

# Long-term clinical benefits and costs of an integrated rehabilitation programme compared with outpatient physiotherapy for chronic knee pain

Sally A. Jessep<sup>a</sup>, Nicola E. Walsh<sup>b</sup>, Julie Ratcliffe<sup>c</sup>, Michael V. Hurley<sup>d,\*</sup>

<sup>a</sup> *Physiotherapy Department, Sevenoaks Hospital, West Kent Primary Care Trust, Sevenoaks TN13 3PG, UK*

<sup>b</sup> *Glenside Campus, Blackberry Hill, University of the West of England, Bristol BS16 1GG, UK*

<sup>c</sup> *School of Nursing and Midwifery, Division of Health Sciences, University of South Australia, Australia*

<sup>d</sup> *Academic Physiotherapy Department, Health and Social Care Research Division, King's College London, UK*

## Abstract

**Background** Chronic knee pain is a major cause of disability in the elderly. Management guidelines recommend exercise and self-management interventions as effective treatments. The authors previously described a rehabilitation programme integrating exercise and self-management [Enabling Self-management and Coping with Arthritic knee Pain through Exercise (ESCAPE-knee pain)] that produced short-term improvements in pain and physical function, but sustaining these improvements is difficult. Moreover, the programme is untried in clinical environments, where it would ultimately be delivered.

**Objectives** To establish the feasibility of ESCAPE-knee pain and compare its clinical effectiveness and costs with outpatient physiotherapy.

**Design** Pragmatic, randomised controlled trial.

**Setting** Outpatient physiotherapy department and community centre.

**Participants** Sixty-four people with chronic knee pain.

**Interventions** Outpatient physiotherapy compared with ESCAPE-knee pain.

**Outcomes** The primary outcome was physical function assessed using the Western Ontario and McMaster Universities Osteoarthritis Index. Secondary outcomes included pain, objective functional performance, anxiety, depression, exercise-related health beliefs and healthcare utilisation. All outcomes were assessed at baseline and 12 months after completing the interventions (primary endpoint). ANCOVA investigated between-group differences.

**Results** Both groups demonstrated similar improvements in clinical outcomes. Outpatient physiotherapy cost £130 per person and the healthcare utilisation costs of participants over 1 year were £583. The ESCAPE-knee pain programme cost £64 per person and the healthcare utilisation costs of participants over 1 year were £320.

**Conclusions** ESCAPE-knee pain can be delivered as a community-based integrated rehabilitation programme for people with chronic knee pain. Both ESCAPE-knee pain and outpatient physiotherapy produced sustained physical and psychosocial benefits, but ESCAPE-knee pain cost less and was more cost-effective.

Clinical Trial Registration No.: ISRCTN63848242.

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**Keywords:** Knee pain; Exercise-based rehabilitation; Physiotherapy; Functioning; Healthcare costs

## Introduction

Chronic knee pain, often diagnosed as knee osteoarthritis [1], is a significant public health problem [2]. It causes pain and disability, impairs psychosocial function and quality of

life, and places a large socio-economic burden on health services [2–7]. As the incidence and prevalence of chronic joint pain is age related, these problems will increase as the number of elderly people increases.

Evidence-based management guidelines [8–10] advocate exercise and patient education/self-management interventions (SMIs) as effective ways of improving pain and physical function in chronic knee pain. In spite of these guidelines,

\* Corresponding author. Tel.: +44 203 299 6022; fax: +44 203 299 6358.  
E-mail address: mike.hurley@kcl.ac.uk (M.V. Hurley).

only one-third of people reportedly receive exercise-based rehabilitation, and this is usually in the form of a short one-off course of physiotherapy involving exercise and advice [11,12]. Moreover, therapeutic benefits diminish if people do not continue to exercise regularly, and most patients do not adhere to therapeutic advice following discharge [13–18]. SMIs help people to understand and cope with their problems more effectively, improve adherence to management advice and reduce healthcare utilisation [19–21].

Exercise and SMIs are frequently delivered separately; SMIs explain the benefits of exercise but rarely have a participatory exercise component, while the patient education element of exercise regimens focuses on how to perform exercise. However, the benefits of exercise and SMIs might be enhanced if programmes integrate the physical approach of exercise with the educational approach of SMIs. In addition, self-management skills could improve adherence to regular exercise and sustain the benefits [22]. Unfortunately, most integrated rehabilitation programmes are long, complex and expensive, and consequently have limited clinical application [23,24].

