem solving.[14 15] Despite evidence supporting group-based PMPs, access to multidisciplinary pain services is limited both in NZ[16] and globally.[17] Barriers to accessing specialist pain services include a shortage of skilled healthcare providers[17]; long waiting times for referral[18]; limited community-based health services; and geographic barriers and transport costs. For Māori, they include a sense of stigma and stoicism, experiences of institutional racism[19] and restricted access to healthcare.[20] These barriers highlight the need for culturally appropriate, innovative approaches to delivering pain management services.[18]

Online-delivered interventions can become a potential solution for addressing some barriers to accessing pain management services.[21] Online technologies have been shown to be efficient and cost-effective in managing long-term health conditions such as hypertension, diabetes, anxiety and depression at the population-level with a high degree of fidelity.[22] Web-based technologies can accommodate remote clinical support for integrated models of care.[23] A growing number of reviews suggest online-delivered CBT-based interventions have mild to moderate effects in improving pain severity and pain-related disability for those with persistent pain.[24 25]

Few randomised controlled trials (RCTs), however, have investigated the clinical effectiveness of online CBT-based interventions when compared with in-person delivered interventions using a non-inferiority design.[26] Herbert et al[27] found that an 8-week internet-delivered acceptance and commitment therapy was as effective as an in-person delivered intervention in improving pain-related disability

immediately after and at 6 months post intervention, respectively, (Standardised Mean Difference (SMD)=0.22; 95% CI, −0.61 to 1.05; SMD=0.48; 95% CI, −0.39 to 1.35; non-inferiority margin: −1). Similarly, Heapy et al[28] found that CBT-based, interactive voice response treatment was as effective as in-person delivered CBT in improving pain intensity after 3 months (SMD=0.07; 95% CI, 0.67 to 0.80; non-inferiority margin: −1); however, it reported no significant difference in pain-related disability, anxiety and depression outcomes.

As these non-inferiority RCTs enrolled veterans with persistent pain, results are unlikely to be generalisable to all people with persistent pain. More importantly, none of these online-delivered interventions included patient codesign. Lack of person-centred collaboration can minimise the importance of values,[29] such as those arising from culture and health beliefs, which form the basis of understanding the needs of individuals and families.[30–32] Further, no previous studies have investigated the relative effectiveness when compared with online group-based PMPs.[26] Two recent feasibility studies have, however, demonstrated that online-delivered group-based PMPs are feasible in a tertiary pain service setting[33] and can be delivered successfully for people living in rural and remote areas.[34] This justifies further investigation using a non-inferiority trial design.[35 36]

In NZ, two of the three major city-based tertiary pain services run group-based, in-person PMPs. We aim to evaluate the clinical and cost-effectiveness of a cocreated culturally appropriate, group-based, online-delivered intervention (iSelf-help) as compared with an in-person delivered PMP in reducing pain-related disability at 6 months.

The objectives of our proposed non-inferiority trial are:
1. To investigate if iSelf-help is non-inferior in terms of effectiveness to group-based in-person delivered PMP in reducing pain-related disability at 6 months.
2. To investigate non-inferiority in terms of efficacy, the acceptability of iSelf-help and its cost-effectiveness when compared with an in-person PMP.
3. To explore the mechanisms of change of iSelf-help using qualitative and quantitative process evaluation including exploratory mediation analyses.

