The Implementation of an Effective Aerobic Walking Program Based on Ottawa Panel Guidelines for Older Individuals with Mild to Moderate Osteoarthritis: A Participant Exercise Preference Pilot Randomized Clinical Trial Protocol Design

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Authors' contributions

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kinesiology and the members in rheumatology and biostatistics. A charter governing the process and the frequency of the DSMB meeting, as well as content of the reports, will be determined as part of the study start-up in conjunction with the DSMB and principal investigators.

Study Protocols

ABSTRACT

Aims: Osteoarthritis is the most common disabling disorder affecting particularly knees. A recent systematic review demonstrated the efficacy of walking programs for improving pain, functional status, endurance, and quality of life, in the management of knee osteoarthritis. Even though evidence suggests that walking provides numerous clinical benefits, older people diagnosed with osteoarthritis avoid physical activity. General objective is to evaluate the effect of participants' exercise preference. We expect to encourage osteoarthritis participants to adhere successfully to a proven effective walking program.
Study Design: This is a 9-month supervised walking program with a 3-month follow-up period using a preference trial design which consists of three single blind randomized clinical trials, based on a participant exercise preference model, to elicit preferences independently of randomization.
Place and Duration: Indoor Walking Club in the City of Ottawa, Billings Bridge Shopping Centre, next door to The Arthritis Society Ottawa office.
Methodology: A total of 69 participants with a confirmed diagnosis of osteoarthritis of the knee will be recruited from the general public from the Ottawa area. We are implementing a knowledge translation strategy, in order to improve adherence and consequently ensure the maintenance of pain relief, functional status and quality of life, among older individuals diagnosed with mild to moderate osteoarthritis. This article summarizes the study protocol of the walking study, by explaining the methods and interventions selected and discussing on the need for this trial.
Conclusion: This proposed pilot randomized controlled trial will address a new knowledge gap by concentring on questions of clinical and scientific importance to improve the understanding related to the efficacy of strategies to promote the adoption and long-term adherence of community-based walking programs.

ABBREVIATIONS

ACR: American College of Rhumatology, ACSM: American College of Sports Medicine, ANCOVA: Analysis of COV Ariance, ANOVA: Analysis Of Variance, BI: Behavioural Intervention, CONSORT: Consolidated Standards Of Reporting Trials, CSER: Canadian Society for Exercise Physiology, DSMB: Data Safety Monitoring Board , EBCPG: Evidence-Based Clinical Practice Guideline, EF: Effect Size, EQ: Euro Qol,

HSD: Honestly Significant Difference, ITT: Intention-To-Treat, KT: Knowledge Translation, KTAC: Knowledge-To-Action Cycle, MCID: Minimal Clinically Important Difference, MI: Multiple Imputation, MMRM: Mixed Model Repeated Measures, OA: Osteoarthritis, PA: Physical Activity, PAR: Physical Activity Recall, PGrip : People getting a Grip on arthritis, QoL: Quality of Life, RCT: Randomized Controlled Trial, S: Supervised, SD: Standard Deviation, SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials, TAS: The Arthritis Society, TUG: Time-Up-and-Go, U: Unsupervised, WBI: Walking program combined with a Behavioural Intervention component, WOMAC: Western Ontario and McMaster Universities Arthritis Index.

1. INTRODUCTION

1.1 Problem

Osteoarthritis (OA) is the most common disabling disorder affecting joints, such as knees and hips. The prevalence of this degenerative disease significantly increases after the age of 40 and is seen principally among older individuals, in relation to the impact of a global ageing population [1]. OA is recognized as the primary cause of long-term disability, worldwide. Indeed, the impairments, disabilities and handicaps associated with knee OA can lead to devastating personal consequences as well as negative effects on the health care system and society at large [2,3]. The Bulletin of the World Health Organization confirmed that approximately 9.6% men and 18.0% women, aged over 60 years old, are diagnosed with OA, in the world [3]. A recent comprehensive systematic review by The Ottawa Panel on Evidence-Based Clinical Practice Guidelines (EBCPGs) Walking Programs in the Management of Osteoarthritis [4] found strong scientific short-term evidence (Grade A recommendations) for improving pain, functional status, endurance, and quality of life on the efficacy of walking programs, either supervised or unsupervised, in the management of mild to moderate OA of the knee. Although evidence suggests that walking provides numerous clinical benefits [4], unfortunately individuals diagnosed with OA gradually become sedentary [5,6] and tend to avoid physical activity (PA) [7]. As a result, the majority of individuals with OA are approximately three times more likely to have difficulties walking more than 0.4 km because of pain [8] and have five or more functional disabilities, such as climbing stairs and performing activities of daily living, compared to healthy individuals [9]. Inactivity leads to decreased endurance and mobility, thus reducing quality of life [10-12].

Although aerobic PA programs, such as walking, can improve short-term effects on clinical, physiological and quality of life outcomes for OA [4,13], enrolment in these types of programs do not guarantee adherence and long-term maintenance. An ongoing concern in research is the high attrition rate (i.e. drop-out rate) ranging from 20% to 39% among OA participants recruited in short-term studies involving PA [4,14,15,44,45]. Of further concern, remaining participants in the short-term intervention trials demonstrated poor adherence (27% to 64%) [14,16,17]. A recently completed randomized controlled trials (RCT) concurs with previous walking studies, demonstrating poor adherence rates of 44.5% for the supervised walking program combined with a behavioural intervention (BI) component and 49.0% for the self-directed walking program (control group) without considering participant preferences, at the 12-month follow-up [18,19]. The term "adherence" means the action of a participant attending all scheduled sessions for a specific treatment in a particular trial [20,21]. Long term RCTs (study period of more than 6 months) involving aerobic PA programs for OA have typically included BI components (e.g. goal settings, participant

education, telephone contacts, face-to-face visits, social/peer support or positive feedback) [6,11,17,22,23]. These studies exhibited lower drop-out rates at follow-up compared to short-term studies which did not use BI (10% to 15% between 2 to 4 months and 10% to 49% between 10 and 18 months). Higher adherence rates were also demonstrated between 2 to 4 months (85% to 90%) and between 10 and 18 months (50% to 90%). Unfortunately, BIs are still rarely included in walking programs [4]. Since long-term RCTs have typically combined BIs, and demonstrated higher adherence rates [22,2], there is a need to further explore long-term community-based aerobic walking programs as recommended by international expert committees for OA [24]. Therefore, the critical challenge is to develop programs that will encourage participants to not only initiate, but also to adhere to a long-term walking program in order to maximize the benefits of walking.

