

Behavioural graded activity results in better exercise adherence and more physical activity than usual care in people with osteoarthritis: a cluster-randomised trial

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Question: Does behavioural graded activity result in better exercise adherence and more physical activity than usual care in people with osteoarthritis of the hip or knee? **Design:** Analysis of secondary outcomes of a cluster-randomised trial with concealed allocation, assessor blinding, and intention-to-treat analysis. **Participants:** Two hundred patients with hip and/or knee osteoarthritis. **Intervention:** Experimental group received 18 sessions of behavioural graded activity over 12 weeks and up to 7 booster sessions over the next year. The control group received 18 sessions of usual care over 12 weeks according to the Dutch physiotherapy guideline. **Outcome measures:** Exercise adherence was measured using a questionnaire and physical activity was measured using the SQUASH questionnaire at baseline, 13, and 65 weeks. **Results:** Adherence to recommended exercises was significantly higher in the experimental group than in the control group at 13 weeks (OR 4.3, 95% CI 2.1 to 9.0) and at 65 weeks (OR 3.0, 95% CI 1.5 to 6.0). Significantly more of the experimental than the control group met the recommendations for physical activity at 13 weeks (OR 5.3, 95% CI 1.9 to 14.8) and at 65 weeks (OR 2.9, 95% CI 1.2 to 6.7). **Conclusion:** Behavioural graded activity results in better exercise adherence and more physical activity than usual care in people with osteoarthritis of the hip or knee, both in the short- and long-term. **Trial registration:** NCT00522106. [Pisters MF, Veenhof C, de Bakker DH, Schellevis FG, Dekker J (2010) Behavioural graded activity results in better exercise adherence and more physical activity than usual care in people with osteoarthritis: a cluster-randomised trial. *Journal of Physiotherapy* 56: 41–47]

Key words: Physiotherapy, Exercise therapy, Osteoarthritis, Patient compliance, Randomized trial

Introduction

Osteoarthritis of the hip and/or knee is a relatively common musculoskeletal disorder, with prevalence increasing with age (Miedema 1997). Osteoarthritis causes impairments such as pain, muscle weakness, loss of range of joint motion, and joint instability. Furthermore, osteoarthritis has a major impact on daily life and often leads to avoidance of physical activity (Dekker et al 1992, Felson et al 2000, McAlindon et al 1993, Steultjens et al 2002). A lack of regular physical activity in people with osteoarthritis of the hip and/or knee is an important risk factor for further functional decline and is associated with increased health care costs (Dunlop et al 2005).

In several clinical practice guidelines, exercise is recommended for people with osteoarthritis of the hip and/or knee (Brandt 1998, Hochberg et al 1995, Jordan et al 2003, Vogels et al 2001, Zhang et al 2005). The goal of exercise is to reduce impairments and improve overall activity, so that ultimately individuals can better meet the demands of daily living (Tan et al 1998). Physiotherapists choose the delivery mode, content, and dosage of exercise based on clinical reasoning (Rothstein et al 2003). Several studies have shown exercise to be beneficial in people with osteoarthritis of hip and/or knee in terms of pain, physical function and self-perceived effect (Fransen et al 2002, van Baar et al 1999). Unfortunately, the immediate effect of exercise seems to decline and finally disappears (Pisters et al 2007).

Adherence within the period of exercise has been shown to be an important predictor of outcome (Marks et al 2005, Roddy et al 2005). Several authors have suggested that low adherence to home exercises after discharge is one of the main reasons for the poor long-term effectiveness of exercise in people with osteoarthritis (Marks et al 2005, Pisters et al 2007, Roddy et al 2005). In order to continue exercise after the cessation of an exercise program, it has been suggested that exercises should be task-oriented and include strategies to change behaviour and encourage self-regulation skills (Veenhof et al 2005). Home exercises that simulate the conditions of daily tasks should enhance adherence to home exercises after discharge and lead to a more physically active lifestyle.

