

# Supplementing a home exercise programme with a class-based exercise programme is more effective than home exercise alone in the treatment of knee osteoarthritis

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**Objective.** The study aimed to compare the relative effectiveness of providing a home-based exercise programme versus home-based exercise supplemented with an 8-week class-based exercise programme in reducing pain and improving function in patients with knee osteoarthritis.

**Methods.** Patients ( $n = 214$ ) with radiologically confirmed knee osteoarthritis were selected. Patients were randomly allocated to either home or home supplemented with class-based exercise programmes. Both groups were given a home exercise programme whilst the supplemented group also attended for 8 weeks of twice weekly knee classes. Assessments of locomotor function, walking pain and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores were made. Assessments were made pre- and post-treatment and also at 6- and 12-month follow-ups. Statistical analysis involved the use of a longitudinal linear model ANCOVA with baseline values entered as a covariate.

**Results.** Patients from the class-based group demonstrated significantly greater improvement in locomotor function ( $-3.7$  seconds; 95% C.I.  $-4.9$  to  $-2.5$ ) and decrease in walking pain ( $-15$  mm; 95% C.I.  $-20$  to  $-11$ ) than the home-based group, at 12-months follow-up.

**Conclusions.** The supplementation of a home based exercise programme with a class-based exercise programme led to clinically significant superior improvement. These improvements were still evident at 12-month review. This is the first trial to evaluate this common physiotherapeutic practice, and based on this evidence, supplementation of home exercises with a class-based exercise programme can be recommended to patients, clinicians and service providers.

KEY WORDS: Exercise, Knee osteoarthritis, Physical therapy, Randomized controlled trial.

Osteoarthritis (OA) is the single most important cause of disability in elderly people in the UK [1]. The knee is the most often affected weight-bearing joint [2], consequently knee osteoarthritis is an extremely common cause of disability in the community [3]. One-third of people aged 63 to 94 years are affected by knee osteoarthritis that often limits the ability to rise from a chair, comfortably walk and use stairs [4]. In addition, knee osteoarthritis causes knee pain that can range from mild to extreme in severity [5].

Physiotherapeutic treatment, and particularly exercise, has been part of the management of knee osteoarthritis for nearly a century [6] and is the second most frequently prescribed treatment after oral medication [7, 8]. What is specifically unknown is whether such exercise should be performed by patients individually, at home, or be undertaken in a class-based setting as evidence exists to support both methods of provision [9–11]. In addition, the long- and short-term effects of supplementing a home-based, individual exercise programme with class-based exercise are unknown.

In this study we compared the clinical effectiveness of supplementing a home exercise programme with a class-based exercise programme against home exercise alone, in the treatment of knee osteoarthritis. A subsidiary goal was to compare the effect of these two interventions on adherence with home exercises.

## Methods

A randomized controlled trial design was used, comparing two methods of providing exercise treatment to patients with knee osteoarthritis. The trial was a single-blind randomized controlled trial with the observer undertaking the outcome assessments, blind to the intervention.

## Subjects

Referrals were from several sources including those from orthopaedic and rheumatology clinics of local hospitals and direct referrals from local general practitioners. Subjects were referred directly to the trial in response to flyers being placed in the hospital notes and a local advertisement for GP patients.

## Inclusion and exclusion criteria

Subjects were included if they met the American College of Rheumatology (ACR) clinical diagnostic guidelines for knee osteoarthritis [12, 13] and had radiological evidence of osteophytes, as reported by a radiologist. Subjects were excluded if they

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(i) had knee OA secondary to inflammatory arthritis, (ii) had significant psychiatric or general medical morbidity that would either preclude their undertaking the exercises or their understanding of the nature of the exercise treatment or (iii) had received an intra-articular steroid injection, in the knee, within 3 months.