To address these issues, an integrated rehabilitation programme entitled ‘Enabling Self-management and Coping with Arthritic knee Pain through Exercise’ (ESCAPE-knee pain) was devised. This improved physical functioning, pain and other psychosocial variables [25], and was more cost-effective than usual primary care [26]. It included elements that enhance adherence, such as using simple equipment, low intensity, functional exercises that were tailored to address each individual’s needs, the benefits were experienced quickly and it was supplemented with written information [15,27]. Although the benefits of the intervention were sustained 6 months after rehabilitation, there was an overall trend towards decline in outcome variables over time. The programme did not incorporate two features known to promote regular exercise: delivery of the programme in the community, and ongoing support from a healthcare professional to reinforce health messages and remotivate people [15–18,27]. Delivering the programme in the community makes inherent sense as this is the setting where the majority of people with the condition are managed. Whether or not ESCAPE-knee pain would be as effective if delivered by a clinician in the community is unknown, but efficacious interventions (carried out in ideal conditions) are often disappointing when delivered in less controllable conditions that prevail in clinical contexts, and frequently require adaptation to ensure clinical feasibility, practicality and maximise effectiveness.

To make the ESCAPE-knee pain programme clinically applicable and to promote long-term adherence to regular exercise, the programme was shortened slightly, delivered in a community centre, and a review session was introduced 4 months after completion of the programme. This study evaluated the feasibility of delivering this programme, and compared its clinical and cost-effectiveness with outpatient physiotherapy. It was hypothesised that: (1) both interventions would increase physical functioning and reduce pain in

the short term, but ESCAPE-knee pain would sustain these benefits for longer than outpatient physiotherapy; and (2) ESCAPE-knee pain participants would have lower healthcare utilisation.

## Method

The aims, design, conduct and data analysis followed a pre-specified protocol (Clinical Trial Registration No.: ISRCTN63848242) and observed the CONSORT recommendations for reporting non-pharmacological interventions [28] and pragmatic trials [29].

### Design

This pragmatic, randomised controlled trial compared outpatient physiotherapy with an integrated rehabilitation programme that combined exercise, patient education, self-management and coping strategies. Pragmatic trials provide information about the clinical and cost-effectiveness of an intervention compared with usual care in the ‘real-life’ clinical situation, by recruiting a representative population and delivering the interventions in the setting and under the prevailing conditions where a healthcare intervention is usually delivered. Consequently, the findings of pragmatic trials are more useful to clinicians because they generalise to clinical practice better than research trials carried out under ideal conditions [29,30].

### Participants

One hundred and seventy potential participants were identified from two local primary care practices. Broad inclusion criteria were adopted: participants had to be over 50 years of age, and had to have consulted a primary care physician for mild, moderate or severe non-specific knee pain lasting for more than 6 months with no identifiable recent cause; these patients would be diagnosed as having clinical osteoarthritis based on their clinical presentation and history [1,31,32]. No attempt was made to identify specific lesions, but people were excluded if they reported their knee pain emanating from knee trauma within the past year. Other exclusion criteria included: lower limb arthroplasty, physiotherapy for knee pain in the preceding 12 months, intra-articular injections in the preceding 6 months, unstable medical or psychological conditions, unable or unwilling to exercise, unable to walk 100 metres, and insufficient command of English to complete the assessment and undertake the intervention. People were not excluded if they had stable comorbidities common in this age group (e.g. type II diabetes, cardiovascular or respiratory disorders), or back, lower or upper limb pain.

Potential participants were sent a letter outlining the study and inviting them to take part. Those who were willing were screened over the telephone for inclusion and exclusion criteria. Subsequently, those people who were willing and eligible were sent an appointment for a baseline assessment

when any additional concerns were addressed, their written consent was obtained and the baseline assessment was performed.

### *Outcome measures*

The primary outcome was self-reported physical function assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The WOMAC is a widely used, validated, disease-specific, self-completed questionnaire which produces a total score between zero and 96 points [33], comprised of subscores for physical function (WOMAC-func, zero to 68 points), pain (WOMAC-pain, zero to 20 points) and stiffness (zero to eight points). Lower WOMAC scores are better; hence, reductions in WOMAC scores indicate improvement.

