Promoting physical activity in patients with rheumatoid arthritis

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Chapter 4

Using Internet technology to deliver a home-based physical activity intervention for patients with rheumatoid arthritis: a randomized controlled trial

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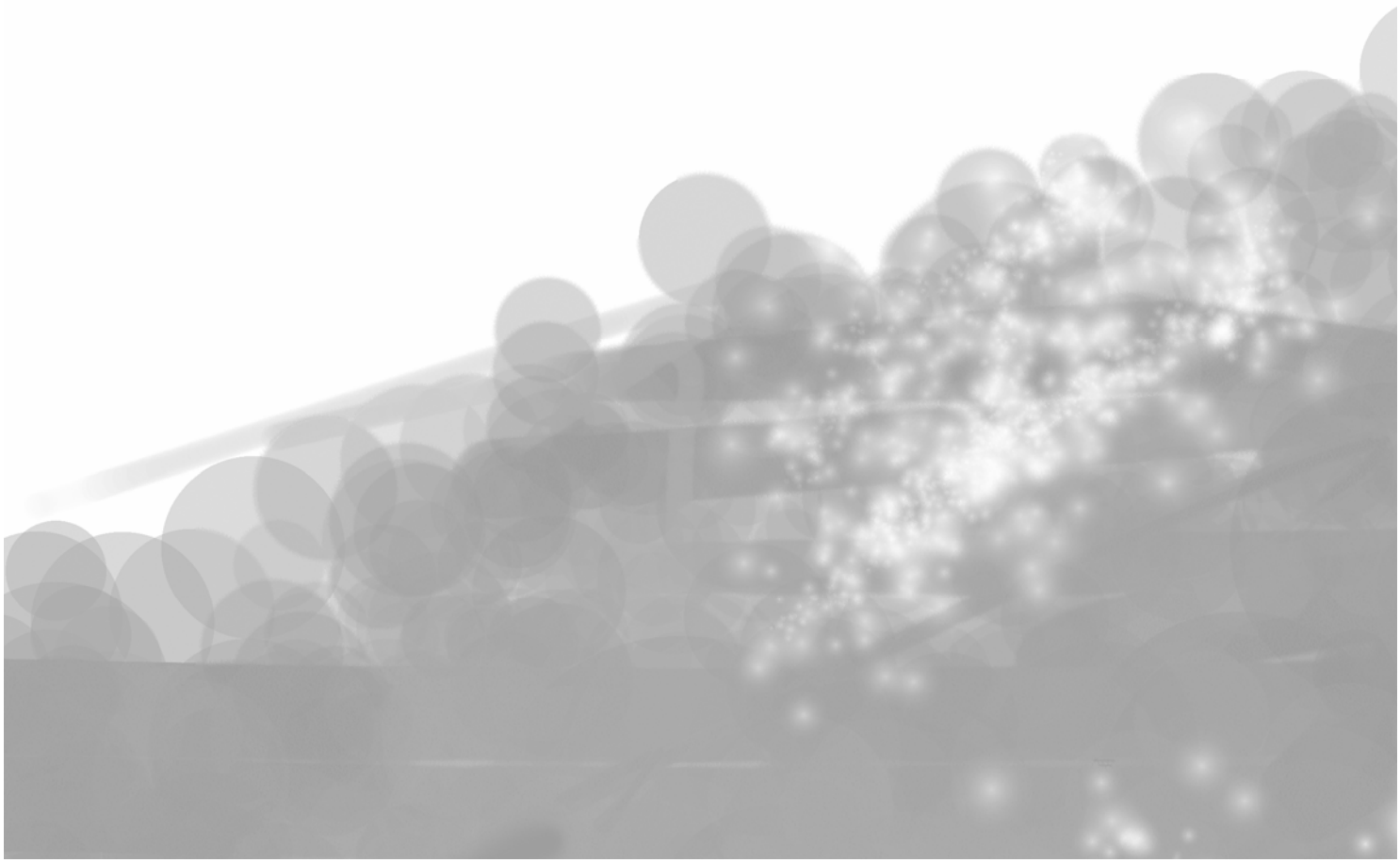

Abstract

Objective. To compare the effectiveness of two Internet-based physical activity interventions for patients with rheumatoid arthritis (RA).