METHODS
Study design
We used a five-step modified participatory action research (PAR) framework with three phases (figure 1) aimed at developing, evaluating and implementing iSelf-help as a recommended approach for developing rehabilitation interventions.[37]
▶ Phase I was cocreating an online-delivered PMP—iSelf-help. The process of cocreating iSelf-help has been completed. This will be reported in another paper.
▶ Phase II is a non-inferiority RCT evaluating the clinical and cost-effectiveness of iSelf-help.
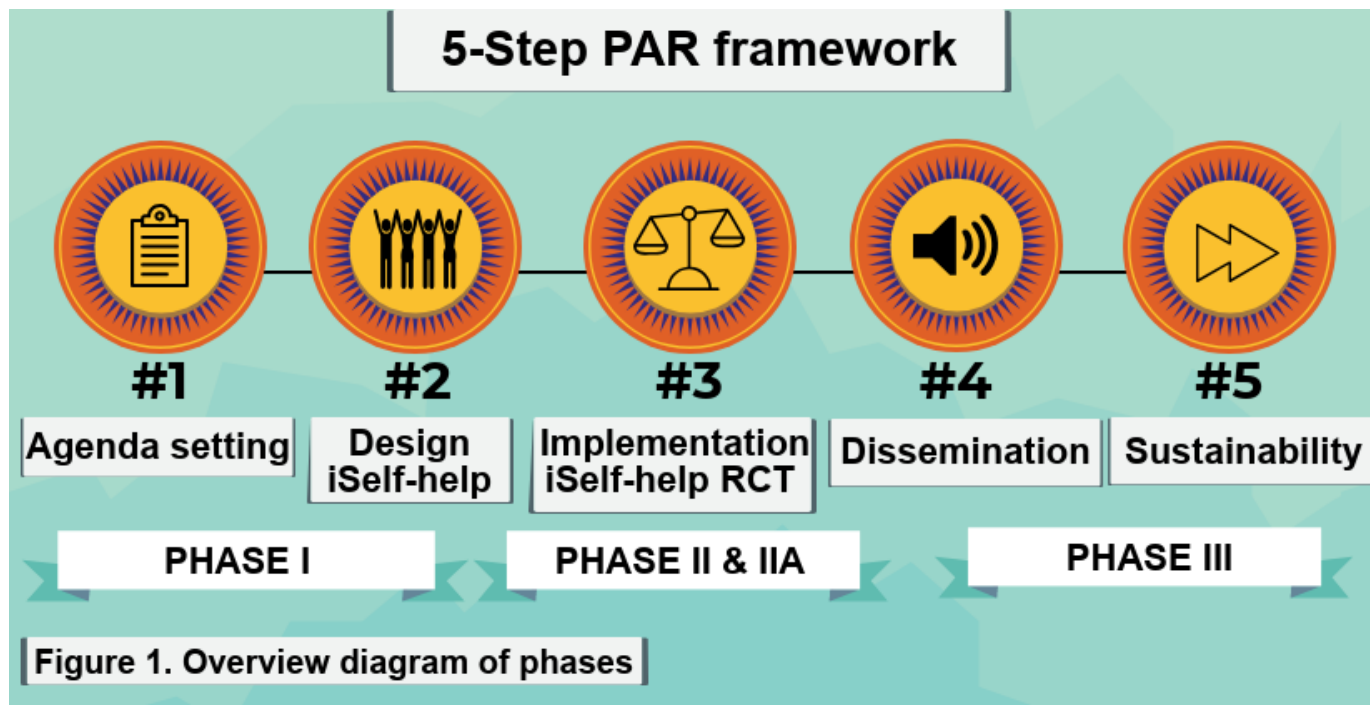
Figure 1 Overview diagram of 5-step modified Participatory Action Research (PAR) framework with three phases.

– Phase IIA is process evaluation embedded within a non-inferiority RCT.
► Phase III is dissemination of study results and planning of iSelf-help implementation.

Phase I: cocreation of an online-delivered PMP (iSelf-help)

We cocreated iSelf-help website and mobile app with our PAR team members. These included a patient advisory group (n=8; 20–60 years of age, 1 man), two pain management service clinicians, two health researchers, two digital health experts and a health literacy expert. The PAR team meetings were held over a period of 9 months to inform content delivery and design features of iSelf-help using a Nominal Group Technique.[38] To ensure the cultural appropriateness of iSelf-help, three focus groups were held with Māori living with persistent pain and their whānau (n=15, 30–70 years of age, 2 men). The focus groups were led by a Māori community manager and two senior Māori researchers. Some selected resources were translated to the Māori language (Te Reo). All participants were provided access to the Beta version. Their feedback was included in the final version of iSelf-help.

Phase II-: the iSelf-help non-inferiority trial
Primary aim

To evaluate non-inferiority in terms of effectiveness of the iSelf-help intervention compared with a group in-person PMP in reducing pain-related disability at 6 months post intervention. We hypothesise that group iSelf-help will not be less effective than a group-based, in-person PMP to a clinically significant extent.

Secondary aims

To assess non-inferiority in term of efficacy and the acceptability of the iSelf-help intervention, and to investigate its cost-effectiveness when compared with an in-person PMP at 6 months post intervention.

Trial design

The iSelf-help trial is a pragmatic, multicentred, assessor-blinded, randomised, two-arm, parallel group, non-inferiority study investigating the effectiveness of an iSelf-help intervention versus group in-person PMP in reducing pain-related disability at 6 months post intervention in persistent non-cancer pain with an embedded process evaluation.

Trial registration

The trial protocol was prospectively registered to the Australia and NZ Clinical Trial Registry in May 2019.

Study setting

Multicentred, conducted at two multidisciplinary tertiary pain services (Wellington and Christchurch) in NZ.

Participants and recruitment strategies

People with persistent, non-cancer pain referred to two major tertiary pain services in NZ, and deemed appropriate for a PMP, will be invited to the study. Clinicians will invite participation by providing an information sheet about the study. Study flyers will also be on display at the clinical consultation rooms of two pain services. Then the contact details of interested patients will be passed on to the blinded outcome assessor.