Veenhof and colleagues recently developed and evaluated an exercise program based on these principles called the 'behavioural graded activity' program (Veenhof et al 2006). This program consists of a period of facility-based intervention followed by booster sessions. It uses principles of operant conditioning (Fordyce et al 1973, Lindstrom et al 1992) and self-regulation (Leventhal et al 1987) and includes booster sessions to improve and maintain adherence (Noland 1989). The program is directed at enhancing exercise adherence and gradually increasing the amount of physical activity in a time-contingent way so that activities are gradually increased by preset quotas regardless of impairments, eg, increasing walking time by

2 minutes per day despite the amount of pain. The ultimate goal is integration of these activities into daily living, so that patients develop a more physically active lifestyle. Earlier research has shown that both behavioural graded activity and physiotherapy intervention according to the Dutch guideline (Vogels et al 2001) result in benefits in terms of pain and physical function measured by WOMAC (Veenhof et al 2006). Long-term benefits in terms of walking and physical function measured by MACTAR-questionnaire were also found. However, it remains unclear if behavioural graded activity succeeds in increasing adherence and physical activity. Therefore, the research questions for the present study were:

1. Does behavioural graded activity result in better exercise adherence than usual care in people with osteoarthritis of hip and/or knee?
2. Does it result in more physical activity than usual care?

Method

Design

An analysis of secondary outcomes of a behavioural graded activity trial was performed (Veenhof et al 2006). This trial was a single-blind cluster-randomised trial comparing a behavioural graded activity with usual care according to the Dutch physiotherapy guideline in patients with osteoarthritis of hip and/or knee. To avoid contamination between the interventions, cluster randomisation was performed at the level of centres, ie, physiotherapy practices. The centres were randomly allocated to deliver one of the two interventions by means of a computer-generated random sequence. Participants chose which centre to attend, being unaware at this time of the intervention that it was allocated to deliver, thereby ensuring that randomisation was concealed. Outcomes were measured at baseline, 13, and 65 weeks at physiotherapy practices not involved in the trial by three trained research assistants who were blinded to group allocation. Blinding was maintained by instructing participants not to talk about their intervention to the research assistants.

Participants, therapists and centres

Patients were included if they had osteoarthritis of the hip or knee according to the clinical criteria of the American College of Rheumatology (Altman et al 1986, Altman et al 1991) and were between 50 and 80 years of age. They were excluded if they had other pathology explaining the complaints; complaints in less than 10 out of 30 days; intervention for these complaints with exercise in the preceding six months; indication for hip or knee replacement within one year; contraindication for exercise; inability to understand the Dutch language; and a high level of physical functioning defined as < 2 on the walking ability and physical function sections of the Algofunctional index (Faucher et al 2003, Lequesne et al 1987). They were recruited directly by the participating physiotherapists or in response to press releases in local newspapers (Veenhof et al 2005). Age, gender, height, weight, location of complaints, duration of complaints, and the presence of other chronic disorders were collected. X-rays of the hip and/or knee were scored by a rheumatologist according to the Kellgren and Lawrence scale; it consists of five levels where 0 = no osteoarthritis, 1 = doubtful osteoarthritis, 2 = minimal osteoarthritis, 3 = moderate osteoarthritis, and 4 = severe osteoarthritis (Kellgren and Lawrence 1957, Ravaud

and Dougados 1997). Pain and physical functioning were measured with the WOMAC (Bellamy et al 1988).

Physiotherapists working in primary care in the Utrecht region were included in the study. They were recruited using the NIVEL National Database of Primary Care Physiotherapists. A random sample of six hundred physiotherapists from Utrecht region was invited to participate. One hundred physiotherapists responded, of whom 87 (working in 72 practices) were willing and able to participate.