Methods. A total of 160 physically inactive patients with RA who had a computer with Internet access were randomly assigned to an Internet-based physical activity program with individual guidance, a bicycle ergometer and group contacts (n=82, Individualized Training; IT group) or to an Internet-based program providing only general information on exercises and physical activity (n=78, General Training; GT group), both lasting 12 months. Outcome measures included quantity of physical activity (questionnaire and activity monitor), functional ability, quality of life and disease activity (baseline, 3, 6, 9 and 12 months).

Results. The proportion of physically active patients were significantly greater in the IT than in the GT group at 6 (38% vs. 22%) and 9 months (35% vs. 11%; both $p<0.05$) regarding a moderate intensity level for 30 minutes in succession on at least 5 days a week, and at 6 (35% vs. 13%), 9 (40% vs. 14%), and 12 months (34% vs. 10%; all $p <0.005$) with respect to a vigorous intensity level for 20 minutes in succession on at least 3 days a week. In general, there were no statistically significant differences regarding changes in physical activity as measured with an activity monitor, functional ability, quality of life, or disease activity.

Conclusion. An Internet-based physical activity intervention with individually tailored supervision, exercise equipment and group contacts is more effective with respect to the proportion of patients who report meeting physical activity recommendations than an Internet-based program without these additional elements in patients with RA. No differences were found regarding the total amount of physical activity measured with an activity monitor.

Introduction

Despite the proven health benefits of regular physical activity (1;2), the majority of the adult population in western nations does not meet the public health recommendations for physical activity (3;4). Recent studies showed that people with arthritis have even higher rates of sedentary behavior than the general population (5;6). This finding is remarkable, since it has been extensively documented that regular exercise does not have deleterious effects and has extensive disease specific benefits such as reduced pain, improved mental health, and delayed onset of disability in patients with rheumatoid arthritis (RA) (7-9) as well as osteoarthritis (10;11).

In addition to individually planned exercise prescription, the adoption of physical activity as part of the arthritis patient's normal life style is nowadays advocated often by promoting low impact daily activities such as walking or cycling (12;13). Recently, various interventions, which were specifically aimed at promoting daily physical activity for patients with arthritis, have been evaluated. The People with Arthritis Can Exercise (PACE) (14) program, which is a recreational, community-based physical activity program, improved mental and physical health status in patients with arthritis. In patients with symptomatic osteoarthritis the effectiveness of a pedometer-driven walking program (15) and the extra benefit of individualized face-to-face physical activity advice in addition to usual care have been established (16).

These interventions were all delivered by means of conventional methods such as face-to-face counseling, group meetings and written information. Although in the general population and diabetic patients the results of Internet-based physical activity programs using websites and e-mail as modes of delivery proved to be promising (17-19), no data in patients with arthritis are yet available. Therefore, the purpose of this study was to compare the effectiveness of two Internet-based physical activity interventions in patients with RA.

Patients and Methods

Study design, patient recruitment and selection, and randomization

This study was a randomized, controlled trial performed between 2002 and 2004 in the rheumatology outpatient clinics of three hospitals (Leiden University Medical Center, LUMC; Haga-Leyenburg Teaching Hospital, The Hague; and Reinier de Graaf Hospital, Delft). In these hospitals three registries, comprising 765, 1122 and 360 patients with a clinical diagnosis of

RA,respectively, were sorted in ascending order by the day of the month of the patients' birthdays or by the date of their forthcoming visit to the outpatient clinic. Then 1100 questionnaires (500 Leiden, 400 The Hague, 200 Delft) were sent to consecutive patients from the three lists. After that, smaller samples of approximately 50 questionnaires were sent, until the target sample size of 160 patients was reached. The questionnaire comprised the following inclusion criteria: not being physically active for 30 minutes in succession on a moderate intensity level on at least 5 days a week (in accordance with the Dutch public health recommendations for physical activity (3)); the availability of a computer with Internet facilities; being able to cycle on a bicycle ergometer; and being interested in a study on a physical activity program. Medical records of the patients who returned the questionnaire and met the inclusion criteria were screened regarding the American College of Rheumatology (formerly the American Rheumatism Association) 1987 criteria for RA (20) (meeting $\geq$4 of 7 criteria at least once during the course of the disease). Eligible patients were then sent an information leaflet about the trial and were invited for an assessment regarding the final inclusion criterion, namely not having cardiopulmonary conditions which would not allow moderately intensive exercise. No details were given regarding the level of individual guidance and counseling, group contacts and availability of exercise equipment with the two interventions. All patients gave written informed consent, and the medical ethics committees of the three centers approved the study protocol. Randomization was performed using a randomization list made up by a random digit generator, using blocks of four patients, with stratification for center and gender. The randomization process was carried out by an independent physical therapist who was not responsible for recruiting the patients.