Inclusion criteria

Adults with persistent non-cancer pain aged 18 years and older will be recruited. Persistent pain is defined as continuous pain lasting for more than 3 months.[39] Participants with any of the following persistent pain conditions will be eligible to be included in the study: (1) persistent primary pain, (2) persistent musculoskeletal pain, (3) persistent posttraumatic and postsurgical pain, (4) persistent neuropathic pain, (5) persistent headache and orofacial pain and (6) persistent visceral pain. Participants currently not experiencing any significant uncontrolled mental health condition with daily access to a computer and/or a smartphone at home, workplace or in a public location, and able to provide written informed consent will be eligible. We will provide internet subscription for the study period for those without internet access.

Exclusion criteria

Participants will be excluded if they currently experience severe depression based on clinical evaluation and from a score of >20 from the seven items of depression subscale of Depression, Anxiety, Stress Scale 21-items.[40] Participants with primary cancer-related pain, planned surgical intervention for their pain during the course of PMP, or concurrent participation in an additional multidisciplinary group-based PMP will be excluded.

Randomisation and concealed allocation

Patients interested in the study will be screened for eligibility by the blinded outcome assessor. Once deemed eligible, and after obtaining informed consent, baseline measures will be recorded by the outcome assessor in Research Electronic Data Capture (REDCap, Vanderbilt University). Participants will then be block randomised (with equal probabilities) using unequal block lengths to the iSelf-help (intervention) or in-person (usual care) PMP groups with stratification by ethnicity (Māori or non-Māori) to ensure that both arms are similar in terms of ethnicity. The randomisation programme (randomizer. org) will be used to generate a randomisation sequence in advance by an investigator of our study team not involved in recruitment, assessment or in statistical analysis. To ensure allocation concealment, a research investigator of our study team will hold the randomisation sequence in sequentially numbered opaque sealed envelopes and will provide envelopes sequentially to a research assistant at the end of baseline assessment. Thus, the research assistant will be blinded to the allocation sequence and the presence of another research investigator (HD) will ensure the envelopes are opened in the correct order.

Intervention-: iSelf-help arm

The cocreated 12-week group-based online intervention (iSelf-help) will be delivered via a smartphone application and via a password-protected website. Participants will have access to the programme during and after the 12-week intervention, for up to 6 months.

iSelf-help

The iSelf-help comprises a home page (figure 2), 12 modules, a community page, a health journal and a direct message function (figure 3, online supplemental files 1 and 2).

Modules

The outline of 12 modules and supporting resources of iSelf-help has been described in online supplemental file 1. The 12 modules are: (0) Welcome page to PMP, (1) Exercise, (2) Sensory nervous system, (3) Stress response, (4) Think, feel, do, (5) Memory of pain, (6) Taking charge, (7) Thinking and doing skills, (8) Medication, (9) Sleep, (10) Making plans with pain, (11) Sharing the journey and (12) Pulling it all together. Each module of iSelf-help will be made available to participants at the beginning of each week. Participants will be asked to use these resources in their own time.

Resources

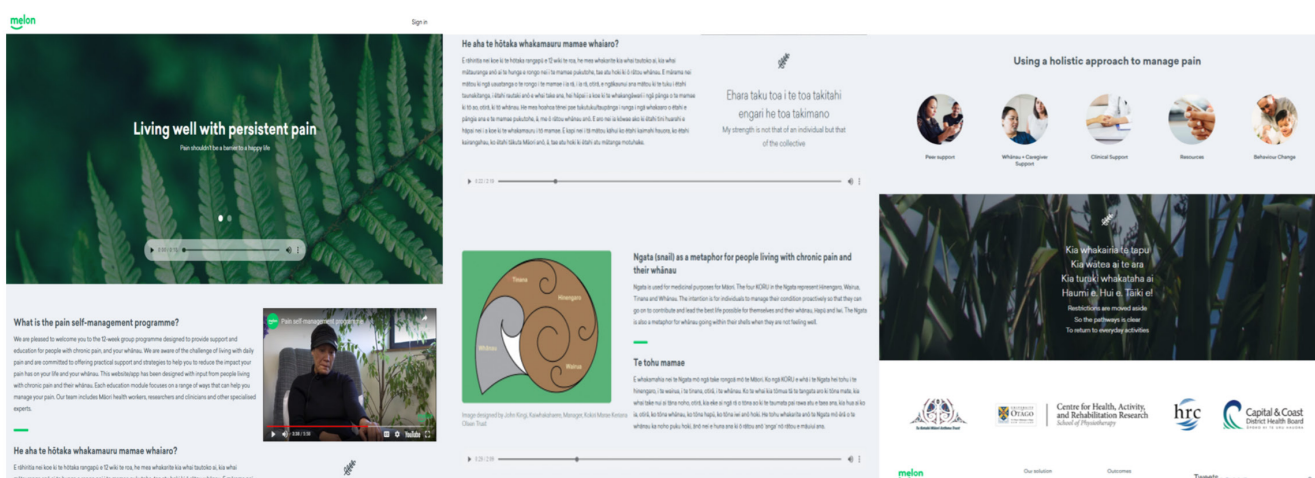Each module comprises a short introductory video (30 s), an educational video from a pain management