### Intervention

The advice and education provided, to both groups, consisted of an initial session drawing from the UK Arthritis Research Campaign's information booklet 'Osteoarthritis of the knee' [14]. At this initial consultation muscle weakness was addressed by including two muscle-strengthening exercises; muscle fatigue was addressed by the performance of a muscular endurance exercise, whilst balance and proprioception were addressed by including manoeuvres that required concentration on maintaining balance during activity. These exercises were based on the exercise programme developed by Hurley and Scott [8]. In order to facilitate maximum improvement the intensity of exercise programmes was individualized to the patient [15]. Initial assessment provided baseline exercise ability, which was reassessed and increased at 4- and 8-week review appointments. If patients were experiencing increased pain due to the exercises, the intensity of the exercise programme was either reduced or continued at the same intensity for a further 4 weeks. Subjects were instructed not to alter their level of analgesia during the course of the trial and were instructed to undertake the home exercises daily.

As well as undertaking the home exercise programme detailed above, the patients allocated to the class programme undertook an 8-week class exercise programme that involved attendance at a physiotherapy department twice weekly, with classes lasting approximately 45 min. During the classes the patients undertook a circuit of exercises supervised by a senior physiotherapist, which consisted of progressive resistance training, accelerated walking and stretching and balance exercises. These exercise classes were based on the exercise programme developed by Hurley and Scott [8]. Classes were small, with a maximum of 12 patients in each class.

### Outcome measures

Outcome measurement was undertaken within a physiotherapy department by a Chartered Physiotherapist, blinded to treatment allocation. The primary outcome measurement of this study was a timed measure of locomotor function.

*Aggregate locomotor function (ALF) score.* An aggregated score of timed locomotor function was used, comprising the summation of the times taken to undertake the activities of walking, stair ascent and descent and transferring to and from a chair. The validity of this measure has been established elsewhere [16]. The mean baseline time to complete the ALF in this sample of knee OA sufferers was 25.5 s [standard deviation (s.d.) 14.0] with a smallest detectable difference (SDD) value of 9.5%. Thus, a change in ALF score of greater than 2.4 s could be confidently attributed to a 'true' effect, and not simply to measurement error. The individual components of the ALF are detailed below.

*Eight-metre walk time.* The patients were asked to walk, at their own naturally preferred 'comfortable' pace, across a distance of 10 m. Timing of the central 8 m allowed one or two steps at either end of the walk for un-timed acceleration and deceleration, a process that has been shown to increase test-retest reliability [17]. The time taken to complete the distance was measured using a hand-held stopwatch (Zeon, UK). Patients were permitted to use walking aids if they required them. Three repetitions of the walk were undertaken and the mean was used for subsequent analysis.

*Stair ascent and descent time.* Patients were asked to ascend and then descend seven steps (four of 15 cm and three of 20 cm height) at their naturally preferred 'comfortable' pace. The method that the patient employed to negotiate the stairs was recorded, i.e. whether they used alternate legs, used the banisters or always led with one leg. Patients were permitted to use the two banisters if they felt it necessary, as the use of banisters has been shown to not affect times [18]. Patients were timed using a hand-held stopwatch and repeated the test four times; the mean was used for subsequent analysis. Four repetitions were used as the stairs used had two step heights, typical of the stairs found in physiotherapy departments, and thus by going over the steps in one direction and then the other ensured that the patients ascended and descended the different height steps twice.

*Transferring from sitting to standing time.* Patients were asked to walk, at their own natural pace, a distance of 2 m to a chair and sit down, then immediately stand up and walk back to the start. Patients were timed using an infrared beam sprint timer system (Cranlea Instruments, Birmingham, UK), as they approached and retreated from the chair. The chair had no arms and a seat height of 0.46 m, typical of the height of a toilet seat [19]. Patients undertook three timed repetitions and the mean was used for subsequent analysis.

*Visual analogue pain score.* Patients completed a 10 cm visual analogue scale based on the degree of pain they had experienced, in the last 7 days, whilst walking on a flat surface. Patients were not permitted to see previous scores.