Interventions and co-interventions

Two Internet-based physical activity interventions that were continued for 12 months were compared; both interventions were delivered through the same website (www.cybertraining.nl). By using a personal password, the patients in the two groups obtained access to two different parts of the website.

Individualized Training (IT) intervention. The web pages of the IT intervention provided a weekly, detailed personal physical activity program consisting of muscle strengthening exercises, range-of-motion (ROM) exercises and cycling on a bicycle ergometer. The program had to be performed 5 times a week on 5 separate days. Every week the patients sent back a filled-in program

schedule by e-mail and subsequently a new schedule was put on the individual's personal web pages. The muscle strengthening and ROM exercises were performed in a sitting, standing or lying position in 3 sets of 10 repetitions per set, with 30 seconds recovery time between the sets. Patients were instructed to hold the end positions of the muscle strengthening exercises for 5 seconds. With some exercises an elastic band (Thera-Band, Hygenic Corporation, Akron, OH) or a wooden exercise stick (Mammoet Sport, Eindhoven, the Netherlands) was used. In addition, a bicycle ergometer (Tunturi E3, Tunturi Oy, Turku, Finland) and a chest band measuring heart rate (Polar T41, Polar Electro Oy, Kempele, Finland) were given on loan to the patients during the study period. During cycling, the heart rate was kept at 60-80% of the predicted maximal heart rate (220 minus age) and the rating of perceived exertion (Borg scale range 0-10) (21) was kept at 4-5. Each cycling session was preceded by a warm-up (2 minutes) and followed by a cool-down (1 minute), with the duration of each cycling session increasing from 10 to 30 minutes per day. The program was tailor-made, meaning that depending on the average heart rate during cycling and the Borg scale, the program was adjusted in terms of duration and/or intensity. To enhance the adoption of physical activity as part of the individual's lifestyle, all patients were advised to engage in other forms of physical activity than using the bicycle ergometer, such as walking or cycling outside. Other forms of physical activity were specifically advised for the remaining two days of the week where the bicycle ergometer was not used and for those patients who did not like cycling on the bicycle ergometer at all.

Patients received weekly, individual distant supervision by two experienced physical therapists, provided by e-mail. In addition, patients were invited to group meetings once every 3 months (three groups in Leiden, four groups in The Hague, two groups in Delft), where new exercises were demonstrated by the physical therapists, extra information about exercise and arthritis was given and patients' experiences were exchanged. Contacts among group members were also facilitated by a discussion forum on the IT group's web pages. Self-management strategies tailored to the patient's needs such as management of pain and fatigue, energy conservation and joint protection were addressed during the group meetings as well as in individual contacts.

General Training (GT) intervention. Patients allocated to the GT group had access to web pages where general information about aerobic, muscle strengthening and ROM exercises and the promotion of physical activity in RA patients was presented. Patients were advised to perform the recommended activities on at least 5 days a week and suggestions were given about how

intensity, frequency and duration could be gradually built up in such a way that the goal of 30 minutes of moderate physical activity on at least these 5 days could be reached. In addition, patients could order a free copy of the 'Beweegwijzer' (Movement guide; 2002, TNO Preventie en Gezondheid, Leiden, the Netherlands), which is a CD-ROM comprising advice about increasing physical activity, developed for the general population. Once a month the information on the web pages was up-dated with new activities and exercises, news items and online leaflets (i.e., a leaflet about walking or about physical activity at the workplace.

Co-interventions. The attending rheumatologists were informed about the treatment allocation and had free choice with respect to their medical prescriptions and other treatment strategies.

Assessment methods

All clinical assessments were done by a single investigator (MHB, movement scientist) who was blinded for the treatment allocation. The measurements were conducted at baseline and after 3, 6, 9, and 12 months. Measures of disease activity, physical activity as measured with the activity monitor, functional ability as measured with the McMaster Toronto Arthritis (MACTAR) Patient Preference Disability Questionnaire (22), and the use of medication were done at baseline, 6 and 12 months only. Patients were repeatedly instructed not to discuss their treatment allocations with the investigator.

