BMC Musculoskeletal Disorders

STUDY PROTOCOL

Open Access

Implementation of back to living well, a community-based program for the tertiary prevention of low back pain: a study protocol

Luciana Macedo[1*], Stephanie Di Pelino[1], Veronica Souza Santos[2], Julie Richardson[1], Joy MacDermid[3], Mark Hancock[4], Michele C. Battie[3], Bruno T. Saragiotto[5], Jill A. Hayden[6], Alison Rushton[3], Tara Packham[1], Matt Freman[1], Steven Bray[1], Meridith Griffin[1], Genevieve Hladysh[7], Pat Miller[1] and Suzan Attwell[8]

Abstract

Background The current literature supports the effectiveness of exercise, education, and self-management interventions for the long-term management of persistent low back pain. However, there is significant uncertainty about the implementation of interventions related to barriers, facilitators, and patient's preferences. This study will evaluate the Back to Living Well program implementation from a participant and organizational perspective. More specifically we address the following objectives: 1) identify program barriers and facilitators from participants' perspectives, 2) identify factors related to program, personal and contextual factors that contribute to negative and positive outcomes, and outcome trajectories, 3) identify factors influencing participants' selection of an in-person or e-health program, and 4) evaluate program specific barriers and facilitators from the organization and care delivery perspectives.

Methods This study will utilize a mixed-method convergent design including a longitudinal cohort strand and a longitudinal qualitative interview strand. The RE-AIM framework will be used to assess program implementation. Participants ($n=90$, 1:1: in person or virtual) who choose to register in the program as well as staff ($n=10$ to 15) involved in the delivery of the program will be invited to participate. Participants will participate in a 12-week physical activity, education, and self-management program. Implementation outcomes will be measured at 3-, 6-, 12-months, and six months after the end of the follow-ups. Interview scripts and directed content analysis will be constructed based on the Theoretical Domains Framework and the Neuromatrix Model of Pain, Theoretical Domains Framework. Staff interviews will be constructed and analyzed using the Consolidated Framework for Implementation Research. Participants will also complete pain, disability, quality of life and psychological questionnaires, wear an activity tracker at all time points, and complete weekly pain and activity limitation questions using a mobile application.

Discussion The study results will provide evidence to inform potential future implementation of the program. An effective, appropriately targeted, and well implemented exercise program for the long-term management (i.e., tertiary prevention) of LBP could minimize the burden of the condition on patients, the health care system and society.

Trial registration ClinicalTrials.gov NCT05929846. This (Registration Date: July 3 2023) study has been approved by the Hamilton Integrated Research Ethics Board Project ID#15,354.

Keywords Implementation, Low back pain, Community-based programs, Tertiary prevention, Self-management

*Correspondence:
Luciana Macedo
macedol@mcmaster.ca
Full list of author information is available at the end of the article

Background

The recent paradigm shift where low back pain (LBP) is now recognized as a long-term health condition rather than a curable injury [1] demonstrates the need for better long-term management of persistent LBP [2]. Persistent LBP often presents with an unpredictable pattern of symptomatic episodes, flares, remission, and recurrence [3–5]. The use of tertiary prevention aims to mitigate the impact of ongoing health conditions that have lasting effects including prevention of flares and long-term disability [6]. In LBP this includes helping people manage their condition in the long-term to improve their ability to maintain function, improve quality of life, and decrease societal costs/burden.

Evidence from systematic reviews on the secondary prevention of LBP, suggests that for persons who have recovered from an acute episode of LBP, exercise combined with education (typically delivered in a group) reduces the risk of a recurrent episode of LBP by 45% within a year compared to minimal intervention (RR = 0.55; 95% CI 0.41, 0.74) [7]. A crucial finding from these reviews is that an exercise program delivered as part of the treatment for current LBP was less effective than long term exercise programs. This probably occurred because patients typically did not continue to adhere with exercise after discharge from care [8]. In fact, a recent randomized controlled trial aimed at preventing recurrence of LBP [9], found that an in-person exercise program was *not* better than education alone at preventing recurrences when people were pain-free after their initial recovery from an acute episode; poor adherence to exercise (only 50% adherence) probably limited the overall treatment benefits. The low adherence was partially attributed to highly variable patient preferences: many patients preferred more convenient exercise options e.g., shorter sessions, flexible timing and less equipment-dependence [10]. This illustrates that patients' preferences do not align with effectiveness studies and suggest that programs with more personalized exercises options, intensity, and frequency may have greater effectiveness [11]. These findings highlight the need to evaluate implementation strategies targeting behaviour change to improve the effectiveness of exercise-based interventions.

