

# Improving rehabilitation for patients with chronic knee pain

**Submission date**  
06/11/2006

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
30/04/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
11/10/2011

**Condition category**  
Musculoskeletal Diseases

☐ Individual participant data

**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 McMaster 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 McMaster 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?
<a href="#">Results article</a>	results	01/06/2009		Yes	No