Sociodemographic and disease characteristics. Sociodemographic characteristics recorded at baseline were age (years), gender, educational level (categorized as low: up to and including lower technical and vocational training; medium: up to and including secondary technical and vocational training; high: up to and including higher technical and vocational training and university), living situation (living alone or with other people) and employment status. In addition, the Body Mass Index (weight in kilograms/height in meters^2), smoking habits (active smoker defined as smoking $\geq$1 cigarettes per day), and the presence of co-morbidity (assessed using a part of the Dutch Arthritis Impact Measurement Scale II (AIMS II) (23) and defined as having $\geq$1 co-morbid conditions) were registered. Disease duration at baseline, the presence of rheumatoid factor, and the past number of disease-modifying anti-rheumatic drugs (DMARDs) received were recorded from the medical records.

Usage of health care. Any changes in the use of medication were registered after 6 and 12 months. The use of health care services and visits to various health professionals over the past 3 months were measured using a diary that had to be filled in at 3, 6, 9, and 12 months.

Usage of website and online physical activity schedules. In both groups, the frequency of logging into the website was recorded by means of a questionnaire to be filled in at 3, 6, 9, and 12 months. In the IT group, the amount of weekly returned physical activity schedules was recorded. Taking into account a 6-week period for getting used to filling in the schedules and an average holiday period of 6 weeks per year, the maximum number of schedules to be returned during the study period was 40. A schedule usage rate was defined as the number of returned physical activity schedules divided by 40.

Outcome measures. The primary outcome measure was the proportion of patients meeting the physical activity recommendations, based on the Dutch public health recommendations for physical activity (3). Fur this purpose, two questions were posed. First, the participants were asked how many days a week they were physically active on a moderate intensity level for 30 minutes in succession with physical activity on a moderate intensity level being defined as any form of physical activity that causes a small increase in breathing or heart rate (such as brisk walking, bicycling, vacuuming, or gardening). Second, participants were asked how many days a week they were physically active on a vigorous intensity level for 20 minutes in succession, with physical activity on a vigorous intensity level being defined as any activity that causes a large increase in breathing or heart rate (such as running, aerobics, or heavy yard work). Based on these 2 questions, the proportion of patients who were moderately active 30 minutes in succession on at least 5 days a week or vigorously active for 20 minutes in succession on at least 3 days a week was calculated.

Secondary outcome measures included the total number of days per week during which patients reported being moderately active for 30 minutes accumulated throughout the day or vigorously active for 20 minutes in succession. The amount of physical activity as measured by an activity monitor (Actilog V3.0; UMC St Radboud Nijmegen, The Netherlands). This activity monitor has the size of a matchbox and consists of a piezo-electric sensor that is sensitive in three directions. Accelerations of the sensor are stored into an internal memory. The microcontroller reads and resets the counter of the activity monitor every second. The integration counter is set at 5

minutes, providing every 5 minutes an activity score that is stored into the internal memory of the activity monitor. At the end of the registration period, data are fed into an external computer (24). Accelerometers based on a piezo-electric sensors were found to be reliable and valid measures of physical activity in healthy persons (25;26) as well as in patients chronic fatigue syndrome (24;27). Furthermore, monitoring for 5 consecutive days has been described to be sufficient to achieve a reliability of 0.80 (28). In this study, the activity monitor was worn around the ankle for 24 hours on 5 consecutive days, except during activities involving water (e.g. taking a bath). During the one-year intervention there were three measurements each consisting of 5 registration days: at baseline, 6 and 12 months. In order to retain 3 complete registration days, the first and the last registration days were omitted for the analysis. Specialized software (Actilog Analyzer V4.3 ®, UMC St Radboud Nijmegen) was used to calculate a general physical activity score over the 3-day period, expressed as the average number of accelerations per 5-minute period over the day, and the total number of five minute high (peak) activity periods over the day, where the average general physical activity score of the GT group was used as the cut-off level.

Another secondary outcome measure was functional ability, assessed with the MACTAR, which includes limitations in daily activities elicited from and ranked by the patient at baseline. The change scores range from -38 (maximum deterioration) to +38 (maximum improvement) (22). In addition, the Health Assessment Questionnaire (HAQ) was used, covering 20 activities of daily living in 8 dimensions, with the score of each activity ranging from 0 (without any difficulty) to 3 (unable to do). The total HAQ score is the average score of the 8 dimensions (range 0=best possible function to 3=worst possible function) (29).