Tertiary prevention for LBP includes helping people manage their condition in the long-term to improve their ability to function. Clinical guidelines [12, 13] and systematic reviews [14] consistently recommend exercise as the first line of care for persistent LBP. A recent systematic review on the secondary and tertiary prevention of LBP identified moderate-quality evidence that exercise can reduce future LBP intensity in the short term and exercise combined with education can prevent future disability due to LBP in the long term [15]. Thus, for persons with persistent LBP, long term adherence to exercise and physical activity (lifestyle modification), education and self-management are recommended for tertiary prevention [16, 17]. However, similar to the behaviour patterns reported in secondary prevention studies, there is often low adherence to long term exercise in this population [18, 19]. In addition, there is a scarcity of evidence on the prevention of flares and the impact they may have on adherence. Thus, there is a need to optimize uptake of exercise in persons with persistent LBP, outside the rehabilitation environment, and improve longer-term adherence to exercise (i.e., maintenance).

The proposed study aims to evaluate the implementation of the Back to Living Well (BLW) program, an evidence-based exercise, self-management, and education program in the community for persons with LBP. The BLW addresses an important gap between the prescription of exercise by a health care provider and engagement and adherence to physical activity in the community by individuals experiencing with back pain [20]. The goal of this program is to enable individuals to act on health care recommendations and engage in physical activity in the community while addressing known barriers to continued physical activity [21, 22]. The implementation evaluation will be conducted from the participants (participant's behaviours) and organization perspectives. We will use the Theoretical Domains Framework (TDF), the Technology Acceptance Model (TAM) and the Neuromatrix Model of Pain (NMP) to construct a theory-based approach to: 1) Identify program barriers and facilitators from the perspective of the participants, 2) Explore factors contributing to negative and positive outcomes as well as outcome trajectories, including how outcomes are related to program, personal and contextual factors, 3) Identify factors influencing participants to select an in-person or e-health program, and 4) Evaluate program specific barriers and facilitators from the organization and care delivery perspectives.

Methods

Study design

This study will be an implementation study using a mixed-method convergent design including a longitudinal cohort strand with an embedded longitudinal explanatory qualitative strand [23] guided by an interpretive description [24]. This design will allow for the observation of outcomes and potential modifiers, including the challenges experienced over time, the strategies participants adopt to navigate their condition, and the organization and care delivery implementation perspectives [25]. We will use the RE-AIM framework to guide implementation [26, 27]. This study was previously registered (NCT03328689) and approved by the ethics

committee of the Hamilton Integrated Health Research Board (HiREB #2721).

Setting

The BLW program was developed within the auspice of the LiveWell programs. LiveWell is a partnership between YMCA Hamilton, Burlington, and Brantford (YMCA HBB), Hamilton Health Sciences (HHS) and McMaster University in Canada. LiveWell programs are focused on improving health outcomes for persons with chronic conditions, including frailty/illness prevention, self-management and easing the transition from hospital to community. Programs for other chronic conditions have been tested for effectiveness and are ongoing at the YMCA Hamilton, Burlington, and Brantford, include programs post-stroke, older adults with cognitive impairment and cancer [28–30]. The BLW Program was previoulsy tested for feasbility [20] and is being fully implemented at 5 YMCA locations (Downtown Hamilton, Les Chater, Ron Edwards, Laurier Brantford, and Flamborough) at the same time of the launch of the study. The YMCA will be responsible for all aspects of program delivery including marketing. The investigators of this study support the implementation through education of the YMCA staff, and the design and production of the virtual content.

Participants

We will recruit study participants who have demonstrated interest by registering for the BLW program. The YMCA will advertise the program through their regular advertising channels including a newsletter, website, and social media, which will include a note about the study and the potential program discount that they may receive for study participation. Program participants, interested in the study, will be referred to the study by the YMCA staff when they enroll in the program. Enrollment in this study is not mandatory for program participation. Prospective participants interested in the study will be contacted by study personnel, who will explain the study and start study procedures. All participants will sign a consent form, through REDCap, prior to their participation.

Study inclusion criteria are: a) having enrolled but have not yet started the BLW program; b) have non-specific LBP which is pain not attributed to a specific diagnosis such as cancer or fracture; [31–33] c) history of persistent LBP (>3 months) that is mild to moderate (<=6/10) or severe (>6/10); [4, 34, 35] and d) 18 years of age or older.

Participants will be excluded if they have a) co-morbidity preventing participation in exercise based on a screening using the Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) that will be completed over the phone, and later confirmed by their family physician; [36] or b) inadequate fluency in English to complete questionnaires or interviews; or are c) currently seeking care elsewhere for LBP. Participation in the YMCA program is not limited to study eligibility criteria; this decision is to the discretion of the YMCA staff running the program.

