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Osteoarthritis project

Submission date
07/05/2015

Recruitment status
No longer recruiting

Registration date
27/05/2015

Overall study status
Completed

Last Edited
06/10/2022

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
Osteoarthritis (OA), the most common type of arthritis, is an incurable, long term condition that causes joints such as the knee to become painful and stiff. Maintaining a healthy weight and regularly exercising can help people manage their symptoms, but OA of the knee can often result in disability and make it hard for people to carry out their normal daily activities. Current medical practice (CMP) in treating OA of the knee is inconsistent and often involves GPs prescribing pain medication for patients waiting for total joint replacement. This treatment method is not very cost effective and can lead to the patient visiting their GP numerous times. Recently, a number of scientists and stakeholders within the Canadian healthcare system partnered with a company called Emovi Inc to develop a care programme for people with OA of the knee. The programme, MyKneeOsteoarthritis.ca, is a personalised treatment plan which includes the creation of a detailed structure and function (biomechanical) report of a patient's knee using a knee kinematic graphic test (KneeKG). The programme also recommends various treatment interventions for each patient to help reduce the risk of their OA knee becoming worse. The aim of this study is to see whether the MyKneeOsteoarthritis.ca programme is effective in improving patient quality of life and joint mobility compared to CMP or CMP and KneeKG alone. Also, an analysis will be conducted to see which care approach is the most cost effective.

Who can participate?
Adults diagnosed with OA of the knee.

What does the study involve?
Participating GP clinics are randomly allocated to deliver one of three care management plans to their patients. Group 1 (control group) GP clinics give their patients CMP. Group 2 (intervention group) GP clinics give their patients CMP and a KneeKG exam. Group 3 (intervention group) GP clinics give their patients CMP, a KneeKG exam and the Mon Arthrose care programme (a light version including 3 visits: one hour training session to the patient and two follow-up sessions to monitor exercises). Participants complete questionnaires and attend clinical assessments before treatment, and then again at 6, 12 and 24 months for follow up.

What are the possible benefits and risks of participating?
There is virtually no risk associated with the equipment and movements to be performed during the KneeKG analysis and the test is noninvasive and painless. Some discomfort may be felt when

wearing the harness and in some rare cases, redness may appear. These usually disappear within hours after the examination. The risk of falling during treadmill walking is minimal. For safety reasons during the examination, a switchblade connected to a rope attached to the treadmill is attached to participant's clothing with a clip. If the clip comes off, the treadmill will stop automatically. There is a risk associated with having X-rays. Even if this exposure is low participants will be made aware of it. During the experiment, X-rays will be limited to one for each knee, so a total of two X-rays. Furthermore, the procedure is limited to the observation of the knee joint and therefore only the lower body region will be X-rayed in order to minimise exposure.

Where is the study run from?
1. University of Montreal Hospital Research Centre (Centre de Recherche du Centre Hospitalier de l'Université de Montréal (CRCHUM)) (Canada)
2. 75 participating GP clinics in Montreal and surrounding suburbs (Canada)

When is the study starting and how long is it expected to run for?
October 2014 to March 2020

Who is funding the study?
1. Ministry of Finance - Partnership Fund for an Innovative and Healthy Quebec (Fonds de Partenariat pour un Québec Innovant et en Santé) (Canada)
2. Emovi Inc. (Canada)
3. Sanofi (Canada)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Better diagnosis and treatment of knee osteoarthritis: a clinical and economic imperative for our health system

Study objectives
The main objectives of this project are to evaluate the effectiveness of Knee Kinematics graphics (KneeKG) and Mon Arthrose program in the treatment of osteoarthritis (OA) of the knee and get socio-economic data to compare the socio-economic impact of the technology and Mon Arthrose program compared to current medical practice (CMP).

Underlying assumptions:
1. We expect that the effectiveness of KneeKG technology with or without Mon Arthrose program will be superior to that of the CMP in 1st line care for the treatment of OA of the knee.
2. We also expect a reduction in direct and indirect costs of 20%, an improvement in the condition of more than 10% of the patient and a difference of knee kinematic parameters between the three health care approaches.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Research Committee, University of Montreal Hospital Research Centre (Centre de Recherche du Centre Hospitalier de l'Université de Montréal (CRCHUM)), 30/04/2015.