Secondary outcomes were: pain (WOMAC-pain), objective assessment of function from the aggregated functional performance time (AFPT) of four common activities of daily living [34], exercise-related health beliefs and self-efficacy [35], Hospital Anxiety and Depression Scale (HADS) [36], and health-related quality of life (EQ5D) [37]. Reductions in AFPT and HADS scores, and increases in other scores indicate improvement.

Healthcare utilisation was assessed using the Client Services Receipt Inventory (CSRI), an interview-based questionnaire which has been used in nearly 200 economic evaluations [38–40], customised to ensure that it was relevant to people with knee pain.

### *Assessment timing*

All measures were assessed at baseline, immediately after the intervention and 12 months after completion of the intervention (primary endpoint).

### *Randomisation*

After baseline assessment, participants were allocated to receive outpatient physiotherapy or ESCAPE-knee pain using a randomisation list generated and held at a centre away from Sevenoaks Hospital to ensure concealed allocation.

### *Blinding*

The assessor was unaware of each participant's treatment allocation.

### *Interventions*

Participants randomised to outpatient physiotherapy followed the usual clinical practice of Sevenoaks Hospital Physiotherapy Outpatient Department. Participants were allocated to whichever clinician was free, had a 30–45-minute assessment and then received the treatment modalities that the

physiotherapist felt necessary, up to a maximum of 10 sessions. The physiotherapists were given no instruction other than to follow their usual clinical practice, and record the number of sessions and treatment modalities used for each participant.

The ethos of ESCAPE-knee pain is that regular exercise can control the symptoms and effects of chronic knee pain. The programme aims to change people's behaviour by challenging inappropriate beliefs regarding their condition and physical activity, encouraging regular exercise and enabling self-management. It achieves this through informal group discussions that promote shared learning, information and advice about simple coping strategies, problem-solving and planning skills, and active participation on a progressive exercise regimen. The regimen is initially devised by the physiotherapist and consists of a circuit of up to 10 exercises tailored to each participant's ability. As the quantity and quality of exercise performance improves, easier exercises are omitted and more challenging exercises are introduced. In this way, participants are continually working near their maximum capabilities in a controlled manner. As the programme progresses, the physiotherapist nurtures each participant's understanding and confidence in their ability to manipulate and adapt exercises to suit their fluctuating symptoms, individual needs and problems. By the end of the programme, participants have learnt how to utilise physical activity to self-manage their symptoms.

The original programme is detailed elsewhere [25, [www.kcl.ac.uk/schools/medicine/research/hscr/escape](http://www.kcl.ac.uk/schools/medicine/research/hscr/escape)]. In this study, the number of sessions was reduced to 10 (from 12), held twice a week for 5 weeks in a local authority adult education centre (previously an outpatient department), with the size of the classes limited to six participants (previously eight), and a review session was added 4 months after completion of the programme. The sessions were supervised by the same physiotherapist from Sevenoaks Physiotherapy Department with more than 20 years of postgraduate clinical experience, but who received no additional training other than being told about the programme's ethos, aims, structure and content, and how to guide the group discussions, and observing some groups being held at another location. Each session began with an informal themed group discussion led by the supervising physiotherapist for 15 to 20 minutes ([Appendix A](#)), followed by a 40-minute, self-paced, progressive exercise circuit to improve quadriceps strength, dynamic control, balance, co-ordination and function. Participants were provided with written information summarising key messages from each session, which served as an aide-memoire following discharge.

After completion of the rehabilitation programme, participants received a written, tailored home exercise regimen, largely comprised of the exercises performed during the supervised circuit, and information about local community exercise facilities, classes, leisure centres and self-help groups. Four months after completion of the programme, the physiotherapist telephoned each participant and invited

them to a 1-hour review session when the key messages were reinforced, and the participant’s home exercise regimen was reviewed and altered if appropriate.

*Sample size*

As this is the first study of an integrated rehabilitation programme for chronic knee pain in people recruited from primary care, delivered in a community setting with 12-month follow-up, there were no data on which to base sample size, so a convenience sample of 60 participants was considered adequate to generate data for sample size calculation in future studies. A 15% increase from baseline in self-reported physical function 12 months after completion of the programme was considered to be a clinically meaningful improvement [41].

*Data analyses*

All clinical and cost data analyses were by intention-to-treat (i.e. participant data were analysed in the groups to which they were randomised) using Statistical Package for the Social Sciences Version 12.0.1 (SPSS Inc., Chicago, IL, USA).

