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Effectiveness and cost-effectiveness of a health coaching intervention to improve the lifestyle of patients with knee osteoarthritis

Submission date
11/11/2013

Recruitment status
No longer recruiting

Registration date
20/12/2013

Overall study status
Completed

Last Edited
17/12/2015

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The overall prevalence of osteoarthritis in the Spanish population is 17% and the prevalence of osteoarthritis of the knee is 10.2%. Osteoarthritis of the knee is a condition which affects patients social and personal lives and it requires highly specialised care. Most clinical guidelines recommend starting treatment with a non-pharmacological approach which should include weight loss, healthy diet, physical exercise, self-management of pain, educational activities and orthotics. Some studies show that only 10% of the population adopts the healthy lifestyle required for active and healthy ageing and more specifically, for the successful management of osteoarthritis of the knee. While patients are generally aware of what a healthy lifestyle implies, they find it difficult to implement the necessary changes. Health Coaching is a behavioural intervention that assists patients in achieving health goals and behavioural changes, in minimizing unhealthy habits, improving self-management of chronic conditions and increasing quality of life (QOL). The main aim of the study is to assess the effectiveness, cost-effectiveness and cost-utility of an intervention based on Health Coaching with support phone calls on QOL, pain, overweight/obesity and physical activity in patients with osteoarthritis of the knee from primary care centres (PCCs) of Barcelona.

Who can participate?
Primary care patients with diagnosis of knee osteoarthritis.

What does the study involve?
The primary health care centres will be randomly allocated to the intervention group or the control group. The intervention group will attend 20 hours of group coaching with follow up and support phone calls. The control group will be managed as per usual.

What are the possible benefits and risks of participating?
If the intervention shows cost-effectiveness and cost-utility in promoting healthy lifestyles and active ageing, the results will be included in the clinical guidelines for the management of osteoarthritis of the knee. There are no possible risks of participating in the study.

Where is the study run from?
Primary care centres (PCCs), Barcelona.

When is the study starting and how long is it expected to run for?
The study is expected to start in early 2014.

Who is funding the study?
The study is not funded at the moment, but it has been sent to three competitive scientific grants.

Who is the main contact?
Dr Anna Berenguera

Contact information

Type(s)
Scientific

Contact name
Dr Anna Berenguera

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Gran Via Corts Catalanes, 587, àtic
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness and cost-effectiveness of a health Coaching intervention to improve the lifestyle of Patients with Knee OsteoArthritis: a cluster randomized clinical trial

Acronym
CPKOA

Study objectives
Main objective:
To analyze effectiveness, cost-effectiveness and cost-utility of an intervention based on health

coaching and telephone support on quality of life, pain, overweight/obesity and physical activity in patients from Primary Health Care Centres (PHCC) of the Barcelona province suffering from osteoarthritis of the knee, compared with standard practice.

Secondary objectives:
To identify the barriers and facilitators of an intervention based on health coaching with a qualitative study that includes individual interviews to patients suffering from osteoarthritis and group interviews with primary care professionals, with the aim to design an intervention adapted to primary care patients and professionals. Based on the experience and opinion of participating patients and professionals, to evaluate the acceptability and feasibility of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of the Primary Health Care University Research Institute-IDIAP JordiGol

Study design
Cluster randomized clinical trial in primary care

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Randomization: To avoid contamination between study groups, the PHCC will be the randomization unit. The PHCCs that agree to participate will be allocated either to the intervention or the control group according to a random sequence generated by a computer programme. The allocation of the PHCC to the study groups will be carried out by an independent researcher. The patients that fulfil the inclusion criteria will be allocated to the treatment group of their PHCC.
Blinding: To avoid bias, the informed consent of participants will be obtained before the

disclosure of the randomization results. Due to the characteristics of the intervention patients, physicians and nurses will know their group allocation. The analyst will not know the allocation group of the patient.

Intervention Group (IG): The intervention consists of a 20-hour coaching group programme conducted by a psychologist coach, with monthly follow-up sessions and telephone support carried out by the primary care nurses. There will be eight patients in each group. The number, frequency and duration of sessions will be adjusted based on the Phase 1 results. The intervention promotes the main elements of the non-pharmacological treatment of knee osteoarthritis: nutrition, physical activity and self-management of pain. Each participant will establish his/her own goals and will draw an action plan for each one of these elements using the tools and techniques provided in each session. Each participant will have an information folder on health coaching for knee osteoarthritis plus a notebook for the sessions of the intensive phase and to register his/her own goals, the process of change and the results accomplished. The study protocol will be published for transparency and reproducibility.
Control Group (CG): The participants allocated to the CG will follow standard primary care practice based on recommendations and brief advice by the primary care physician and/or nurse, as recommended by the clinical guidelines. These recommendations to control pain, maintain functionality and prevent progression of disease include: weight control, correct body posture, thermotherapy, adherence to treatment, physical exercise, rest and orthosis.