We will recruit 45 participants in the in-person and 45 participants in the e-health program for a total of 90 study participants in the quantitative strand. This overall sample size will be sufficient for the descriptive analysis of quantitative outcomes trends and explorations of the influences of psychosocial factors and exercise participation. To recruit a diverse population, we will purposively recruit participants with an equal balance of men/women, and targeted recruitment of non-binary genders and balance across age groups (<30, 31 to 60, >65 years of age). We also selected our locations to increase our likelihood of including participants from diverse social economic and cultural backgrounds. We will purposefully recruit at least 15 participants with 'mild to moderate' pain and at least 15 participants with 'severe' pain to each of the in-person and e-health modalities. The inclusion of participants with varying pain levels will allow for greater understanding of how pain levels play a role in adherence to the intervention and outcomes. From the longitudinal cohort (quantitative) strand, we will purposively sample 12–15 participants for variation in age, gender, pain level and locations for the qualitative strand [37].

Individuals involved in the delivery and planning of the program as well as other YMCA staff involved in the coordination and booking of the YMCA program (including front desk booking appointments) will be asked to participate in our qualitative interviews to address implementation research questions. We will conduct 10–15 interviews YMCA staff after 6 months of program launch and another set of interviews after the last study participant complete the program.

Intervention – back to living well: community-based exercise and education

All program activities will be delivered by the YMCA as part of their usual activities. All staff involved in the delivery of the program will undergo two half-day training sessions, plus training updates and debriefing sessions regularly (~every 2–3 months). The program will be delivered by LiveWell Specialists who are kinesiologists by background and currently working at the YMCA. A training competency list was developed to support training of staff [See Additional File 1].

Prior to starting the program, all program participants will have a physical assessment by a LiveWell Specialist (kinesiologist) when physical impairments (e.g., comorbidities, other musculoskeletal pain, functional limitations) will be assessed. At this appointment a short

screening questionnaire including potential back pain red flags will also be administered [38]. If any of the red flag questions are positive, or if there are questions about the safety of the participant in engaging in the program, the participant will be referred for an online assessment with a physiotherapist. The physiotherapist will be responsible for clearing the participant, referring for medical care as needed, and providing general recommendations about the program based on co-morbidities (e.g., knee osteoarthritis). The LiveWell Specialist (kinesiologist) will also assess baseline capacity and design an individualized program based on individuals' functional goals.

The program will be delivered either in-person or online depending on the participant's preferences. Both in-person and online programs will be delivered using four main guiding principles: graded activity, functionally focused exercises, safety and ergonomics, and use of culturally safe and appropriate biopsychosocial language. Participants will be taught principles of graded activity [39] and will be instructed on how to use these to progress their exercises over time. Further, all exercises will be functionally focused and will mimic day to day activities or build capacity towards performance of activities of daily living. Exercises might start with one joint movement and will progress to multi-joint exercises. All exercises will be completed with proper body positioning to avoid compensations and overload joints and the spine. Finally, positive language consistent with pain education and the biopsychosocial model will be used. Positive language will be balanced with communication that incentivizes participation and accountability.

All participants will be asked to exercise three times per week, (as per World Health Organization recommendation) [40], will watch 12 educational videos (~3 min each) on self-management (developed by the investigators), and will complete weekly action planning. The education and the self-management sessions will be delivered online using 12 animated videos, that will be assigned weekly, through the YMCA e-health platform. The program aligns with current evidence on exercise for LBP [7, 14, 15, 41]. Education will be integrated and comprise information on LBP, [16, 42], introduction to self-management, [43, 44] graded activity and pain neurophysiology [45]. All participants will be encouraged to complete a weekly action plan with the support of the LiveWell specialist as part of the self-management component. Strategies to improve long-term adherence will include a suite of behaviour change techniques (BCTs) [46] shown to be effective for increasing motivation [47] and physical activity [48], including: self-monitoring-behaviour, goal-setting-behaviour, behavioural practice, feedback on behaviour, action planning, and social support provided through group-based exercise [49, 50] Table 1.

In person

The 12-week BLW program will consist of 45-min exercise sessions, three times per week. During the first day of the week participants will engage in group classes designed for a whole body functionally based workout. During the class, instructors will provide 3 different variations (light, moderate and vigorous intensity) of each exercise and will support participants in selecting the appropriate level as well as progression. Before or after this class, instructors will review the educational video assigned for the week and discuss goal setting and action planning with participants. The second day of the week will consist of an individualized fitness center program designed by the LiveWell specialist. While group classes will be used, a portion of each session will be individualized and tailored to each person's functional goals and preferences [34, 51–53]. During the third day participants will be encouraged to complete the fitness center program unsupervised or attend any other available activities at the YMCA (e.g., yoga, Pilates, Aquafit).