Intervention

The experimental group received a behavioural exercise program (see Appendix 1 on the eAddenda for details). The intervention was directed at a time-effective increase in the level of activities, with the goal of integrating these activities into daily living. The intervention also included individually-tailored exercises aimed at reducing any impairment limiting the performance of these activities. The complete protocol included written materials such as education messages, activity diaries, performance charts. The intervention consisted of a maximum of 18 sessions over a 12-week period, followed by five booster sessions in Week 18, 25, 34, 42, and 55. In Week 18 and 25, participants were allowed to receive 2 sessions. Physiotherapists delivering the experimental intervention received 2 days of training, which focused on the specific skills necessary to provide behavioural graded activity. Physiotherapists in the experimental group were also supported and advised by phone and meetings during the study.

The control group received usual care according to the Dutch physiotherapy guideline for patients with hip and/or knee osteoarthritis (Vogels et al 2001). This guideline consists of general recommendations, emphasising the provision of information and advice, exercise, and encouragement of a positive attitude to coping with symptoms (see Appendix 2 on the eAddenda for details). The intervention consisted of a maximum of 18 sessions over a 12-week period. The intervention was discontinued within this period if, according to the physiotherapist, all goals had been achieved. At the end of the 12-week period, physiotherapists advised participants to maintain exercising at home. The physiotherapists delivering the control intervention received 4 hours of training about the guideline.

Both the experimental and control interventions were delivered to participants individually by physiotherapists in primary care for 30 minutes per session. All physiotherapists documented every session on standardised forms, including information about deviations from the protocol.

Outcome measures

Exercise adherence was measured as whether participants carried out the home exercises (ie, exercises aimed at increasing strength, joint range of motion and joint stability) or activities (ie, performance of walking, ascending stairs, and cycling) recommended by their physiotherapist (Sabate 2003). Participants self-rated their adherence to recommendations for home exercises and activities on a 5-point scale where 1 = almost never; 5 = very often (Sluijs et al 1993). Participants were asked separately about whether they carried out their exercises and activities. Adherence was reported as 'Yes' when participants rated themselves 4 (often adherent) or 5 (very often adherent).

Table 1. Baseline characteristics of participants.

Characteristic	Randomised (n = 200)		Lost to follow-up (n = 21)	
	Exp (n = 97)	Con (n = 103)	Exp (n = 10)	Con (n = 11)
Age (yr), mean (SD)	65 (7)	65 (8)	63 (7)	65 (9)
Gender, n males (%)	24 (25)	22 (21)	4 (40)	1 (9)
Body mass index (kg/m ²), mean (SD)	28 (4)	29 (5)	29 (4)	31 (4)
Co-morbidity, n (%)	63 (68)	65 (64)	7 (70)	8 (73)
Radiological evidence of osteoarthritis, n Kellgren & Lawrence score ≥ 2 (%)	56 (74)	45 (64)	4 (40)	3 (27)
Location of osteoarthritis, n (%)				
Knee	67 (69)	63 (61)	5 (50)	6 (55)
Hip	22 (23)	28 (27)	2 (20)	2 (18)
Both knee and hip	8 (8)	12 (12)	3 (30)	3 (27)
Duration of complaints, n (%)				
< 1 yr	23 (24)	24 (23)	2 (20)	3 (27)
1–5 yr	39 (41)	33 (32)	3 (30)	4 (36)
> 5 yr	33 (35)	46 (45)	5 (50)	4 (36)
Pain (0-20), mean (SD)	9 (3)	9 (3)	10 (2)	8 (3)
Physical function (0-68), mean (SD)	29 (13)	29 (10)	30 (11)	28 (11)

Exp = experimental group, Con = control group,

Physical activity was measured using the SQUASH (Short Questionnaire to Assess Health Enhancing Physical Activity) (Wendel-Vos et al 2003). The SQUASH collects days per week, average time per day, and effort for physical activities such as commuting activities, leisure time and sport activities, household activities, and activities at work or school. Using the Ainsworth Compendium of Physical Activities (Ainsworth et al 2000), an intensity score (metabolic equivalents) was assigned to all physical activities. This was then used to determine whether patients met the updated recommendations for physical activity from the American College of Sports Medicine and the American Heart Association (Haskell et al 2007). The recommendation for physical activity is moderate-intensity aerobic physical activity for a minimum of 30 minutes on at least five days a week, or vigorous-intensity aerobic physical activity for a minimum of 20 minutes on at least three days a week, or some combination of moderate-and vigorous-intensity activities (at least 450 MET·min·wk). For older adults, moderate intensity was defined as activities with an intensity of 3–5 MET and vigorous intensity was defined as activities with an intensity of ≥ 5 MET (Nelson et al 2007). Physical activity was reported as meeting the recommendation for physical activity (Yes/No) and as number of days per week with at least 30 minutes of moderate to vigorous physical activity.

