BMJ Open

Combined online interactive mindfulness and exercise programme (MOVE-Online) compared with a self-management guide for adults with chronic pain: protocol for a randomised controlled feasibility trial

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To cite: Deegan O, Fullen BM, Casey M-B, *et al*. Combined online interactive mindfulness and exercise programme (MOVE-Online) compared with a self-management guide for adults with chronic pain: protocol for a randomised controlled feasibility trial. *BMJ Open* 2022;**12**:e058265. doi:10.1136/bmjopen-2021-058265

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-058265).

Received 25 October 2021
Accepted 19 January 2022

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ABSTRACT

Introduction Online pain management programmes (PMP) have growing evidence as effective interventions for individuals with chronic pain (CP). Mindfulness-based stress reduction (MBSR) is a psychological intervention proven to be effective in the management of CP. There is also a large body of evidence for the efficacy of exercise in the management of CP however, there are limited studies combining both these interventions and none to date delivering a combined intervention in the form of an online PMP. This study aims to explore the acceptability and feasibility of delivering a combined MBSR and exercise online PMP for adults with CP, and will examine the feasibility of conducting a randomised controlled trial of a combined MBSR and exercise online programme compared with an online self-management guide.

Methods and analysis A parallel-group, feasibility randomised controlled trial (RCT) will be conducted among participants in Ireland, which will include an embedded qualitative study. Seventy-five participants will complete an online consent form and be individually randomised to one of two groups. Group A will participate in live online MBSR and supervised exercise sessions (2 hours MBSR, 1 hour exercise) once a week for 8 weeks. Group B will receive access to an 8-week online self-management guide, released biweekly and containing eight self-directed modules. Analyses of the feasibility study will be descriptive and will address the outcomes relating to the feasibility and acceptability of the interventions and procedures of the study including recruitment and eligibility, data collection methods, intervention adherence, engagement and attrition rates, intervention acceptability and participants' subjective perceptions of the programmes. Comparisons of clinical treatment effects, using validated patient-reported outcome measures will be explored descriptively to consider the viability of investigating a combined online MBSR and exercise intervention in a future fully powered RCT.

Ethics and dissemination This study was approved by the Mater Misericordiae University Hospital Institutional Review Board (1/378/2124) and the University College Dublin Human Research Ethics Committee (LS-20-76-Deegan-Doody). Informed consent will be obtained from each participant prior to randomisation. The results of this feasibility study will be published in peer-reviewed academic journals and presented at national and international conferences.

Trial registration NCT04899622.

Strengths and limitations of this study

- ► The unique study design, delivering an online pain management programmes (PMP), has the potential to overcome barriers to participation in PMPs.
- ► This study will not determine the effectiveness of the Mindfulness Online and Virtual Exercise-Online programme, but will explore the feasibility and acceptability of its implementation.
- ► Using the internet as a delivery mode for the intervention may exclude some participants with chronic pain who have lower digital literacy and those who do not have access to the internet or a device to go online.
- ► As is common to all trials of this type including complex interventions, it is not possible to blind the therapists or study participants.

INTRODUCTION

Chronic pain (CP) is a worldwide health problem, associated with substantial emotional distress, functional impairment and reduced quality of life. CP is highly prevalent internationally and confers a burden on individuals, healthcare systems and economies.[1 2] A comparative study, including 18 national surveys[2] (n=42 249), reported an incidence of a CP condition of 37% in developed countries and 41% in developing countries. Despite its high prevalence, CP remains one

of the most under-recognised and undertreated medical problems in the Western world.[3] CP is also associated with a high socioeconomic cost. In Europe, national healthcare and socioeconomic costs are reported to represent 3%–10% of gross domestic product,[1] which represents a burden equal to other public health concerns such as depression and substance abuse.[4]

Pain management programmes (PMP) have been recommended in the treatment of CP.[5 6] Studies have shown PMPs to be effective in reducing pain interference,[7] pain intensity,[8 9] disability[9] and distress associated with CP.[9] However, a number of barriers to their widespread implementation have been identified, including geographical distance from PMPs, functional disability limiting the mobility of people with CP and economic limitations.[1] Online interventions have the potential to address these barriers.[10] Systematic reviews have reported internet-delivered interventions to be effective for reducing pain[11] and disability,[12] decreasing pain catastrophisation,[10] increasing pain self-efficacy[13] and improving quality of life for individuals with CP.[13] Minimal outcome differences have been reported in studies comparing individuals who attended online programmes and those who attend in person.[14] The problem of high drop-out rates in studies of online healthcare interventions has also been noted,[12] however may be improved with increased interactivity, encouraging longer term engagement.[15] A recent systematic review[13] highlighted that no studies have investigated the use of synchronous teletherapy involving live interactions between health professionals and patients with CP.

