

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 04/05/2011	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 29/06/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study type(s)

Treatment

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(s)

Self-reported pain [WOMAC (VAS) pain subscale]

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

FI-70211

Sponsor information

Organisation

Kuopio University Hospital (Finland)

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

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	01/09/2015		Yes	No
	protocol				

[Protocol article](#)

29/01/2013

Yes

No