1.2 Objectives

In this proposal, we will emphasize on the importance of focusing on Evidence-Based Clinical Practice and Knowledge Translation (KT) implementation. The literature shows that considering participants' exercise preference [21] improves clinical outcomes. In fact, Cahill et al. [25] confirmed that the inclusion of participant exercise preference increases participants' satisfaction with care and consequently may enhance adherence to treatment, since it has shown to prevent discouragement and desire to drop-out of the study [26,27]. The term 'participant exercise preference' reveals the individual's personal expression of a value following informed reflection on pros (benefits) and cons (risks) of the interventions proposed, based on his/her values, beliefs and needs [28]. Therefore, preference is a promising element to enhance walking adherence, that has not yet been applied to a long-term RCT consisting of aerobic walking programs [21], not been studied among older adults with OA and has not been investigated with adherence as the primary outcome. It is likely that participants' exercise preference will offer a promising avenue if used as a KT strategy to implement successfully a proven walking program, in terms of improving adherence over the long-term [18,19].

The main objective of this pilot RCT is to evaluate the effect of participants' exercise preference. We will examine the hypothesis that participants who follow their preferred aerobic walking program: 1) supervised (S) or 2) unsupervised (U), combined with a BI component, will be more encouraged and satisfied, thus enhancing their walking adherence through the 9-month study period, compared to individuals who do not obtain their preferred choice of aerobic walking program, among people diagnosed with knee OA. Moreover, when there is no preference for a specific aerobic walking program (supervised vs. unsupervised), it is hypothesized that the supervised aerobic walking program (S) with a BI component will demonstrate an improvement in walking adherence compared to the unsupervised aerobic walking program (U) with an identical BI component through the 9-month study period, among people diagnosed with knee OA. We will secondly evaluate if favorable effects on pain, functional status, quality of life, physiological and economic outcomes [29] will be demonstrated among participants who present a preference, either supervised or unsupervised and who obtain their preferred choice of program compared to participants who did not obtain their preferred choice of program through the 9-month study period. We will be conducting a pilot RCT which is powered enough to measure an effect of the primary outcome (walking adherence) but could serve as a feasibility study, by 1) demonstrating if the recruitment process and rate, design, interventions and selected outcome measures are feasible and by 2) determining the variance of our primary outcome measure (walking adherence). If it is not demonstrated feasible, we will use these data to plan a larger and more rigorous RCT.

2. MATERIALS AND METHOD

2.1 Study Design

This is a 6-month supervised walking program with a 3-month follow-up period using a preference trial design which consists of two single blind RCTs, based on a participant exercise preference model [25], to elicit preferences independently of randomization (Fig. 1). Before randomization, each participant will be informed of their choice of walking supervision (supervised or unsupervised) using the same effective walking program in terms of frequency, duration, and walking intensity (Table 1). All outcomes are reliable and validated and are based on The Ottawa Panel guidelines (2012) [4]. Eligible and consenting participants, recruited from the city of Ottawa, will be stratified on whether they do or do not have a preference for supervision of the walking program (preference for supervised or unsupervised, or no preference). Within each of these three groups, based on their stated exercise preference, participants will then be randomized to one of the two modes of supervision for the effective walking program: (a) a supervised walking program supplemented with a multifaceted BI (at a walking club, supervised by an exercise therapist) (S), or (b) a self-directed unsupervised walking program combined with an identical BI (no supervision) (U) (Fig. 1 for more details).

The term 'adherence' refers to the extent to which a person follows an intervention recommended by his health professional. Therefore, a participant will be described as non-adherent if not attending and completing the treatment sessions prescribed [31,15]. It is important to mention that health behaviour is defined as any activity undertaken by a person to preserve good health [21]. Given that health behaviours are beneficial only if they are maintained over the long-term, the most important challenge is to develop strategies that will encourage people to adhere permanently to a pattern of behaviour to maximize the benefits of the intervention. This strong protocol is based on the SPIRIT statements.

2.2 Sample Size Calculation

The goal of this trial is to compare the primary outcome 'adherence with the intervention' for: a) the group of participants with a preference for a supervised walking program (S) who obtain their preferred choice of program compared to the group of participants with the same preference who did not obtain their preferred choice of program; b) the group of participants with a preference for an unsupervised walking program (U) who obtain their preferred choice of program compared to the group of participants with the same preference who did not obtain their preferred choice of program. It is expected that adherence will be high among participants with a preference and who will obtain their choice of exercise program, and low among participants with a preference that will not obtain their exercise program of choice. It is expected that adherence levels among participants with no preference will be better in the supervised group compared to the unsupervised group. Nevertheless, all tests will be two-sided. Based on previous experience with arthritis patients, our preliminary results concur with existing literature that 2/3rds of the study participants sample have a preference [21]. A total of 46 participants with a preference for the supervised (S) or unsupervised (U) program will be recruited. Twenty-three participants with a preference for supervised program (S) will be recruited, and after randomization, half of the group will obtain their preferred exercise program of choice (S) while the other half of participants will not obtain their preferred exercise program of choice (U). Similarly 23 participants with a preference for unsupervised program (U) will be recruited, and after randomization, half of the group will obtain their