Mindfulness-based stress reduction (MBSR) is a group-based intervention that has a large evidence base in the treatment of chronic disease.[16 17]An overview of systematic reviews and meta-analyses for mindfulness-based interventions demonstrated significant improvements in depressive symptoms, anxiety, quality of life and physical functioning.[18] In addition, MBSR has been shown to be associated with reduced catastrophisation, improved self-efficacy and increased acceptance with a similar effectiveness to cognitive behavioural therapy in adults with CP.[19] There is also some evidence to support the effectiveness of psychological therapies, including MBSR, for reducing pain and disability when the interventions are delivered in an online format.[20]

The recently published National Institute for Health and Care Excellence guidelines[21] for the management of chronic primary pain recommend that supervised group exercise programmes be offered to individuals with CP in addition to encouragement to remain physically active to optimise long-term general health. A broad spectrum of physical activities are potentially beneficial for individuals with CP including aerobic and strength exercises, flexibility, core and balance exercises, yoga, pilates and tai-chi.[22 23] There have been limited studies combining both MBSR and exercise and none to date delivering a combined intervention in the form of an online PMP. Furthermore, there have been no studies which have examined the effectiveness of interactive 'live' online PMPs, and in particular when compared with control interventions. Moreover, no studies have explored the acceptability and feasibility of these programmes.

Aims and objectives

The aims of this study are (1) to explore the acceptability and feasibility of delivering a combined MBSR and exercise online programme for adults with CP and (2) to examine the feasibility of conducting a randomised controlled trial to assess the effectiveness of a combined MBSR and exercise online programme compared with an online self-management guide. The key outcomes to be examined include (1) estimates of recruitment, recruitment challenges, retention rates; (2) feasibility and acceptability of data collection instruments and data collection procedures; (3) intervention adherence, engagement and attrition rates and (4) feasibility and acceptability of the interventions.

In line with standard feasibility study objectives,[24] improvements regarding clinical outcomes will be secondary and descriptive. An exploratory analysis of between group clinical effects will be conducted, using a number of validated patient-reported outcome measures, at baseline, immediately post-intervention and at a 3-month follow-up. The study will also investigate the experiences of a purposeful sample of individuals participating in the Mindfulness Online and Virtual Exercise (MOVE)-Online programme using embedded focus group interviews.

METHODS AND ANALYSIS

This study protocol is reported according to the guidelines presented in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement for clinical trial protocols.[25]

Study design

The study is a parallel-group, feasibility randomised controlled trial with an embedded qualitative study.

Study sample size and study setting

A sample size of 60 participants was considered appropriate for a feasibility study to assist with estimation of sample size for a fully powered RCT.[26] A recent study by Lewis *et al*[27] concluded that there is no overall consensus in relation to appropriate sample sizes in a pilot or feasibility study with recommendations varying from 10 to 12 per group through to 60–75 per group. Billingham *et al*[28] in an audit of sample size of pilot and feasibility studies reported a median sample size for pilot and feasibility studies of 30–36 per group. A sample size of 60 participants in the study was considered appropriate and allowing for a potential attrition rate of 20%, we aim to recruit 75 participants in total.

The trial is a collaboration between University College Dublin, Ireland and a Pain Management Clinic in a large Irish University teaching hospital. The participants will be

	STUDY PERIOD					
	ENROLMENT	BASELINE MEASURES	ALLOCATION	POST ALLOCATION		
TIMEPOINT		No more than 4 weeks prior to commencing intervention		Baseline	Post-intervention (8 weeks)	Follow-up (12 weeks)
ENROLMENT						
Identification	x					
Eligibility screening	x					
Online outcome measures		x				
Informed consent	x					
Fitbit provision			x			
Randomisation			x			
Group allocation			x			
INTERVENTIONS						
MOVE-Online Programme				◄	►	
Online self-management guide				◄	►	
DATA COLLECTION						
Demographics		x				
Patient reported outcome measures		x			x	x
Physical activity data				x	x	
Adverse effects				◄	►	

Figure 1 Standard Protocol Items: Recommendations for Interventional Trials diagram. MOVE, Mindfulness Online and Virtual Exercise.[23]

based in Ireland, and will be participating in the online intervention remotely, from their homes.

Participants

Adults (aged 18 years and older) who have been diagnosed by a consultant in pain medicine or a general practitioner with any type of CP condition persisting for over 12 weeks' duration and who report a pain intensity of >3 on a Numerical Rating Scale are eligible for inclusion in the study. Participants must be able to provide informed consent and communicate effectively in the English language. Figure 1 shows the SPIRIT diagram for the trial.[25] Exclusion criteria include; need for further diagnostic evaluation (determined by physician), presence of any contraindications to participation in an exercise programme (severe shortness of breath at rest, angina, uncontrolled diabetes or epilepsy, recent (previous 3 weeks) myocardial infarction, pulmonary embolism, deep vein thrombosis or asthma attack), presence of active cancer, concurrent participation (or in the previous 3 months) with any form of psychological, physiotherapy or supervised exercise in addition to the study intervention, presence of substance misuse (diagnosed by a physician), untreated psychosis, acute depression, suicidality and inability to take part in an online exercise programme. Other standard MBSR potential exclusion criteria (e.g. Post Traumatic Stress Disorder, recent bereavement) will be investigated as exclusion criteria on an individual basis.

