

# Effectiveness of Behavioral Graded Activity in Patients With Osteoarthritis of the Hip and/or Knee: A Randomized Clinical Trial

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**Objective.** To determine the effectiveness of a behavioral graded activity program (BGA) compared with usual care (UC; exercise therapy and advice) according to the Dutch guidelines for physiotherapy in patients with osteoarthritis (OA) of the hip and/or knee. The BGA intervention is intended to increase activity in the long term and consists of an exercise program with booster sessions, using operant treatment principles.

**Methods.** We conducted a cluster randomized trial involving 200 patients with hip and/or knee OA. Primary outcome measures were pain (visual analog scale [VAS] and Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]), physical function (WOMAC), and patient global assessment, assessed at weeks 0, 13, 39, and 65. Secondary outcome measures comprised tiredness (VAS), patient-oriented physical function (McMaster Toronto Arthritis Patient Preference Disability Questionnaire [MACTAR]), 5-meter walking time, muscle strength, and range of motion. Data were analyzed according to intent-to-treat principle.

**Results.** Both treatments showed short-term and long-term beneficial within-group effects. The mean differences between the 2 groups for pain and functional status were not statistically significant. Significant differences in favor of BGA were found for the MACTAR functional scale and 5-meter walking test at week 65.

**Conclusion.** Because both interventions resulted in beneficial long-term effects, the superiority of BGA over UC has not been demonstrated. Therefore, BGA seems to be an acceptable method to treat patients with hip and/or knee OA, with equivalent results compared with UC.

**KEY WORDS.** Osteoarthritis; Physiotherapy; Behavioral treatment; Graded activity; Exercise therapy; Booster sessions; Randomized controlled trial.

## INTRODUCTION

Osteoarthritis (OA) is a common joint disorder that causes pain, joint stiffness, muscle weakness, and joint instability and threatens mobility and an active lifestyle (1,2). There is strong evidence that exercise therapy has a short-term

benefit for OA. Exercise therapy involves the prescription of muscular contraction and bodily movement to ultimately improve the individual's overall function and to help meet the demands of daily living (3,4). Beneficial effects of exercise therapy on pain, physical function, and patient global assessment (PGA) have been demonstrated (5,6). Therefore, exercise therapy is recommended as an intervention to decrease the problems associated with OA and to stimulate the patient's functioning and activities (7–9). In line with these recommendations, exercise therapy is of central importance in the Dutch guidelines for clinicians and physiotherapists (10,11).

Although exercise therapy is beneficial in the short term, beneficial posttreatment effects of exercise therapy in patients with OA seem to decline over time and eventually disappear (5,6). This was found in studies by van Baar et al (12,13), comparing treatment from general practitioners (usual care) with treatment from general practitioners plus a 12-week period of exercise therapy. After 12 weeks, exercise therapy was found to be more effective in reducing pain and disability compared with usual care. The size of the effects were medium and small, respectively. However, at 24 weeks, exercise therapy was only associated

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with a small to moderate effect on pain, and at 36 weeks no differences were found between intervention groups.

To enhance long-term effects of exercise therapy, integration of exercise therapy with daily performed activities based on cognitive-behavioral principles and additional booster sessions seems promising (14,15). The graded activity intervention is an exercise program applying operant behavioral principles to increase the time of performance of daily activities. Operant behavioral principles include positive reinforcement of healthy behavior and consequent withdrawal of attention towards pain behavior; pain management is time contingent instead of pain contingent (16–18). Several studies investigated the effectiveness of graded activity programs, mainly in workers with subacute nonspecific low back pain. Positive effects were found on the duration of sick leave; however, the effects on pain and functional status were not significant (15,17,19,20). So far, no studies have been performed on the effectiveness of graded activity in patients with an irrecoverable chronic disease, such as hip and/or knee OA. Because these patients tend to avoid pain by decreasing their activities, such intervention seems appropriate to increase their level of activities.

The objective of the current study was to compare the effectiveness of a behavioral graded activity program (BGA) with physiotherapeutic usual care (UC), according to the Dutch physiotherapy guidelines (11), in patients with OA of the hip and/or knee. The hypothesis was that in the long term (>6 months after treatment) BGA results in less pain, less limitations in activities, and better PGA compared with treatment according to the guideline.

## PATIENTS AND METHODS

**Study design.** A cluster randomized trial was conducted, comparing 2 interventions: BGA and UC. Assessments were conducted at 0, 13, 39, and 65 weeks. The study was approved by the Medical Ethical Committee of the VU University Medical Center, Amsterdam, The Netherlands.

**Study population.** *Physiotherapists.* A random sample of 600 physiotherapists, practicing in primary care in the same district in the central region of The Netherlands, were invited (by letter) to participate in the study. This sample, obtained from the Netherlands Institute for Health Services Research national database of physiotherapists, was representative of all primary care physiotherapists in The Netherlands. A total of 100 physiotherapists responded, 87 of whom (divided over 72 practices) were willing and able to participate. To avoid contamination of interventions, cluster randomization was performed at the level of the participating physiotherapeutic practices. The participating practices were randomly assigned to 1 of the 2 treatment regimes by means of a computer-generated random sequence table.

