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Effective and cost-effective rehabilitation for knee pain in a community population

Submission date
18/07/2002

Recruitment status
No longer recruiting

Registration date
18/07/2002

Overall study status
Completed

Last Edited
12/07/2010

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

Study website
http://www.kcl.ac.uk/gppc/escape

Contact information

Type(s)
Scientific

Contact name
Dr Mike Hurley

Contact details
Physiotherapy Division
King's College London
Rehabilitation Research Unit
King's Healthcare (Dulwich)
East Dulwich Grove
London
United Kingdom
SE22 8PT
+44 (0)20 7346 6022
mike.hurley@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H0599

Study information

Scientific Title

Study objectives
Primary hypothesis was that participation on the rehabilitation programme would improve function better than usual primary. Subsidiary hypotheses were that rehabilitation would be equally effective whether delivered to individuals or groups of people. Group rehabilitation would be more cost-effective than individual rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local Research Ethics Committees (RECs) of
1. King's College, Guy's and St Thomas' (ref: 01-128)
2. The Lewisham Hospital NHS Trust (ref: 01/10/17)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Knee pain

Interventions
The rehabilitation regime is supervised by a research worker who has not performed that particular patient's assessment. The exercise regime consists of 12 x 30 minutes supervised exercise sessions, two a week for 6 weeks. The classes will be closely supervised by the applicant or research assistant, and performed on individual patients or in groups of eight patients who will rotate around exercise stations and will involve:

1. 24 isometric quadriceps: Maximal Voluntary Contractions (MVCs) will be performed with the patients seated and their knees flexed at 90°F as described in the quadriceps strength assessment. The MVCs will be performed in four groups of six MVCs, each contraction will be maintained for about 4 seconds and each group of six contractions separated by 1 minute rest to minimise fatigue. Vigorous verbal encouragement and visual feedback from the computer screen will facilitate maximum effort. All the contractions will be voluntary, no electrical stimulation will be used.
2. Five minute on a static exercise bike: Initially the patients will pedal without resistance, but after two to three sessions resistance to pedalling will be increased to increase quadriceps strength.
3. One minute of isotonic knee extension (concentric quadriceps contractions) and flexion (eccentric quadriceps contractions) to 90°F, using therapeutic resistance bands to increase quadriceps strength and dynamic control.
4. Three 'functional' exercises (eg sit/stand, step-ups, step-downs) and three balance/co-ordination exercises (unilateral stance, balance boards) will each be performed for one minute. As the quantity and quality of the exercises improve they will be progressed by increasing the number of repetitions or resistance (e.g. sit/stand from lower chair, step-ups on to higher block) and more challenging exercises were introduced (e.g. unilateral stance on balance board).

Self-care advice:
All patients attending the exercise sessions (whether treated individually or in small groups) will receive arthritis self-care advice emphasising: the importance of regular controlled exercise; methods of controlling joint pain, eg cold and heat packs; joint protection; medication; problem solving and planning to promote adoption of lifestyle changes to promote joint health, ie the importance of weight loss, incorporation of regular exercise into daily routine. This will be provided by the research worker supervising the exercise, who will answer specific questions, and will be reinforced with written information.

Discharge policy:
After 12 rehabilitation exercise sessions (the primary outcome measure end-point) the patients will be discharged with specific advice and written instructions to perform a simple, home exercise programme consisting of four exercises they are familiar with performing during their rehabilitation. The total exercising time will be about 15 min, three times a week. In addition, they will be supplied with contact addresses where the patients can exercise in the community.

Changes in the intervention group will be compared with changes in the control patients who remain under routine GP management.

Data Analysis Plan:
Cluster randomisation requires that analyses take into account clustering, if the individual patient is chosen as the unit of analysis (which maximises power); this is most effectively done by multilevel modelling (level 1 = participants; level 2 = GP surgeries). Cluster randomisation is less likely than individual randomisation to achieve adequate balance in patient and cluster characteristics, and multilevel modelling also allows such potential confounding factors to be modelled.

Outcomes are measured at baseline, at 6 weeks (ie end of the intervention or control period) and 6 months after the end of the intervention. These repeated measures will be represented as a further level of clustering (measurements within participants) in a multilevel model. Multilevel

modelling accommodates missing data for repeated measures efficiently, maximising the power of the analyses and the available information about outcome. The analytic framework of multilevel modelling can be extended to binary variables.

Outcome measures at baseline and at the 6-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 primary outcome [function-WOMAC(func)] will be assessed, first, by investigating whether outcomes differ significantly overall by groups and, second, by carrying out paired comparisons between (a) the individually treated patients and control group and (b) patients treated in classes and control group if overall significant differences by group are observed. These analyses will be adjusted for baseline measures. No test of the interaction between time of outcome measurement and intervention group is planned.

The following additional analyses are planned. Two tests of interaction will be carried out to investigate whether the effect of intervention is influenced by (a) depression or (b) self-efficacy. 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 (eg compliance) will be included in analyses of WOMAC(func) 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(func)] 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 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
Self-reported functioning Western Ontario and McMasters University Osteoarthritis Index (WOMAC) sub-score for physical function 6 months after completing rehabilitation.

Secondary outcome measures
1. Aggregated functional performance time (AFPT) 18
2. Exercise health beliefs and self-efficacy questionnaire (ExBeliefs) 19
3. Hospital Anxiety and Depression Scales
4. Self-reported health status EuroQoL
5. Condition specific patient preference health related quality of life questionnaire (McMaster Toronto Arthritis, MACTAR)
6. Quadriceps strength and voluntary activation
7. Costs of rehabilitation evaluated using Client Services Receipt Inventory

Overall study start date
01/01/2000

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Patients who have attended their General Practitioner (GP) practice complaining of knee pain and for whom the GP feels that some intervention is appropriate
2. Patients who give informed consent to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
418

Key exclusion criteria
1. Lower limb arthroplasty
2. Physiotherapy for knee pain in preceding 12 months
3. Intra-articular injections in preceding 6 months
4. Unstable medical conditions
5. Unable/unwilling to exercise
6. Severe lack of mobility
7. Unable to understand English

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Physiotherapy Division
London
United Kingdom
SE22 8PT

Sponsor information

Organisation
Arthritis Research Campaign (UK)

Sponsor details
Copeman House
St Mary's Court
St Mary's Gate
Chesterfield
United Kingdom
S41 7TD
+44 (0)1246 558033
info@arc.org.uk

Sponsor type
Charity

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (UK) - (previously Arthritis Research Campaign [ARC])

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	main results	15/10/2007		Yes	No
Results article	results of economic evaluation	15/10/2007		Yes	No
Results article	results	11/02/2010		Yes	No