Quality of life was measured with the Rheumatoid Arthritis Quality of Life (RAQoL) questionnaire, consisting of 30 items with a yes/no (1/0) response format. The overall score is the sum of the individual item scores, with a lower score indicating better quality of life (range 0-30) (30). In addition, a validated Dutch version of the RAND 36-Item Health Survey (31) was used, which includes 8 subscales. Each subscale generates a score from 0 to 100, with higher scores indicating better health. The RAND can be converted to two summary scales: the physical and mental component summary scale.

Disease activity was measured with the 28-joint Disease Activity Score (DAS28) with four variables, a validated composite index containing the 28-joint count for tenderness, the 28-joint count for swelling, erythrocyte sedimentation rate and the patient's overall assessment of well-being (32).

Statistical Analysis

The target study sample size was based on the proportion of participants that would meet the Dutch public health recommendation for physical activity. Based on the results of former studies (33;34), it was estimated that 50% of the patients in the IT group and 25% of the patients in the GT group would meet the recommendation after 12 months. With 80% power and a significance level of 0.05, 59 patients would be required in each group. To compensate for an expected dropout rate of 15%, we planned to enroll at least 80 patients in each group.

Differences between the groups at baseline, the use of health care services and change in DMARD medication during the study were analyzed by the Mann-Whitney U test or Chi-square test where appropriate. A Pearson chi-square test or a Fisher's exact test was used when the two groups were compared with respect to a dichotomous outcome measure. For continuous outcome measures within each group at each follow-up time point change scores from baseline with the 95% confidence interval (95% CI) were computed. The differences between the two groups at the various time points were analyzed according to the changes scores during follow up. Effect sizes were calculated as the difference in changes from baseline between the IT and GT group, divided by the pooled SD of the change scores of the two groups. To compare the effectiveness over the total period of one year, repeated measures were analyzed with a general linear mixed model, with patient number as a random factor and treatment, time, and treatment $\times$ time interaction as fixed effects. The interaction term was used to determine whether there was a significant change in time between the two groups. Furthermore, to assess the effect of time within both groups a mixed-effects model was used with patient number as random effect and time as covariate.

The primary analyses of effectiveness were based on intention to treat as initially assigned. All available data were used. As a secondary analysis a per protocol analysis on the physical activity outcome measures was done, comparing only the patients in the IT intervention group who had a high (75-100%) schedule usage rate with all the patients in the GT intervention group. With all analyses a p-value of less than 0.05 was adopted as the criterion for statistical significance. All data were analyzed using SPSS version 12.0 software (SPSS, Chicago, IL).