*Clinical data*

The effect of the intervention on all outcomes was assessed by comparing between-group changes at 12 months using

analysis of covariance to correct for baseline values. Level of statistical significance was set at  $P < 0.05$ . Treatment effect size (ES) was calculated from Cohen’s  $d$  [42] with an ES between 0.01 and 0.19 considered small, between 0.2 and 0.79 considered medium, and  $>0.79$  considered large.

*Intervention costs*

To estimate intervention costs that can be generalised beyond a specific locality [43], national tariffs for initial physiotherapy assessment and subsequent treatment were taken from the Department of Health database [44]. Costs are presented in Pounds Sterling (£), standardised to 2005 prices. For outpatient physiotherapy, the sum of one initial assessment (at £36 per session) plus the number of treatment sessions (at £26 per session) was calculated to produce the cost of outpatient physiotherapy per patient. For ESCAPE-knee pain, the first three sessions were considered to be assessment sessions to allow the physiotherapist to familiarise themselves with each of the six participant’s capabilities (at £36 per session, total £108), the subsequent seven sessions were considered to be follow-up sessions (at £26 per session, total £182), telephone contact to arrange the review session was costed as a non-face-to-face contact (at £9 per participant, total £54), and the review session was considered to be an assessment session (at £36). The costs of these sessions were summed to obtain a total cost for the programme, then divided by the class size ( $n = 6$ ) to give a cost per participant per programme of £63.62. Costs were calculated for participants with complete datasets.

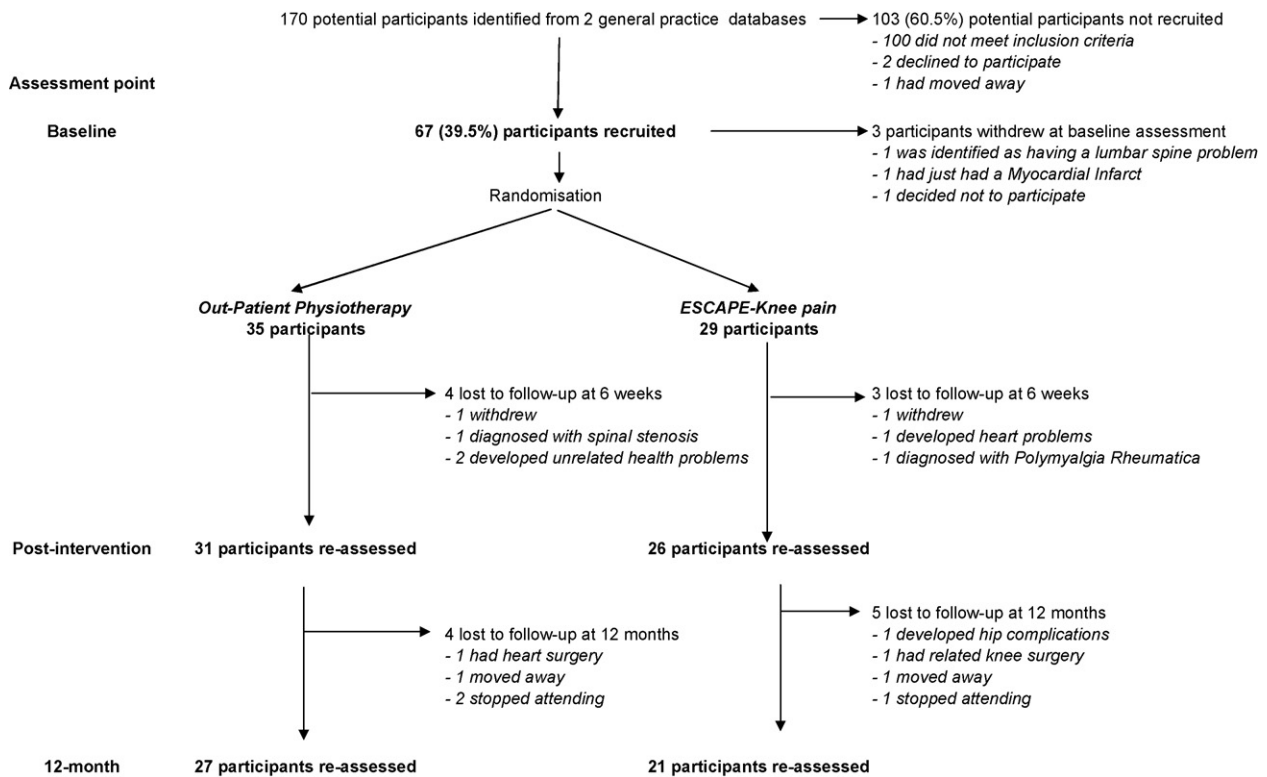


Fig. 1. Flowchart of recruitment and retention of trial participants.