preferred exercise program of choice (U) while the rest will not obtain their preferred exercise program of choice (S). Within the no preference group (n=23), after randomization, half of the group will be randomly allocated in the supervised program (S) while the other half of participants will be allocated to the unsupervised program (U) (Fig. 1). The two primary comparison groups are: a) preference for S group obtaining their choice (S) vs. preference for S group not obtaining their choice (U); b) preference for U group obtaining their choice (U) vs. preference for U group not obtaining their choice (S). For each of these primary comparisons, we will be able to detect a moderate effect size of 0.5 for adherence with a significance level of 0.05 (0.05/2=0.025; the alpha was adjusted to accommodate the two primary objectives) and power of 80% based on a two sided Student's t-test. A moderate effect size of 0.5 is necessary in order to justify a greater clinical impact of this EBCPG implementation, depending on its relative costs and benefits, since the supervised program will be more expensive to conduct than the unsupervised approach [46]. In particular, for a standard deviation of 0.433 [18,19] for the adherence to intervention outcome, a moderate effect size corresponds to a difference in adherence of 0.22 (i.e 22%) (Effect size (EF) = Minimal clinically important difference (MCID) / Standard deviation (SD)). Brosseau et al. [18,19] performed a similar study and confirmed that the adherence (based on attendance marked in logbooks) of a supervised aerobic walking program with behavioural interventions decreased from 80% at the initial evaluation (0-3 months) to 45% at the end of the study (9-12 months). According to Rejeski et al. [32], a difference of 22% in adherence is considered an important difference when an exercise logbook was used for self-reporting the percentage of total exercise sessions performed in aerobic exercise program for osteoarthritis of the knee [33,32]. Therefore, the evidence supports the plausibility of seeing a difference in adherence of 22%.

2.3 Study Sample

Sixty-nine older adults with knee OA who are not already engaged in regular PA will be recruited (Fig. 1). Potential participants will be assessed through an admission questionnaire and a face-to-face interview by the Research Coordinator to ensure that they meet the study's selection criteria [2,22,34]. The inclusion criteria include: 1) Diagnosed with OA of the knee, based on the clinical symptoms of OA following the American College of Rheumatology (ACR) criteria for knee, including radiographic evidence according to the Kellgren-Lawrence grading scale during a radiological assessment of OA (1 - 3) [35,36], 2) Aged between 55 and 80 years old [1], 3) Able to walk for a minimum of 20 minutes at their own pace and 4) Available three times a week over a period of 9 months for 45 minutes (Supervised group: during the operating hours of the Walking Club; i.e. 7:30 to 10:00 am) [37], 5) No evidence of other illness judged by the physician to make participation in this study inadvisable, 6) No evidence of mental health condition.
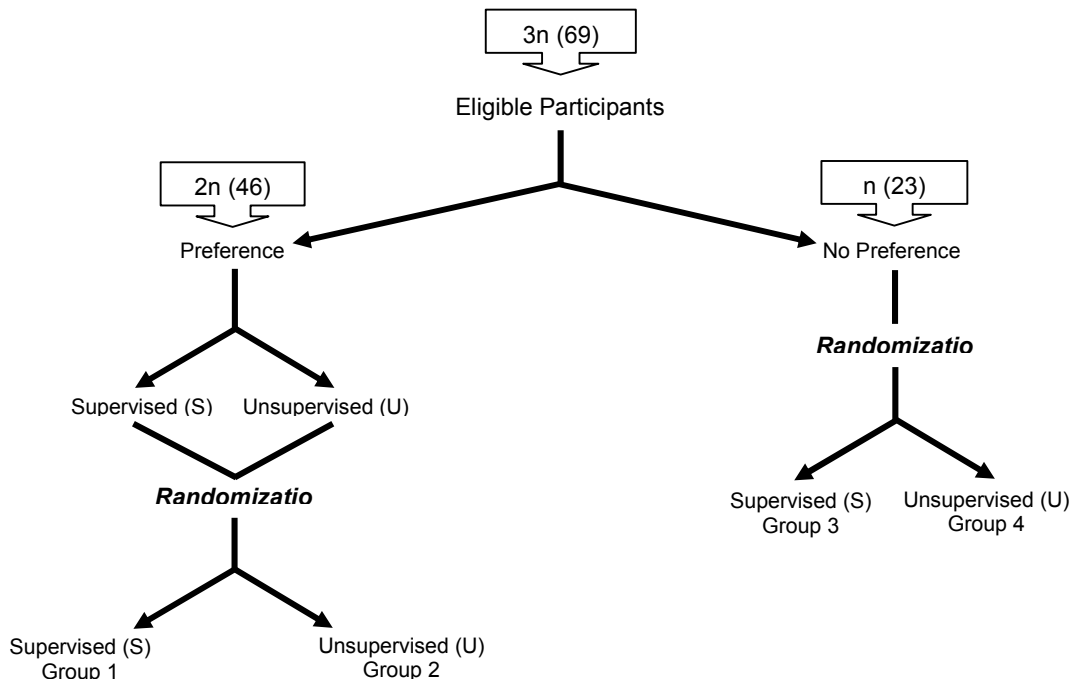
Fig. 1. The adapted randomized participant-preference design
Used with permission from Patient's Preference and Randomization: New Paradigm of Evidence-based Clinical Research. Millat B, et al. World Journal of Surgery, 29. Copyright © 2005 [30]. Sample size calculation performed according to current literature (2/3rds of study participants sample have a preference [27]).

