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Supervision preference for an effective walking program among older individuals with osteoarthritis of the knee

Submission date
02/05/2013

Recruitment status
No longer recruiting

Registration date
24/05/2013

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common disorder affecting joints, such as the knees and hips. Currently, more than 4.4 million Canadians suffer from OA, with the majority being individuals over the age of 40 years. Although walking is a safe and accessible form of physical activity recommended for individuals with OA, arthritic individuals continue to avoid this form of physical activity as they believe that it may increase knee pain. Walking is less expensive, relieving the economic burden on both patients and the health care system. Unfortunately, inactivity leads to decreased endurance and mobility, resulting in a reduced quality of life. In addition, the majority of OA individuals are more likely to have difficulties walking and experience functional limitations. The challenge is to develop strategies to encourage OA patients to consider the benefits of physical activity and walking. It is essential to provide a stimulating program in order to support participants to not only initiate, but to also adhere to and incorporate walking into their daily activities. It is important to allow patients to express themselves and make a choice on which program best suits them. This motivates the participants, resulting in greater adherence to walking programs. The aim of this initial study is to see whether participants, who follow their preferred aerobic walking program, adhere to walking, compared to individuals who did not obtain their preferred choice of aerobic walking program. Regular participation in a walking program can improve pain relief, functional status and quality of life among older individuals with OA of the knee.

Who can participate?
69 individuals, aged over 40 years, with mild to moderate knee OA, will be recruited in Ottawa. Study participants will have to be available three times a week over a period of 9 months, be able to walk for a minimum of 20 minutes at their own pace, and show no evidence of other health problems that may make participation in this study inadvisable.

What does the study involve?
Participants will be randomly allocated to one of two groups. The participants in the supervised community-based walking program will walk three days per week, at a shopping mall in the city of Ottawa. A physical therapist will be present for all sessions, in order to supervise the

participants and record attendance. The participants from the self-directed unsupervised program will follow the same effective walking program, but will be invited to walk without supervision. The individuals in both the groups will follow behavioral education program.

What are the possible benefits and risks of participating?
The results of this study may contribute to the future improvement of patient care. Study participants can gain clinical benefits from enrolling in a walking program, including pain relief, as well as improved functional status and quality of life. This study may also improve physiotherapy practice by investigating the benefits of physical activity on the quality of life of patients with OA. This study will involve minimal risks. Participants could feel muscle or joint discomfort and knee pain during and after walking. They will be free to reduce their pace and duration of their walking sessions or stop at anytime.

Where is the study run from?
The only center that will be involved is the walking club in the Billings Bridge Shopping Centre, Ottawa, Canada, in collaboration with The Arthritis Society, Ottawa.

When is the study starting and how long is it expected to run for?
The study started in April 2012 and is expected to complete in December 2014.

Who is funding the study?
The Arthritis Health Professions Association (AHPA) (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title
The implementation of an effective aerobic walking program based on Ottawa Panel guidelines for older individuals with mild to moderate osteoarthritis: a PEP (Preference Exercise Preference) pilot RCT

Study objectives
We will examine the hypothesis that participants who follow their preferred aerobic walking program: 1) supervised (S) or 2) unsupervised (U), combined with a behavioral component, will be more encouraged and satisfied, thus enhancing their walking adherence at 9 months, compared to individuals who do not obtain their preferred choice of aerobic walking program, among people diagnosed with knee osteoarthritis.
Moreover, when there is no preference for a specific aerobic walking program (supervised vs. unsupervised), it is hypothesized that at 9 months the supervised aerobic walking program (S) with a behavioral component will demonstrate an improvement in walking adherence compared to the unsupervised aerobic walking program (U) with an identical behavioral component, among people diagnosed with knee osteoarthritis.

On 11/03/2014 the anticipated end date was changed from 01/09/2013 to 01/12/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Name: University of Ottawa - Office of Research Ethics and Integrity (REB), Ethics Approval Notice, Health Sciences and Science REB
Date of approval: 01/23/2013
Reference number: H01-07-08C

Study design
Interventional randomized single-centre study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Osteoarthritis (OA)

Interventions
Participants will express their preference, and then are randomized to one of two walking programs:
1. Supervised aerobic walking program (S):
All the participants in the supervised aerobic walking program based on the Ottawa Panel guidelines (2012) will walk three days per week, for 6 months in a Walking Club at The Billings

Bridge Shopping Centre 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. 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. The exercise therapist will provide pedometers and heart rate monitors, record attendance, number of steps, and vital signs, and will help the participants complete their individual 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. Regarding the intensity of the walking period, the participants will stay between 60-80% of their maximum heart rate, using a heart rate monitor offered during the walking sessions.

2. Unsupervised aerobic walking program (U):
Participants from the unsupervised walking program involving the same effective walking program (duration, frequency, intensity) will be invited to walk by themselves, without supervision for 6 months (in addition to the 3-month follow-up period where they are free to walk according to their preference). 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. The exercise therapist will offer one introductory session to describe how the pedometers work so that they can carry out a self-directed walking program. The coordinator will explain how to record the number of walking sessions and the daily step count (pedometer) in their log books. The exercise therapist will review the log books at the measurement sessions.