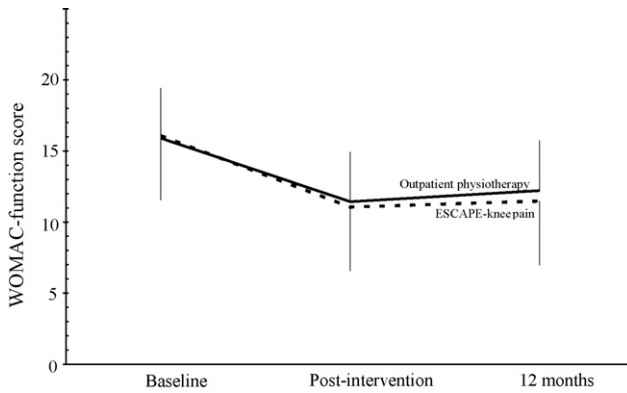


Fig. 2. Physical function at baseline, after completion of the intervention and 12 months after completion of the intervention. Data presented as mean (95% confidence interval error bars).

### Healthcare resource utilisation

Management of all participants' knee problems continued at each participant's primary care physician's discretion, and the CSRI collected all primary and secondary health contacts, investigations, interventions [44,45] and medication [BNF] related to the participant's knee pain, covering the period between baseline and the 12-month assessment retrospectively. National reference costs were applied. As this study was interested in changes in healthcare utilisation following the intervention, baseline data are not presented.

### Incremental cost-effectiveness ratio

This was calculated using each participant's data with complete datasets, by calculating the difference in the total costs of the two interventions divided by the difference in the EQ5D data of the two interventions.

Table 1

Anthropometric characteristics of the participants at baseline, presented as mean (range) unless stated.

	Outpatient physiotherapy	ESCAPE-knee pain
Number of participants (females)	35 (22)	29 (22)
Age (years)	67 (51 to 76)	66 (53 to 81)
Height (metres)	1.66 (1.38 to 1.87)	1.66 (1.49 to 1.85)
Weight (kilogrammes)	78 (51 to 118)	81 (57 to 110)
Body mass index	29 (20 to 47)	30 (20 to 42)
Duration of knee pain (years)	12 (0.5 to 55)	13 (1 to 30)

### Results

The flowchart of trial participants (Fig. 1) shows that of the 170 potential participants approached, 64 were randomised. At 12 months, 16 (25%) participants had withdrawn, eight from each intervention.

At baseline, there were no differences in the anthropometric characteristics or clinical variables of participants allocated to outpatient physiotherapy or ESCAPE-knee pain (Table 1). There were no differences in any of the baseline characteristics between participants who remained in the trial and those who withdrew.

No adverse events due to the interventions were reported.

### Attendance

The median number of outpatient physiotherapy treatment sessions was four (interquartile range two to six sessions); four participants had one treatment session, 21 participants had three to six sessions, and three participants had seven or more sessions. In almost all cases, these consisted of exercise ( $n=29$ ) and advice ( $n=26$ ), and a minority of participants had electrotherapy ( $n=10$ ) or manual therapy ( $n=6$ ). Most participants ( $n=19$ ) had completed their treatment within 5

Table 2

Clinical outcomes, presented as mean (standard deviation).