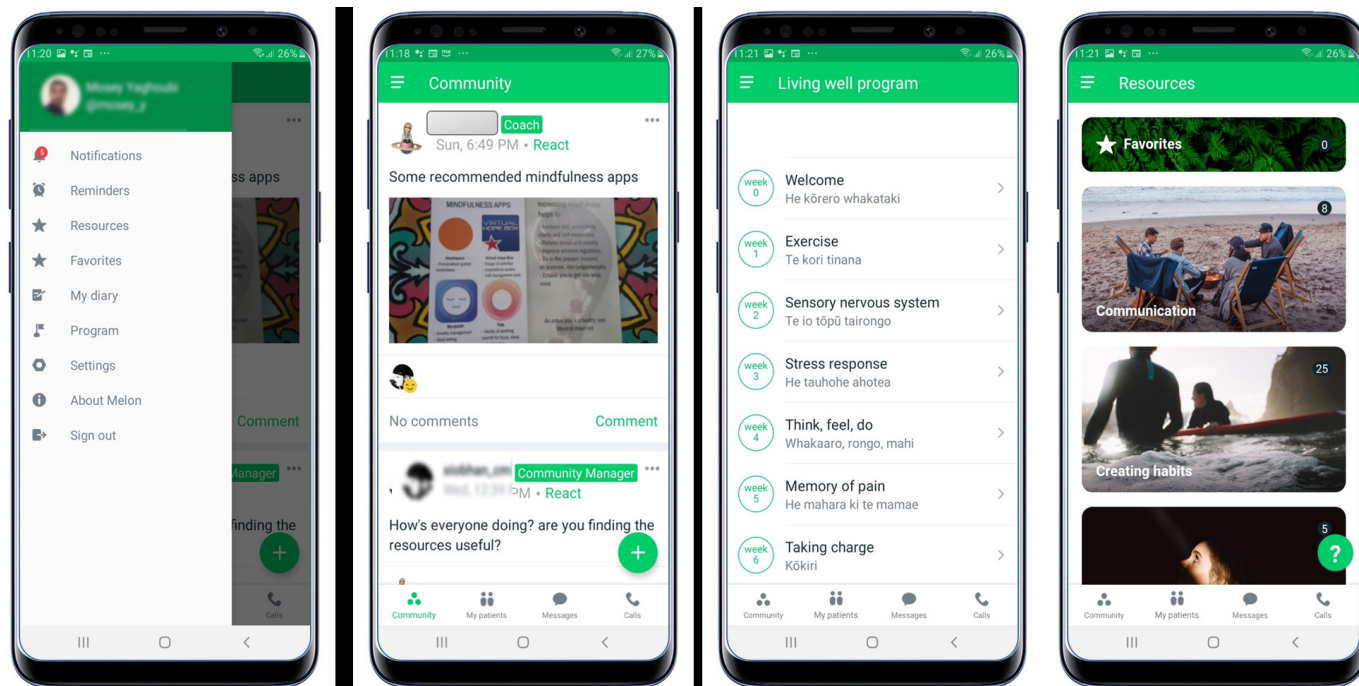**Figure 2** iSelf-help website home page

Figure 3 iSelf-help mobile application interface designed by Melon Health.

clinician (5 min), videos of patient stories sharing their experiences of managing pain relevant to the module (3–8 min), relaxation podcasts (5 min) and additional resources such as animations, illustrated texts and links to additional resources (figure 3).

Video-conferencing sessions
In addition, the iSelf-help arm with 8–12 participants/group at baseline will receive two 60-minute online group interactive sessions via Zoom weekly for 12 weeks. An overview of these sessions is in online supplemental file 2.

Intervention providers and training
The PMP clinical delivery team include two physiotherapists, two psychologists, an occupational therapist and a pain medicine specialist. The two lead physiotherapists are experienced pain management clinicians with over 10 years of experience in delivering group-based PMPs. All clinicians were involved in creating clinical contents corresponding to their modules. A training session on Zoom conferencing was provided to all clinicians and a technical support person will be available throughout the weekly conferencing sessions in order to provide technical assistance for the Zoom meetings.