Data analysis

The target sample size was 200 participants which provided 80% power to detect a 25% between-group difference in patient global assessment and small to medium-sized effects (0.2–0.4) in pain and physical functioning, at two-sided significance level of 0.05 given a maximum loss to follow-up of 20%.

The statistical analyses were carried out according to the intention-to-treat principle. For dichotomous variables (adherence to exercise and activities, and meeting the recommendation for physical activity), odds ratios (95% CI) were calculated. For continuous variables (days per week with at least 30 minutes of moderate to vigorous physical activity),

Table 2. Baseline characteristics of therapists and centres.

Characteristic	Exp	Con
Therapists	(n = 26)	(n = 29)
Age (yr), mean (SD)	40 (7.9)	41 (7.9)
Gender, n males (%)	15 (58)	18 (62)
Qualifications, n postgraduate (%)	9 (35)	5 (17)
Experience (yr), mean (SD)	16 (7)	16 (8)
Centres	(n = 23)	(n = 23)
Participants (n/centre), mean (SD)	3.7 (3.1)	3.6 (3.0)

Exp = experimental group, Con = control group,

mean difference (95% CI) between groups was calculated. Data were analysed using logistic or linear regression analyses. Confounding effects and effect modification of the baseline scores of each outcome measure, duration of symptoms, location of osteoarthritis (hip, knee, or both), radiological evidence, body mass index, co morbidity, age, sex, and recruitment method (physiotherapist or newspaper) were investigated and analyses adjusted accordingly.

Results

Flow of participants, therapists, centres through the trial

A total of 200 people with osteoarthritis participated in the trial: 97 participants in the experimental group and 103 participants in the control group. The experimental and control groups had similar baseline characteristics (Table 1). Measurements at Week 13 were collected from 90 experimental participants (93%) and 102 control participants (99%) and at Week 65 from 87 experimental participants (90%) and 92 control participants (89%) (Figure 1). Fifty-five physiotherapists in 46 centres delivered the intervention; the characteristics of therapists and centres are presented in Table 2.