Recruitment and screening

Study recruitment commenced in February 2021 and it is anticipated that data collection will be completed in March 2022.

Participants will be recruited using two recruitment approaches:

1. The study information leaflet (online supplemental information, appendix 1), along with a link to the study website (www.move-online.me) will be distributed to the members of a national patient support organisation in Ireland for people living with CP. This organisation has consented to email the study information to their members via the organisation administrator and display information on the organisation website. If a member is interested in participating, they will be invited to contact the primary researcher by email or by phone.
2. Patients diagnosed with CP who are currently on a waiting list for a multidisciplinary PMP at a consultant-led pain clinic at a large academic teaching hospital in Dublin, Ireland will be contacted by the primary researcher and informed about the study. Patients who are provisionally interested in participating in the study will be sent a participant information leaflet and the study website details by email. These patients will be invited to review the study information and make contact with the primary researcher by phone or email.

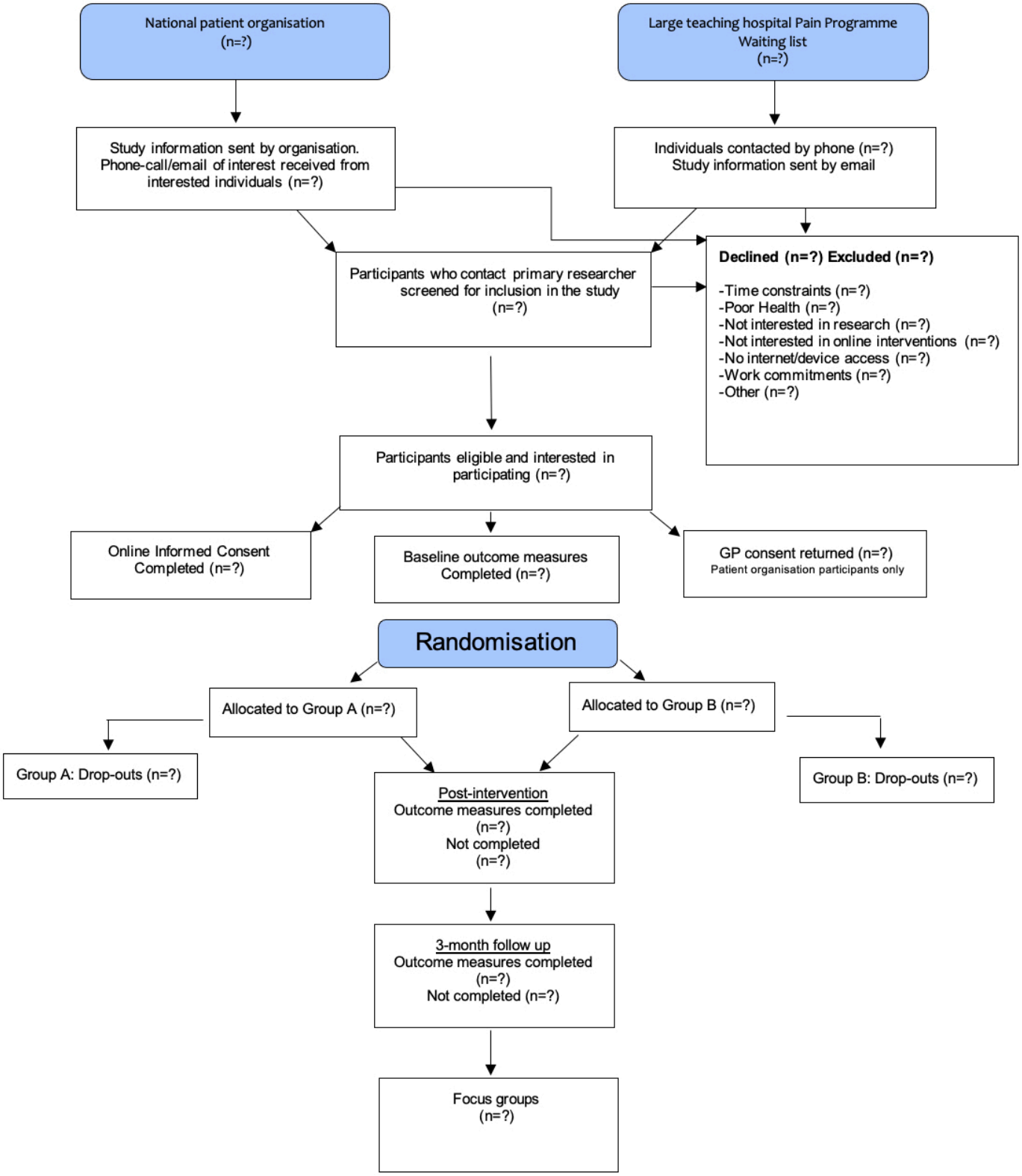

Figure 2 Adapted CONSORT diagram for pilot feasibility studies,[25] illustrating participant progression through the study. CONSORT, Consolidated Standards of Reporting Trials.