All the participants (from both groups) will have to follow the existing evidence-based structured education program developed by The Arthritis Society (TAS) called Stay Active /Manage your OA pain . It will consist of the following components: (1) short- and long-term goal setting at the walking club each 3 months; (2) monthly face-to-face counselling wherein participants receive moral support/encouragement to continue walking; (3) number of steps measured with a pedometer; (4) walking logbooks to record the duration (min/day), frequency (days/week) and intensity of their walking sessions each week using the calendar included in the PAR.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
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 divided by the number of walking sessions prescribed (3 times a week as recommended in the Ottawa Panel guidelines, 2012) and recorded in the participants logbooks (each week). The calendar proposed by the 7-Day Physical Activity Recall (PAR) incorporated in the logbooks will be used as a self-report questionnaire, to calculate the number of walking sessions each

participant will attend each week. 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. In fact, Rauh et al. (1992) 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 with an electronic system. For the supervised group (S), we will take the attendance at the walking club to confirm what is writing 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. The use of pedometers to monitor walking attendance in older adults appears to be another reliable and valid instrument. Generally used by elderly people, pedometers are easy to use and provide an objective measurement of walking adherence.

Key secondary outcome(s))

All the secondary outcomes measures will be assessed each 3 months.
1. 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:
1.1 mobility
1.2 self-care
1.3. usual activities
1.4. pain/discomfort
1.5. 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.
2. Three secondary outcomes, pain, stiffness and functional status, will be measured 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 in several RCTs involving walking programs designed for individuals with OA.
3. Gait speed (time to walk 6 meters), Timed-up-and-Go (TUG) test and the Number of steps completed during the walking sessions measured with a pedometer.
4. Self-efficacy will be measured with the Chronic Disease Self-Efficacy Scale www. patienteducation.stanford.edu/) which is a multidimensional scale including
4.1. Self-Efficacy to Perform Self-Management Behaviours
4.2. General Self-Efficacy
4.3. Self-Efficacy to Achieve Outcomes
5. In addition, PA behaviour will be measured with an adapted PACE instrument (www. paceproject.org/Measures.html). The PACE instrument measures PA behaviours and is a multidimensional tool measuring: 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.
6. Walking endurance (6-min walk-test) and change in blood pressure and heart rate will also be measured.
7. The level of physical fitness will be measured through the 7-Day (PAR), a generic instrument principally created to measure the level of physical activity.
8. An Adherence questionnaire will be completed in order to identify combined positive and negative factors that can generally determine participants' walking adherence.
9. Exercise preference may change during the 9-month period of the study for many reasons, therefore we will evaluate if the preference has changed over time, using periodic questionnaire.

10. 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).
11. A Stair Climbing questionnaire will finally be completed during the walking sessions to assess the level of difficulty to go up and down the stairs. All these measures were extensively used in RCTs and are validated.

Completion date
01/12/2014

Eligibility

Key inclusion criteria
69 older adults with knee OA who are not already engaged in regular PA will be recruited. 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 studys selection criteria. 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 (Grade 1 - 4)
2. Aged over 40 years old
3. No evidence of mental health condition
4. Able to walk for a minimum of 20 minutes at their own pace
5. Available three times a week over a period of 12 months (for 45 minutes during the operating hours of the Walking Club; i.e. 7:30 to 10:00 am)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
69

Key exclusion criteria
1. No confirmation of an OA diagnostic of the knee, based on the clinical symptoms of OA following the ACR criteria for knee, including radiographic evidence according to the Kellgren-Lawrence grading scale during a radiological assessment of OA (Grade 1 - 4)
2. Healthy individual
3. Younger than 40 years old
4. Uncontrolled hypertension: Systolic BP >160 mm Hg
5. Individuals who are obese (BMI > 30 kg/m2)

6. Not able to walk for a minimum of 20 minutes at their own pace
7. Unavailable three times a week over a period of 12 months (for 45 minutes during opening hours of the Walking Club)
8. Other illness, judged by the patient or study physician to make participation in this study inadvisable
9. Following a concomitant OA treatment at the same period (e.g. physiotherapy, acupuncture, etc.)
10. Participating in regular physical activities more than two times per week for more than 20 minutes per session
11. Cognitive deficits resulting in inability to understand instructions
12. Inability to communicate in English or French
13. Surgery planned in the next year
14. Intention to move away from Ottawa in the next year

Date of first enrolment
25/04/2012

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
Canada

Study participating centre
University of Ottawa
Ottawa
Canada
K1H 8M5

Sponsor information

Organisation
University of Ottawa (Canada)

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Charity

Funder Name
Arthritis Health Professions Association (AHPA) 2012 Arthritis Research Foundation Movement and Mobility Award

Funder Name
Dr Lucie Brosseau, University of Ottawa, Research Chair Award (salary support for research staff)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Thesis results	In French	01/01/2017	09/08/2021	No	No