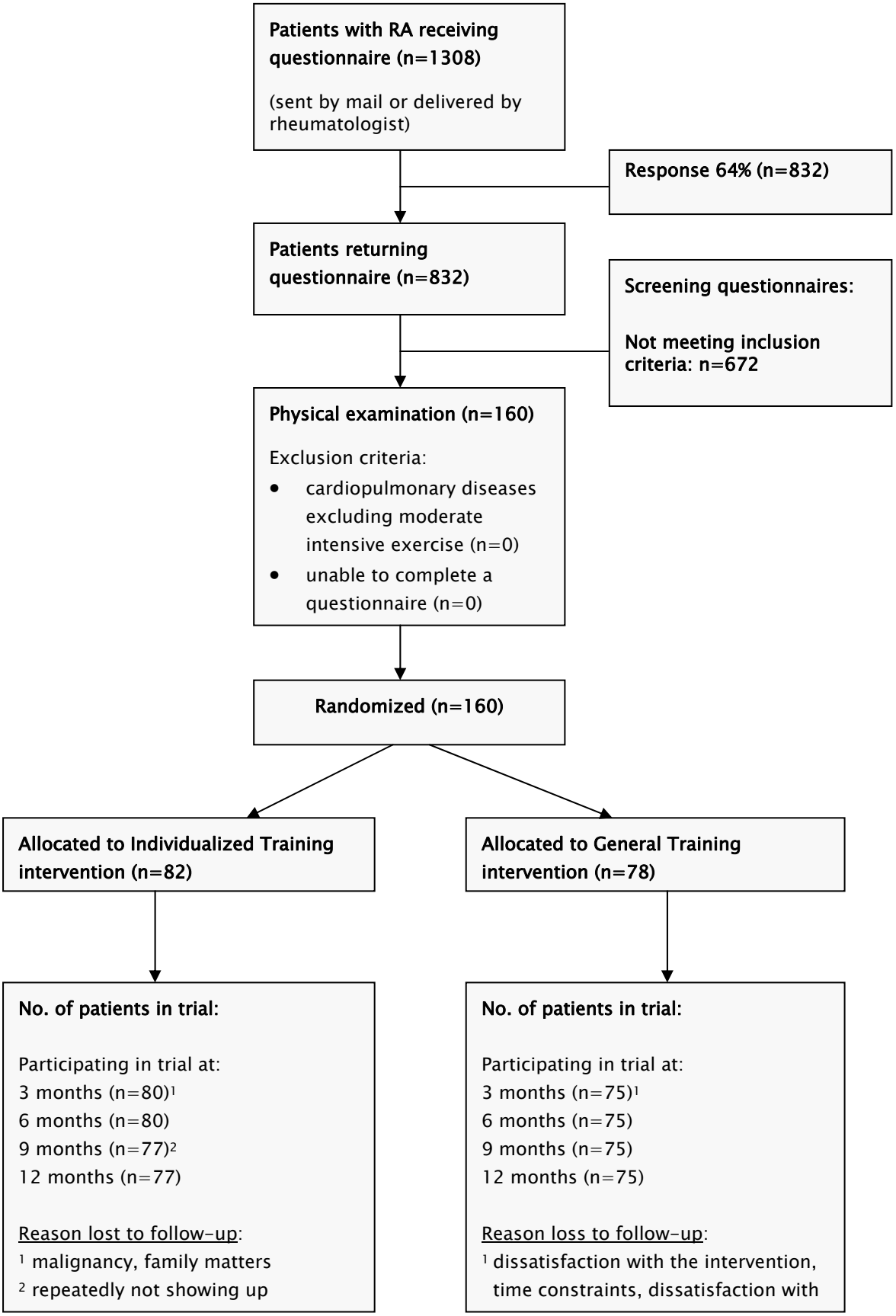

Figure 1. Flow diagram of the trial.

Results

In total, 1308 patients with RA were sent a questionnaire (Figure 1), with 832 questionnaires being returned (response rate 64%). Of these, 160 patients fulfilled the initial inclusion criteria, had a verified diagnosis of RA and were subsequently invited for the final screening visit. All these 160 patients were eligible for the study and were randomized, with 82 patients being allocated to the IT and 78 to the GT group. There were no significant differences between baseline characteristics of patients in the IT and GT groups (Table 1). Five patients from the IT group (6%) and three patients from the GT group (4%) were lost to follow-up (Figure 1).

Table 1. Baseline demographic and clinical characteristics* of 160 patients with RA participating in a randomized controlled trial comparing the effectiveness of two Internet-based physical activity programs*

	Individualized Training group (n=82)	General Training group (n=78)	P-value†
Age, years; median (IQR)	49.5 (12.9)	49.8 (13.9)	0.66
Duration of RA, years; median (IQR)	7.6 (8.8)	5.5 (11.3)	0.09
Past number of DMARDs, median (IQR)	1.0 (1.3)	1.0 (2.0)	0.098
Body Mass Index, kg/m^2; median (IQR)	25.7 (5.5)	25.1 (7.3)	0.47
Female	62 (76)	60 (77)	0.85
Rheumatoid factor positive	53 (65)	46 (60)	0.46
Current treatment			
NSAIDs	58 (71)	50 (64)	0.37
DMARDs	74 (90)	70 (90)	0.92
Presence of co-morbidity	38 (46)	29 (37)	0.24
Current smoker	17 (21)	20 (26)	0.46
Living alone	15 (18)	12 (15)	0.62
Education level‡			
Low	15 (18)	15 (19)	
Medium	50 (61)	42 (54)	0.60
High	17 (21)	21 (27)	
Gainfully employed	47 (57)	46 (59)	0.83

* Values are the number (%) of patients, unless indicated otherwise. Interquartile ranges (IQRs) are expressed as the net result of 75th percentile minus the 25th percentile. NSAIDs = nonsteroidal anti-inflammatory drugs; DMARDs = disease-modifying antirheumatic drugs.

† Differences were analyzed using Mann-Whitney U test or chi-Square test where appropriate.