Session 1
One 60-minute video-conferencing session/week will be delivered via an online self-management platform (Zoom) by two dedicated pain management clinicians (a lead facilitator and a supporting clinician). Each session comprises education (30 min), advice on guided exercises and reflection (15 min) and relaxation techniques (15 min). Education sessions will focus on knowledge and CBT-based self-management skills (eg, pain education,

activity pacing, relaxation and distraction techniques) similar to an in-person PMP. Participants will be encouraged to attend the first session and any of the six sessions from the remaining 11 weeks.

Session 2
Later in the same week, an interactive 60-minute closed-group video-conferencing session via Zoom will be led by a peer-support facilitator (eg, a trained volunteer from patient advisory group). The group discussion will focus on self-reflection, goal setting, and the sharing of experiences with peers about what went well, and what did not, over the week and developing a peer support network. It will also provide an opportunity for practicing guided relaxation techniques and exercises (15 min). Participants will be asked to attend these sessions at their own discretion.

Peer interaction and safety
The community page of iSelf-help will provide opportunities for peer-interaction throughout the 12-week period. Participants will be encouraged to share their reflections and stories in the community page. A community manager (personnel with a health background) will monitor the posts in community page to identify and manage any potential safety risks for participants (see online supplemental file 3 for crisis response management). This may include monitoring posts for any inappropriate comments such as bullying, offensive language tones and posts of self-harm or threats to others.

Health journal
Participants can to track their sleep, activity levels, energy levels, mood and frequency of completing their breathing

exercises with daily reminders (via app) throughout the 12-week period.

Comparator: in-person PMP (usual care) arm

Pain service site 1
The usual care arm with 8–12 patients/group at baseline will attend one 180-minute session/week over 12 weeks at Wellington, which is the current delivery model. Each session comprises weekly review (15 min), two education sessions (45 min each), group exercise (45 min), relaxation (20 min) and a debrief session (10 min). Weekly education modules focus on a range of self-management strategies (eg, pain education, CBT and activity scheduling) as delivered by pain management service clinicians.

Pain service site 2
All patients referred to pain management service in Christchurch will be invited to a Burwood Advancement, Screening and Education programme (BASE) educational seminar (7 hours in duration). BASE seminar involves chronic pain education and overview of self-management principles. On completing the BASE seminar and based on psychometric scores, patients are classified as having mild, moderate or high needs. Those classified with mild and moderate needs will be referred to attend the Burwood Brief Pain Self-management (BPSM) programme.[41] BPSM is an in-person delivered, 120-minute group-based session/week over 5 weeks. Each session comprises weekly review (15 min), relaxation (15 min), group exercises (30 min), problem solving techniques for common difficulties associated with persistent pain such as sleep, flare-ups, communication, maintenance, and stress (30 min) and a goal setting/trouble shooting session (30 min).[41]

As part of usual practice, the pain management service clinicians in both sites continually reflect after every in-person PMP session and following every cohort and take feedback from patients to adapt and improve their in-person delivery.

Reporting of adverse events
The research team will monitor for, and report to an internal Data Monitoring Committee at the School of Physiotherapy, Centre for Health, Activity and Rehabilitation Research any adverse events (safety). For example, an exaggeration of pain or pain-related symptoms such as an increase in psychological distress or severe depression found in both groups during the 12-week intervention and at the 6-month follow-up periods. Participants will be supported to seek medical advice and can withdraw from the study.

Adherence and retention to iSelf-help intervention
Strategies to promote adherence to iSelf-help intervention include bi-weekly 'nudges' via posts in the community page throughout the 12-week period. After the 12-week period, telephone follow-up appointments for both groups will be scheduled by an independent outcome

assessor to increase participant retention. Reasons for non-adherence in the iSelf-help intervention protocol will be recorded by the clinicians delivering intervention. Reasons for non-retention (eg, lost to follow-up) will be recorded by the outcome assessor.

Concomitant care
Both iSelf-help and usual care participants can consult (via telephone or via individual consultations) with clinicians from their respective pain management service during the intervention and 6 month postintervention period as is usual clinical practice. Participants of iSelf-help will not, however, be able to participate in an in-person PMP during or until 6 months after completing their intervention (ie, following final outcome assessment).

Outcome measures
Primary outcome
The primary outcome will be pain-related disability assessed using a modified Roland Morris Disability Questionnaire (RMDQ)[42] at the 6 months postintervention follow-up. RMDQ is a 24-item self-report measure used to assess current disability from daily activities due to persistent pain (score range of 0–24), with greater scores indicating greater disability.[42] Modified for this trial will be the references to 'back pain' replaced by 'pain' as we anticipate a heterogeneous group of participants with persistent pain. The modified RMDQ has demonstrated excellent internal reliability (Cronbach of 0.92),[43] test–retest reliability and validity in participants with persistent pain in a diverse group of health conditions and body sites.[44] The minimal clinically important change of RMDQ is 3.[45] Previous persistent pain RCTs[28 46] have used modified RMDQ as a primary outcome measure. This should enhance the comparability of our trial results with other trials and in future meta-analyses.