2.4 Interventions

2.4.1 Supervised aerobic walking program (S)

All the participants in the supervised aerobic walking program based on the Ottawa Panel guidelines (2012) [4] and PGrip (People getting a Grip on arthritis) program will walk three days per week, for 6 months in an indoor Walking Club in the City of Ottawa, next door to The Arthritis Society Ottawa office (in addition to the 3-month follow-up period where they are free to walk according to their preference). Each participant will receive a pedometer, to monitor the number of steps per walking session [2]. Since the group is supervised, an exercise therapist with certification from either the Canadian Society for Exercise Physiology (CSEP) (Certified Exercise Physiologist), or American College of Sports Medicine (ACSM) (Clinical Exercise Specialist) will supervise all walking sessions. Therefore, the exercise therapist will perform the following tasks: 1) provide pedometers and heart rate monitors, 2) record attendance, number of steps, and vital signs, and will 3) give instructions on how to complete individual daily logbooks. He/she will provide a detailed orientation of the walking club and the walking program for each participant. Each walking session will start with a 5-minute warm-up period, including stretching exercises of the upper and lower extremities. Participants will subsequently be required to walk for 45 minutes in the shopping mall. At the end of the walking session, participants will perform a 5-minute cool-down period [39]. Regarding the intensity of the walking period, the participants will stay between 60-80% of

their maximum heart rate (220-age), using a heart rate monitor offered during the walking sessions (Table 1).

2.4.2 Unsupervised aerobic walking program (U)

Participants from the unsupervised walking program will be involved in the same training progression related to the effective walking program [4] (Table 1), but will be invited to walk by themselves, without supervision, i.e. at anytime and anywhere except at the Billings Bridge Shopping Centre, for 6 months (in addition to the 3-month follow-up period where they are free to walk according to their preference). The research coordinator will offer one introductory session to describe how the pedometers work so that they can carry out a self-directed walking program. She or he will also explain how to record the number of walking sessions and the daily step count (pedometer) in their log books. An independent evaluator will review the log books at the measurement sessions. To avoid potential contamination, individuals in group U will have no contact with the individuals in group S, who are registered at The Pace Setters Walking Club, next door to The Arthritis Society Ottawa office.

	Week No.	Phase	INDIVIDUAL AEROBIC WALKING TRAINING		
			Duration (min/day)	*Intensity (% HRmax)*	*Frequency (days/wk)*
Progression Phase	1-4	Progression	25	60	3
	5-8	Progression	30	65	3
	9-12	Progression	35	70	3
	13-16	Progression	40	75	3
	17-20	Progression	45	80	3
Follow-Up Phase	21-26	Maintenance	45	80	3
	27-38				

Table 1. Individual aerobic walking training progression
Participants' aerobic walking training, related to the progression of their walking duration, intensity and frequency, throughout the study period, based on the Ottawa Panel et al., 2012 [4]

2.4.3 Behavioural intervention (BI)

The exercise therapist will be trained before implementing the existing evidence-based structured education program developed by The Arthritis Society (TAS) educational program: "Stay Active/Manage your OA pain". Combined with a multifaceted BI, the education program will ensure participants' adherence, through the 6-month progression phase of the study period (Table 1). Based on a variety of sources of evidence including the Ottawa Panel CPGs [4], the BI will consist of the following components: (1) short- and long-term goal setting, according to other physical activities or functional concerns, at the walking

club each 3 months (at baseline, 3, 6 and 9 months); (2) moral support to continue walking every 3 months; (3) number of steps measured 3x/week with a pedometer; (4) daily walking logbooks to record the duration (min/day), frequency (days/week) and intensity of their walking sessions using the calendar included in the PA [2,18,19]. Barriers will also be identified and documented, as well as strategies to overcome them, in order to ensure long-term maintenance of walking.

2.4.4 Strategies to improve adherence

The term 'adherence' will be used throughout this protocol, even though other studies only used the term 'compliance'. The reason is that compliance seems to reflect negative connotations, by indicating a more passive role of the participant following only the medical instructions. Since adherence means the action of a participant attending and participating in all scheduled treatment sessions, in a particular trial [25], generally a participant will have less than 100% adherence to interventions and study procedures. From an adherence viewpoint, the more control over the administration of the intervention the better. There are various reasons for non-adherence, such as the participant experiencing side effects and is unwilling to change his/her behaviour, the instructions are not understood, there is a lack of family support, or even if the individual changes his/her mind to participate [25].

Based on previous work, different steps will be taken prior to enrolment to improve adherence among all participants. Therefore, since we are performing a 6-month supervised walking program (+ 3-month follow-up period), we will encourage participants to follow the structured walking program considering exercise preference. In addition, other relevant actions such as: (1) selecting participants likely to follow the protocol, according to the inclusion criteria, and (2) optimizing participant's experience, by involving them more in the decision-making process and respecting their exercise preference can improve adherence. If participants in the unsupervised group state a preference to be supervised at the beginning of the study, they will be offered a free membership to the affiliated indoor Walking Club, at the end of the follow-up. To ensure participant retention and complete follow-up, we will track the data in the logbooks from participants who choose to withdraw from the study and identify personal factors influencing their low adherence and/or intention to drop-out. They will still receive reasonable compensation, relevant to their levels of participation.

Finally, we will consider participant adherence to other aspects of the study such as their attendance to measurement sessions. To perform this task, the exercise therapist will take attendance following the appropriate list of participants, each walking session.

2.5 Measurements

Measurement sessions will be scheduled every three months over the course of the 9-month study (i.e. at baseline, 3, 6, and 9 months). The blinded independent evaluator will assess the four main outcomes (adherence, quality of life, pain and functional status), and other relevant information. The evaluator will meet with each participant individually and will assist them with the questionnaire. The outcome assessment will be completed at the Walking club in a closed and private room after opening hours. The primary outcome will be participants' adherence to their respective walking program (S vs. U). Secondary outcomes measures will include: pain, stiffness, functional status, gait speed, number of steps completed during the walking sessions, self-efficacy, PA behaviour, walking endurance, change in blood pressure and heart rate, level of physical fitness, long term goal attainment, and stair climbing difficulty.