*Patients.* Inclusion criteria were OA of the hip or knee according to the clinical criteria of the American College of Rheumatology (ACR) (21,22). Exclusion criteria were as follows: other pathology explaining the symptoms; symptoms on <10 of 30 days; treatment for these symptoms

with exercise therapy in the preceding 6 months; <50 or >80 years of age; indication for hip or knee replacement within 1 year; contraindication for exercise therapy; inability to understand the Dutch language; and a high level of physical function, because patients who perform at a high level of physical function at baseline do not need to increase their level of physical function. A high level of physical function was operationalized on a score <2 on the walking ability and physical function sections of the Algofunctional index (23). Patients were recruited in 2 ways. First, patients referred to physiotherapy were recruited by the participating physiotherapists at their first visit to the physiotherapist of their own choice (November 2001 to May 2003). Because the recruitment rate was rather slow, a second recruitment strategy was used, i.e., patients responded to articles in local newspapers about the benefit of exercise therapy and the performed study (November 2002 to May 2003). Patients who responded to the newspaper articles were allocated to a physiotherapist participating in the trial by choosing one from a list of participating physiotherapists. At this time, the patients were not aware of the type of intervention (BGA or control) to which the physiotherapists were assigned. An extensive description of the recruitment strategies and the influence of these strategies on the study population are published elsewhere (24). The same inclusion procedure was performed for all patients. First, they received oral information by telephone, after which a first screening was performed (by telephone). If patients were eligible, written information was sent and a final screening visit at home was planned (to control for the ACR criteria and exclusion criteria) and, if patients were willing and eligible, informed consent was signed.

**Interventions.** *BGA.* BGA is a behavioral treatment integrating the concepts of operant conditioning with exercise therapy comprising booster sessions. BGA was based on the time-contingency management as described by Fordyce et al (16) and as applied by Lindström et al (17). The intervention is directed at increasing the level of activities in a time-contingent manner, with the goal to integrate these activities in the daily lives of the patients. Appendix A presents a description of the concept and content of the BGA intervention as applied in our study. The BGA treatment was outlined in a complete protocol and included written materials (e.g., education messages, activity diaries, performance charts). The treatment consisted of a 12-week period with a maximum of 18 sessions, followed by 5 preset booster moments with a maximum of 7 sessions (in weeks 18, 25, 34, 42, and 55, respectively).

*Usual care.* The physiotherapists in the UC group were advised to treat patients according to the Dutch physiotherapy guidelines for patients with hip and/or knee OA (11). This guideline consists of general recommendations, emphasizing provision of information and advice, exercise therapy, and encouragement of a positive coping with the symptoms (Appendix B) (11). The treatment consisted of a maximum of 18 sessions within a period of 12 weeks. The treatment could be discontinued within the 12-week pe-

riod if, according to the physiotherapists, all treatment goals had been achieved.

Both BGA and UC were administered individually by physiotherapists in primary care and included home-based exercises. One session in primary care lasted ~30 minutes. Physiotherapists in both treatment groups received education on the allocated treatment, and the BGA physiotherapists were supported and advised by telephone and meetings during the study. BGA physiotherapists received 2-day training, which focused on specific skills necessary to perform a behavioral treatment such as BGA. The UC physiotherapists received 4-hour training concerning the Dutch guidelines. All physiotherapists documented every session on standardized registration forms, including deviations from the protocol.

**Outcome assessment.** Demographic and clinical data were collected for each patient, including age, sex, education, height, weight, location of OA, duration of symptoms, and the presence of other chronic disorders. Radiographs of the hip and/or knee were scored by a rheumatologist following a standardized procedure according to the Kellgren and Lawrence scale (consisting of 5 degrees: 0 = no OA, 1 = doubtful OA, 2 = minimal OA, 3 = moderate OA, and 4 = severe OA) (25,26).

**Impairments.** Patients rated their pain at the moment of assessment and tiredness in the past week on a visual analog scale (VAS; range 0–10). Furthermore, pain in the last 48 hours was assessed with the pain subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC; range 0–20) (27). Measurements of assisted active range of joint motion (ROM) of the knee (flexion, extension) and hip (flexion, extension, external rotation, internal rotation, abduction) were performed with a goniometer, according to a standardized protocol (28). Isometric muscle strength of the knee (extension) and hip (extension, abduction) was measured with the MicroFet (Hoggan, West Jordan, Utah), a hand-held dynamometer (29). The measurements of both ROM and muscle strength were repeated 2 times, and the average score was used in the analyses (12).

**Physical function.** Physical function was assessed with the physical function subscale of the WOMAC (27,30) and the McMaster Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR) (27,31). The ability to walk was measured by a 5-meter walking time test (in seconds).

**Activity level.** The level of physical activity was determined by the total minutes of performed activities as assessed by the Short Questionnaire to Assess Health Enhancing Physical Activity (32).

**Self-perceived change.** PGA was assessed by patients on an 8-point scale (1 = vastly worsened, 8 = completely recovered) (33).

**Health-related quality of life.** Quality of life was determined with the Medical Outcomes Study Short Form 36 (SF-36). All 8 subscales were assessed (34).

All outcome measures had good psychometric qualities. Primary outcome measures were pain (VAS and WOMAC), physical function (WOMAC), and PGA, according to the core set of outcome measures of clinical trials with pa-

tients with OA defined by Outcome Measures in Rheumatology Clinical Trials III (35). All primary and secondary outcome measures were obtained at baseline, 13 weeks, 39 weeks, and 65 weeks, with the exception of the outcome measures ROM, muscle strength, and walking time, which were obtained at baseline, 13 weeks, and 65 weeks. Assessments were performed on a test location in the presence of research assistants; the exception was the assessment at 39 weeks, consisting of only questionnaires, which was sent by mail.

**Blinding.** Three trained research assistants, who were blinded for the assigned treatment, performed all assessments. Patients were instructed not to give information about the allocated treatment to the research assistants. The research assistants were asked to guess the assigned treatment immediately after measurements at week 13 and week 65. Because of the type of intervention, patients and physiotherapists could not be blinded for the assigned treatment.