An adapted Consolidated Standards of Reporting Trials diagram (figure 2) for pilot feasibility studies[29] illustrates participant flow through the study including initial telephone screening, recording of consent, collection of baseline measures via online forms and randomisation to group A or B.

Randomisation

Participants will be individually randomised to one of two treatment arms. Group A will receive 8 weeks of MBSR and exercise classes delivered live online once per week. Group B will receive access to an online self-management guide with one online orientation meeting at the beginning of the 8-week intervention. Each participant will be allocated a unique code and randomised using the online software application 'www.sealedenvelope.com' by the primary researcher and the randomisation allocations will be shared with the therapists implementing the intervention. It is not possible to blind the therapists or study participants to group allocation. Participants will be contacted by email by the primary researcher and informed of their group allocation. Randomised participants will be assigned log-in details, which will allow access to a specific members area of the website based on their group allocation.

Reasons for non-participation

Individuals will be clearly informed that participation in the study is optional and participants do not need to report why they do not wish to participate. However, any reasons that participants do provide in relation to their decision to decline to participate in the study following the screening phone call will be recorded. This data may help to identify potential barriers to recruitment and analysis of this data will be relevant when exploring the acceptability and accessibility of the intervention and recruitment process.

Intervention

The study interventions are described below with reference to the Template for Intervention Description and Replication guidelines for better reporting of interventions.[30]

Content

Intervention A, MOVE-Online programme is an 9-week online interactive intervention combining MBSR and exercise to assist in the management of CP, accessible to participants from their homes. A live online 2-hour orientation session will be provided to all participants prior to commencing the intervention. Following this, the participants will attend weekly online classes for 3 hours in duration (2 hours of MBSR, 1 hour exercise) for 8 weeks. The classes will be delivered in a group setting, and will be led by mindfulness instructors with MSc degrees in mindfulness-based interventions. The programme content will be based on the standard MBSR programme developed at The Centre for Mindfulness in Medicine, University of Massachusetts and is tailored towards key concerns and difficulties experienced by individuals with CP.[31] Participants will practice different forms of mindfulness practice including mindful movements based on gentle mindful yoga, sitting meditation and bodyscan practice, as well as informal practices such as mindful eating, speaking and listening, and mindfulness of daily activities. Mindful yoga as specified in the MBSR Curriculum Guide[31] comprise specified gentle mindful movement practices with a focus on practicing non-judgemental awareness. Verbal guidance will be given to guide all of the mindfulness practices during the live classes. In addition, participants will be given access to audio and video MBSR resources via the members area of the study website (www.move-online.me) which will include a weekly handbook and access to audio and video-guided mindful movement practices. Participants will be encouraged to use these resources to complete weekly home practices.

Following this, participants will attend a 1-hour class of online supervised exercise. The exercise class will be delivered live online by a Chartered Physiotherapist with experience in delivering online exercises classes. It will consist of a range of flexibility and strengthening exercises which will be advanced every 2 weeks for the duration of the 8 week programme. The exercise programme was devised based on evidence from the literature regarding exercise for adults with CP[22 32 33] and with input from three experts working in the field of PMP research and delivery. Recommended exercise repetitions and set numbers will be provided, however the participants will be encouraged to modify this as needed to individualise the programme to their own ability level. The exercises will also be available in video format on a mobile exercise application which each participant will be invited by email to download. This application will allow the participants to review the exercises between sessions, record on the application if they have completed each exercise and in addition rate their pain experience while completing the exercises. Feedback from the exercises recorded on the application will be monitored by the Chartered Physiotherapist delivering the exercise class. If there are any significant pain flare-ups or adverse effects to exercise reported, necessary modifications to exercises will be discussed with the participant. In addition, the participants will be asked to wear a Fitbit activity monitor over the 8 week intervention period.

For intervention B, the group will have access to an online CP self-management guide. Participants will receive standard evidence-based self-help information, which they will access independently via the members area of the study website (figure 3). The self-help information included in the online self-management guide was devised using recommended resources for guiding the production of materials for patients with CP found in the Scottish Intercollegiate Guidelines Network (SIGN) guidelines.[5] The information will be presented in the form of general text, links to online resources, audio files and videos. The information in this members area will be updated biweekly during the 8-week programme with the participants receiving an email update that the information has been updated. Group B will also be requested to wear Fitbit activity monitors over the course of the 8-week intervention period.