*Western Ontario and McMaster Universities OA Index.* The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a tri-dimensional, disease-specific, self-administered health status measure [20]. The Likert scale version (LK3.0) of the questionnaire was used. Missing data and scoring procedures followed the WOMAC user guidelines [21].

*Adherence to home exercise.* In order to assess adherence to the home exercise programme patients were required to complete a Likert-scale adherence questionnaire at their 6- and 12-month post-treatment assessments. The questionnaire asked the patients to detail how many times they had performed the home exercises in the last week, how long they spent doing the exercises, if they had stopped doing the exercises and if so when. In addition, the patients were asked if they felt their physical activity levels had gone up, stayed the same or gone down in the previous 6-month period.

*Sample size.* Based on work by Hurley and Scott [8] and data obtained from a pilot study, it was estimated that a sample size of 76 in each group would have 80% power to detect a difference of 4 s in ALF between the class and home exercise groups at 12-month review, assuming that the common s.d. was 8.7, using a two-group *t*-test with a 0.05 two-sided significance level. A 20% dropout rate at short-term follow-up, immediately post-treatment, and 30% at 12-months follow-up was expected. These dropout levels have been described, for similar trials, as the maximum rates that can be accepted without rendering the trial invalid [22]. Thus, 100 patients were recruited to each group. Sample size estimation was performed with the nQuery Advisor (Version 3.0) software [23].

### Ethical approval and assignment

Ethical permission for the trial was obtained from the Central Manchester Healthcare Trust's local ethics committee. Written consent was obtained from subjects according to the Declaration of Helsinki. Blinded allocation was carried out using a

computerized minimization algorithm built into an Access (Microsoft Corporation) database. In order to control for two important prognostic factors [24] stochastic minimization was used to allocate patients. Important prognostic factors, given equal weighting in subsequent analysis, were identified as obesity [body mass index (BMI)  $\geq 30$ ] and gender, as the risks of increased rate of disease progression are raised in obese patients and in females [25, 26].

*Statistical analyses*

Data were recorded at baseline prior to randomization, post-treatment and at 6- and 12-months follow-up. The main statistical analysis comparing the two therapies was based on a general linear mixed model ANCOVA applied to longitudinal data in which a variance term is fitted to account for within-subject correlation [27]. The analysis was carried out using Stata Release 7 (Stata Statistical Software, StataCorp, TX, USA, 2001). For each outcome the model was fitted to the outcome across the three post-treatment time points including BMI, age, gender and the pre-randomization values as covariates. Normal probability plots were used to check the distributional assumptions of the model. For some outcomes there was evidence of skewness. There was also a ceiling and floor effect in outcomes based on questionnaires such as the WOMAC, particularly those dimensions based on a limited

number of questionnaire items. In order to check whether such violations of distributional assumptions affected the conclusion, confidence intervals were also computed using a non-parametric bootstrap [28].