**Statistical analysis.** The target sample size was 200 patients. This number yields a power of 80% to detect a 25% difference in PGA and small to medium effect sizes (0.2–0.4) in the pain and physical functioning outcome measures at a 2-sided significance level of 0.05 given a maximum loss to followup of 20% (36).

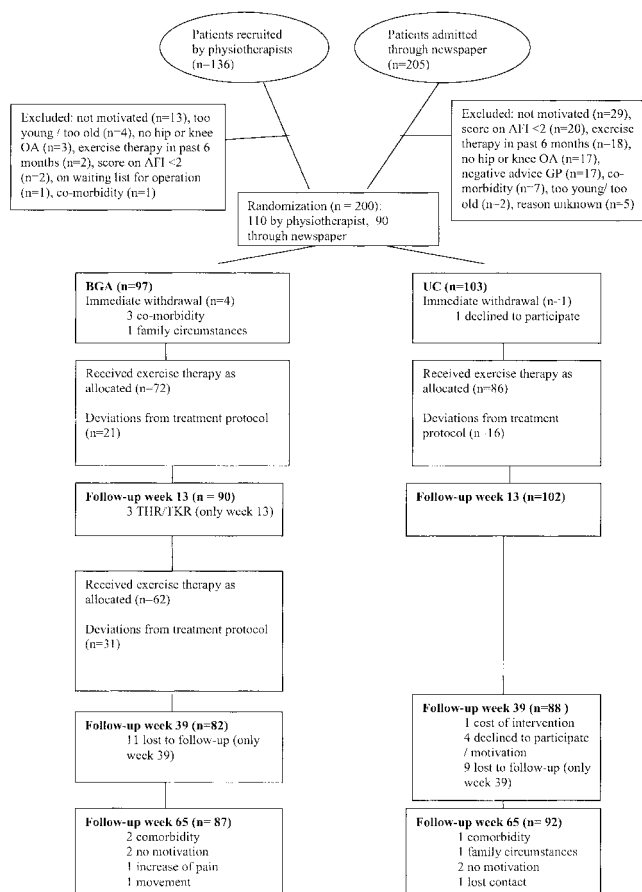
The ratings of PGA were dichotomized as improved (completely recovered, very much improved, and much improved) versus not improved (slightly improved, not changed, slightly worsened, much worsened, and vastly worsened), and odds ratios were calculated to test differences between groups. Muscle strength data were corrected for body mass by dividing the raw scores by the patient's weight. Next, Z scores were computed and added for knee (containing 2 items, extension, both sides) and hip (containing 4 items, extension and abduction, both sides) separately, as described by Steultjens et al (37). Concerning ROM, mean scores of the left and right side were calculated and used for analyses, as described by Steultjens et al (38).

The statistical analysis was carried out according to the intent-to-treat principle. Patient data were analyzed in the intervention group to which they had initially been assigned. This included withdrawals and patients not treated according to the assigned treatment. Baseline comparability was performed by descriptive statistics to examine if randomization was successful. Change scores were calculated by subtracting the baseline scores from the post-treatment scores (weeks 13, 39, and 65, respectively) and were compared for the 2 intervention groups using Student's *t*-test. To adjust for differences in patients' condition, multiple linear regression analyses were performed with the change scores as the dependent variable and type of intervention as the independent variable. The following characteristics were used as covariates in the adjusted analyses: the baseline score of each outcome measure, duration of symptoms, location of OA (hip, knee, or both), age, sex, and recruitment method (physiotherapist or newspaper). *P* values less than 0.05 were considered statistically significant.

In addition, multilevel analyses and per-protocol analyses were performed. With multilevel analysis, it is possible to correct on one side for dependency of observations within subjects and, on the other side, to take into account the variation between physiotherapists (39,40). To check whether multilevel analyses on the physiotherapist level were required, independency of observations within and among physiotherapists was determined by calculation of intraclass correlation coefficients. Per-protocol analyses were performed, excluding all patients with deviations from the treatment protocol. Deviations were defined as <6 sessions of physiotherapy within the first 12 weeks (both groups), <2 booster sessions (BGA) after the first 12 weeks, or a total hip/knee replacement during the entire study period (both groups).

## RESULTS

**Study participants.** Information regarding the patient flow through the trial is presented in Figure 1. During the study, 110 patients were recruited by participating physiotherapists and 90 patients were recruited through articles in local newspapers. A total of 200 patients were included: 97 patients in the BGA group and 103 patients in the UC group.



**Figure 1.** Patient flow diagram through the study. OA = osteoarthritis; AFI = Algofunctional Index; GP = general practitioner; BGA = behavioral graded activity; UC = usual care; THR = total hip replacement; TKR = total knee replacement.

**Table 1. Baseline characteristics of both intervention groups\***

Characteristics	BGA (n = 97)	UC (n = 103)
Female sex	73 (75)	81 (79)
Age, mean $\pm$ SD years	65.1 $\pm$ 7.4	64.5 $\pm$ 8.3
Location of OA		
Knee	67 (69)	63 (61)
Hip	22 (23)	28 (27)
Both	8 (8)	12 (12)
Duration of symptoms		
<1 year	23 (24)	24 (23)
1–5 years	39 (41)	33 (32)
>5 years	33 (35)	46 (45)
Radiologic evidence of OA (K/L $\geq$ 2; n = 146)		
Knee (n = 101)	26 (52)	31 (61)
Hip (n = 51)	18 (86)	29 (97)
Comorbidity	63 (68)	65 (64)
Body mass index, mean $\pm$ SD	28.2 $\pm$ 4.2	28.8 $\pm$ 4.6

\* Values are the number (percentage) unless otherwise indicated. BGA = behavioral graded activity program; UC = usual care program; OA = osteoarthritis; K/L = Kellgren and Lawrence score.