A follow-up period of 3 months will directly follow the 6-month intervention period. Given our target sample size and the study period, data collection is estimated to take 39 months (36 months to measure the short-term effects and three months to measure the long-term effects) and data analysis is estimated to take 3 months.

2.5.1 Screening measurement

At the first visit, the eligible participant will provide his/her written informed consent [38]. Study participants will be assessed and classified according to the American College of Rheumatology functional classification [15]. A complete medical history and examination will also be performed. A questionnaire will be completed concerning factors that could influence adherence to the walking programs, such as occupation, previous PA, proximity to the walking club, use of medications and non-pharmaceutical interventions, etc.

The participant will then be asked by the research coordinator to express his/her walking supervision preference and all the reasons behind his/her choice: 1) preference for supervised (S) or unsupervised (U) walking program or 2) no preference. The participants' exercise preference level will be estimated using a visual analogue scale, where 50-100% will represent a strong preference for one type of walking supervision (participating in a supervised or unsupervised walking program), 1-49% weak preference, and where 0% will represent a no preference for one mode of walking supervision (supervised or unsupervised) (Fig. 2).

According to this measurement, study participants will be randomly allocated to one of the two walking programs (S and U). Therefore, the participants' stated exercise preference will be independent of randomization [39] (Fig. 1).

2.5.2 Primary measurement

Adherence will be measured to determine the effect of the type of supervision (supervised vs. unsupervised) on the sustainability of the walking program. Program adherence to treatment will be monitored and calculated as a proportion of the number of walking sessions attended and completed divided by the number of walking sessions prescribed (3 times a week as recommended in the Ottawa Panel guidelines, 2012) [4] and recorded in the participants' logbooks [6,18,19,21,23,32]. The calendar proposed by the 7-Day Physical Activity Recall (PAR) [40] incorporated in the logbooks will be used as a self-report questionnaire, to calculate the number of walking sessions each participant will complete every week. For the supervised group (S), we will take the attendance at the walking club to confirm what is written in the walkers' logbooks. The logbook will also be used as a tool to measure other valid measurements of the physical activity level, using METS, pedometric and walking endurance measurements. It is important to note that this method of assessment was used in various RCTs that studied the impact of walking programs in the management of OA among older individuals [18,19,23].
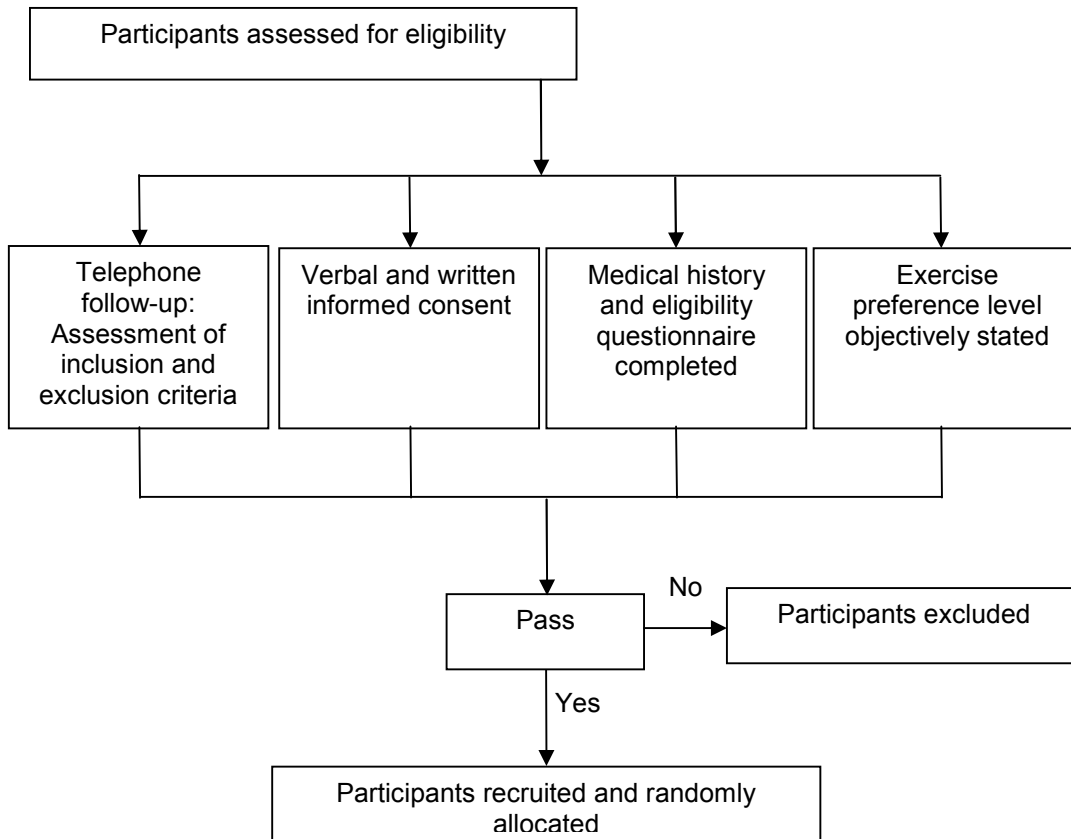
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┌─────────────────────────────────────────┐
│     Participants assessed for eligibility │
└─────────────────────────────────────────┘
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| Telephone follow-up: Assessment of inclusion and exclusion criteria | Verbal and written informed consent | Medical history and eligibility questionnaire completed | Exercise preference level objectively stated |

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        ┌────────┐    No    ┌──────────────────────┐
        │  Pass  │ ───────→ │ Participants excluded │
        └────────┘          └──────────────────────┘
            │ Yes
            ▼
┌──────────────────────────────────────┐
│ Participants recruited and randomly   │
│ allocated                             │
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Fig. 2. Eligibility and screening
Different steps for screening eligible participants.