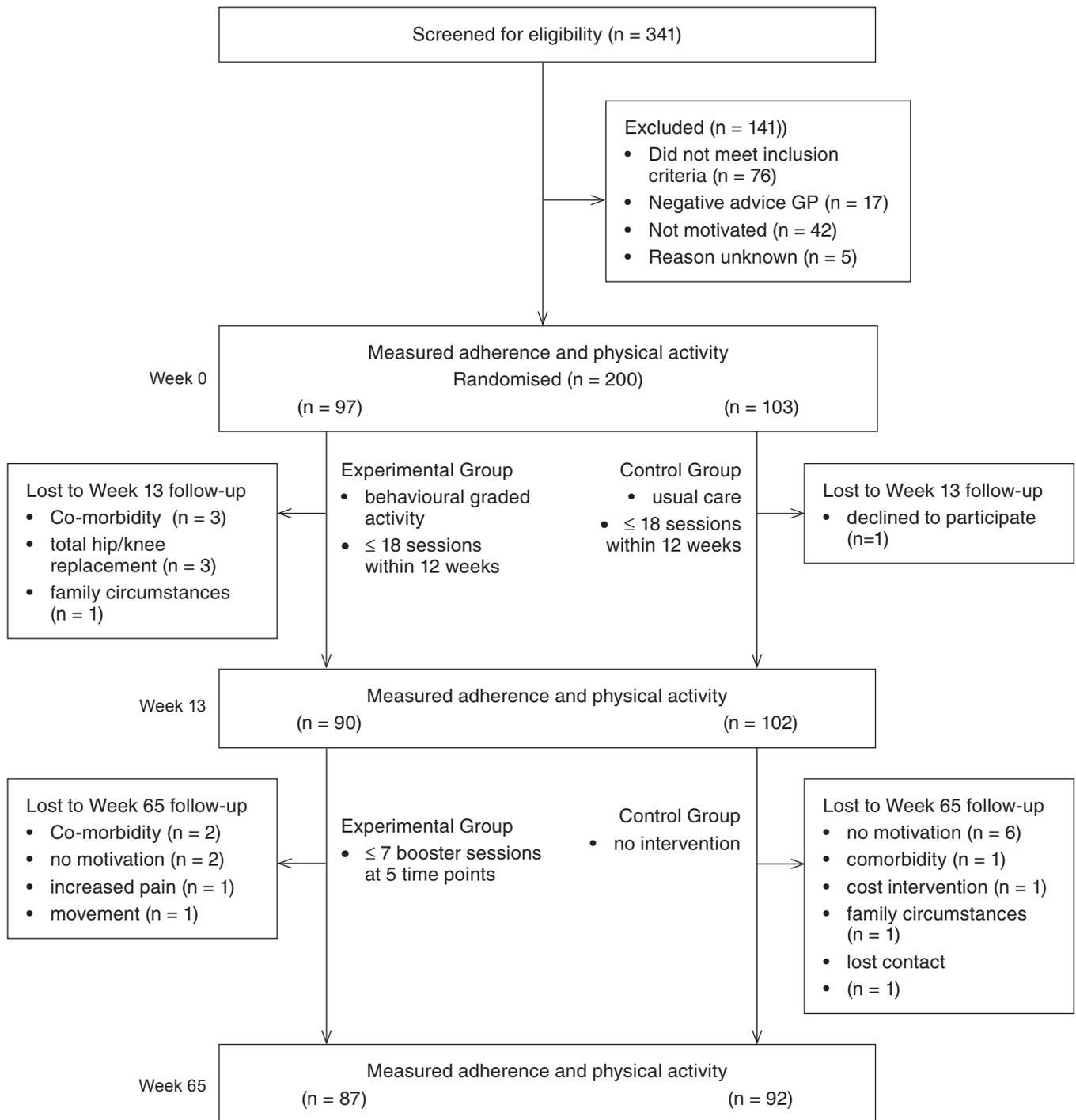


Figure 1. Design and flow of participants through the trial.

Compliance with trial method

Overall, 33 participants (17%) deviated from the study protocol. For 10 control participants (10%), intervention was terminated within 6 sessions. For 6 experimental participants (6%), the intervention was terminated within 6 sessions, and in 17 participants (18%) less than 2 booster sessions were performed. Experimental participants received on average 9.8 out of 18 (SD 3.5) sessions over the 12 week period while control participants received 11.7 (SD 4.3) resulting in the experimental group receiving 1.9 (95% CI 0.8 to 3.0) fewer sessions than the control group. The experimental group received on average 4.8 (SD 1.6) booster sessions.

Effect of intervention

Group data at 13 and 65 weeks are presented in Table 3 for exercise adherence and in Table 4 for meeting recommendations for physical activity, while group data at baseline, 13, and 65 weeks are presented in Table 5 for days per week with physical activity.

Exercise adherence: Exercise adherence was self-rated by 148 participants (77%) in Week 13 and 168 participants (94%) in Week 65. There were more missing data in Week 13 due to the erroneous use of an incomplete questionnaire for a short period. The missing data were distributed equally between the groups.

Table 3. Number of adherent participants (%) in each group and odds ratios (95% CI) between groups for those participants advised to perform exercises and/or activities by their physiotherapist.

