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The efficacy of a walking program for osteoarthritis of the knee

Submission date
27/12/2006

Recruitment status
No longer recruiting

Registration date
27/12/2006

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Rising healthcare costs, limited resources, and the aging population have created new and growing challenges in the management of osteoarthritis (OA). The promotion of physical activity (PA) is a priority for health organizations serving the general population and is highly recommended for individuals affected by chronic diseases. PA combined with strategies that promote PA behaviour, and self-management interventions can reduce the risk of disability and negative consequences of inactivity related to OA. The purpose of this study was to compare improvements in quality of life, pain, mobility, and endurance, adherence rates, and confidence and self-efficacy after completing a 12-month walking program based on evidence found by the Ottawa Panel.

Who can participate?
A total of 222 adults with knee OA were recruited. The average age of participants was 63.4 years. Participants were eligible to participate in the study if they had a confirmed diagnosis with mild to moderate OA according to the American College of Rheumatology criteria, reported pain for at least 3 months, expected their medication to change during the study period, demonstrated an ability to walk for a minimum of 20 minutes at their own pace with minimal reports of pain, were able to be treated as an out-patient, and were available three times a week over a period of 12 months.

What does the study involve?
The participants were randomly allocated to one of three groups: 1) Walking and Behavioural intervention, which included the supervised walking program combined with a behavioural intervention and an educational pamphlet on the benefits of walking for OA, 2) Walking intervention wherein participants only received the supervised walking program intervention and the educational pamphlet, 3) Self-directed control wherein participants only received the educational pamphlet.

What are the possible benefits and risks of participating?
The walking program, either supervised or unsupervised can improve quality of life, pain,

mobility, and endurance. The risks of participating in a PA intervention such as a walking program are minimal, as participants may succumb to an injury, but this was not observed in this study.

Where is the study run from?
The study took place at three shopping centres in the Ottawa, Canada region: St.Laurent Shopping Centre, Billings Bridge Shopping Centre, and Les Promenades de l'Outaouais.

When is the study starting and how long is it expected to run for?
The study started in January 2007 and ran until May 2010. Participants were recruited until December 2009.

Who is funding the study?
The study was funded by the Canadian Institutes of Health Research (CIHR), University Research Chair (salary support for research staff), and the Ministry of Human Resources (summer student program) (Canada).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-82367

Study information

Scientific Title
The impact of a community-based aerobic walking program for older individuals with mild to moderate knee osteoarthritis

Acronym
RCT on walking

Study objectives
As long as individuals with OsteoArthritis (OA) continue to walk regularly, they will benefit from the positive effects of exercise and sustain a better Quality of Life (QoL) than those who do not. We also hypothesise that adding a tailored behavioral intervention to the Walking program (WB) will increase long-term adherence to the program and improve QoL.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of the Ottawa Hospital (Canada), 03/11/2006

Study design
Single-centre randomised parallel trial with study participant, investigator, outcome assessor and data analyst blinded

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
1. Long-term structured aerobic walking program and educational pamphlet: walking program (45 minutes per session, three sessions a week during 18 months)
2. Long-term structured aerobic walking and behavioral approach and educational pamphlet: walking program (45 minutes per session, three sessions a week during 18 months) and behavioral approach (average 10 minutes per session, three sessions a week during 12 months)
3. Home self-directed walking program and educational pamphlet: self-directed walking program (45 minutes per session, three sessions a week during 18 months)

Intervention Type
Behavioural

Primary outcome measure
1. The Arthritis Impact Measurement Scale (AIMS2), each 3 months during 18 months
2. The Short Form health survey (SF-36), each 3 months during 18 months

Secondary outcome measures
1. Overall adherence and maintenance of physical activity (the number of walking sessions attended divided by the number of walking sessions prescribed), every 3 months during 18 months
2.Change in level of PA measured using the seven-day Physical Activity Recall (PAR), each 3 months during 18 months
3. Self-efficacy capacity will be measured using the Arthritis Self-Efficacy Scale (ASES), each 3 months during 18 months
4. Aerobic capacity (Volume of Oxygen inspired by the body in one minute [VO2max]), each 6 months during 18 months
5. Walking endurance (six-minute walk-test), each 3 months during 18 months
6. Blood pressure and heart rate, each 3 months during 18 months
7. Functional status will be measured using the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) questionnaire, each 3 months during 18 months
8. Gait speed (time to walk six metres), each 3 months during 18 months
9. Resource utilisation, each 3 months during 18 months
10. Cost (i.e. time lost from paid work), each 3 months during 18 months
11. Quality-adjusted life expectancy (societal-preference-based values will be elicited indirectly through completion of the EuroQoL questionnaire [EQ-5D]), each 3 months during 18 months

Overall study start date
01/01/2007

Completion date
30/07/2010

Eligibility

Key inclusion criteria
1. Male and female patients with osteoarthritis of the knee
2. 60 years and older
3. Pain for at least last 3 months

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants

240

Key exclusion criteria
1. Participation during the previous six months in regular Physical Activity (PA) or aerobic sports more than or equal to two times per week for more than 20 minutes per session
2. Presence of pain at rest or at night
3. Current rehabilitation treatment or previous corticosteroids injection within the last 12 months or any other pain-related treatment besides medication for arthritis
4. Uncontrolled hypertension: Systolic Blood Pressure (BP) more than 160 mmHg
5. Individuals with obesity (Body Mass Index [BMI] more than 30 kg/m^2)
6. Other illness, judged by the patient or study physician to make participation in this study inadvisable
7. Significant cognitive deficit resulting in an inability to understand or comply with instructions
8. Surgery planned in the next year
9. Intention to move away from Ottawa in the next year
10. Inability to communicate in English or French
11. Unwillingness to sign informed consent

Date of first enrolment
01/01/2007

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
Canada

Study participating centre
University of Ottawa
Ontario
Canada
K1H 8M5

Sponsor information

Organisation
University of Ottawa (Canada)

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Sponsor type
University/education

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ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (grant no.: MCT-82367)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	13/10/2012		Yes	No
Results article	results	12/12/2012		Yes	No