The BGA group and the UC group had similar baseline characteristics and baseline values of the outcome measures, as presented in Table 1. Assessment at week 13 was completed by 90 BGA patients and 102 UC patients, 82 BGA patients and 88 UC patients completed the week 39 assessment, and 87 BGA patients and 92 UC patients completed the trial up to 65 weeks. The numbers and reasons of patients lost to followup were similar in the intervention groups, with the exception that more UC patients were lost to followup because of lack of motivation (7 UC patients versus 2 BGA patients). For 10 UC patients, treatment deviated from the study protocol because treatment was terminated within 6 sessions; 12 UC patients received total hip replacement (THR) or total knee replacement (TKR) during the study period. For 23 BGA patients, treatment deviated from the protocol: for 6 BGA patients, treatment was terminated within 6 sessions, and for 17 BGA patients, <2 booster sessions were performed. Seven BGA patients received THR or TKR. Patients who completed treatment according to protocol were similar to patients who did not complete treatment, with the exception of pain at baseline. Patients who did not complete treatment reported significantly more pain at baseline than patients who did complete treatment (VAS score 4.8 versus 3.7). One patient of the BGA group reported adverse effects (increase of pain) and withdrew at the end of the therapy (after 3 booster sessions).

**Treatment.** Fifty-five physiotherapists (26 BGA and 29 UC) treated patients included in the study. The mean number of treated patients per physiotherapist was 3.6 and varied between 1 and 11. The patients who were allocated to the BGA group received a mean  $\pm$  SD of 14.1  $\pm$  5.5 treatment sessions versus 11.7  $\pm$  4.3 sessions in the UC group ( $P < 0.01$ ).

BGA treatment was mainly directed towards improve-

Table 2. Primary outcome measures: improvements and differences between intervention groups\*

Outcome measures	BGA	UC	Difference between BGA and UC, Mean (95% CI)	Adjusted difference, Mean (95% CI)†
Pain at assessment, VAS (range 0–10)				
Baseline, no.; mean $\pm$ SD	97; 4.3 $\pm$ 2.8	103; 3.7 $\pm$ 2.5		
$\Delta$ Week 13–baseline	90; -0.61 (-1.2, -0.005)	102; -0.47 (-1.0, 0.1)	-0.14 (-0.9, 0.6)	0.26 (-0.4, 0.9)
$\Delta$ Week 39–baseline	82; -0.15 (-0.8, 0.5)	88; 0.62 (0.0, 1.2)	-0.77 (-1.7, 0.1)	-0.26 (-1.0, 0.5)
$\Delta$ Week 65–baseline	87; -1.01 (-1.7, -0.3)	92; -0.58 (-1.1, -0.03)	-0.44 (-1.3, 0.5)	0.14 (-0.6, 0.8)
Pain, subscale WOMAC (range 0–20)				
Baseline, mean $\pm$ SD	97; 9.1 $\pm$ 3.3	103; 8.7 $\pm$ 3.1		
$\Delta$ Week 13–baseline	90; -2.35 (-3.0, -1.7)	102; -2.20 (-2.9, -1.5)	-0.15 (-1.1, 0.8)	0.17 (-0.6, 1.0)
$\Delta$ Week 39–baseline	82; -2.30 (-3.3, -1.3)	88; -1.00 (-1.8, -0.2)	-1.30 (-2.5, -0.1)	-0.97 (-2.1, 0.2)
$\Delta$ Week 65–baseline	87; -3.90 (-4.7, -3.1)	92; -3.20 (-3.9, -2.5)	-0.70 (-1.8, 0.4)	-0.32 (-1.3, 0.6)
Physical function, subscale WOMAC (range 0–68)				
Baseline, mean $\pm$ SD	97; 28.7 $\pm$ 12.5	103; 29.1 $\pm$ 9.9		
$\Delta$ Week 13–baseline	90; -5.98 (-8.0, -4.0)	102; -5.21 (-6.9, -3.5)	0.76 (-3.4, 1.8)	-0.56 (-3.0, 1.9)
$\Delta$ Week 39–baseline	82; -6.94 (-9.6, -4.3)	88; -5.22 (-7.4, -3.0)	-1.72 (-5.1, 1.6)	-1.30 (-4.4, 1.8)
$\Delta$ Week 65–baseline	87; -7.35 (-10.4, -4.3)	92; -7.29 (-9.3, -5.2)	-0.07 (-3.6, 3.5)	0.27 (-2.9, 3.4)
Patient global assessment, total no.; no. (%) improved‡				
Week 13	90; 37 (41)	102; 37 (36)	0.81 (0.5, 1.5)§	0.88 (0.5, 1.6)§
Week 39	79; 33 (42)	86; 24 (28)	0.54 (0.3, 1.03)§	0.55 (0.3, 1.1)§
Week 65	86; 48 (56)	88; 43 (49)	0.76 (0.4, 1.4)§	0.87 (0.5, 1.6)§

\* Values are the number; mean (95% CI) unless otherwise indicated. Negative signs indicate improvement within groups or improvement in favor of BGA (in case of differences in change between groups). BGA = behavioral graded activity program; UC = usual care program; OR = odds ratio; 95% CI = 95% confidence interval; VAS = visual analog scale;  $\Delta$  = change; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

† Analyses are adjusted for the baseline score of each outcome measure, duration of complaints, location of osteoarthritis (hip, knee, or both), age, sex, and recruitment method (physiotherapist or newspaper).