2.5.3 Secondary measurements

a) Behavioural outcomes: Self-efficacy will be measured with the Chronic Disease Self-Efficacy Scale (www.patienteducation.stanford.edu/) which is a multidimensional scale including 1) Self-Efficacy to Perform Self-Management Behaviours, 2) General Self-Efficacy, and 3) Self-Efficacy to Achieve Outcomes. In addition, PA behaviour will be measured with an adapted PACE instrument (www.paceproject.org/Measures.html). The PACE instrument measures PA behaviours: 1) PA stages, 2) PA Change Strategies, 3) PA pros and cons, 4) PA confidence, 5) PA family support, 6) PA friend support, 7) PA closest friend support, PA enjoyment, 8) PA recreation choices, 9) PA environment factors [41]. Walking endurance (6-min walk-test) as well as change in blood pressure and heart rate [24] will also be measured. The level of physical fitness will be evaluated through the 7-Day (PAR), a generic instrument [40] principally created to measure the level of physical activity. Finally, an Adherence questionnaire will first be developed, based on current literature, and then completed by the participants in order to identify combined positive, negative and no influence factors, on a scale between -1 to+1, that can generally determine participants' walking adherence. Exercise preference may change during the 9-month period of the study for many reasons (e.g. weather, holidays, work, family commitment) therefore we will evaluate if the preference has changed over time, and use the data in the subsequent analysis. Long Term Goal

Attainment Scaling, a validated tool, will measure participants' long term goal attainment levels. This tool includes five goal attainment levels: 1) -2 (much worse than expected), 2) -1 (somewhat less than expected), 3) 0 (expected level), 4)+1 (somewhat better than expected) and 5)+2 (much better than expected) [21,42].

b) Clinical outcomes: Quality of life will be assessed using the 'EuroQoL Index (EQ-5D-5L)'. This generic instrument is the most commonly used and extensively validated measure of health-related quality of life. Five domains are included in this measure: 1) mobility, 2) self-care, 3) usual activities, 4) pain/discomfort, 5) anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. It is important to mention that the EQ-5D-5L was used to measure quality of life in various RCTs that studied the impact of walking programs in the management of OA, in older people [43]. Three secondary outcomes, pain, stiffness and functional status, will be examined using the 'Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)' questionnaire. This five-point questionnaire contains 3 dimensions: pain (5 questions), stiffness (2) and function (17). The WOMAC instrument has been used to report pain and functional status [44] in several previous RCTs involving walking programs designed for individuals with OA.

Other quantitative continuous functional outcomes will be measured such as: Gait speed (time to walk 6 meters) [23,47], Timed-up-and-Go (TUG) test [48] and the Number of steps completed during the walking sessions measured with a pedometer. A Stair Climbing questionnaire will finally be completed during the evaluation sessions to assess the level of difficulty to go up and down the stairs [19]. All these measures were extensively used in RCTs and are validated.

2.6 Trial Conduct

2.6.1 Recruitment process

All aspects of participant recruitment explained below will be discussed among all research staff. Strategic plan will consist of posting recruitment posters at the Ottawa office of TAS located at The Billings Bridge Shopping Centre in order to seek contact referral groups at the early stage of the study, with the help of health professionals (physiotherapists, occupational therapist, etc.) dealing everyday with arthritic people. We will also contact the Division of Rheumatology based in the Riverside Campus of the Ottawa Hospital to recruit patients from rheumatology clinics. A letter describing the rationale of our study will be sent to each physician, followed-up with a visit at their office, in order to refer participants. As a complementary source of recruitment, we will use media advertising such local newspapers to recruit participants and disseminate information about the trial, given the success of recruitment through the use of media advertising in previous RCT (85%) [18,19,47,49]. Consequently, a recruitment of 69 participants during 3 consecutive months is realistic for the proposed pilot RCT. Based on previous similar RCTs, the study of Brosseau et al. (2012a, b) [18,19] demonstrated a successful recruitment of 80 participants with mild to moderate OA of the knee in 4 months.

2.6.2 Screening and Allocation

Participants who are interested in participating in the study will contact the principal investigator directly. Telephone follow-up will be provided by the study coordinator to assess inclusion/exclusion criteria. Fig. 2 presents more information on the eligibility and screening

process of this walking study. If deemed eligible, the research coordinator will contact the Methods Center. Prior to running the randomization software, the Methods Center employee will document each participant's study ID. After running the randomization software, the Methods Center employee will document the treatment assignment. To perform a stratified block randomization, the research coordinator will obtain two series of opaque envelopes from the Methods Center according to the randomly generated sequence for each of the two blinded comparisons (preference for supervised (S) or unsupervised (U) vs. no preference). Research staff and the evaluator will be unaware of the treatment. Study participants will then be randomly allocated to one of the two walking programs (S and U), using the central randomization scheme [19].

All information obtained will be kept secret at all times. Rather than using names, code numbers will be given to identify each participant. The same code will be used on each questionnaire. All the questionnaires will be kept in a locked filing cabinet in the research lab of the director. Only the research staff will know the secret code and will have access to the filing cabinet.

2.7 Statistical Methods

2.7.1 Statistical analysis

Descriptive statistics including means, medians, standard deviations and interquartile ranges for continuous outcomes and proportions for discrete outcomes will be used to summarize the baseline variables in the study groups. Also, the analytic procedures will determine if the recruitment flow and rate, design, interventions and selected outcome measures are feasible for a large-scale RCT and to identify the variance of walking adherence in order to calculate the sample size required for the future large-scale RCT. The purpose of this analysis is threefold: to provide a descriptive summary of the variables; to provide summaries of the variables on which to compare the study groups; and to assess whether the distributions of the variables satisfy the underlying assumptions of the statistical methods to be considered, using SPSS software. An intention-to-treat basis (ITT) for efficacy will be conducted. Multiple imputation (MI) and mixed model repeated measures (MMRM) procedures will be used for accommodating missing data.