Each group will have 12–15 participants, a group size considered ideal for intervention A; allowing for group

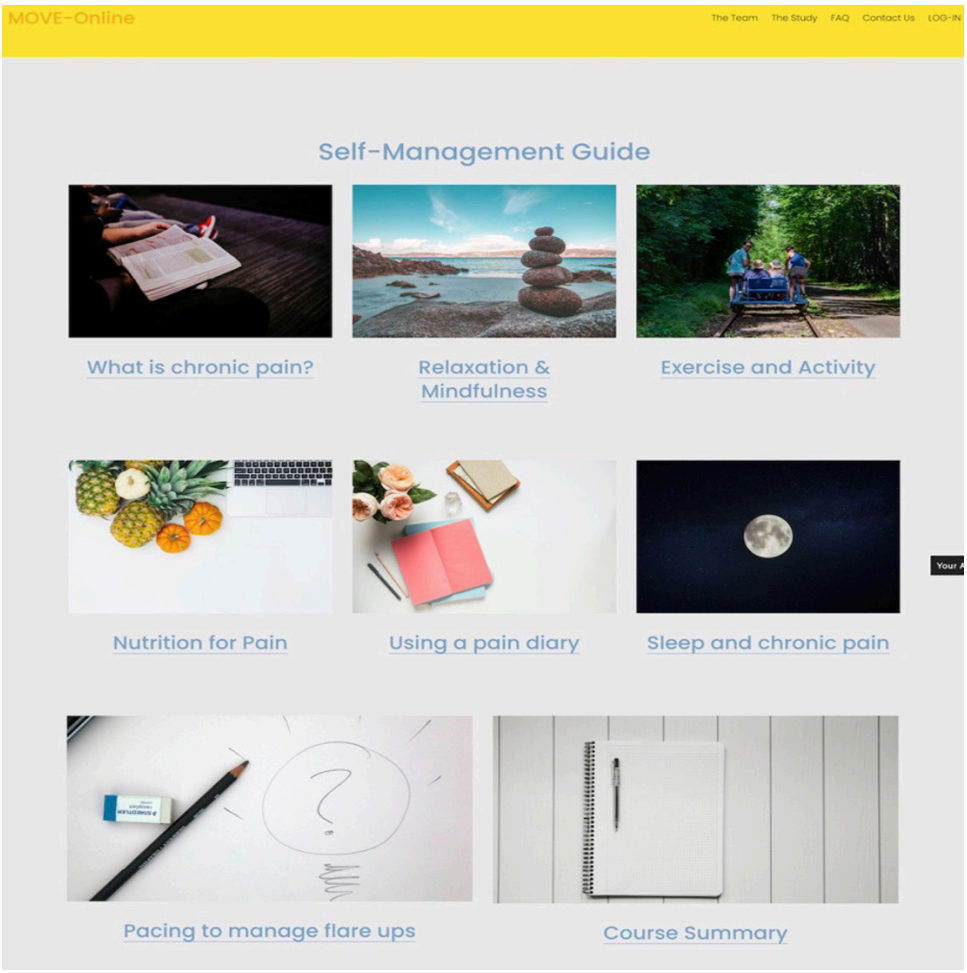

Figure 3 Online self-management guide website page displaying the guides' eight modules; What is CP, CP and nutrition, Sleep issues with CP, activity and exercise, pacing, using a pain diary, relaxation and mindfulness and course summary. CP, chronic pain.

work and also provide the necessary therapeutic space for each of the participants.[6] Certain features of potentially useful group influences can become weakened with groups that contain smaller numbers and the influence exerted by the therapist can be weakened with groups containing larger groups.[6]

Online therapists

The therapists who will deliver the MBSR component of the interventions are qualified mindfulness teachers with MSc degrees in mindfulness-based interventions from University College Dublin (UCD). They each have a minimum of 4 years' experience delivering MBSR programmes in person and online. The exercise component will be delivered by an experienced Chartered Physiotherapist with an MSc. Degree in Advanced Physiotherapy Studies from UCD who has 12 years' experience delivering exercise interventions in person and online. The therapists will follow an online protocol manual (online supplemental information, appendix 2) developed specifically for the MOVE-Online intervention. Prior to commencing the programme, one training sessions of 1-hour duration will be held with the primary researcher and the therapists which will cover the administration of the programme, familiarisation with the treatment protocols and treatment fidelity processes (online supplemental information, appendix 2).

The therapists will interact once weekly live online with the group A participants. Between sessions, a study email address will be provided for the participants who have any further questions about the exercise or MBSR classes. Given the explorative nature of the study, no specific time limit for follow-up support by each therapist will be set. We anticipate that each therapist may spend an additional 1 hour responding to follow ups from the group on a weekly basis.