‡ Assessment OR <1 indicates improvement in favor of BGA.

§ Values are OR (95% CI).

ment of activities (e.g., walking, climbing stairs, gardening)/decrease of limitations in activities (in 92% of sessions), reduction of impairment in bodily functions (e.g., muscle strength, ROM; 53%), and increase of participation (51%). The BGA physiotherapists followed the interventions as described in the BGA protocol for most patients; activities were chosen by 86% of the patients, baseline values were determined for 70%, and a gradually increasing exercise program was made (84%) and executed (84%).

The main treatment goals of the UC intervention were improvement of activities/decrease of limitations in activities (in 84% of sessions), reduction of impairments in bodily functions (76%), and reduction of pain (64%). The most common UC interventions were exercise therapy of bodily functions (81% of sessions), exercise therapy of activities (74%), and providing information and advice (56%). The UC group applied more passive interventions compared with the BGA physiotherapists: manipulating joints (41% of sessions versus 3%) and massage (21% of sessions versus 2%).

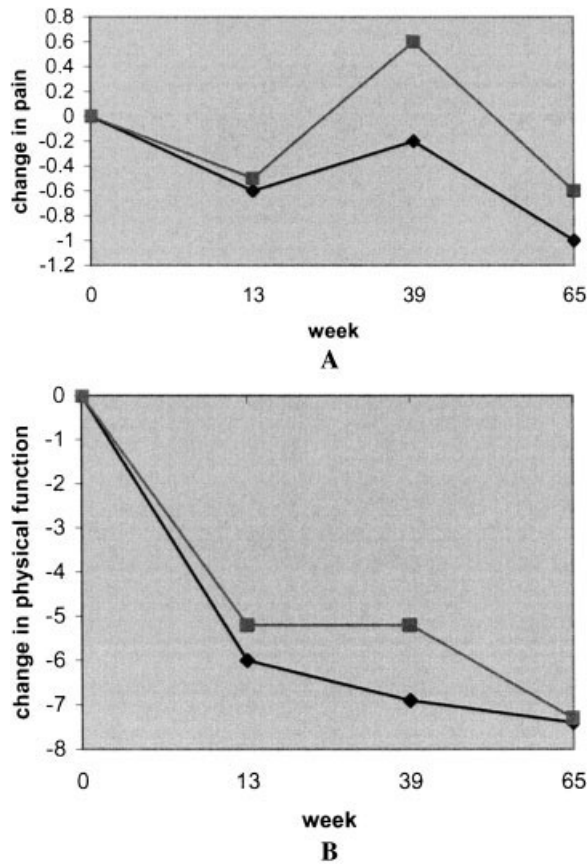
BGA patients reported adhering to home activities significantly more frequently compared with the UC patients, both at 13 and 65 weeks: at 13 weeks, 75% of the BGA patients reported exercising frequently or very frequently

compared with 44% of the UC patients (chi-square  $P < 0.01$ ); at 65 weeks, 56% and 33%, respectively, reported adhering to the exercises (chi-square  $P < 0.01$ ).

**Blinding.** The research assistants were asked to guess the assigned treatment immediately after week 13 and week 65 assessments. The research assistants guessed the assigned treatment for 57% of patients after 13 weeks (Cohen's  $\kappa = 0.14$ ) and for 46% of patients after 65 weeks (Cohen's  $\kappa = -0.09$ ).

**Outcome.** The results of the intent-to-treat analyses on the effectiveness of treatment of the primary outcome measures are presented in Table 2. All primary outcome measures demonstrated significant improvements within both groups, and improvements increased with time.

For the primary outcome measures, pain and physical function, an overview of the changes over the course of the trial is given in Figure 2. After 13 weeks, BGA patients showed improvements in WOMAC pain and physical function of 25.8% and 20.8%, respectively, compared with baseline; the improvement of BGA patients increased to 42.8% and 25.6%, respectively, after 65 weeks compared with baseline. This pattern was similar for the scores



**Figure 2.** A, Change in pain (visual analog scale) over time. B, Change in physical function (Western Ontario and McMaster Universities Osteoarthritis Index). Negative signs indicate improvement. Diamonds = behavioral graded activity group; squares = usual care group.

of UC patients: 25.3% and 17.9% improvement compared with baseline on WOMAC pain and physical function, respectively, after 13 weeks, and 36.8% and 25.1% improvement, respectively, compared with baseline after 65 weeks. The differences between the groups in improvement for pain, physical function, and PGA at all assessments were in favor of the BGA group. However, the differences were small and not statistically significant.

The results of the secondary outcome measures are presented in Table 3. In general, the pattern was the same as for the primary outcome measures: there was statistically significant improvement within groups, and differences between groups were in favor of BGA, but were mostly not significant. Exceptions were the 5-meter walking time and physical function as assessed on the MACTAR, showing significant beneficial results in favor of BGA, especially in the long term. No differences were found in the 8 subscales of the SF-36, except for a beneficial effect of UC on the role physical functioning subscale.

Alternative analyses (multilevel analysis and per-protocol analysis) yielded similar results (data not shown). Intraclass correlation coefficients among and within physiotherapists were estimated as  $<0.01$ ; therefore, all multilevel analyses were performed on the patients' level. The per-protocol analysis was restricted to 80, 68, and 72

UC patients and 64, 58, and 63 BGA patients at weeks 13, 39, and 65, respectively.

