ISRCTN05305406 https://doi.org/10.1186/ISRCTN05305406

Acupuncture in a group setting for chronic knee pain: ScrutiKnee

Submission date
18/05/2012

Recruitment status
No longer recruiting

Registration date
18/05/2012

Overall study status
Completed

Last Edited
20/10/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is a common cause of pain and disability, affecting one in five people aged over 50 in the UK. Previous studies show that acupuncture (a form of ancient Chinese medicine in which fine needles are inserted into the skin at certain points on the body) is effective in treating pain in people with mild to moderate OA of the knee. Studies also show that every person with osteoarthritis of the knee should be offered exercise and advice. What we dont yet know is whether exercise, advice and acupuncture can help people with severely painful knee osteoarthritis, who may otherwise be considered for joint replacement surgery. Another issue is cost. In some clinics in the NHS, acupuncture is being given to a group of patients at the same time to reduce its cost. There has been no research on how well acupuncture works when it is given to people who are part of a group, nor whether or not this reduces the cost of treatment. ScrutiKnee is a initial small study. So it is not designed to see if exercise, advice and acupuncture are effective, but it is designed to provide information for a larger study which will test whether these treatments are effective and cost-effective. ScrutiKnee will find out whether patients are interested in participating, and how we can best measure the changes we want to measure, such as pain and the use of health services.

Who can participate?
Men and women over the age of 45 can take part in ScrutiKnee, if they have had painful OA knees for at least a year, and if the pain has troubled them for most days in the previous month. The pain must be of a particular severity, as scored by the common scale, the Oxford Knee Score.

What does the study involve?
Patients who might be eligible are identified from their general practitioner's (GPs) databases and sent a letter. If patients are interested in taking part and seem eligible, they are phoned and sent an information leaflet about the study. Those still interested are invited to attend the research centre and consented to have their knees examined by a research nurse. Participants are selected at random to receive one of three treatments. All participants receive a booklet on self-management advice and exercises which is considered standardised care. The three treatment groups are:
1. The standardised care on its own
2. Standardised care plus acupuncture as part of a group with other participants, and

3. Standardised care plus acupuncture one-to-one with the practitioner.
The acupuncture clinic is in Plymouth (Teaching) Primary Care Trust. The acupuncture is provided by a Chartered Physiotherapist trained in acupuncture. A course of acupuncture consists of six to ten treatments over 12 weeks the treatment stops at six weeks if there is no improvement in the symptoms.
Participants are asked at the start and at the end of the treatment period to complete questionnaires about the impact their knee pain has on their life.
In addition, since this is a initial study arranged to help design the main study, participants are asked to write comments on their experiences in the study. Some participants are also invited for interview to report their experiences in greater detail.

What are the possible benefits and risks of participating?
Stuides shows that advice and exercise can produce long-term benefit for people with OA knee. It is not clear whether acupuncture provides any additional pain relief for people with severely painful OA knee. However there could be benefits to future patients by showing whether or not acupuncture is worth providing in the NHS for people with severely painful OA knee. The risks of taking part are minimal. Acupuncture is a very safe treatment when given by properly trained clinicians. Occasionally acupuncture can make people feel nauseous or faint or experience a temporary increase in pain either during or after treatment. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?
The study is run from the Peninsula Medical School, University of Plymouth, and the Peninsula Clinical Trials Unit (PenCTU) based in Plymouth.

When is the study starting and how long is it expected to run?
February 2012 to September 2012

Who is funding the study?
National Institute for Health Research, Research for Patient Benefit (NIHR-RfPB) (UK)

Who is the main contact?
Dr Adrian White
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Study website
http://sites.pcmd.ac.uk/scrutiknee/

Contact information

Type(s)
Scientific

Contact name
Dr Adrian White

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11589

Study information

Scientific Title
Pilot study of acupuncture in a group setting for chronic knee pain: ScrutiKnee

Study objectives
ScrutiKnee is a pilot randomised controlled trial that will provide information to help develop a subsequent trial that will evaluate the effectiveness and cost-effectiveness of group acupuncture in severe knee osteoarthritis. ScrutiKnee is a feasibility study designed particularly to test recruitment rate and resources required, and to establish the best method to measure the use of health service resources.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11589

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cornwall and Plymouth Ethics Commitee First MREC approval date 24/11/2011, ref: 11/SW/0277

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Patient information sheet can be found at http://sites.pcmd.ac.uk/scrutiknee/includes/docs/study_participant_information_leaflet_2.pdf

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Potentially eligible patients will be identified from GP registers and sent an invitation to participate. Those who respond will be screened by telephone and sent a participant information leaflet. Those still interested will be invited to attend the research centre. After giving consent and providing baseline information, all participants will receive a booklet on self-management advice and exercises, which is considered standardised care. Participants will be randomised to three groups:
1. Standardised care alone
2. Standardised care plus group acupuncture, or
3. Standardised care plus individual acupuncture.

Acupuncture: Group or individual acupuncture using semi-standardised formula, exercise and advice leaflet, purpose-designed leaflet for patients with moderate to severe knee pain. A course of acupuncture consists of six to ten treatments over 12 weeks.

Knee symptoms will be assessed before and after the course of treatment using common outcome measures. Participants will also be asked to write comments on their experiences in the study, and some participants will also be invited for interview to report their experiences in greater detail to provide information that will optimise the design of the subsequent main study. The trial duration for each participant is 14 weeks.

Follow Up Length: 3 month(s); Study Entry : Single Randomisation only

Intervention Type
Procedure/Surgery

Primary outcome measure
Western Ontario and McMaster Universities Arthritis Index (WOMAC) at baseline and 3 months

Secondary outcome measures
1. Oxford Knee Score at baseline and 3 months
2. Use of health and social service resources

Overall study start date
22/02/2012

Completion date
28/09/2012

Eligibility

Key inclusion criteria
1. Pain in one or both knees for at least a year, troublesome for most days in the previous month
2. Meets the clinical American College of Rheumatology (ACR) criteria for the diagnosis of osteoarthritis (at least three of the following):
2.1. Age at least 45 years
2.2. Stiffness, if present, lasts =30 minutes
2.3. Crepitus
2.4. Bony tenderness
2.5. Bony enlargement
2.6. No palpable warmth
3. Not had Knee Joint Replacement (KJR) in index knee, nor currently referred for surgery
4. Oxford Knee Score (OKS) =28
5. Able to travel to attend clinic
6. Able to complete outcome measures
7. Can be contacted by telephone; Target Gender: Male & Female ; Lower Age Limit 45 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Steroid injection or acupuncture to knee in the last two months
2. Hyaluronic acid injection, arthroscopy or serious injury to knee in last six months
3. Had Knee Joint Replacement (KJR) in index knee, or currently referred for consideration of surgery of the index knee
4. Clinical diagnosis of severe osteoarthritis of the ipsilateral hip
5. Not willing or able to provide informed consent
6. Bleeding disorder undiagnosed or severe
7. Concurrent medical conditions which would impair participation
8. Currently participating in any other interventional clinical trial

Date of first enrolment
22/02/2012

Date of final enrolment
28/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
I T T C Building
Plymouth
United Kingdom
PL6 8BX

Sponsor information

Organisation
NHS Plymouth (UK)

Sponsor details
Derriford Hospital
Derriford Road
Plymouth
England
United Kingdom
PL6 8DH

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - Research for Patient Benefit (RfPB) (UK)

Results and Publications

Publication and dissemination plan
Study main report in submission revisions; report of nested qualitative study in preparation

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	16/02/2016		Yes	No