2.7.2 Primary analysis

1) Participants with a preference for a supervised walking program (S) and who obtain their preferred choice of program vs. participants with the same preference who did not obtain their preferred choice of program will be compared on program 'adherence' at 9 months using the Student's t-test. If significant baseline imbalances between these two study groups are found, adherence to treatment comparisons will be made using analysis of covariance (ANCOVA) adjusting for baseline differences (past studies have identified five important covariates, namely: age, sex, severity of OA, external support and, level of education [34]). In addition, a repeated measure analysis of variance (ANOVA) with the between factor preference group (S vs. U) and the within factor assessment time (0, 3, 6, 9 months) will be used to assess differences in adherence between the supervised (S) and unsupervised (U) groups over time. Tukey's honestly significant difference (HSD) multi-parameter test for comparing the pair wise differences and orthogonal polynomials for trend analysis will be considered. The above analyses will be repeated using ANCOVA to control for these covariates if they were not balanced at baseline. 2) This analysis will be repeated for participants with a preference for an unsupervised walking program (U) who obtained their

preferred choice of program vs. participants with the same preference who did not obtain their preferred choice of program.

2.7.3 Secondary analysis

A similar plan to the above primary analysis will be conducted for the three secondary research questions: 1) When there is no preference, participants receiving the S vs. U will be compared as in the primary analysis 2.7.2 above; 2) When there is a preference for a supervised walking program (S) and participants obtain their preferred choice of program, a similar analytical strategy as in 2.7.2 will be used for the continuous secondary outcomes (i.e. WOMAC pain and functional status, QoL), and for the discrete secondary outcomes (i.e. Long Term Goal Attainment Scaling, Stair Climbing), chi-square analysis techniques will be used for comparing groups and assessing trends over time and logistic regression will be used if significant baseline imbalances in important covariates are found; 3) This similar analytical strategy (i.e. 2.7.3, number 2) will be used for the continuous secondary outcomes (i.e. WOMAC pain and functional status, QoL) when there is a preference for an unsupervised walking program (S) and participants obtain their preferred choice of program.

3. DISCUSSION

The Ottawa Panel experts, related to the Ottawa Panel EBCPGs [4] on effective walking programs in the management of knee, are in agreements with other studies and reviews, since the evidence strongly recommends to OA people to perform a low-impact aerobic physical activity, particularly walking, for a minimum of 3 times a week at a moderate pace, in order to minimize any related limitations [8,17].

BI strategies have been used in other chronic health conditions to improve long-term maintenance of PA programs, such as walking, with varying success. The scientific literature demonstrated that multifaceted BIs seem to have the greatest results on long-term adherence to treatments, the level of physical activity performed, and the quality of life [27]. The systematic review by Tilbrook et al. [21] found conclusive results when considering participants' preferences in 11 selected RCTs for musculoskeletal conditions. In other words, the authors stated that participants who were allocated to their preferred treatment demonstrated improved clinical outcomes compared to participants who did not receive their preferred treatment. Both the consideration of participants' exercise preference [27] and behavioural strategies such as goal setting, face-to-face visits, social/peer support, or positive feedback [50] are key components that may enhance adherence rates, since the belief that physical activity causes an increase in pain to the affected joint is often strongly expressed by the majority of OA individuals and results in a negative chain reaction. The current literature also confirmed that participants' expectation toward efficacy of a treatment represents an important factor to consider when measuring adherence. As explained by the theory of planned behaviour, if an individual demonstrates negative attitudes (risks, time commitment, laziness, etc.) toward a particular treatment, before randomization, he or she will be less motivated in performing or following the intervention [51]. In our proposed RCT, these components mentioned above will be identified and applied to better understand their effects on long-term adherence.

Given that the data on the efficacy of BIs are more limited than those on OA aerobic training, it is likely that participants' exercise preference will offer a promising avenue in terms of improving adherence over the long-term [18,19]. Participants' exercise preference will be evaluated as a KT strategy to implement an evidence-based long-term walking intervention,

in which adherence will represent the primary outcome. Surprisingly, this outcome has not yet been examined in previous RCTs focussing on participant preference [8]. To fill this new knowledge gap in the scientific literature, the first step is to identify the most effective intervention, based on EBCPGs (i.e. Knowledge Creation of the KTAC framework). Afterwards, it is important to ensure the integration of recommendations of the Ottawa Panel guidelines into the interventions, by implementing innovative KT strategies, such as participant's exercise preference (Action Cycle concepts of the KTAC framework) (Fig. 3) [52].

We will monitor knowledge use, i.e. conceptual knowledge use (e.g. level of intention to continue walking, identification of perceived motivators/reasons to continue walking, level of importance to follow walking goal, etc.) and instrumental knowledge use (e.g. adoption of new strategies to maintain walking goal, etc.) as well as clinical outcomes to measure the impact on participants of using and applying the knowledge (e.g. pain, functional status, quality of life, etc.).

Some limitations of the walking study should be addressed. First of all, this is a 6-month supervised walking program with a 3-month follow-up period using a preference trial design which consists of two single blind RCTs, based on a participant exercise preference model [25], to elicit preferences independently of randomization. As known, RCTs are considered the gold standard for assessing the effectiveness of interventions [28]. The main concern is that participants' exercise preference could influence adherence, when it is not possible to blind the participants to the physical interventions [30], like in this walking study. However, an innovative robust approach is to use the randomization process and consider the exercise preference before randomization, using the data in the subsequent analysis. This approach will allow for an unbiased evaluation of the effects of exercise preference on walking adherence, avoiding any selection bias.