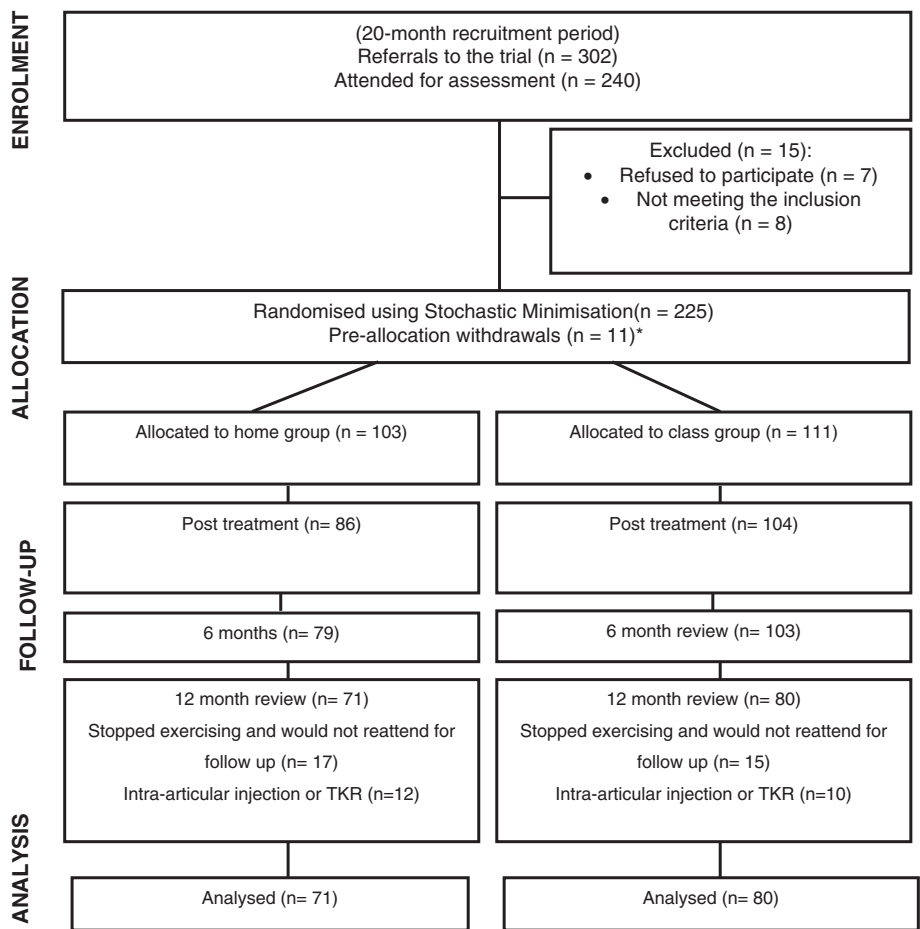
Standardized response means (SRM) were calculated by taking the adjusted difference between the change scores of the intervention groups and dividing it by the pooled standard deviation of the change score. An SRM size of 0.2 was regarded as small, of 0.5 as medium and 0.8 as large [29].

In a randomized trial such as this there is inevitably some missing outcome data. Given this may bias the estimate of the treatment effect, the relationship between missing data and outcome was investigated. Logistical regression was used to investigate the predictors of loss to follow-up. Variables that were found to predict loss to follow-up were included as covariates into the statistical model to reduce bias.

**Results**

*Participant flow*

A CONSORT diagram [30] detailing the flow of participants through each stage of the trial can be seen in Fig. 1. Over the 20-month recruitment period 302 referrals to the trial were received. Despite a second appointment being sent out to patients 62 (21%) patients did not attend for assessment. Of the 240 patients



\* Patients who withdrew themselves from the trial before being aware of treatment allocation.

TKR = total knee replacement surgery

FIG. 1. A CONSORT diagram showing participant flow through the trial.

who attended for assessment 225 gave their written consent and were subsequently enrolled onto the trial. Of the 225 patients who consented to join the trial 214 were allocated to treatment after 11 patients withdrew from the trial prior to allocation. These patients had been considered suitable for exercise by their referring physician but withdrew due to personal concerns regarding co-morbidity. Of the 214 patients allocated into the two groups 190 (89%) patients attended for post-treatment assessment. The loss to review at this point consisted of 17 patients from the home treatment group and 7 patients from the class group. At 6-month review 182 (85% of allocated patients) attended for reassessment with a total of 24 patients being lost from the home group and 8 patients lost from the class groups. At 12 months 151 (71% of allocated patients) attended for assessment with 32 being lost from the home group and 31 from the class group. The predominant reason for non-attendance was that the patients did not want to attend for review because they had stopped doing their home exercises ( $n=17$  home group,  $n=15$  class group). The second biggest cause of loss to follow-up was patients being no longer included in the trial following recent injection or surgical treatment ( $n=12$  home group,  $n=10$  home group).