## DISCUSSION

We assessed the effectiveness of an operant BGA program comprising booster sessions compared with UC according to the Dutch physiotherapy guidelines for hip and/or knee OA in a single-blind, cluster randomized controlled trial. Both interventions were administered by physiotherapists in primary care, and both groups reported beneficial effects in the long term. The differences between the groups in improvement in pain, functional status, and PGA were small and not significant. The differences were, however, generally in favor of the BGA group. This pattern was similar to the scores on the secondary outcome measures, with the exception of the scores on the MACTAR and 5-meter walking test. For these outcome measures, significant differences were found in favor of BGA at week 65. Furthermore, BGA patients reported adhering to the home exercises and activities significantly more than the UC patients.

Based on the literature (5,6), we expected only short-term (posttreatment) effects and no long-term effects from UC. Surprisingly, the beneficial effects of UC remained stable and even slightly increased in the long term; as a result, the BGA and UC interventions were approximately equally effective. An explanation for the unexpected beneficial long-term effects of the UC group is a general change of approach in physiotherapy. First of all, the shift from a more passive approach (e.g., massage therapy and physiotherapy modalities) to an active approach (exercise therapy, education), as advocated in the guidelines, is gaining more support in the physiotherapy profession (9,11,41,42). Within this active approach, the exercises have recently become more functional and task oriented (43–45). This shift from the level of impairment in body functions (e.g., muscle strength, ROM) to the functional activities level (e.g., walking, climbing stairs) could be confirmed in the registration forms of the physiotherapists. The UC applied in our trial was an adaptation of the exercise therapy protocol of van Baar et al (12). In the study by van Baar et al, exercise therapy was mainly directed towards improvement of muscle strength (93% of treatments), improvement of ROM (85%), and reduction of pain (80%). We expected that the goals of the UC physiotherapists would be comparable with those of van Baar and colleagues' study, namely, at the level of impairment in body functions. However, in the present study, improvement of activities/decrease of limitations in activities (84% of treatments) was the most frequently mentioned intervention in the UC group.

Apart from the enhanced functional orientation in the UC group, the contrast between the intervention groups was lower than expected in other respects. First, we expected that BGA patients would participate in at least 5 sessions more than the UC group, because BGA patients received additional booster sessions after the first 12 weeks of treatment. However, the average number of sessions was 14.1 for the BGA group versus 11.7 for the UC group, which was still a significant difference ( $P < 0.01$ ). Second, the contrast between interventions was smaller