Secondary outcomes
Secondary outcomes listed in table 1 include anxiety, depression, stress, pain severity and interference, health-related quality of life, acceptance, self-efficacy, catastrophising, fear avoidance, medications and healthcare use. All are validated self-reported outcome instruments recommended for persistent pain RCTs.[47] Other outcomes include protocol adherence, group interaction and satisfaction.

Treatment fidelity
In line with the recommendations of group-based behaviour-change interventions,[48] we will use an audio-visual observation method using an observational checklist of therapist delivered 60-minute iSelf-help videoconferencing session (with therapist and participants consent) to explore the fidelity of iSelf-help delivery.[49]

Protocol adherence
Protocol adherence will be measured by tracking the frequency and duration of iSelf-help platform usage and

Table 1 Overview of outcome measures of iSelf-help trial

Primary outcome measure	Instruments
Pain-related disability	Modified Roland Morris Disability Questionnaire[54]
Secondary outcome measures	
Anxiety	Depression, Anxiety, Stress Scale (DASS-21),[53] 21-items
Depression	DASS-21[53]
Stress	DASS-21[53]
Pain severity and interference	Brief Pain Inventory short form,[59] 9-items
Health-related quality of life	EQ-5D-5L,[60] five dimensions with five levels of severity
Acceptance	Chronic Pain Acceptance Questionnaire,[61] 8-items
Self-efficacy	Pain Self-Efficacy Questionnaire,[62] 10-item
Catastrophising	Pain Catastrophising Scale,[63] 13-items
Self-as-context	Self Experiences Questionnaire,[64] 15-items
Fear of movement and reinjury	Tampa Scale for Kinesiophobia,[65] 11-items
Current medications	Use of prescription and over-the-counter pain, pain-related, antidepressant and anxiolytic medications.[57]
Healthcare use	TiC-P questionnaire[66]—Data on frequency of visits to health professionals and services (ie, general practitioner, nurse, physiotherapist, occupational therapist, medical specialist, psychologist, counsellor, hospital emergency department and in-patient admissions)
Other outcomes	
Adherence	Frequency and duration of website usage, Monitoring the participation in weekly interactive online group discussions
Acceptability and satisfaction	A customised questionnaire based on a previous randomised controlled trial[57]
Adverse events	Frequency and severity of such events

by monitoring participation in weekly videoconferencing sessions.

Group interaction
Guided by the mechanisms of action in group-based interventions (MAGI) framework,[50] both qualitative and quantitative data will be used to analyse group interaction. The qualitative data from moderated online group interactions of iSelf-help groups will be inductively analysed using a content analysis approach[51] to explore the nature of group interaction. The quantitative data will include the number of personal stories shared and reactions to posts in the online community page, attendance at weekly peer-support sessions and debrief meetings with the peer-support facilitator after each peer-support meeting.

Treatment acceptability and satisfaction
The treatment acceptability and satisfaction of iSelf-help group participants will be assessed using a customised participant acceptability and satisfaction questionnaire, using an ordinal item with five options from 'very dissatisfied' to 'highly satisfied' and an open-ended question on 'any other comments about the iSelf-help programme'.[46]

Sample size estimation
The trial sample size was calculated based on providing 80% power to detect non-inferiority, using a 95% one-sided CI. The margin for non-inferiority was a three points difference (the minimal clinically important change) on the RMDQ Scale, assuming no actual difference in size of change between the two groups (iSelf-help and in-person PMP). The SD for changes in RMDQ was calculated from data reported in a previous trial[52] of 471 participants, with 397 excluding the wait-list control group.[52] The SD at baseline for RMDQ was approximately 5.0 (4.8–5.2 over the four groups),[52] slightly higher at 3 months being around 5.7 (5.4–5.9 over the three groups with follow-up) and with correlations over 3 months of around r=0.5 (estimated from reported data to be 0.44–0.57 over the three groups with follow-up), giving an estimated SD for changes of 5.4, which we have used for the 6-month changes here given the conservative rounding at each stage of the calculations. Allowing for a mean of 10 participants per group at baseline and a loss of 20% over the 6 months, that is, a mean of 8 participants per group at follow-up, with an Intraclass correlation coefficient (ICC) of 0.1 for RMDQ changes, design effects at follow-up are conservatively estimated to be 1.7. A total of n=70 participants would be needed in each group at 6-month follow-up. To allow for the approximately 20% loss to follow-up, n=90 (across 9 groups) will be recruited into each arm of the study at baseline (n=180); that is 18 groups of 10 in total.