### Baseline characteristic of patients

The baseline characteristics of the two group allocations can be seen in Table 1.

TABLE 1. Baseline characteristics of both treatment groups

	Home ( $n=103$ )		Class ( $n=111$ )	
	Mean	S.D.	Mean	S.D.
Age	64.9	9.7	64.5	9.9
BMI	30.2	5.3	29.4	5.2
ALF	26.5	14.8	24.5	13.2
VAS (pain): available score 0–100	62.3	18.6	63.3	17.4
WOMAC (pain): available score 0–20	10.0 <sup>a</sup>	3.7	9.6 <sup>a</sup>	3.7
WOMAC (stiffness): available score 0–8	4.5 <sup>a</sup>	1.7	4.2 <sup>a</sup>	1.8
WOMAC (physical function): available score 0–68	30.8 <sup>a</sup>	14.4	29.6 <sup>a</sup>	13.7

<sup>a</sup>Smaller data set due to incomplete/incorrect completion of WOMAC questionnaire.

TABLE 2. Comparison of home and class groups for ALF score

ALF (s)	Home		Class		Mean difference <sup>a,b</sup>	95% C.I. <sup>c</sup>	Standardized response mean	<i>p</i>
	Mean	S.D.	Mean	S.D.				
Baseline	26.5	14.8	24.5	13.2				
Post-treatment	24.4	10.8	18.7	5.9	–3.45	–4.46 to –2.44 <i>–4.39 to –2.47</i>	0.40	<0.001
6 months	25.4	11.2	20.6	10.8	–2.56	–3.81 to –1.31 <i>–3.89 to –1.39</i>	0.23	<0.001
12 months	24.8	9.7	19.1	5.4	–3.68	–4.87 to –2.50 <i>–4.81 to –2.58</i>	0.47	<0.001
12-month LVCF	25.6	10.2	20.9	10.7	–2.70	–3.82 to –1.58	0.26	<0.001
Interaction								0.671
Pooled estimate					–2.89	(–3.96 to –1.82)		<0.001

<sup>a</sup>Estimated treatment effect adjusted for BMI, age, gender and baseline values.

<sup>b</sup>Negative values for mean differences reflect improvement.

<sup>c</sup>Bootstrap confidence intervals in italics.

12 month LVCF: intention to treat analysis using Last Value Carried Forward imputation.

### Investigation of loss to follow-up

The pattern of follow-ups was broadly similar for each of the outcomes. Loss to follow-up was of a magnitude reported by previous authors in this field [31]. Logistic regression analysis of loss to follow-up at the three time points confirmed that patients in the class group were more likely to respond at post-treatment and 6 months but not at 12 months, but baseline patient characteristics did not appear to affect response. For the trial's primary outcome measure (the ALF score), the odds ratio of an outcome being recorded in the class group as compared with the home exercise group was 2.3 (95% C.I. 0.94–5.4,  $P=0.067$ ) at post-treatment and 3.9 (95% C.I. 1.67–9.3,  $P=0.002$ ) at 6 months. At 12 months loss to follow-up was no longer associated with treatment group (odds ratio = 1.1; 95% C.I. 0.6–0.20,  $P=0.728$ ).

In a secondary analysis, patients who attended for review only up to 6 months post-treatment appeared to have poorer locomotor function, regardless of treatment, compared with those with complete follow-up (ALF scores for incomplete follow-up were increased by 1.93 s, 95% C.I. 0.34–3.52,  $P=0.018$ ). When an interaction term was fitted to the model, the treatment effect did nevertheless appear to be similar between patients with only post-treatment follow-up and those with up to 6-month and complete follow-up data ( $P=0.345$ ).

### Comparison of treatments

The results for primary and secondary outcomes are given in Tables 2–5. For quantitative outcomes (Tables 2–4) non-parametric bootstrap confidence intervals have been added below the confidence intervals based on normal approximation. The limits are approximately the same and lead to the same conclusions regarding treatment effect.