e-Health

The e-health program will be delivered using the YMCA streaming platform. All participants will undergo online assessments as per in person program and will complete asynchronous exercise sessions three times per week (30 min /session) for 12 weeks. In contrast to the in-person program option, the exercise program will be delivered using a pre-packaged exercise material that can be streamed online on demand (Y@HOME+) and completed independently at home. Participants will be asked to complete 2 exercise videos per week plus an additional Y@HOME+on demand program of their choosing. The exercise videos were developed to simulate the in-person classes. However, when necessary, exercises will be individualized; specific exercises that align with their

Table 1 Education videos

Low back pain diagnosis and natural history (MP4)—3:59
Evidence on low back pain management (MP4)—3:38
Pain neuroscience education part 1 (MP4)—4:18
Pain neuroscience education part 2 (MP4)—4:35
Graded activity (MP4)—4:46
Energy conservation part 1 (MP4)—4:45
Energy conservation part 2 (MP4)—2:38
SMART Goals (MP4)—3:05
Self managing your back pain—Action planning (MP4)—4:59
Self managing your back pain—Preventing a flare (MP4)—3:08
Self managing your back pain—Managing a flare (MP4)—3:48
Building a positive relationship with physical activity (MP4)—3:38

functional goals will be provided by the LiveWell Specialist based on the initial assessment. Further, participants will receive a phone call from the LiveWell Specialist at 3- and 7-weeks of the intervention to support implementation, address questions about safety and exercise progression, discuss education material and action planning or address problems with program adherence.

Data collection and implementation outcomes

The RE-AIM framework, including Reach, Effectiveness, Adoption, Implementation (fidelity), and Maintenance will be used to evaluate the implementation of the intervention. Table 2 provides details on specific questions and data that will be collected to address each domain.

Reach

Qualitative and quantitative methods will be used to determine the reach of the intervention into the target population. Demographic data (gender, age, duration of pain) will be collected across non-participants and eligible participants, as well as program record data on:

Interest

The number of participants that reach out to the YMCA for information about the program that ultimately register for the study and the number of participants enrolled in the program across all sites.

Recruitment

The proportion (i.e., frequency and percentage) of eligible patients who consent and enroll, as well as the proportion (i.e., frequency and percentage) of participants that need a physiotherapist assessment prior to starting the program.

We will also compare the characteristics of participants compared to non-participants (eligible but do not consent). Qualitative semi-structured interviews with YMCA staff will also provide information on the reach of the program.

Effectiveness

To measure the outcomes and adverse events of the intervention, patient-oriented outcomes measures and actigraphy will be collected. The primary effectiveness outcome of the study is the Roland Morris Disability Questionnaire (RMDQ). Secondary outcomes include the self report flare pain (Numerical Rating Scale (NRS)), activity limitation, anxiety/depression (Center for Epidemiological Studies-Depression Scale (CES-D), EQ-5D-5L), fear of movement (TAMPA Scale of Kinesiophobia), self-efficacy (Pain Self-Efficacy), coping (Coping Strategies), pain catastrophizing (Pain Catastrophizing Scale), health-related quality of life (EQ-5D-5L), physical activity (International Physical Activity Questionnaires (IPAQ)), actigraph data (Vector of magnitude + steps). We will also measure adherence to the exercise sessions and the education program using the Exercise Adherence Rating Scale (EARS), as well as the program data collected from the YMCA including the number of exercise and education sessions attended. Attrition will be determined based on the proportion (i.e., frequency and percentage) of participants who withdrawn from the intervention. Long term adherence to exercise will be measure based on participant collective yearly attendance at the YMCA (via card swipes) and YMCA membership retention.

Adoption

Setting and individual level data will be collected to gather willingness to initiate and actively participate in program.

Setting level

Setting level data will capture the number of sites involved in the study and delivering the program, the number of sessions being delivered within each site, and the characteristics of participants attending the program in-person and online as well as in-person classes by YMCA location, from program records and qualitative interviews of both staff and participants.

Staff level

Staff level data will gather information about the proportion (i.e., frequency and percentage) of staff who received training to deliver the program and the rotation of staff across sites including proportion (i.e., frequency and percentage) of those who leave the program from site records. To determine the time, resources, and effectiveness of staff training, qualitative interviews will collect data from YMCA staff.

Implementation

The fidelity of the intervention delivery will be completed through random audits (see Additional File 2). Adaptions to the interview will be tracked throughout the implementation, as well as from qualitative staff interviews. Costs of the intervention (money and time) will be collected through interviews and from program records to determine the proportion (i.e., frequency and percentage) of participants requiring financial assistance.