Data collection
As illustrated in figure 4, an outcome assessor (blinded to group allocation) will record the outcomes online in

	Enrolment	Allocation	Post allocation															
STUDY PERIOD																		
Time point	$-t_0$	0	t_1	t_2	t_3	t_4	t_5	t_6	t_7	t_8	t_9	t_{10}	t_{11}	t_{12}	t_{13}	F_1	F_2
Enrolment																	
Eligibility screen	X																
Informed consent	X																
Allocation		X															
Intervention																	
Control			←————————————————→														
iSelf-help			←————————————————→														
Assessments																	
Demographics	X																
Primary outcome																	
Pain-related disability	X														X	X	X
Secondary outcomes																	
Anxiety	X														X	X	X
Depression	X														X	X	X
Stress	X														X	X	X
Pain interference	X														X	X	X
Quality of life	X														X	X	X
Acceptance	X														X	X	X
Self-efficacy	X														X	X	X
Catastrophising	X														X	X	X
Self-as-context	X														X	X	X
Fear of movement	X														X	X	X
Medications	X														X	X	X
Healthcare use	X														X	X	X
Adherence			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Figure 2. Schedule for enrolment and intervention per group. t0: baseline; t1-12: 12-week intervention; t13: Post-intervention; F1: 3-month follow-up after intervention; F2: 6-month follow-up after intervention.

Figure 4 Outcome measures and time points of data collection for iSelf-help trial.

REDCap at four time points namely: baseline (t0), after intervention (12 weeks) (t13), and at 3 month (F1) and 6 month (F2) postintervention follow-up. Participants in both groups will be given an online link to complete the self-report questionnaires in REDCap. They will be offered support by the blinded assessor to complete these forms, at the predefined time points, as required.

Data management

All data will be kept confidential and anonymous, with only researchers directly involved in the study having access to the participants' details. Hard copies of all the collected data will be stored in secure files. Electronic data including REDCap will be kept on a secured shared drive that will be available only to the researchers and to the IT staff. Participant data will be double entered into an access database by a blinded research assistant. All statistical analyses will be conducted using non-informative group codes until the planned analyses are completed.

Statistical analyses

Baseline demographic and clinical characteristics will be described for participants in both groups. Linear mixed models will be used to model continuous outcomes (including RMDQ scores) collected over time (baseline, 12 weeks, 3 months and 6 months) with random effects for participants and groups to accommodate the clustered data. No additional clustering for the two centres will be incorporated in analyses. For each model, an unstructured covariance matrix (and possibly other plausible structures if these are justified by theoretical considerations) for the longitudinal data will be investigated as an alternative to compound symmetry with positive correlations, with selection based on Bayesian Information Criterion values. Marginal and conditional residuals will be investigated to ensure model assumptions are sufficiently well satisfied

and natural logarithmic transformations of dependent variables investigated to see if this improves meeting these assumptions. If model assumptions cannot be sufficiently well satisfied through such transformations, quantile mixed models will be used for analyses instead, modelling medians. For count outcomes, including healthcare use, Poisson or, if there is overdispersion, negative binomial mixed models will be used. Zero-inflated models will be considered if there is an excess of zero values. All models will include the stratification variable (Māori ethnicity). For any missing data, multiple imputation through chained equations and using forms of regression appropriate to the missing variables will be used for the main analyses (with additional analyses based on available data used to investigate the robustness of findings). Pattern-mixture models will be used to explore plausible scenarios of informative missingness. The primary analysis will be guided by intention-to-treat principles to address the effectiveness question, but a secondary analysis will investigate the per protocol efficacy question for those attending at least 70% of their sessions. Success for the intervention will be demonstrated by non-inferiority in changes of RMDQ at 6 months for the effectiveness question. Statistical analyses will be conducted using R V.4.0.2 (or later) with two-sided p<0.05 used for statistical significance and one-sided 95% CIs used for non-inferiority.

Economic evaluation

A health system perspective covering hospitalisations, outpatient and primary care visits, medications, programme (Phases I and II) and out-of-pocket costs will be adopted as per local guidance.[53] The base-case analysis will accrue all iSelf-help costs (from Phases I and II) to the iSelf-help arm participants. To assess the iSelf-help intervention as an ongoing service in NZ, a

scenario analysis will amortise the iSelf-help intervention design and development costs (from Phase I) over its expected useful life (ie, future pool of potential users). Incremental cost-effectiveness ratios will be calculated per three-point improvement in the RMDQ and per quality-adjusted life year (QALY) gained (from the EQ-5D-5L). Cost-effectiveness acceptability curves will be generated to allow the decision-maker to assess the probability that the iSelf-help intervention will be cost-effective (vs usual care) at a range of willingness-to-pay thresholds for the improvement in the RMDQ and per QALY gained. Subgroup analysis will assess the cost-effectiveness in participants who adhere (≥70%) to the iSelf-help intervention.