**ALF score.** Statistical analysis tested for any difference in the treatment effect according to length of follow-up (post-treatment, 6 months or 12 months post-treatment) by adding a time–treatment interaction term to the statistical model. For the ALF score a likelihood ratio test did not suggest an interaction ( $P=0.671$ ). In the absence of an interaction it was appropriate to examine the pooled treatment effect across the three time points. The pooled estimate of treatment effect of class as compared with home exercise programmes is highlighted in Table 2. For the ALF score there was a reduction in the score of 2.89 s (95% C.I. 1.82–3.96,  $P<0.001$ ) after adjustment for baseline values, BMI, age and gender. A cross-sectional analysis is given for each of the three follow-up points giving the effect of treatment, again adjusted for baseline ALF, BMI, age and gender. Comparing the adjusted class

TABLE 3. Comparison of home and class groups for VAS pain score

VAS (mm)	Home		Class		Mean difference <sup>a,b</sup>	95% C.I. <sup>c</sup>	Standardized response mean	<i>p</i>
	Mean	s.d.	Mean	s.d.				
Baseline	62.3	18.6	63.3	17.4				<0.001
Post-treatment	54.8	18.9	37.3	16.9	-18.1	-21.8 to -14.4 <i>-21.7 to -14.4</i>	1.01	<0.001
6 months	54.6	21.8	43.0	18.1	-11.4	-15.6 to -7.10 <i>-15.5 to -7.25</i>	0.57	<0.001
12 months	59.1	18.2	43.6	18.1	-15.2	-19.5 to -10.9 <i>-19.6 to -11.1</i>	0.84	<0.001
12-month LVCF	58.9	19.2	44.1	18.6	-14.2	-18.7 to -11.1	0.78	<0.001
Interaction								0.004
Pooled estimate					-14.9	-18.1 to -11.7		<0.001

<sup>a</sup>Estimated treatment effect adjusted for BMI, age, gender and baseline values.

<sup>b</sup>Negative values for mean differences reflect improvement.

<sup>c</sup>Bootstrap confidence intervals in italics.

12 month LVCF: intention to treat analysis using Last Value Carried Forward imputation.

TABLE 4. Comparison of home and class groups for WOMAC domain scores

WOMAC domain	Home		Class		Mean difference <sup>a,b</sup>	95% C.I. <sup>c</sup>	Standardized response mean	<i>p</i>
	Mean	s.d.	Mean	s.d.				
<b>Pain</b>								
Baseline	9.99	3.71	9.63	3.69	-	-	-	
Post-treatment	9.04	3.84	7.50	3.95	-1.23	-2.03 to -1.46 <i>-2.04 to -0.44</i>	0.32	0.006
6 months	9.13	3.99	8.04	3.60	-0.84	-1.70 to -0.14 <i>-1.69 to -0.01</i>	0.27	0.041
12 months	9.38	3.53	8.05	3.81	-1.32	-2.33 to -0.35 <i>-2.34 to -0.34</i>	0.36	0.036
12-month LVCF	9.77	3.78	8.21	3.69	-1.29	-2.06 to -0.53	0.42	0.001
Interaction								0.752
Pooled estimate					-1.18	-1.85 to -0.52		0.001
<b>Stiffness</b>								
Baseline	4.53	1.68	4.18	1.81	-	-	-	
Post-treatment	4.19	1.84	3.36	1.93	-0.53	-0.97 to -0.09 <i>-0.96 to -0.09</i>	0.28	0.019
6 months	4.09	1.77	3.37	1.78	-0.41	-0.85 to 0.03 <i>-0.83 to 0.02</i>	0.23	0.068
12 months	3.97	1.59	3.36	1.81	-0.39	-0.89 to 0.11 <i>-0.87 to 0.11</i>	0.23	0.129
12-month LVCF	4.17	1.63	3.49	1.82	-0.46	-0.84 to -0.07	0.27	0.02
Interaction								0.814
Pooled estimate					-0.46	-0.81 to -0.12		0.009
<b>Physical function</b>								
Baseline	30.8	14.4	29.6	13.7				
Post-treatment	28.1	14.7	23.6	13.9	-3.19	-5.84 to -0.09 <i>-5.87 to -0.57</i>	0.22	0.018
6 months	29.8	14.5	26.6	14.2	-2.37	-4.86 to 0.03 <i>-4.84 to 0.09</i>	0.17	0.062
12 months	30.7	16.5	26.5	13.6	-5.00	-8.97 to -0.10 <i>-9.47 to -1.27</i>	0.33	0.014
12-month LVCF	31.6	15.8	27.8	14.1	-3.50	-6.43 to -0.55	0.23	0.02
Interaction								0.504
Pooled estimate					-3.39	-5.58 to -1.20		0.003