**Table 3. Secondary outcome measures: improvements and differences between intervention groups\***

Outcome measures	BGA	UC	Difference between BGA and UC, Mean (95% CI)	Adjusted difference, Mean (95% CI)†
Tiredness past week, VAS (range 0–10)				
Baseline, no.; mean ± SD	97; 5.3 ± 2.4	103; 4.9 ± 2.3		
Δ Week 13–baseline	90; -1.28 (-1.8, -0.8)	102; -0.84 (-1.5, -0.6)	-0.44 (-1.2, 0.3)	-0.10 (-0.7, 0.5)
Δ Week 39–baseline	82; -0.59 (-1.9, -0.7)	88; 0.31 (-1.3, 0.1)	-0.89 (-1.7, -0.1)	-0.47 (-1.2, 0.3)
Δ Week 65–baseline	87; -2.13 (-3.1, -2.0)	92; -1.12 (-2.1, -1.0)	-1.01 (-1.9, -0.1)	-0.49 (-1.1, 0.1)
Muscle strength hip, Z score				
Baseline, no.; mean ± SD	97; 0.23 ± 3.8	103; -0.17 ± 3.1		
Δ Week 13–baseline	87; 1.07 (0.5, 1.6)	98; 0.13 (-0.4, 0.6)	0.94 (0.2, 1.7)	0.75 (0.04, 1.5)
Δ Week 65–baseline	77; 0.29 (-0.3, 0.9)	79; -0.22 (-0.9, 0.5)	0.51 (-0.4, 1.4)	0.12 (-0.6, 0.9)
Muscle strength knee, Z score				
Baseline, no.; mean ± SD	97; 0.05 ± 1.6	103; -0.02 ± 1.9		
Δ Week 13–baseline	89; 0.40 (0.1, 0.7)	100; 0.25 (-0.01, 0.5)	0.15 (-0.3, 0.5)	0.15 (-0.2, 0.5)
Δ Week 65–baseline	75; -0.32 (-0.7, 0.03)	86; -0.38 (-0.8, 0.1)	0.06 (-0.5, 0.6)	-0.03 (-0.4, 0.4)
ROM: hip flexion to extension in degrees				
Baseline, no.; mean ± SD	97; 129.64 ± 14.6	103; 126.29 ± 15.8		
Δ Week 13–baseline	89; 1.77 (-0.3, 3.8)	100; 2.78 (0.7, 4.8)	-1.01 (-3.9, 1.9)	-0.42 (-3.1, 2.3)
Δ Week 65–baseline	82; -0.80 (-3.4, 1.8)	89; -0.29 (-2.9, 2.3)	-0.51 (-4.1, 3.1)	0.10 (-3.2, 3.4)
ROM: knee flexion to extension in degrees				
Baseline, no.; mean ± SD	97; 122.21 ± 15.9	103; 124.32 ± 12.1		
Δ Week 13–baseline	90; 3.17 (1.4, 4.5)	101; 2.52 (0.8, 4.3)	0.65 (-1.8, 3.1)	0.47 (-1.9, 2.8)
Δ Week 65–baseline	84; 4.79 (0.9, 8.6)	91; 3.55 (1.8, 5.3)	1.24 (-2.8, 5.3)	1.02 (-2.9, 5.0)
Physical function, MACTAR (range -15 to 15)				
Baseline, no.; mean ± SD	97; 6.41 (5.2, 7.6)	102; 5.30 (4.0, 6.6)		
Δ Week 13–baseline	90; 6.41 (5.2, 7.6)	102; 5.30 (4.0, 6.6)	1.11 (-0.6, 2.9)	1.00 (-0.8, 2.8)
Δ Week 39–baseline	93; 4.28 (2.5, 6.0)	97; 2.16 (0.5, 3.8)	2.12 (-0.3, 4.5)	1.96 (-0.4, 4.3)
Δ Week 65–baseline	87; 6.02 (4.4, 7.6)	92; 3.27 (1.6, 4.9)	2.75 (0.5, 5.0)	2.56 (0.3, 4.9)
Physical function, 5-meter walking in seconds				
Baseline, no.; mean ± SD	97; 4.8 ± 1.2	103; 4.8 ± 1.5		
Δ Week 13–baseline	90; -0.41 (-0.6, -0.2)	102; -0.19 (-0.4, 0.0)	-0.22 (-0.5, 0.04)	-0.20 (-0.4, -0.01)
Δ Week 65–baseline	87; -0.44 (-0.7, -0.2)	92; -0.13 (-0.3, -0.04)	-0.31 (-0.6, -0.03)	-0.33 (-0.6, -0.1)
Physical activity (SQUASH, no.; mean ± SD minutes)				
Baseline	97; 1,761 ± 1,221	103; 1,664 ± 984		
Δ Week 13–baseline	80; 170 (-44, 383)	89; 266 (19, 513)	-96 (-427, 236)	-67.7 (-390, 254)
Δ Week 39–baseline	72; -101 (-356, 154)	66; -248 (-615, 9)	148 (-225, 520)	148.1 (-183, 479)
Δ Week 65–baseline	77; 12 (-247, 271)	78; 87 (-150, 324)	-74 (-428, 280)	-47.6 (-368, 273)
SF-36, subscale role physical function (range 0–100)‡				
Baseline, no.; mean ± SD	97; 40.0 ± 40.7	103; 45.2 ± 41.7		
Δ Week 13–baseline	90; 14.1 (4.9, 23.3)	102; 15.2 (5.1, 25.2)	-1.1 (-14.8, 12.5)	-4.88 (-16.5, 6.7)
Δ Week 39–baseline	82; 12.1 (1.6, 22.5)	88; 9.2 (-1.4, 19.9)	2.8 (-2.0, 17.7)	0.88 (-11.6, 13.4)
Δ Week 65–baseline	87; 8.00 (-3.7, 19.7)	92; 17.8 (6.0, 29.5)	-9.8 (-26.3, 6.8)	-14.7 (-27.5, -1.9)

\* Values are the number; mean (95% CI) unless otherwise indicated. Positive signs indicate improvement (within groups) or improvement in favor of BGA patients (in case of differences in change between groups), with the exception of tiredness and 5-meter walking. ROM = range of motion; MACTAR = McMaster Toronto Arthritis Patient Preference Disability Questionnaire; SQUASH = Short Questionnaire to Assess Health Enhancing Physical Activity; SF-36 = Medical Outcomes Study Short Form 36; see Table 2 for additional abbreviations.

† Analyses are adjusted for the baseline score of each outcome measure, duration of symptoms, location of osteoarthritis (hip, knee, or both), age, sex, and recruitment method (physiotherapist or newspaper).

‡ No significant differences were found on the other 7 subscales of the SF-36. These results have been omitted because of limitations of space.

than expected because not all BGA patients were treated according to the protocol. Specific elements of the BGA program were described in the registration forms, and baseline values were determined for only 70% of the BGA patients and an exercise protocol was only made for 84%

of the BGA patients. This might indicate that other specific elements of BGA, such as reinforcing feedback and extinction of pain behavior (not registered), also may not be adequately executed. Possibly, a 2-day course is too short to completely master the skills that are necessary to treat

patients according to a BGA protocol, as was suggested by King et al (46). The results of other studies on the efficacy of BGA are comparable: no differences were found in pain and physical functioning as reported on self-administered questionnaires. Positive effects were found in patient-specific measures (47) and in returning to work or other behavior (less sick leave) (15,19,20). In our study, beneficial effects were also found for the patient-specific measure MACTAR and the 5-meter walking time test. Finally, considering the lower contrast, the present study might have been underpowered.

Especially for the outcome measure MACTAR, the significant difference between both groups after 65 weeks seems to be clinically relevant. Although no research has been conducted on the minimal clinically important difference/improvement of the MACTAR, a difference of 46% (6.02 for BGA compared with 3.27 for UC) can be interpreted as a clinically relevant difference. The clinically important difference of the walking time test is less convincing (an improvement of 9% compared with baseline in BGA patients versus 3% in UC patients). Although both interventions were approximately equally effective, it is our opinion that the overall improvement within groups was also clinically relevant. Angst et al (48) concluded that changes >12% compared with baseline, in pain and physical function, can be detected as minimal clinically important differences. In our study, we found changes in pain after 65 weeks of 43% (BGA) and 37% (UC), and changes in physical function of 25% (both groups). Tubach et al (49) stated that the minimal clinically important improvement for relative changes (changes compared with baseline) were between 32% and 40% for pain (VAS) and between 21% and 26% for physical function (WOMAC). Besides this, 56% of the BGA patients and 49% of the UC patients reported, after 65 weeks, improvement on the PGA, a measure that is often used as an indicator for clinically relevant differences.