Adherence to recommendations	Groups				Odds ratio between groups*	
	Week 13		Week 65		Week 13	Week 65
	Exp	Con	Exp	Con	Exp relative to Con	Exp relative to Con
Exercises	53/71 (75)	32/71 (44)	46/79 (59)	24/72 (34)	4.3 (2.1 to 9.0)	3.0 (1.5 to 6.0)
Activities	51/70 (74)	26/54 (48)	32/71 (46)	17/54 (32)	3.1 (1.4 to 6.9)	1.8 (0.8 to 3.8)

Exp = experimental group, Con = control group, * = adjusted for site of osteoarthritis (hip, knee, both)

Table 4. Number of participants (%) in each group meeting recommendation for physical activity* and odds ratios (95% CI) between groups.

Physical activity	Groups				Odds ratio between groups #	
	Week 13		Week 65		Week 13	Week 65
	Exp (n = 90)	Con (n = 102)	Exp (n = 87)	Con (n = 92)	Exp relative to Con	Exp relative to Con
Meeting recommendation	84 (93)	77 (76)	76 (87)	67 (73)	5.3 (1.9 to 14.8)	2.9 (1.2 to 6.7)

Exp = experimental group, Con = control group, * = moderate physical activity for > 30 min x 5 days/wk or vigorous physical activity for > 20 min x 3 days/wk, # = adjusted for baseline scores and duration of complaints.

In both groups, most participants were advised to carry out home exercises: 71 participants (97%) in the experimental and 71 participants (95%) in the control group during the first 12 weeks and 79 participants (96%) in the experimental and 72 participants (84%) in the control group by 65 weeks. Of those participants who were advised to carry out exercises, adherence to recommended exercises was significantly higher in the experimental group than the control group at 13 weeks (OR 4.3, 95% CI 2.1 to 9.0), and at 65 weeks (OR 3.0, 95% CI 1.5 to 6.0) (Table 3).

More participants in the experimental group were advised to perform home activities than in the control group: 70 participants (96%) in the experimental and 54 participants (73%) in the control group during the first 12 weeks, and 71 participants (88%) in the experimental and 54 participants (66%) in the control group over the following year. Of those participants who were advised to perform activities, adherence to recommended activities was significantly higher in the experimental group than the control group at 13 weeks only (OR 3.1, 95% CI 1.4 to 6.9). At 65 weeks, there was no significant difference between the groups (Table 3).

Physical activity: Significantly more of the experimental than control group met the recommendations for physical activity at 13 weeks (OR 5.3, 95% CI 1.9 to 14.8) and at 65 weeks (OR 2.9, 95% CI 1.2 to 6.7) (Table 4). The experimental group performed at least 30 minutes of walking on 1.6 days (95% CI 0.8 to 2.4) more than the control group at 13 weeks and on 0.7 days (95% CI 0.1 to 1.5) more at 65 weeks (Table 5). There was no significant difference between the groups for cycling or sports.

Discussion

The results of our study demonstrate that behavioural graded activity resulted in better adherence to home exercises and activities compared with usual care, both in the short- and long-term. Furthermore, it resulted in more participants meeting the recommendation for physical activity. The greater amount of physical activity in the experimental group was mainly due to an increase in the time spent walking.

In the control group, exercise adherence was relatively low, both in the short- (44%) and long-term (34%), but comparable with the findings of previous research (Marks et al 2005). In the experimental group, exercise adherence was considerably higher, both in the short- (75%) and long-term (59%). Exercise adherence declined in the long-term in both groups. However, the majority of the experimental group were still adherent in the long-term.

In patients with osteoarthritis, lack of regular physical activity is an important risk factor for worsening of limitations. Dunlop et al (2005) demonstrated that lack of regular vigorous physical activity almost doubled the odds of worsening of limitations and that regular vigorous physical activity reduced this worsening by as much as 32%. The results of our study show that the level of physical activity was higher in the experimental group than in the control group. We found a 5.3 fold in the short term and 2.9 fold in the long term greater odds of people receiving behavioural graded activity meeting the recommendation for physical activity compared with those receiving usual care, mainly due to an increase in the amount of time spent walking in the behavioural graded activity. The difference in physical activity between the groups may be due to the fact that more of the experimental group were advised to perform home activities than the control group. In the experimental group, the most problematic activities were increased gradually

Table 5. Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for days per week with at least 30 minutes of moderate to vigorous physical activity.