<sup>a</sup>Estimated treatment effect adjusted for BMI, age, gender and baseline values.

<sup>b</sup>Negative values reflect improvement.

<sup>c</sup>Bootstrap confidence intervals in italics.

12-month LVCF: intention to treat analysis using Last Value Carried Forward imputation.

treatment with the home group suggests that the reductions in ALF scores were 14, 11 and 15% greater, in the supplemented group, at post-treatment, 6-month and 12-month reviews. Small-sized standardized response means were evident at all follow-ups.

*Visual analogue score.* For the visual analogue score (VAS) there was evidence of difference in treatment effect between time points with a time-treatment interaction term that was statistically significant ( $P=0.004$ ). A cross-sectional analysis is presented in

TABLE 5. Activity changes in each treatment group

	6 months				12 months			
	Home ( <i>n</i> )	Home (%)	Class ( <i>n</i> )	Class (%)	Home ( <i>n</i> )	Home (%)	Class ( <i>n</i> )	Class (%)
Increased	4	6.5	12	14.3	3	4.3	12	15.4
Same	41	66.1	57	67.9	42	60.0	47	60.3
Decreased	17	27.4	15	17.9	25	35.7	19	24.4
Responses	62	60.2	84	75.7	70	68.0	78	70.3
Group size	103		111		103		111	

Table 3. For the VAS there was evidence of difference in treatment effect between time points. There was evidence of a substantial improvement in the VAS at all follow-ups. Comparing the adjusted class treatment with the home group suggests that the reductions in VAS scores were 33, 21 and 25% greater in the supplemented group at post-treatment, 6 months and 12 months, representing moderate to large standardized response means.

**WOMAC.** Likelihood ratio tests did not suggest time-treatment interactions for the three WOMAC domain scores. In the absence of an interaction it was appropriate to examine the pooled treatment effects across the three time points. The pooled estimates of treatment effect of class as compared with home exercise programmes are detailed in Table 4. For the WOMAC pain domain there was a reduction in score of  $-1.18$  (95% C.I.  $-1.85$  to  $-0.52$ ), for the stiffness domain  $-0.46$  (95% C.I.  $-0.81$  to  $-0.12$ ) and for the physical function domain  $-3.39$  (95% C.I.  $-5.58$  to  $-1.20$ ) after adjustment for baseline values, BMI, age and gender. These represent small standardized response means.

**Adherence to home exercise.** At 6 and 12 months subjects were asked the frequency with which they conducted their home exercise programme and the time they took performing the programme. At 6 months the median response was 'twice a week' for both groups. At 12 months the median response for the class group was unchanged whilst for the home group it had reduced to 'once per week'. At both 6 months and 12 months there was no significant difference in the frequency of exercise (Mann-Whitney *U*-test,  $P=0.96$  and  $0.29$  respectively). There was no evidence to suggest that the time spent exercising differed between groups. At both 6 and 12 months the median time spent exercising was 'less than 15 minutes' for both groups (Mann-Whitney *U*-test,  $P=0.60$  and  $0.34$  respectively). However, there was some suggestion of increased physical activity in the class group, with a greater proportion reporting an increase in activity and a correspondingly small proportion reporting reduced activity (see Table 5).