Moreover, previous RCT on walking programs for older individuals with OA of the knee attained a poor consent rate of 54.4% [18] (accepted to enrol in the study). We expect a similar consent rate for the pilot RCT proposed. Therefore, it will be essential to support the decision-making process of the participant, before the beginning of the study, by giving him/her all the relevant information to help him/her easily assess the advantages and disadvantages of joining the pilot RCT.
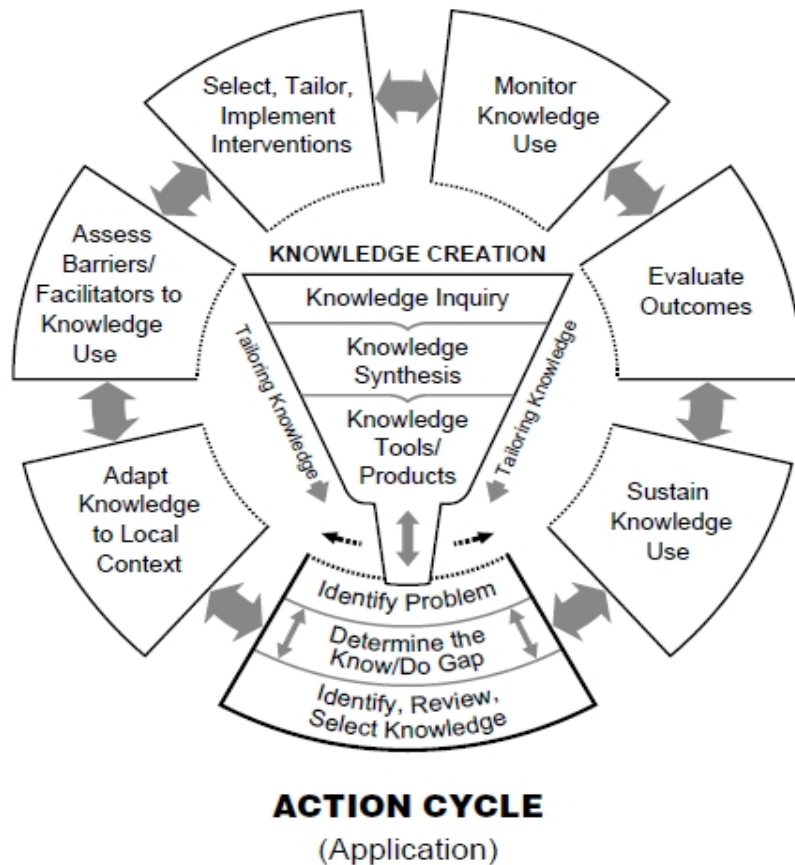
Fig. 3. The knowledge translation in health care action cycle
Used with permission from Straus SE, Tetroe, J & Graham ID. Introduction Knowledge translation: What it is and what it isn't, in Knowledge Translation in Health Care: Moving from Evidence to Practice (eds SE Straus, J Tetroe and ID Graham), John Wiley & Sons, Ltd, Chichester, UK. 2013. doi: 10.1002/9781118413555.ch01 [52].

Finally, the 7-Day Physical Activity Recall (PAR) will be used as a self-recorded questionnaire, to assess the duration (min/day) of doing moderate physical activities (such as walking). Even though, it represents a self-management measurement, Rauh et al. [53] showed that the PAR appeared to be administratively feasible and demonstrated relevant validity. Several trials confirmed that a daily recording is more accurate among an older population when self-reporting. Also, the use of pedometers to monitor walking adherence in older adults appears to be another reliable and valid instrument [54]. Generally used by elderly people, pedometers are easy to use and provide an objective measurement of walking adherence [23,55]. Therefore, we will be using pedometers as a second tool to measure objectively the adherence rate, as well as a motivational tool for the participants. In fact, the study of Motl et al. [56] demonstrated evidence of strong and statistically significant correlations between scores from the 7-Day PAR self-report measure and the objective device, pedometer step counts, based on a multi-method analysis. More sophisticated tools are also available to replace pedometers, such as accelerometers. Even if accelerometers give more relevant information other than just daily steps count, they are very costly and

seem to have similar problems than pedometers, i.e. replacing the batteries often and wearing the device insufficiently or not at all [57].

4. DISSEMINATION AND CONCLUSION

This proposed pilot RCT is based on solid methods, since it will follow the SPIRIT recommendations. The reporting of the pilot study will be eventually based on the CONSORT guidelines also. It will address questions of clinical and scientific importance to identify the main strategies to promote the long-term adherence of community-based walking program. It will also guide clinical decision-making of health professionals in rehabilitation sciences, by disseminating scientific results through professional scientific journals. If results of this study show this is indeed advantageous, it will finally assist the health care providers through their decision-making process, by 1) implementing an evidence-based walking program in existing health organizations (e.g. Public Health: City of Ottawa) and 2) referring OA patients, who prefer to walk inside with a group, to walking clubs in Ottawa walking. Moreover, the Walking Club at The Billings Bridge Shopping Centre has a strategic location, since next door to TAS Ottawa office. The sustained goals are to encourage: 1) Shopping Centre to promote better communication between TAS and the existing walking club, 2) the health professionals from TAS to refer OA patients to the existing walking club (to become new members), by respecting their exercise preference, and 3) the current members from the walking club to welcome participants from the study to continue walking with members of the walking club and, implement the same effective aerobic walking program beyond the study.

KEY MESSAGE

Preference is an innovative approach for improving walking adherence, not yet studied among OA population.

CONSENT

All authors declare that written informed consent was obtained from each participant.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and have therefore been performed in accordance with the ethical standards.

The Research Ethics Board from the University of Ottawa approved this pilot study (#H01-07-08C) and will be available if urgent changes need to be made on the proposal. The clinical study has been also registered with the International Standard Randomised Controlled Trial Number Register (ISRCTN) and Current Controlled Trials.

ACKNOWLEDGEMENTS

COMPETING INTERESTS

Authors have declared that no competing interests exist.

TRIAL REGISTRATION: ISRCTN, http://www.controlled-trials.com/ISRCTN51981241/, ISRCTN51981241

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