ISRCTN63848242 https://doi.org/10.1186/ISRCTN63848242

Improving rehabilitation for patients with chronic knee pain

Submission date	Recruitment status	[ ] Prospectively registered
06/11/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/10/2011	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Sally Jessep

Contact details
Physiotherapy Department
Sevenoaks Hospital
Hospital Road
Sevenoaks
United Kingdom
TN13 3PG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRF/03/03

Study information

Scientific Title

Acronym
7OAKS-ESCAPE

Study objectives
1. For patients with chronic knee pain a rehabilitation regimen delivered in the community with regular follow-up reduces pain and disability better than routine physiotherapy and these benefits are maintained over time
2. The rehabilitation regimen reduces healthcare utilisation and is ultimately less costly than routine physiotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Maidstone & Tunbridge Wells Local Ethics Committee on the 18th December 2003 (ref: 149/9/03).

Study design
The trial is a pragmatic, randomised, single blind study and a pilot for a potentially larger project.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Chronic knee pain, osteoarthritis

Interventions
Interventions:
Group one: Innovative exercise and education programme - this is a course of ten sessions each consisting of some education and some exercise
Group two: Routine physiotherapy

Outcome evaluation:
Outcome measures at baseline and at 12-month follow-up assessment will be summarised using appropriate descriptive statistics. Primary analyses will be by intention-to treat. The level of

significance will be set at p<0.05. The effect of the intervention on the Western Ontario and McMasters Universities Osteoarthritic Index (WOMAC) functional score will be assessed, first, by investigating whether outcomes differ significantly overall by groups.

These analyses will be adjusted for baseline measures. The following additional analyses are planned. Two tests of interaction will be carried out to investigate whether the effect intervention is influenced by:
1. Depression (Hospital Anxiety and Depression [HAD] score), or
2. Self-efficacy (Arthritis Self-Efficacy Score)

For all outcomes, both unadjusted (adjusting only for the baseline measure) and adjusted analyses (adjusting for other potential confounding factors) will be carried out; the latter will be interpreted as 'sensitivity analyses' to explore the robustness of the unadjusted analyses to possible confounding. Finally, process variables characterising the success with which the intervention was delivered (e.g. compliance) will be included in analyses of WOMAC functional score only, in order to interpret better the overall effects of the intervention.

Economic evaluation:
The primary economic evaluation will be a cost-effectiveness analysis comparing changes in the primary outcome (WOMAC) and total societal costs for each group. The secondary economic evaluation will be a cost-utility analysis based on utility weights associated with EuroQoL Health Survey (EQ-5D) health states. Cost-effectiveness acceptability curves will be employed for both the cost-effectiveness and cost-utility analyses in order to better inform decisions about the relative cost-effectiveness of the three treatments. Supplementary evaluation will take the form of a cost-consequences analysis, examining total and component costs alongside all outcomes.

The data analyses would be conducted in a manner consistent with those employed in the clinical evaluation (for example, on an intention-to-treat basis, and adopting the same conventions with respect to cluster randomisation, missing items scores, missing observations etc.). Cost differences between groups will be tested using the student's t-test. Cost data are often skewed, violating the normality assumption underpinning the validity of the t-test. If this is the case, bootstrap replications of the original data will be performed to check the robustness of the t-test results. Sensitivity analyses will be performed to check the assumptions made in the cost calculations and analyses. In addition, the EuroQoL will enable calculation of cost per Quality Adjusted Life Year (QALY) for the interventions.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Western Ontario and McMasters Universities Osteoarthritic Index (WOMAC) functional score at 12 months.

Secondary outcome measures
1. Aggregate Functional Performance Test (AFPT)
2. Health-related quality of life using the Euroquol
3. Exercise self-efficacy
4. Depression using the Hospital Anxiety and Depression scale

Overall study start date
01/03/2004

Completion date
01/03/2007

Eligibility

Key inclusion criteria
1. Over 50 years of age
2. Presented to their General Practitioner with chronic knee pain

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
1. Unstable, co-existing medical or psychological conditions
2. Those treated with physiotherapy to the knee in the previous 12 months
3. Those receiving an intra-articular injection to the knee in the previous six months
4. Other joint pain that would prevent them participating in an exercise programme
5. Taking steroids
6. Wheelchair bound
7. A poor command of English

Date of first enrolment
01/03/2004

Date of final enrolment
01/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Physiotherapy Department
Sevenoaks
United Kingdom
TN13 3PG

Sponsor information

Organisation
Physiotherapy Research Foundation (UK)

Sponsor details
Chartered Society of Physiotherapy
14 Bedford Row
London
United Kingdom
WC1R 4ED

Sponsor type
Research organisation

Website
http://www.csp.org.uk

ROR
https://ror.org/04sn78z72

Funder(s)

Funder type
Research organisation

Funder Name
Physiotherapy Research Foundation (UK) (ref. PRF/03/3)

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	01/06/2009		Yes	No