

A pragmatic randomised controlled trial in primary care to determine the effectiveness of active physiotherapy treatment and enhanced pharmacy review for knee pain

Submission date 03/01/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/01/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/03/2007	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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

S0646

Study information

Scientific Title

Acronym

TOPIK (Treatment Options for Pain In the Knee)

Study objectives

The primary objective of this trial is to examine the clinical effectiveness, of two innovative interventions: enhanced pharmacy review and active physiotherapy, compared with a control group receiving an advice and information booklet reinforced with telephone support.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Knee pain

Interventions

1. Pharmacy review of medication
2. Active physiotherapy management
3. Advice leaflet

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Change in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 6 months.

Secondary outcome measures

Anxiety and Depression (HADS); Confidence in managing pain, function, and other symptoms associated with arthritis (Arthritis Self-Efficacy Scale); Overall health status (EuroQoL).

Overall study start date

01/05/2001

Completion date

31/03/2005

Eligibility**Key inclusion criteria**

1. Male and female patients aged 55 years and above
2. Pain with or without stiffness in one or both knees
3. Considered suitable for primary care management by GP
4. Able to read English
5. Available for telephone contact
6. Able and willing to consent to participation

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

325

Key exclusion criteria

1. Patients with potentially serious pathology (e.g. inflammatory arthritis, malignancy) on the basis of GP diagnosis or past medical history
2. Patients with severe disability: WOMAC Physical Function score ³ 40
3. Patients already on a surgical waiting list
4. Patients who have already had an exercise programme for their knee problem within the previous 3 months (normal recreational involvement in sport or exercise will not be an exclusion)
5. Patients who have received an intra-articular injection to the knee in the last 6 months
6. Patients who have a knee replacement
7. Patients unable or unwilling to receive the study interventions, or for whom the interventions are contraindicated

- 8. Patients with acute trauma
- 9. Knee pain due to malignancies

Date of first enrolment

01/05/2001

Date of final enrolment

31/03/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Primary Care Sciences Research Centre

Keele

United Kingdom

ST5 5BG

Sponsor information

Organisation

Arthritis Research Campaign (ARC) (UK)

Sponsor details

Copeman House

St Mary's Court

St Mary's Gate

Chesterfield

Derbyshire

United Kingdom

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info@arc.org.uk

Sponsor type

Charity

Website

<http://www.arc.org.uk>

ROR

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign

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?
Results article	Results	11/11/2006		Yes	No