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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

Registration date
03/01/2003

Overall study status
Completed

Last Edited
06/03/2007

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

England

Study participating centre
Primary Care Sciences Research Centre
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign

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	11/11/2006		Yes	No