Study design

Randomised controlled cluster trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
Current inteerventions as of 14/09/2018:
Three types of care management will be compared:
1. CMP from General Practitioner (GP)
2. CMP alongside a KneeKG exam with treatment recommendations based on knee biomechanics
3. CMP alongside a KneeKG exam and 3 visits at an Mon Arthrose center, patient training of their condition and follow-up of home based exercises by a kinesiologist

Previous interventions:
Three types of care management will be compared:
1. CMP from General Practitioner (GP)
2. CMP alongside a KneeKG exam with treatment recommendations based on knee biomechanics
3. CMP alongside a KneeKG exam and a structured care program called Mon Arthrose (3 visits at an Mon Arthrose center, patient training of their condition and follow-up of home based exercises by a kinesiologist)

Intervention Type
Mixed

Primary outcome measure
Phase 1: difference between the three groups at 6 months (0 to 6 months) of the variation of the overall score Knee Osteoarthritis Outcome Score (KOOS5) including 5 dimensions
Phase 2: difference in direct and indirect costs for the three therapeutic models at 6, 12 and 24 months

Secondary outcome measures
Current secondary outcome measures as of 18/09/2018:
1. Difference in joint biomechanics, as measured by KneeKG at 6 months, as defined by the normal to abnormal passage of at least one biomechanical risk factor from the following:
1.1. Absolute difference in biomechanical factors

1.2. Difference in objective functional tests (30-second sit-stand test and quadriceps strength measured with a dynamometer
2. Overall Knee Osteoarthritis Outcome Score (KOOS5) at 12 months

Previous secondary outcome measures as of 14/09/2018:
Phase 1: difference in joint biomechanics, as measured by KneeKG, between the three groups at 6 months, as defined by the normal to abnormal passage of at least one biomechanical risk factors from the following.
Improved absolute different biomechanical factors. Difference in objective functional tests (30 second chair test and quadriceps strength)
Comparison of overall score of Knee Osteoarthritis Outcome Score (KOOS5), to 12 months between the three therapeutic models (1- GP group, 2- GP group and KneeKG, 3- GP group with KneeKG and My Osteoarthritis program)

Previous secondary outcome measures:
Phase 1: difference in joint biomechanics, as measured by KneeKG, between the three groups at 6 months, as defined by the normal to abnormal passage of at least one biomechanical risk factors from the following.
Improved absolute different biomechanical factors.
Comparison of overall score of Knee Osteoarthritis Outcome Score (KOOS5), to 12 months between the three therapeutic models (1- GP group, 2- GP group and KneeKG, 3- GP group with KneeKG and My Osteoarthritis program)
Phase 2: difference at 6, 12 and 24 months in quality of life, knee function, pain and global impression of change

Overall study start date
01/10/2014

Completion date
30/03/2020

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Suffering of OA of the knee as physician-diagnosed according to the criteria of the American College of Rheumatology: The patient has a radiographic knee X-ray confirming the presence of osteoarthritis II, III or IV according to the scale of Kellgren-Lawrence for at least one knee; and at least 1 of the 3 following signs: Age ≥40; Morning stiffness <30 minutes; Crepitus
3. OA is the leading cause of pain
4. Being able to walk on a treadmill (exclude problem of balance patient who limps, which uses cane or walker).
5. Having experienced as pain worse in the last 7 days for at least one knee, a ≥4/10 pain intensity on a scale of 0-10, where 0 = 'no pain' and 10 being 'worst possible pain'
6. Being able to read, understand and respond to questionnaires in French
7. Agreeing to participate in the study and sign the consent form

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000

Total final enrolment
515

Key exclusion criteria
1. Suffer from secondary OA or inflammatory arthritis (according to Arden 'Best Practice & Research') or ochronosis, acromegaly, hemochromatosis, calcium pyrophosphate arthropathy (MPPC), Marfan syndrome, Ehlers-Danlos syndrome, epiphyseal dysplasia, osteonecrosis/bone infarction, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, reactive arthritis (Reiter's), gouty arthritis, SAPHO syndrome, Paget disease
2. Have seen a specialist (orthopedist, a rheumatologist or specialist in musculoskeletal disorders) in the past for problems with the affected knee
3. Suffer from active cancer (with or without pain)
4. Fracture history or septic arthritis in the knee
5. Pregnant or suspected to be

Date of first enrolment
01/07/2015

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
Canada

Study participating centre
University of Montreal Hospital Research Centre (Centre de Recherche du Centre Hospitalier de l'Université de Montréal (CRCHUM))
900 St Denis
Montreal
Canada
-

Study participating centre

75 General Practice Clinics
Montreal and surrounding suburbs
Montreal
Canada
-

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Organisation
University of Montreal Hospital Research Centre (Centre de Recherche du Centre Hospitalier de l'Université de Montréal (CRCHUM))

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Sponsor type
Research organisation

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Funder(s)

Funder type
Other

Funder Name
Minstery of Finance - Partnership Fund for an Innovative and Healthy Quebec (Fonds de Partenariat pour un Québec Innovant et en Santé) (Canada)

Funder Name
Emovi Inc. (Canada)

Funder Name
Sanofi Canada

Results and Publications

Publication and dissemination plan
Results will be published in scientific journals as well as disseminated among the GP community via training sessions. The knowledge transfer to the community will be performed in collaboration with FMOQ (Fédération des médecins omnipraticiens du Québec).

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof N Hagemeister (Nicola.hagemeister@etsmtl.ca). When people want to access some of the data, they have to fill out a request form and the modalities of transfer are decided for every query, depending on the use of the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	03/04/2020	Yes	No
Results article	Secondary analysis	05/08/2022	06/10/2022	Yes	No