Variable	Baseline assessment		Immediately post-intervention		12-Month follow-up		Difference between groups at 12 months <sup>a</sup>
	Outpatient physiotherapy	ESCAPE-knee pain	Outpatient physiotherapy	ESCAPE-knee pain	Outpatient physiotherapy	ESCAPE-knee pain	
WOMAC-func <sup>b</sup>	15.9 (10.4)	16.1 (11.8)	11.4 (12.20)	11.6 (9.5)	12.2 (13.7)	11.5 (12.1)	0.06
WOMAC-pain <sup>b</sup>	5.7 (3.2)	5.6 (3.4)	4.0 (3.6)	3.2 (2.7)	4.2 (4.0)	3.2 (3.3)	0.27
AFPT (seconds) <sup>b</sup>	43.5 (12.8)	41.8 (11.9)	39.1 (10.4)	39.9 (9.3)	43.8 (17.5)	41.4 (13.0)	0.15
HADS-anxiety <sup>b</sup>	3.6 (2.4)	4.2 (2.9)	4.2 (3.3)	4.4 (3.5)	4.5 (2.9)	4.9 (3.9)	-0.17
HADS-depression <sup>b</sup>	2.7 (1.7)	2.7 (1.7)	3.0 (2.4)	2.4 (1.3)	3.2 (2.4)	2.7 (1.9)	0.23
Ex-beliefs	66.2 (6.7)	66.2 (12.7)	68.2 (6.0)	71.5 (8.4)	66.2 (6.9)	70.8 (8.2)	-0.61 <sup>c</sup>
EQ5D	0.76 (0.09)	0.73 (0.14)	0.77 (0.20)	0.81 (0.11)	0.73 (0.23)	0.78 (0.174)	0.24

ESCAPE-knee pain, Enabling Self-management and Coping of Arthritic knee Pain through Exercise; WOMAC-func, Western Ontario and McMaster Universities Osteoarthritic Index, functioning subscale; WOMAC-pain, Western Ontario and McMaster Universities Osteoarthritic Index, pain subscale; AFPT, aggregate functional performance time of four common activities; HADS-anxiety, Hospital Anxiety and Depression Scale, anxiety subscale; HADS-depression, Hospital Anxiety and Depression Scale, depression subscale; Ex-beliefs, exercise beliefs and self-efficacy; EQ5D, health-related quality of life.

<sup>a</sup> Effect size calculated from Cohen's  $d$  [29].

<sup>b</sup> Lower values are better.

<sup>c</sup>  $P=0.035$ .



Table 3

Costs of the interventions and healthcare utilisation related to knee pain, presented as mean (standard deviation) in Pounds Sterling (£) at 2005 prices.

Resource	Outpatient physiotherapy costs (£)	ESCAPE-knee pain costs (£)
Intervention costs	130.37 (77.38)	63.67 <sup>a</sup>
Healthcare utilisation		
Outpatient visits	78.58 (125)	57.88 (87)
Accident and emergency	3.55 (20)	–
Other secondary care	308.00 (1106)	126.08 (407)
General practitioner visit	33.23 (41)	34.85 (37)
Nurse visit	6.77 (14)	2.77 (6)
Other primary care	–	2.25 (8.17)
Medication	22.07 (35)	32.21 (64)
Total costs	582.57 (1157)	319.71 (469)

<sup>a</sup> Cost of running the programme assuming six participants attend the complete programme (three assessment sessions at £36 per session, seven treatment sessions at £26 per session, £9 telephone contact to arrange the review session at £36).

weeks, and nearly all ( $n=27$ ) had completed their treatment within 10 weeks.

In ESCAPE-knee pain, 24 of 29 (83%) participants attended eight or more sessions, four participants attended six or seven sessions, and one participant attended four sessions. Twenty-six participants (89%) attended the review session.

### Clinical outcomes

Participant's physical function (WOMAC-func) showed sustained improvement for 12 months after completion of the intervention (Table 2, Fig. 2), but there were no between-group differences in participant's physical function (ES 0.06;  $P>0.5$ ) or any other clinical outcome, apart from participant's exercise health beliefs which were better in ESCAPE-knee pain participants (ES 0.6;  $P=0.035$ ).

### Costs

Outpatient physiotherapy cost £130.37 per patient (SD 77.38) compared with £63.62 for ESCAPE-knee pain (Table 3). Total costs (intervention plus healthcare utilisation) were £583 for outpatient physiotherapy and £320 for ESCAPE-knee pain, largely due to the lower costs of ESCAPE-knee pain and lower utilisation of secondary care services in the year following completion of the programme (Table 3).

The incremental cost-effectiveness ratio showed that ESCAPE-knee pain was associated with marginally greater improvements in EQ5D scores but lower costs than outpatient physiotherapy, and hence was more cost-effective.

### Discussion

This pragmatic study established the feasibility of delivering ESCAPE-knee pain – a community-based reha-

bilitation programme that integrated patient education, self-management strategies and exercise for people with chronic knee pain – and compared it with outpatient physiotherapy management. The hypothesis that ESCAPE-knee pain would sustain greater benefits than outpatient physiotherapy was not supported as both interventions produced similar sustained improvements in physical function and other clinical outcomes. Lower intervention costs and reduced healthcare utilisation did support the hypothesis that ESCAPE-knee pain would be less costly and more cost-effective than outpatient physiotherapy. However, these results need to be confirmed in larger studies.

