

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

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

### Contact name

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### Contact details

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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 <sup>3</sup> 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

S41 7TD

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info@arc.org.uk

**Sponsor type**

Charity

**Website**

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

ROR

https://ror.org/02jkpm469

## 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?
<a href="#">Results article</a>	Results	11/11/2006		Yes	No