Telephone follow-up calls will facilitate adherence in the intervention group. Before data collection, participants from both groups will receive reminders. Empathic communication with the study participants will be maintained during all phases.

Recruitment: In addition to considering the results of Phase 1, recruitment will take place through:
1. Patients who go to the doctor for knee osteoarthritis or other health problems
2. People with a diagnosis of knee osteoarthritis in the electronic medical records
3. Information posters in the waiting rooms of the PHCCs
If the patient agrees to participate, the physician and/or nurse will give him/her a 'commitment folder' and the informed consent form. The patient must study the documentation and bring it back to the PHCC within two weeks.

Sample size: The sample size calculation is based on the minimal significant change in the clinical parameters and in the impact of the osteoarthritis using the WOMAC index. In order to achieve a power of 80% (beta: 0.2) and a significance level (alpha) of 0.05 for a two-tailed comparison, 124 participants will have to be recruited in each group to detect differences equal or higher than 5 units in the WOMAC index. An estimated standard deviation of 14, a correlation between the first and second measurement of 0.6 and 20% loss to follow-up have been assumed for these calculations. To take into account the randomization by PHCC, we consider a design effect of 1.45 with a mean number of patients per intervention group of 10 and an intraclass correlation coefficient of 0.05. The required sample size has been estimated at 180 patients per group: 9 primary care teams with 20 patients each will be recruited for each study group. The statistical package GRANMO v7.12 (IMIM, BCN, Spain) was used for sample size calculation.

Intervention Type
Behavioural

Primary outcome measure

1. Quality of life as measured by the WOMAC index (Batlle, 2009). The results will be measured in both groups three weeks before the intervention, immediately after the Intensive Phase and after 3, 6 and 12 months of recruitment.
2. Weight in kilograms and physical activity will be registered monthly. The weight will always be obtained using the same scale of the PHCC.
3. During the first interview we will obtain the height (in meters).

Secondary outcome measures
Clinical dependent variables:
1. Pain (ICOAP, Maillafet, 2009)
2. Weight (in kg. Scale at PCC)
3. Physical Activity (IPAQ- Puig, 2012, Pedometer)
4. Nutrition (PREDIMED)

Clinical variables:
Drug prescription, diagnostic tests, waist circumference, height, co-morbidities, duration of disease in years, duration of knee osteoarthritis in years (all with ad-hoc questionnaire).

Cost-related variables:
1. Direct medical costs:
1.1. Cost of coaching in osteoarthritis intervention
1.2. Cost of visits to the GP
1.3. Cost of visits to the nurse
1.4. Cost of visits to the physiotherapist
1.5. Cost of visits to specialist MD
1.6. Cost of medical tests
1.7. Cost of pharmacological treatment
1.8. Operating costs of the PCC
1.9. Cost of disposable medical equipment
1.10. Cost of transport (ambulance)
1.11. Cost of home assistance
2. Indirect medical costs: costs due to loss of productivity (days of sick leave)

Overall study start date
01/02/2014

Completion date
01/02/2016

Eligibility

Key inclusion criteria
Phase 1. The four discussion groups will include 8-12 primary care professionals working with patients with osteoarthritis

Phase 2.
1. Level 1 - Inclusion criteria to be determined by the physician:
1.1. Primary care patients with clinical and radiological diagnosis of knee osteoarthritis in the Kellgren-Lawrence stages 1-3
1.2. To be able to read and write

1.3. To have a mobile phone
1.4. To be able to go to the primary health care centres (PHCC)
1.5. To agree to participate
2. Level 2 - Inclusion criteria to be determined by the psychologist:
2.1. Patients that deliver the 'commitment folder' within the period agreed

Phase 3. The four discussion groups will include 8-12 primary care professionals working with patients with osteoarthritis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Phase 1: 8-12 primary care professionals working with patients with OAPhase 2: 360 participantsPhase 3: 8-12 primary care professionals working with patients with OA

Key exclusion criteria
Phase 2. Exclusion criteria:
1. Patients with knee osteoarthritis in the Kellgren-Lawrence stages 0 and 4
2. Patients with rheumatoid arthritis, fibromyalgia and other systemic rheumatological conditions
3. Patients on a waiting list for orthoses
4. Patients admitted during the past three months for cardiovascular diseases
5. Patients suffering from Parkinson disease, Pagets disease, cognitive deterioration, metastatic cancer, severe mental diseases and personality disorders
6. Women who are pregnant or planning a pregnancy

Date of first enrolment
01/02/2014

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
Spain

Study participating centre
Gran Via Corts Catalanes, 587, àtic
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Spain
08007

Sponsor information

Organisation
IDIAP Jordi Gol (Spain)

Sponsor details
Gran Via Corts Catalanes, 587, àtic.
Barcelona
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08007

Sponsor type
Research organisation

Website
https://www.idiapjgol.org

ROR
https://ror.org/0370bpp07

Funder(s)

Funder type
Research organisation

Funder Name
IDIAP Jordi Gol (Spain)

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?
Protocol article	protocol	25/02/2015		Yes	No