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Effectiveness of a group based cognitive behavioural training program in people with knee osteoarthritis pain

Submission date
15/03/2011

Recruitment status
No longer recruiting

Registration date
04/05/2011

Overall study status
Completed

Last Edited
29/06/2016

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Effectiveness of a group based cognitive behavioural training program in people with knee osteoarthritis pain: a single-blind randomised controlled trial

Study objectives
There is a lack of data on rehabilitation and its cost effectiveness in cognitive behavioral treatment (CBT) modalities of knee osteoarthritis (OA). Therefore, we want to test a CBT model created by Linton in treating patients with knee OA related pain. The proposed research measures the effectiveness and cost effectiveness of a CBT rehabilitation program in patients with knee OA related pain.
The proposed study is interdisciplinary clinical research on OA. The research hypothesis is that patients with symptomatic knee OA benefit from a CBT rehabilitation program. The specific aims of the proposed research are:
1. To determine the effect of the intervention in terms of self-reported physical function and pain, pain related work absence, number of pain related health care visits and health related quality of life (HRQoL)
2. To determine the effect of the intervention on psychological variables such as depression, anxiety, sense of coherence, pain catastrophiSing, kinesiophobia, self efficacy and life satisfaction.
3. To run a cost utility analysis of the intervention based on quality adjusted life years (QALY)

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Kuopio University Hospital, Kuopio, Finland, 02/03/2011, ref: 14 /2011

Study design
Single-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
A CBT rehabilitation program with 6 weekly meetings will be held by a psychologist. The program takes place in a group of 10 persons according to the model presented by Linton. Each session lasts for 2 hours with a 1520 minutes break in the middle to enhance peer support and social bonding. The outline of the sessions include introduction (15 min), lecture period (knowledge and insight, max 15 min), problem-solving (in pairs, 1520 min), skills training (1520 min), homework assignments (15 min) and a resume (feedback) of the session (15 min).

Added as of 21/03/2012.
Based on previous study on patients with knee OA the WOMAC pain subscale at baseline was 59.3 mm and a standard deviation of 16.2 mm (Tubach F, et al. Evaluation of clinically relevant changes in patient reported outcomes in knee and hip osteoarthritis: the minimal clinically important improvement. Ann.Rheum.Dis. 2005;64(1):29-33.). We postulated a mean of at least 48 mm in WOMAC pain subscale at baseline. When comparing mean pain scores between the groups, a two-tailed Student t test with a 5% significance level was used (Campbell MJ, et al. Estimating sample sizes for binary, ordered categorical, and continuous outcomes in two group comparisons. BMJ 1995;311(7013):1145-8). A 20% reduction in primary outcome (WOMAC pain) due to the intervention was considered as being clinically relevant. In order to have 80% test-power and 20% drop-out rate at least 54 patients per group needed to be included in our trial, so we have decided that the target number of participants is 108.

Intervention Type
Behavioural

Primary outcome measure
Self-reported pain [WOMAC (VAS) pain subscale]

Secondary outcome measures
1. Self-reported physical function, pain and stiffness [WOMAC] (VAS) physical function and stiffness subscales, numeric pain rating scale (NPRS), mean and worst pain (past week, 3 months)
2. Depression, anxiety, sense of coherence, pain catastrophising, kinesiophobia, self-efficacy and life satisfaction (BDI-21, BAI, 13-item SOC scale, PCS, TSK, Pain Self-Efficacy Questionnaire, 4-item LS scale)
3. Health-related quality of life and cost effectiveness [RAND-36 (SF-36), 15D, QALY, OA related sick leave, use of pain medication, knee OA related health care visits]
4. GAC (global assessment of change)

Overall study start date
23/08/2011

Completion date
31/12/2013

Eligibility

Key inclusion criteria

1. Age 35-75 years
2. Pain within the last year in or around the knee occurring on most days for at least a month
3. Knee pain greater than or equal to 40 mm on a 100 mm visual analogue scale (VAS) in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale for one week prior to study entry
4. KL 2-4 radiographic knee OA
5. Able to attend six training sessions

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
108

Key exclusion criteria
1. Severe psychiatric or psychological disorder
2. Other back or lower limb pain symptoms more aggravating than knee pain
3. Previous lower extremity arthroplasty or planned lower extremity joint surgery
4. Inability to finish the study or unlikely to be compliant

Date of first enrolment
23/08/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Finland

Study participating centre
Kuopio University Hospital
Kuopio
Finland
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Sponsor information

Organisation
Kuopio University Hospital (Finland)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00fqdfs68

Funder(s)

Funder type
University/education

Funder Name
Kuopio University Hospital (Finland) EVO grant

Funder Name
Suomen Lääketieteen Säätiö

Alternative Name(s)
Finnish Medical Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Finland

Funder Name
The Duodecim Foundation (Finland)

Funder Name
Finnish Cultural Foundation (Finland)

Alternative Name(s)
Finnish Cultural Foundation, SKR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Finland

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	29/01/2013		Yes	No
Results article	results	01/09/2015		Yes	No