Outcome measures

Primary outcome measures

Acceptability and feasibility outcomes

The outcomes of interest under examination relate to the acceptability and feasibility of the study recruitment, methodology and intervention and are as follows; recruitment rates, eligibility criteria, data collection, attrition (non-return of outcome measures and participant withdrawals), resources needed to deliver the

Table 1 Overview of feasibility and acceptability outcomes and evaluation methods

Outcome	Evaluation
Recruitment and eligibility	
	► Number (of participants) identified through patient organisations membership ► Number identified via waiting list at the hospital department of pain medicine ► Number screened for eligibility ► Number eligible following screening ► Reasons for ineligibility ► Number completed consent forms ► Number randomised ► Reasons for non-participation following eligibility screening
Data collection	
	► Percentage (of participants) completing patient-reported outcome measures (PROM) at baseline, post-treatment and 3-month follow-up ► Numbers of missing items from patient reported outcome measures
Attrition	
	► Rates of intervention drop-outs (group A) ► Reasons for intervention drop out (group A) ► Rates of intervention drop-outs (group B) ► Reasons for intervention drop out (group B)
Resources needed	
	Length of time required for: ► Training time with therapists ► Therapists to administer the study (weekly class and email interaction)
Participants' adherence	
	Number of: ► Classes attended: exercise and MBSR (group A) ► Log-ins to online self-management guide (group B) ► Log-ins to weekly website resources (group A) ► Orientation attended (group B) ► Home exercises completed via application (group A) ► Activity logged on Fitbit (groups A and B)
Participants' acceptability of data collection and intervention	
	1. Satisfaction with the intervention: Completion of Client Satisfaction Questionnaire-8[42] 2. Interface Usability: Completion of the System Usability Scale *Via focus groups*: 1. Impressions and experience of participating in the intervention (eg, what was helpful, not helpful) 2. Impressions and experience of completing the PROMs

intervention and complete the data collection process, participants adherence to the intervention, therapists adherence to the support protocol and participants acceptability of the intervention and study procedures. The acceptability and feasibility outcomes assessed are summarised in table 1 with the associated means of evaluation described.

Secondary outcome measures

Patient-reported outcome measures

The patient-reported outcome measures included in this trial are based on the IMMPACT (Initiative on Methods, Measurement and Pain Assessment in Clinical Trials) recommendations for outcome measures for use in CP clinical trials.[34] Table 2 lists the validated patient-reported outcome measures which will be completed by all randomised participants, including participants who withdraw, prior to commencing the study (within a maximum of a 2-week period), following the 8-week intervention period and at a 12-week follow-up.

Adverse events

The occurrence of any adverse events will be monitored by the treating therapists throughout the 8-week intervention period. Any adverse events that occur will be recorded by the primary researcher and reported with the study results.

Physical activity measures

This study will collect objective physical activity data using the Fitbit Charge 4 activity monitor (which each participant will receive by post). The Fitbit Charge 4 is designed as a wrist strap and provides information about steps, distance travelled and active minutes. Participants will receive a Fitbit by post and will be encouraged to wear the monitor at all times for the duration of the intervention. The collected Fitbit data will be automatically downloaded to a centrally administered website, allowing downloading of information from a central website facilitating the primary researcher to capture the data remotely. A recent trial[35] also successfully used Fitbit activity monitors to collect data on a CP cohort as they participated in a multidisciplinary pain programme intervention.

Quantitative data collection

Data will be collected via a number of methods.

- Initial screening data will be collected via a telephone interview with the participants, conducted by the primary researcher.
- Consent forms (online supplemental information, appendix 3) will be completed by participants via an online form received by email from the primary researcher, using a secure study email account. Following this, patient-reported outcome measures will also be completed via an online form and via a link sent from the secure study email account to the participants email addresses. Two additional reminders will be sent when online measures have not been completed, 1 and 2 weeks following the initial email. Data from online patient reported outcome measures will be extracted to password protected excel files by the primary researcher.
- Activity data will be collected online via the study account Fitbit dashboard. Each participant will be instructed to sync their device regularly to an account which will be created for each participant using a

Table 2 Overview of secondary outcome measures

Secondary outcome measure	Instrument
Pain (intensity, interference)	Brief Pain Inventory (BPI)[43]
General and domain-specific pain-related disability	Pain Disability Index (PDI)[44]
Perceived improvement	Patient Global Impression of Change (PGIC) scale[45]
Depression	Patient Health Questionnaire-9 (PHQ-9)[46]
Health-related quality of life	Short Form-36 Health Survey (SF-36)[47]
Anxiety	General Anxiety Disorder-7 (GAD-7)[48]
Self-efficacy	Pain Self Efficacy Questionnaire (PSEQ)[49]
Catastrophising	Pain Catastrophising Scale (PCS)[50]
Fear of pain and consequent avoidance of physical activity	Fear Avoidance Belief Questionnaire (FABQ)[51]
Participants gender, age, occupation, relationship status, level of education, pain diagnosis, years with CP	Initial online questionnaire

CP, chronic pain.

unique email address. Reminder emails will be sent to participants who have not synced their device for 10 days. Data for each participant will be extracted remotely from the Fitbit website to password protected excel files.