Table 2 Summary of outcomes, measures, and analysis plan using the RE-AIM framework

RE-AIM Element	Outcome Measure; Source	Data Collection Time Point; Data Analysis
Reach		
The reach of the intervention into the target population		
Interest	Proportion of participants that reach out to the YMCA for information about the program that ultimately register for the study; YMCA records Number of participants enrolled in the program across all sites until last participant completes follow-up; Program records	End of recruitment; Proportions
Recruitment	Proportion of eligible patients who consent and enroll; Self-report Proportion of participants that needed an assessment; Program records	End of recruitment; Proportions
Characteristic of participants compared to non-participants/eligible but do not consent	Demographics, Gender, Age, duration of pain; Self-report	End of recruitment; Descriptive statistics
Use of qualitative methods to understand reach/recruitment	Longitudinal qualitative interview with YMCA staff	End of recruitment; Qualitative Description
Effectiveness		
Positive and adverse effects of the intervention		
Measure of primary outcomes	Disease specific disability (RMDQ); Self-report	T_0, T_3, T_6, T_{12}; Linear Mixed models
Measure of broader outcomes	Self Report Flare Pain (NRS) Activity Limitation Anxiety/Depression Fear of Movement (TAMPA Scale of Kinesiophobia) Self-efficacy (Pain Self-Efficacy) Coping (Coping Strategies_ Pain Catastrophizing (Pain Catastrophizing Scale) Health related QOL (EQ-5D-5L) Physical Activity (IPAQ) Actigraph data (Vector of magnitude + steps); Self-report	T_0, T_3, T_6, T_{12}; Linear Mixed models
Adherence to the exercise program	How many exercise sessions each participant attended; YMCA records Exercise Adherence Rating Scale (EARs); Self-report	T_3, T_6, T_{12}, descriptive statistics
Long-term adherence to exercise	How many times over the year the participant attended the YMCA (via card swipes); YMCA records Membership – for how-long participant kept their YMCA membership for; YMCA records	T_{12}, descriptive statistics
Adherence to education program	How many videos the participants watch and for how long; Program records	T_3, descriptive statistics T_{12}, how many times they have logged in
Measure of short-term attrition and differential rates by patient characteristics or treatment condition	The proportion of participants withdrew from the intervention, with reasons; Program records	T_3, descriptive statistics
Use of qualitative methods to understand outcomes	Participant interviews	T_0, T_3, T_6, T_{12}; qualitative description

Table 2 (continued)

RE-AIM Element	Outcome Measure; Source	Data Collection Time Point; Data Analysis
Adoption		
Representation of setting and intervention agents who are willing to initiate and actively participate in the program		
Setting Level		
Number of sites involved in the study	Number of YMCA sites delivering the program; Program records	T_{12}; descriptive statistics
Program offering per site	Number of sessions being delivered within each YMCA and participants per class (e.g., morning, afternoon, evening) and registration offering; YMCA records	T_{12}, descriptive statistics
Characteristics of participants per offering	Characteristics of participants attending in person vs online as well as in person classes (morning, afternoon etc.); YMCA records + Program records	T_{12}, descriptive statistics
Use of qualitative methods to understand adoption at setting level (e.g., setting requirements to run the program)	Interview with YMCA staff	T_{12}, qualitative description
Qualitative interview to understand choice between in person and online	Interviews with participants	$T_{3,}$ qualitative description
Staff Level		
Number of staff trained to deliver the program	Staff trained and staff trained that do not deliver the program; YMCA records	T_{12}, descriptive statistics
Number of staff that leave the program (rotation)	Proportion of staff that leave the program and reason; YMCA records	T_{12}, descriptive statistics
Time and resources required to procure and train staff (also relates to maintenance)	Qualitative interview with YMCA staff	$T_{12,}$ Interview with staff
Effectiveness of staff training	Qualitative interview with YMCA staff	$T_{12,}$ Interview with staff
Implementation		
Fidelity to the intervention and adaptions		
Fidelity of intervention delivery	Random audits: classes meet class requirements as per class checklist (components of intervention list); Program records	Bi-monthly until T_{12}; Descriptive analysis (90% of components included to maintain fidelity, proper language used)
Adaptions made to intervention during study and checklist	YMCA staff interviews	$T_{3,}$ T_{12}, qualitative description
Cost of intervention (money and time)	Proportion of participants who asked for financial assistance; YMCA records Participant interviews with questions on costs and burden of intervention	$T_{3,}$ $T_{6,}$ T_{12}; Descriptive analysis and interpretative description of qualitative interviews
Maintenance		
Extent to which program becomes sustained over time		
Individual Level		

Table 2 (continued)

RE-AIM Element	Outcome Measure; Source	Data Collection Time Point; Data Analysis
Long term adherence to physical activity	Length of YMCA membership; YMCA records Sessions attended over 12 months; YMCA records Activity monitor results demonstrating increase activity; Activity monitors Qualitative interviews	T_3, T_6, T_{12}; Descriptive statistic Qualitative analysis results on physical activity
Setting Level		
If program is still ongoing after 6 months post study funding	Proportion of sites continuing program; YMCA records	Six months past T_{12}; descriptive statistics
Rotativity of YMCA staff	Number of Livewell specialists leaving and being trained over the period of the study; YMCA records	During the study up to six months post end of study recruitment; descriptive statistics
Use of qualitative methods data to understand setting level (e.g., perceived burden of training)	Staff Interviews	End of program; qualitative description

Maintenance

Individual and setting level data will determine the extent to which the intervention becomes sustained over time.