Physical activity (days/wk)	Groups				Difference within groups				Difference between groups *					
	Week 0		Week 13		Week 65		Week 13 minus Week 0		Week 65 minus Week 0		Week 13 minus Week 0		Week 65 minus Week 0	
	Exp (n = 97)	Con (n = 103)	Exp (n = 90)	Con (n = 102)	Exp (n = 87)	Con (n = 92)	Exp	Con	Exp	Con	Exp	Con	Exp	Con
Walking	2.0 (2.6)	1.6 (2.4)	3.6 (3.0)	1.5 (2.3)	2.7 (2.9)	1.6 (2.3)	1.5 (3.1)	-0.1 (2.4)	0.7 (3.1)	0.0 (2.3)	1.6 (0.8 to 2.4)	0.7 (3.1)	0.7 (0.1 to 1.5)	
Cycling	2.8 (2.7)	2.1 (2.5)	2.9 (2.8)	2.5 (2.5)	2.7 (2.9)	2.2 (2.6)	0.2 (2.6)	0.4 (2.4)	-0.1 (2.7)	0.0 (2.5)	-0.2 (-0.9 to 0.5)	0.3 (1.7)	-0.1 (-0.9 to 0.7)	
Sports	0.8 (1.6)	0.5 (1.0)	1.0 (2.1)	0.7 (1.2)	1.1 (1.9)	0.7 (1.3)	0.2 (1.7)	0.1 (1.0)	0.3 (1.7)	0.2 (1.4)	0.1 (-0.3 to 0.5)	0.4 (3.4)	0.1 (-0.4 to 0.5)	
Total	4.6 (2.7)	3.9 (2.9)	5.6 (2.2)	4.2 (2.8)	5.0 (2.6)	3.6 (2.9)	0.9 (3.0)	0.3 (3.1)	0.4 (3.4)	-0.3 (3.1)	0.7 (-0.2 to 1.6)	0.7 (3.1)	0.7 (-0.3 to 1.7)	

Exp = experimental group, Con = control group, * adjusted for duration of complaints

and previous research has shown that walking is the most prevalent limitation in activities in people with osteoarthritis (Ewert et al 2004).

There are a few limitations to this study that need to be mentioned. First of all, the design of our study does not allow any conclusions to be drawn about which aspect of behavioural graded activity (eg, booster sessions) is most important for improving exercise adherence and physical activity. Second, a gold standard in measuring exercise adherence does not exist (Sluijs et al 2006). In our study, exercise adherence was measured using a self-report questionnaire. Although used widely, the validity of using self-report questionnaires to measure exercise adherence is debatable. They are known to overestimate adherence and are susceptible to bias caused by memory, social desirability, and need for social approval (Sluijs et al 2006). However, a self-report questionnaire is a simple measurement to collect and is probably no more subject to bias than diaries and interviews. Although accelerometers/pedometers provide reasonably accurate measures of walking, they cannot evaluate other types of activities. Importantly, it is unlikely that potential sources of bias inherent in self-reports explain the between-group differences, because both groups had similar baseline adherence.

In conclusion, behavioural graded activity with booster sessions results in better exercise adherence and a greater amount of physical activity than usual physiotherapy intervention, both in the short- and long-term. Integration of behavioural graded activity principles and adding booster sessions to exercise programs seems to be useful in enhancing exercise adherence and physical activity after discharge from physiotherapy intervention. ■

eAddenda: Appendix 1 and Appendix 2 available at JoP.physiotherapy.asn.au

Ethics: The Medical Ethical Committee of the VU University Medical Center, Amsterdam, The Netherlands approved this study. Written informed consent was gained from participants before the study began.

Competing interests: None declared.

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