As for the design of the study, some comments can be made. First, patients were recruited in 2 ways: referrals to physiotherapists and responses to articles in local newspapers. However, the influence of these 2 recruitment strategies on the study population and results of the study were investigated. It appeared that recruitment method affected clinical characteristics and physical functioning of the patients, but recruitment method was not an effect modifier because it did not affect treatment outcome (24). Second, a longer followup might give a more definite answer on the effectiveness of BGA, because the time between the last session (week 55) and last assessment (week 65) was only 10 weeks. Third, because BGA consists of more sessions and requires training of physiotherapists, it is important that the clinical evaluation of such new treatment programs is accompanied by an economic evaluation. This economic evaluation on the cost-effectiveness of BGA will be performed in the direct future. Finally, because the goal of the present study was to investigate whether BGA was more effective than UC, there was no reason for including a no-treatment control group. Because we lacked such no-treatment group, we were not able to attribute the within-group improvement to either treatment (BGA or UC) or other factors. Considering the slowly

deteriorating condition of OA and the limited evidence in the literature on long-term effects of exercise therapy, improvement in time is very improbable. Therefore, we believe both interventions had beneficial effects over time.

In conclusion, both treatment groups showed beneficial long-term effects. The differences between BGA and UC on most outcome measures were in favor of BGA. However, these differences were small and not significant, with the exception of the patient-oriented physical function and 5-meter walking time test. Because, unexpectedly, UC also showed beneficial effects in the long term, the BGA and UC treatments were approximately equally effective. Whether both treatments differ in costs and whether specific groups of patients with OA particularly benefit from BGA need to be investigated.

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### Appendix A: Description of the behavioral graded activity (BGA) intervention

Content	BGA consists of 3 phases: <ol style="list-style-type: none"> <li>1. Starting phase: provision of educational messages, selection of problematic activities and treatment goals, and determination of baseline value.</li> <li>2. Treatment phase: increase of the selected activities, gradually and in a time-contingent way, by means of an exercise program, which is reproduced in performance charts.</li> <li>3. Integration phase: support and reinforcement of the behavioral change and integration of the increased level of activities in the daily living of the patient (maximum of 7 sessions in 5 determined booster sessions in week 18, 25, 34, 42, and 55).</li> </ol>
Educational messages	Not pain relief, but improvement of functioning is the primary goal of the treatment. Exercise and physical activity are recommended. The performance of physical activity should not depend on the amount of pain.
Activities	Problematic activities (maximum of 3) are selected by patients on activity list. Individually tailored exercises, to improve impairments limiting the performance of these activities, are selected.
Goals	For each activity and each exercise, short-term and long-term goals are set and recorded in a treatment agreement form.
Baseline values	To determine baseline values, patients perform the selected activities until (pain) tolerance during 1 week and record these activities in a diary.
Gradually increasing exercise program	An individually based scheme is made on a time-contingent basis for each activity and exercise, starting slightly under baseline values and gradually increasing towards the preset short-term goal. Patients should neither underperform nor overperform this gradually increasing scheme.
Visual reproduction	Performance charts are used to record and visualize the performance of activities and exercises.
Reinforcement	Positive reinforcement is given towards healthy and active behavior; pain behavior is extinguished.
Stopping rule	The gradual increase of activities has to be interrupted when an active inflammatory process is suspected or diagnosed (e.g., redness of the knee, increase in knee effusion, or comparable symptoms). Hereafter, the increase of activities starts at a lower level. In case of recurrent inflammatory processes, the treatment goal needs to be changed and the rate of increasing activities needs to be decelerated.
Duration	Maximum of 18 sessions within first 12 weeks. Additional booster sessions in week 18, 25, 34, 42, and 55.

### Appendix B: Description of the usual care intervention (6)

Content	The guideline describes 3 distinct patient profiles, which are based on 6 main problem areas.
Patient profiles	<p>Patient profile A: Active inflammatory process in the joint is predominant; most important symptoms are pain and impairments related to movement of hip/knee.</p> <p>Patient profile B: Patient has episodes with pain symptoms, impairments related to movement, which gradually results in limitations of activities as well as episodes of pain. Patient looks for solutions himself and needs extra guidance during episodes of intense pain.</p> <p>Patient profile C: Patient has long-lasting or chronically recurring symptoms; limitations of activities and possible participation problems are of central concern. Patient experiences little or no control over the situation.</p>
Main problem areas	The guideline describes 6 problem areas for patients with osteoarthritis: impairments related to active inflammatory processes, pain, impairments related to movement, limitations of activities, participation problems, and inadequate coping strategies. On the basis of these problem areas, physical therapists can classify patients as having 1 of the 3 defined patient profiles.
Central goal	To counter the effect of osteoarthritis by decreasing the patient's pain, limitations of activities, and participation problems. In other words, to optimize the patient's level of activity and participation in life.
Therapeutic approach	For each identified problem area, treatment goals and interventions are advised. Possible interventions are: <ul style="list-style-type: none"> <li>– providing information and advice</li> <li>– exercise therapy</li> <li>– passive interventions, such as traction to the joint and transcutaneous electrical nerve stimulation (TENS) (only in active inflammatory processes)</li> <li>– stimulating and increasing the level of activities</li> <li>– stimulating compliance with therapy</li> </ul>
Duration	Maximum of 18 sessions within 12 weeks.