Individual level

Long term adherence to physical activity will be determine based on length of YMCA membership and sessions attended over 12 months through site records. Activity monitor data will demonstrate increased physical activity and through qualitative interviews with participants.

Setting level

Setting level data will capture the proportion of sites continuing the program after study funding concluded and the rotativity of YMCA staff through site records and qualitative methods.

Quantitative strand

Patient-oriented outcomes will be collected at baseline, 3 months (after the intervention), 6- and 12-months follow-up. All study outcomes have been mapped onto the RE-AIM framework, along with the data source [Table 2]. Quantitative outcomes will be collected primarily using REDCap, by phone or mailed paper copies as per participant's preference. In addition, to evaluate symptom trajectories, an Ecological Momentary Assessment (EMA) with weekly data collection over a mobile app will be conducted. EMA involves repeated sampling of participants current behaviour and experiences in real time in their natural environment [54]. Weekly outcomes will be collected for 1-year using a smartphone application (MetricWire Inc.) or using a REDCap survey as per participant's preferences.

Weekly measure

Weekly measures will include self-report flare [55] and pain as described below, activity limitation and anxiety/depression questions from the EQ-5D-5L and one question about hours of exercise (light, moderate or vigorous) [56] performed over the previous week.

Demographics (baseline only)

We will collect sex, gender (self-report), ethnicity, work status, education, and social economic status. We will also use a family/work questionnaire to identify social roles [57].

Disability

Disease specific disability will be assessed using the Roland Morris Disability Questionnaire (RMDQ) [58] This questionnaire has well documented validity, reliability and responsiveness (Minimal Clinical Important Difference (MCID) = 5). [58, 59].

Pain

Pain intensity over the last week: on average, at its worse and at its best will be measured using a NRS from 0–10. [59] This core outcome measures in LBP has MCID = 2 [59, 60]. We will report each pain question separately and as an average of the 3 assessments.

Flare

Two methods will be used to identify a flare. Self-reported status based on a Delphi study definition: Have you had a worsening of your condition that is difficult to tolerate and impact usual activities and/or emotions [55] and using a operational definition: Participants will meet the criteria for activity-limiting flare if pain has increased at least 2 points on a NRS- 10 point scale (MCID) over the previous week [58] and pain is identified to be limiting on EQ-5D-5L activity limitation question.

Health related quality of life

Health-related quality of life will be assessed using the EQ-5D-5L [56]. There are validated utility tables for Canada specifically derived from the EQ-5D-5L, which is the most commonly used measure of health-related quality of life.

Physical activity

Physical activity will be assessed indirectly using the International Physical Activity Questionnaire (IPAQ-short form), [61] use of the participant's swipe cards at the YMCA, a diary that will be collected at each follow-up, and step counts and intensity minutes measured using an activity monitor. Participants will wear an activity monitor (ActiGraph GT9X-BT) for 7 days prior to the intervention, and at each follow-up to track change in physical activity over time.

Exercise & program adherence

Adherence to the exercise program will be assessed using the Exercise Adherence Rating Scale (EARS). This is a 16-item, self-reported scale to assess the adherence of prescribed exercises, which consists of 3 Sects. [62]. The items of section B and C are scored using a 5-point Likert scale with scores ranging from 0 to 64. A higher overall score indicates better exercise adherence. Section A allows individuals to provide qualitative information about their adherence behavior and is therefore not scored. Program adherence will be measured through YMCA attendance tracking or through tracking of online activity.

Depression

Depression will be assessed depression using the Center for Epidemiologic Studies Depression Scale (CES-D) questionnaire [63].

Psychological questionnaires

We will also collect psychological measures that have been described to be associated with the experience of LBP or as prognostic indictors: Fear of movement (Tampa Scale for Kinesiophobia); [64] Self-efficacy (Pain Self-Efficacy Questionnaire); [65] coping towards LBP (Coping Strategies Questionnaire); [66] pain catastrophizing (pain catastrophizing scale) [67].

Qualitative strand

The research staff conducting interviews has extensive experience in qualitative methods including a PhD in rehabilitation science. They will be independent from other aspects of the project such as recruitment and audits.