- Exercise adherence data will be collected on the exercise application. Each participant will be encouraged weekly by the Chartered Physiotherapist delivering the exercise class, to record their exercise programme completion (number of repetitions and sets) and pain levels experienced while completing the exercises using the application. This information will be extracted from the exercise application host account and stored in secured excel file format.
- Website analytics will provide information in relation to the interaction of individuals with the website material. Information on content interaction will be available via the website host analytics.
- Participant adherence (weekly attendance at the live MBSR and exercise classes) will be measured by the treating therapists for group A. Group B adherence will be monitored via the total number of log-ins to the online self-management guide in the members area of the website in addition to attendance at the orientation of the 8-week programme.

Qualitative data collection

An online qualitative study will take place via focus groups, following the intervention, with a purposeful sample of participants from group A. Participants who completed the study along with individuals who withdrew from the study will be invited to participate. Studies have found[36] that many online health interventions have been developed in response to a technological innovation rather than being driven by user need. The authors and others[12] suggest that the needs and perspectives of individuals in pain should be integral to the development process of online therapies. Embedded focus groups within this feasibility study will assist with the interpretation of the feasibility and acceptability findings in the study. The purposeful sample of participants invited by email to participate will be sent a patient information leaflet via email outlining the details of the focus groups. Those who choose to participate will be requested to sign an additional online consent form. The research team will develop a number of open-ended questions that will prompt participants to talk about their experiences, positive and negative in relation to the interventions and the delivery method.

The focus groups will be conducted by researchers not involved in the study data collection or the study interventions. Focus groups will be scheduled online with participants for approximately 60 min.

Data analyses

Quantitative analyses

As this is a feasibility study, there is no formal sample size calculation. Sixty participants is considered a large enough sample to consider the practicalities of recruitment and delivering the intervention.[26] Baseline characteristics for demographic and clinical data of the participants will be reported using descriptive statistics, including variance estimates and covariances or correlations over time.

The primary analysis will focus on a description of feasibility and acceptability outcomes. Recruitment and eligibility will be analysed by investigating the numbers of: (1) participants assessed for eligibility, (2) participants meeting eligibility and (3) participants consented and enrolled in the study, out of the total number who expressed interest from both the patient support organisation and hospital setting. Reasons for ineligibility and reasons for non-participation will be reported at each stage.

Analysis of the data collection methods will investigate (1) the number of participants completing the outcome measures at each time point, (2) time taken to complete the measures and (3) number of missing items and (4) number of participants completing outcome measures

at all time points. Attrition will be analysed by reporting the percentage of withdrawals in both groups, with a 50% attendance required for intervention completion based on previous studies investigating PMPs for CP.[37 38] Descriptive statistics; means and SD will be reported for the length of time therapists spend delivering the intervention; for live class time, class preparation time and time spent on follow-up emails. Participant adherence to the intervention will be analysed by reporting the number of (1) classes attended (group A), (2) logins to website for weekly resources (group A), (3) orientation meeting attendance (group B), (4) home exercises completed via the exercise application (group A) and (5) number of log-ins to online self-management guide (group B). Interaction with the online self-management guide will be described from the website analytics in terms of number of log-ins to each section of the self-management guide and the number of pages views. Participant acceptability of intervention and data collection measures will be analysed by the Client Satisfaction Questionnaire-8 (CSQ-8).

An exploratory analysis of between-group differences in the secondary outcome measures will be conducted according to an intention-to-treat principle, that is, all randomised participants will be included in the main analysis and will be analysed as randomised, regardless of protocol adherence. The current study is not powered to detect statistically significant between-group differences in the secondary outcomes. Rather, analyses of between group differences will be computed primarily for descriptive purposes in order to inform decisions regarding the selection of measures for a possible future clinical trial.

The secondary exploratory analysis will include the analysis of the secondary outcomes measures post-intervention and at a 12-week follow-up. Linear mixed models on the outcome measures over time will be fitted to evaluate the effectiveness of both interventions, which intrinsically adjusts for pre-treatment scores. Effect sizes and 95% CIs for between groups contrasts will be reported. An up-to-date version of SPSS will be used to conduct the analyses. A data monitoring committee will not be required due to the feasibility design of the study. This study design will not require blinding and interim analyses. Raw data from the study may be accessed via the UCD Research Repository, Doctoral Theses Repository.

Missing data

The primary researcher will ensure that participants are fully assessed at all time points. Baseline data will be checked for missing data by the primary researcher and participants will be encouraged to complete any missing answers. Online questionnaires will help minimise missing data at each time point and the primary researcher will follow-up on any missing data by telephone at each time point. Analysis of missing data patterns including monotonicity, and demographic and clinical correlates of non-responses, will inform the need for multiple imputation or other methods for compensating for missing data.