## Discussion

The supplementation of a home exercise programme with a class-based exercise programme did result in an improvement in locomotor function. The short-term, small-sized treatment effects are of similar magnitude to those found in previous studies comparing exercise with control [32, 33], whilst the 12-month treatment effect was greater than previously reported long-term review data [32, 34]. A clinically significant large-sized reduction in the pain experienced during walking was evident at all follow-ups. The size of these effects was considerably larger than in previously reported work investigating 6 months of home exercise against control [9] and work comparing 3 months of exercise classes with control [32]. Within the home exercise group, improvement in locomotor function, pain and WOMAC score was very small, smaller than in previously reported work [32]. The home exercise

programme alone did not appear to be clinically effective, whilst supplementing it with class based exercise led to clinically significant reductions in walking pain.

At both 6 months and 12 months there was no significant difference in the frequency of performance of home exercise or the time spent exercising between the groups. There was, however, some suggestion of increased physical activity levels in the class group. Adherence to the home exercise programme could be classified as poor as the amount of home exercise undertaken by the patients was markedly less than recommended by the physiotherapist. This is a finding that has been reported by previous authors [35]. The problem of non-adherence to exercise treatment has long been recognized [35] and is particularly relevant in the management of knee osteoarthritis, where a dose response between increased adherence and benefit has been identified by several authors [36, 37]. This is also a feature observed in preliminary assessment of this trial's data.

The main threats to the validity of the trial were controlled for by adopting a blinded assessment, randomized controlled trial methodology. The trial was undertaken with blinded assessment, thus a degree of control for experimenter expectancy was ensured. However, without a non-intervention control group the chance of a systematic error due to an unconscious belief, on the part of the assessor, that both exercise programmes should improve symptomatology may have led to a falsely high improvement within both groups. This was combated by ensuring that a standardized assessment protocol was adopted for each assessment, but an expectation of effect or willingness to please the investigator may also have led patients to perform in a manner that was superior to their normal practice. Another potential threat to the validity of the trial's findings was use of analgesics. Whilst patients were advised to keep their analgesic levels stable during treatment it is possible that analgesic use was not equivalent across the groups.

Dropouts were high, although of a magnitude described in previous trials [38]. The effect of loss to follow-up was analysed and found not to be influential in overall treatment effect. The trial had strong generalizability and represented the clinical situation. In order to control for threats to the trial's validity the selection criteria were designed to include typical patients with knee osteoarthritis who might be referred to physiotherapists for treatment. Selection criteria were designed following a review of the literature and in discussion with expert clinicians in the field. In addition, the two interventions were designed to be representative of current clinical practice after reviewing the literature and discussion with expert clinicians in the field.

In summary, the implications of this trial were significant. The supplementation of a home-based exercise programme with a class-based exercise programme led to superior improvement in walking pain and to a lesser extent in the locomotor function of the supplemented group. Importantly, the improvement was still evident 12 months following the cessation of the exercise classes. The effect of the treatments can be confidently generalized to the population of patients with knee osteoarthritis and reveal that the size of the differential improvement between treatments in VAS pain scores can be considered clinically significant at post-

treatment and 12-month follow-up assessments. Thus, this trial has demonstrated that the provision of class-based exercises is a clinically effective addition to the home treatment of knee osteoarthritis.

The authors have declared no conflicts of interest.

<i>Rheumatology</i>	Key messages
	<ul style="list-style-type: none"> <li>• Supplementing home-based exercise with a class-based exercise programme produced clinically significant improvement in levels of walking pain experienced.</li> <li>• The clinically significant improvements were evident at 12-month review.</li> </ul>

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