Participant interviews

Semi-structured participant interviews will be conducted at baseline, at post-program, 6- and 12-months (see Additional file 3). We will use a theory-based approach to identify barriers and enablers to the program focusing on exercise adherence (i.e., behavior change) [68, 69]. Guided by the conceptual models of the TDF and the NMP, the following areas will be addressed using a semi-structured interview script for the time-based interviews: a) barriers and enablers to the program and long-term adherence, b) factors guiding the selection of e-health or in-person interventions, c) description of symptoms, impairments and difficulties with day to day activities; d) strategies used to deal with flares or episodes of illness; d) intrinsic and extrinsic contextual factors that exacerbate and alleviate their condition; e) perceptions of key disablement issues related to gender; f) interventions, practical strategies and supports used to manage disability (e.g., exercise).

The TDF provides a theoretical scaffold to frame assessment of the cognitive, affective, social and environmental influences on behavior [68, 69]. The TDF was used for the development of interview questions related to objectives 1 and 3. In addition, this will be augmented by the neuromatrix model of pain, that will be a focal point for addressing objective 2 of how intervention, personal and environmental factors interact in the symptom trajectory [70, 71]. The TAM [71] will be used to understand barriers and enablers of the online intervention as it relates to core components of the model: perceived usefulness, attitudes to towards use, behavioural intention and behavioural usage. Interview question map is available on Additional File 3.

In order to promote reflection on their experience with the BLW program and LBP symptom trajectory, following the initial interview the interviewer will share verbal summaries of their participant profiles with each individual and ask them to consider what changes have occurred, how these occurred, and how these have affected their functioning. This strategy will allow for triangulation and confirm our description of change across time through a collaborative and reflective approach [72]. We will conduct data collection and analysis iteratively as each interview will inform the other. Interviews will be audio-recorded and transcribed verbatim and entered into Dedoose to aid team-based analysis. Interview guides will be iteratively modified for subsequent interviews to reflect emergent themes and challenges.

Organization perspective interviews

Interviews with YMCA staff will also be conducted using a semi-structured interview guide which will have questions mapped to the Consolidated Framework for Implementation Research (CFIR), primarily focusing on the organization specific domains (see Additional file 4) [73]. Interviews with staff will occur at 6 months after implementation, after the first cohort of participants complete the program on all sites and again after all study participants have completed the intervention. Interviews will last for approximately 45–60 min. As per participant interviews, analysis will be concurrent with interviews and the interview guide will be iteratively modified for subsequent interviews to reflect emergent themes and challenges.

Finally, to further address our implementation questions, YMCA staff delivering the program will be audited by research study members for the fidelity of delivery of the program using the audit checklist (see Additional File 2). Audits will occur bi-monthly for 1 year or until the last study participant completes the study.

Data analysis

Quantitative analysis

We will present descriptions of demographic data and patient-reported outcomes by mean and standard deviations for continuous variables, and frequency and percentage for categorical or dichotomous variables. Weekly pain and activity limitation outcomes will be analyzed using mixed effect models to evaluate how outcomes change over time as well as how anxiety/depression, exercise level predicts outcomes over time after controlling for age and gender [74, 75]. Disaggregated presentation of data for men/women/nonbinary (if declared) will

be conducted using Sex and Gender Equity in Research (SAGER) guidelines [76].

Qualitative analysis

We will follow the Standards for Reporting Qualitative Research (SRQR) [77] guideline in our reporting. We will use interpretive description methodology to develop knowledge that will inform implementation [78]. We will perform two rounds of directed content analysis using the TDF, TAM and NMP and the RE-AIM framework [79].

Given the longitudinal nature of the interviews, after the completion of the Round 1 interviews we will develop a code book to guide our analysis based on an open coding procedure and code transcripts using a team approach [25]. Using the coded transcripts at Round 1, we will develop in depth summary profiles for each participant. Longitudinal qualitative interviews will explore challenges identified in Round 1 on subsequent interviews and we will ask the participant to consider what changes occurred (if any). At a final stage of the analysis, we will compare longitudinal summary profiles of participants to document similarities and differences in the episodic nature of disability experienced by participants over time.

Once codes and themes are initially formulated, they will be shared with other members of the research team who will review and refine, providing feedback on illustrative quotes and themes. Findings will be reviewed through the lens of a rehabilitation health care professional. Verification (i.e., researchers' convergence on themes), referential adequacy (i.e., substantiating comments with adequate quotes), triangulation (i.e., consideration of the results from both the quantitative and qualitative strands), researcher triangulation (i.e., involving multiple research team members in the analysis process) and an audit trail will be used to ensure methodological rigor [80].

Analysis of interviews conducted with YMCA staff will follow similar process as per the patient interviews. However, during the final process of the analysis, deductive analysis with themes mapped to the CFIR will also be conducted [73].