Analysis of physical activity data

The following data will be collected for each trial participant at baseline and on completion of the treatment: average daily step count, distance travelled and active minutes. The number of participants reaching the global recommendations for physical activity for health[39] will also be recorded. Descriptive statistics will be obtained for the Fitbit variables at baseline and by treatment arm. Linear mixed models will be used to analyse the change in measures between groups.

Qualitative analyses

The focus group interviews will be audio-recorded and transcribed verbatim via an online video conferencing platform and verified by a member of the project team, omitting any names, locations or information that could identify any individual. The deidentified transcripts will be analysed using a thematic analysis; an evidenced-based analytical approach well suited to exploring subjects' views. Thematic analysis is an independent qualitative descriptive approach described as 'a method for identifying, analysing and reporting patterns (themes) within data'.[40]

This study will feature an open research question, focused on peoples' experiences and views of the featured interventions for CP. Standards of verification will be adhered to including member checks, peer debriefing, external audit, negative case analysis, rich description including citations from the interview transcripts identified to participant and line number.[41]

Patient and public involvement statement

Neither patients nor members of the public were involved in the design of the feasibility study, however the focus group interviews will provide insight for improvements and suggestions for changes in the programme recruitment methods, data collection methods and programme content. It is anticipated that the results of the qualitative study will help to guide the recruitment, data collection and intervention design of a larger RCT investigating the efficacy of the intervention.

Ethics and dissemination

This study was approved by the Mater Misericordiae University Hospital Institutional Review Board (1/378/2124) and the University College Dublin Human Research Ethics Committee (LS-20-76-Deegan-Doody) prior to commencing recruitment (December 2020) and will be conducted in accordance with the Helsinki Declaration ensuring the welfare and rights of all its participants. All modifications to the approved study design will be communicated to both review boards for approval. Informed consent will be obtained from each participant prior to randomisation via an online consent form.

All data will be handled according to General Data Protection Regulation (EU 2016/679) with all participants assigned a study code to deidentify data and any personal information about participants will be stored separately

from deidentified data. Data collected via online forms will be stored on secured servers at University College Dublin. The final trial data set will be accessible by the primary researcher and the study supervisors. The results of this feasibility study will be published in peer-reviewed academic journals, and presented at national and international conferences.

DISCUSSION

This feasibility randomised controlled trial will explore the acceptability and feasibility of delivering a combined MBSR and exercise online programme for adults with CP and will examine the feasibility of conducting a randomised controlled trial in the future to assess the effectiveness of a combined MBSR and exercise online programme compared with an online self-management guide. Given the novelty of the combining of MBSR and exercise for the treatment of CP and the nature of the online, live, interactive, group delivery, assessing the acceptability and feasibility of the intervention and study procedures is of great importance in informing the design of a future fully powered RCT.

In the design of this study, we have endeavoured to address the most recent recommendations that have been made to enhance the delivery of online interventions for CP.[13] By utilising a live delivery method for the intervention to a group of individuals with CP, we have included two key recommendations; (i) increased therapist interaction: which has been perceived to be more helpful for participants and offers greater compliance, (ii) group peer interaction: taking advantage of technology that will allow CP patients to interact directly with others undergoing similar challenges, a technique which has been found to be effective in improving coping in patients with CP.[12]

This feasibility RCT should be considered in light of several limitations. The RCT is not powered to detect the effectiveness of the programme, however it aims to objectively analyse the feasibility and acceptability of delivering a novel online PMP, which can inform the design of a fully powered RCT to determine the effectiveness of the intervention. While an online PMP has the potential to overcome geographical and physical barriers associated with participation in a face-to-face PMP, the online format may exclude participants with lower digital literacy and or internet access. Blinding will not be possible of the therapists or the participants who take part in the programme.

Challenges faced by the healthcare sector in closing the gap between CP treatment demands and the availability of resources in the form of PMPs can be potentially addressed using internet-based interventions such as this, reducing costs for healthcare providers and providing care pathways with reduced barriers for patients[11 13]

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Acknowledgements Ahmad Salma (Chartered Physiotherapist) and Colette Kealy (Mindfulness Instructor) contributed to the delivery of the online programme content.

Contributors OD, BMF and CMD were responsible for the study conception and design. CMD was responsible for the funding acquisition. M-BC and RS contributed to the design of the study. RS oversaw the study analysis planning, conducted the sample size calculation and will assist with the study analysis. OD, CMD, BMF and M-BC contributed to the design of the interventions. With respect to this protocol, the manuscript was drafted by OD and was critically revised by CMD with further revisions by BMF, M-BC, CH and RS. All authors read and approved the final manuscript.

Funding This work is funded by the UCD Centre for Translational Pain Research. Award/Grant number is not applicable.The funding source have no role in the study design, collection, management, analysis or interpretation of data, writing of the report or the decision to submit the report for publication.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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