Phase IIA: trial process evaluations

The process evaluation embedded within RCTs is recommended for evaluating complex interventions.[54] This is to understand how components of a complex intervention produce change, the delivery of trial processes and the contextual factors influencing future implementation of trial findings.[49 54 55] These evaluations are integral for providing explanations to trial outcomes and to understand future implementation challenges in different settings.[49 54] We will use mixed methods to explore possible mechanisms of action of iSelf-help, acceptability and satisfaction, and identify enablers and barrier to future implementation processes. We will be guided by MAGI framework[50] to inform our interview questions and analysis of participant and provider interviews.

Participant experiences

Semistructured individual interviews (n=15 to 20) will be conducted with iSelf-help group participants to understand the following: treatment experiences, reasons for use/non-use of iSelf-help, components of iSelf-help that worked or did not and trial implementation procedures. Purposive sampling will be used to maximise the range of viewpoints of people from (a) both users and non-users of iSelf-help, (b) multiple ethnicities (eg, Māori, Pasifika, Asian and NZ/European), and (c) sociodemographic factors (eg, age, gender and socioeconomic status). Separate interviews will be held with the participants of in-person PMP groups (usual care) to understand the impact of in-person delivery and the nature of group interactions. All interviews will be held face to face, by telephone or by videoconferencing.

Provider perspectives

Semistructured face-to-face individual interviews (n=5) will be held with multidisciplinary clinicians of PMP, and peer-support facilitator and administrators following the last PMP and iSelf-help group intervention. These will explore their perspectives on delivering and moderating iSelf-help (ie, trial processes), and the enablers and barriers to implement iSelf-help in a tertiary care pain management service.

Qualitative data analysis

For both participant and provider interviews, the meetings will be audio-recorded and transcribed verbatim. Data will be analysed with the general inductive approach,[56] an approach appropriate when the research questions are essentially evaluative. This method recognises that personal experiences form an important aspect of the iterative approach and should contribute to theory or model development where appropriate.[56] It uses a constant comparison framework to analyse qualitative data.[56] Transcription and analysis will begin immediately after the first interview so that any unconsidered relevant questions might be added to the following interview sessions. Independent parallel coding and group verification of a summary of the results will be conducted to verify trustworthiness and robustness of data analysis.

Mediational analyses

Exploratory mediational analyses will be undertaken based on testing hypotheses raised by the logic model developed in Phase I (reported in another paper) and trial outcome, using selected secondary outcome data.

Patient and public involvement

The five-step modified PAR framework actively involves service users in a collaborative partnership in all three phases of this project. Engaging patients using PAR in developing health interventions enhances the social validity of the research[57]; it promotes improved uptake and sustained use of iSelf-help. Significant inputs and discussions from the PAR team helped the codesign phase of iSelf-help (Phase I). For the RCT (Phase II), a PAR team member (a patient previously completed in-person PMP) has been identified as a peer-support facilitator to facilitate discussions for iSelf-help. Inputs received from the PAR team will inform the dissemination of the study findings (Phase III).

Ethics and dissemination

Ethical approval was obtained from the Health and Disability Ethics Committee, Ministry of Health (HDEC18/CEN/162).

Phase III: dissemination and implementation

We will be guided by the inputs of our PAR team to disseminate the study findings. The World Health Organization-ExpandNet scalability framework[58] will be used for disseminating our findings. The two main tangible deliverables from the research include (1) iSelf-help online intervention and (2) a NZ-specific, culturally appropriate 'Pain Self-help' website providing general information about persistent pain that includes some of the stories of people living with pain and the educational resources developed for iSelf-help. In consultation with our PAR advisory group, key stakeholders such as the NZ Pain Society, Arthritis NZ and Health Navigator Charitable Trust will be engaged for knowledge translation via national meetings and endorsement. Summary reports will be provided to the Ministry of Health, the District

Health Boards, Accident Compensation Corporation (NZ's no-fault accidental injury scheme) and Māori and Pacific health providers in the community. We will implement a wider dissemination strategy by engaging with our university communication team. This could involve dissemination via national and international media to ensure our results reach the wider public.

DISCUSSION

This pragmatic non-inferiority RCT is the first head-to-head evaluation to determine the clinical and cost-effectiveness of a culturally tailored, online-delivered PMP (iSelf-help) when compared with an in-person delivered PMP. Our PAR framework provides a model for future studies codeveloping online solutions that can be scalable and potentially address the needs of high-risk populations, such as Indigenous and culturally and linguistically diverse communities.[29] The COVID-19 pandemic has already led to the rapid adoption of remotely delivered services for pain management globally.[36] If proven effective, the results from this trial could empower people with persistent pain by integrating online-delivered PMPs as part of their routine care.

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