It is not surprising that both of these interventions demonstrated good short-term improvements in function and pain, since both comprised exercise and self-management advice which are known to be effective [8–10,19–21,46–49]. What is surprising is the extent of the improvement and that these improvements were sustained. A 25% improvement in self-reported function is well above the level considered to be clinically meaningful [41,50], and occurred in people with comparatively good baseline function. These findings confirm exercise-based rehabilitation as an effective way of managing chronic knee pain, with benefits sustained for longer than previously thought.

An important difference between the interventions was cost. Innovative healthcare interventions are usually more expensive than current treatments. ESCAPE-knee pain is unusual because although the differences in the clinical outcomes were marginal, the programme's group delivery and reduced healthcare utilisation made it more cost-effective. These cost differences were calculated at the level of the individual participant. If the cost differential was extrapolated to the large population of people with chronic knee pain, the programme could have substantial healthcare savings. Moreover, as chronic knee pain is slowly progressive with increasing healthcare costs, the savings could be greater over time.

Initiation and maintenance of regular exercise requires people to hold 'appropriate' exercise health beliefs (e.g. that exercise is safe and has wide health benefits), and to have high exercise self-efficacy (i.e. they are confident in their ability to exercise by knowing what to do, how to do it and have the necessary equipment, facilities, support, etc.) [35,51,52]. These traits are enhanced by people experiencing positive benefits from an exercise regimen that requires few additional resources [53–55], and were important considerations during the design of the ESCAPE-knee pain programme. Participation in the programme, including the review session, may provide people with ongoing 'supported self-management', reassurance, remotivation and reinforcement of important health messages, and is reflected in the sustained improvement in exercise health beliefs and self-efficacy. This provides a theoretically based, working hypothesis about the mechanism by which sustained improvements and cost-savings could be achieved; future studies are needed to confirm this hypothesis.

The main limitation of this study is its relatively small size. It was designed as a feasibility study to see if the ESCAPE-knee pain programme could be delivered in the community, and to generate preliminary data regarding short- and long-term outcomes, but the inferences that can be drawn from small feasibility trials must be considered with caution. In particular, the volatility of economic data – where one or two expensive procedures in a few people can produce large standard deviations and skew results – can lead to erroneous conclusions. Therefore, while the study succeeded in establishing the feasibility of the programme and indicated its potential clinical effectiveness, costs and mechanism of action, these must be confirmed in a larger study.

Another limitation of this study is the reliance on participant recall to measure healthcare utilisation. Inaccurate or biased recall due to memory and cognitive impairments is a concern in elderly people. However, none of the participants had overt memory problems, and data from patient recall can correlate well with data from other sources [56–58].

The difficulty in describing malleable interventions is an unavoidable problem that hinders replication. The details of the intervention have been made publically available ([www.kcl.ac.uk/schools/medicine/research/hscr/escape](http://www.kcl.ac.uk/schools/medicine/research/hscr/escape)), but the programme should be regarded as being highly adaptable to the needs of patients and clinicians. The adaptability of the programme is one of its strengths and attractions. It allows clinicians to tailor management to individual's needs, making it clinically relevant and useful. Moreover, the clinician is not constrained by strict research protocols that are often difficult to implement in clinical contexts.

The positive experiences of the ESCAPE-knee pain programme and its effectiveness and efficiency have prompted the Physiotherapy Department at Sevenoaks Hospital to adopt the programme as the preferred clinical service for people referred with chronic knee pain.

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*Conflict of interest:* None declared.

### Appendix A. Outline of the informal themed group discussions of the ESCAPE-knee pain programme

Session	Theme of informal discussion
1	Aims and objectives of programme activity levels and views on exercise
2	Personal objectives, goal setting and action plans early home exercises
3	Pacing and activity–rest cycles
4	Drug management review action plans
5	Diet and healthy eating
6	Intermediate home exercise programme review
7	Pain gate review action plans
8	Managing pain exacerbation and 'flares'
9	Mini-relaxation deep breathing techniques
10	Advanced exercises for home programme review action plans, information on activities in the community pursuing exercise and activity

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