Our integration points for the quantitative and qualitative strands will occur through the experimental, analytical experimental and inferential analysis steps [81]. At the experimental stage, we will use quantitative measures of flares and exercise to determine inflection points in which qualitative interviews will be triggered. In addition, as part of the longitudinal qualitative approach, we will develop quantitative and qualitative profiles of the participants to guide the development of interview questions for subsequent interviews. In both the analytical experimental and inferential steps, participants profiles will be used to propose participant phenotypes explaining symptom trajectory over time and consider how psychosocial, environmental and interventions factors interact as barriers or facilitators of positive change [82].

Discussion

This study aims to evaluate the implementation of a community-based program for persistent low back pain across multiple sites. We will be explicitly looking at barriers and facilitators to the implementation of the BLW program and evaluate the participant's outcomes over time. By using the RE-AIM framework, we will gain a comprehensive understanding of the potential scalability of the program, while aiming to gather further perspective about exercise adherence, education, and self-management in the tertiary prevention of LBP.

The study's strength is its longitudinal mixed methods design with the use of important frameworks to guide design and analysis. There were a few limitations identified in our previous pilot that this study aims to address [20]. Firstly, this study will scale up recruitment as compared to our previous pilot and offer more classes at new locations at different times as well as an online program option. We anticipate attracting different demographics by opening the program in areas of low socioeconomic profile and rural location. Additionally, in comparison to our pilot study, recruitment will not be limited to those recently discharged from care (< 3 months), which will increase access to the BLW program.

The results of this study will be used to refine the intervention, including the education program. Other results, including adherence metrics, will allow the research team to estimate the implementability of the intervention to a broader context. These estimates will be contextualized by the qualitative findings which will provide important insights into how to optimize the program across key implementation domains. Next steps will be to support the widespread implementation of the program across Ontario, Canada and internationally including a broader implementation evaluation with a focus on therapists and stakeholder organizations. By assessing implementation of the program using the RE-AIM framework, we will gain comprehensive knowledge about potential national and international scalability of the program.

Abbreviations

LBP	Low back pain
BLW	Back to Living Well
RE-AIM	Reach, effectiveness or efficacy, adoption, implementation, and maintenance
TDF	Theoretical domains framework
TAM	Technology Acceptance Model
NMP	Neuromatrix model of pain
HBB	Hamilton, Burlington, Brantford
HSS	Hamilton Health Sciences

PAR-Q+	Physical activity readiness questionnaire for everyone
BCT	Behaviour change techniques
EMA	Ecological momentary assessment
NRS	Numeric rating scale
RMDQ	Roland morris disability questionnaire
MCID	Minimal clinical important difference
IPAQ	International physical activity questionnaire
EARS	Exercise adherence rating scale
CES-D	Center for epidemiologic studies depression scale
CFIR	Consolidated framework for implementation research
SAGER	Sex and gender equity in research
SRQR	Standards for reporting qualitative research
KT	Knowledge translation
MOOC	Massive open online course

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-024-07712-7.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

Acknowledgements
Not applicable

Authors' contributions
LM, JM, MH, MB, GH, JR conceptualized the implementation and evaluation of the study. BS, JH, AR, TP, SB, MG will support additional implementation and evaluation of the study. PM and SA will provide the patient perspective in the design, execution, analysis, interpretation of findings. SD will support coordination of site implementation, data collection, and evaluation. The authors have read and approved the manuscript.

Authors' information
LM, JM, MH, and MB have expertise in low back pain clinical research. GH is the coordinator of the LiveWell programs. JR has experience in developing and evaluating LiveWell programs. BS has expertise in e-health interventions for low back pain. JH has expertise in exercise therapies for low back pain and knowledge translation. AR, TP, SB, MG have expertise in qualitative and mixed methods. SD is a research coordinator with expertise in mixed methods research in low back pain studies and community-based interventions.

Funding
Canadian Institutes of Health Research.

Availability of data and materials
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study has been approved by the Hamilton Integrated Research Ethics Board Project ID#15354.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]School of Rehabilitation Science, McMaster University, Hamilton, ON, Canada. [2]School of Rehabilitation Science, McMaster University and Master's and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo, Sao Paulo, Brazil. [3]Western University, London, ON, Canada. [4]Macquarie University, Sydney, Australia. [5]Discipline of Physiotherapy, Graduate School of Health, Faculty of Health, University of Technology Sydney, Sydney, Australia. [6]Dalhousie University, Halifax, NS, Canada. [7]YMCA Hamilton, Burlington and Brandtford, Canada. [8]Hamilton, Canada.

Received: 6 May 2024 Accepted: 19 July 2024
Published online: 27 July 2024

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