‡ Low: up to and including lower technical and vocational training; medium: up to and including secondary technical and vocational training; high: up to and including higher technical and vocational training and university.

Concurrent interventions and usage of health care

No significant differences between the two groups were found with respect to the proportion of patients in whom the DMARDS were changed or in the proportion of patients visiting a rheumatologist, general practitioner, physical therapist, rheumatology nurse specialist, occupational therapist, dietician or social worker one or more times (data not shown). A significantly greater proportion of patients in the IT group underwent surgery during the study as compared to the GT group (12% vs. 5%, $p=0.02$).

Usage of website and online physical activity schedules

After 3 months, 63 patients (86%) in the IT group and 9 (16%) in the GT group logged in to the website at least once a week. These numbers (%) were 60 (75%) and 4 (6%) after 6 months, 46 (62%) and 3 (5%) after 9 months, and 42 (55%) and 5 (7%) after 12 months in the IT and GT groups, respectively (all $p<0.001$). The median schedule usage rate of the patients in the IT intervention group was 55% (interquartile range 74.4). The schedule usage rate was high (75-100%) in 35 patients (43%), sufficient (50-75%) in 8 patients (10%) and low (<50%) in 39 patients (48%).

Primary outcome measure

The proportion of patients who were physically active at a moderate intensity level for 30 minutes in succession on at least 5 days a week was significantly greater in the IT than in the GT group at 6 (38% vs. 22%; $p=0.041$) and 9 months (35% vs. 11%; $p=0.001$) (Table 2). Due to a logistic failure during the study, no data at 3 months were available. In addition, the proportion of patients meeting this activity level at any follow-up time point was significantly greater in the IT group.

The proportion of patients who were physically active on a vigorous intensity level for 20 minutes in succession on at least 3 days a week was significantly greater in the IT than in the GT group at 6 (35% vs. 13%), 9 (40% vs. 14%), and 12 months (34% vs. 10%; all $p<0.005$). Moreover, the proportion of patients who met this recommendation at any time follow-up point was significantly greater in the IT group.

Table 2. Numbers (%) of patients with RA being physically active for 30 minutes in succession on at least 5 days a week and being vigorously active for 20 minutes in succession on at least 3 days a week in a randomized clinical trial comparing two Internet-based physical activity programs*

	IT group all patients	IT group schedule users	GT group	P-value IT group all vs. GT group#	P-value IT group schedule users vs. GT group†
Moderate activity for 30 minutes in succession on at least 5 days a week					
Baseline	0 (0)	0 (0)	0 (0)		
3 months	no data	no data	no data		
6 months	29 (38)	17 (52)	15 (22)	0.041‡	0.003‡
9 months	26 (35)	18 (51)	7 (11)	0.001‡	<0.001‡
12 months	19 (26)	14 (42)	11 (15)	0.120	0.002‡
At least on one time point#	42 (54)	25 (71)	21 (30)	0.003‡	<0.001‡
Vigorous activity for 20 minutes in succession on at least 3 days a week					
Baseline	5 (6)	1 (3)	1 (1)	0.109	0.557
3 months	27 (39)	16 (46)	14 (25)	0.093	0.036‡
6 months	27 (35)	17 (49)	9 (13)	0.002‡	<0.001‡
9 months	29 (40)	22 (65)	9 (14)	0.001‡	<0.001‡
12 months	26 (34)	22 (65)	7 (10)	<0.001‡	<0.001‡
At least on one time point#	45 (64)	29 (85)	25 (38)	0.002‡	<0.001‡

* Values are the number (%) of patients, unless indicated otherwise. See Table 1 for additional definitions.

† Chi-Square test performed for intention to treat analysis (Individualized Training group all vs. General Training group all) and per protocol analysis (Individualized Training group schedule users vs. General Training group all). Schedule users = the 35 patients in the IT group who had a high (75-100%) schedule usage rate.

‡ $p<0.05$ IT group vs. GT group.

At least on one time point = number of patients meeting the physical activity recommendation on at least one of the follow-up time points.

Secondary outcomes measures

The changes in the average number of days a week on which the patients were physically active on a moderate intensity level for 30 minutes accumulated are shown in Table 3. The increase was significantly greater in the IT group than in the GT group at 6 months (mean difference between groups 1.1 days a week). The changes in the average number of days on which patients were physically active on a vigorous intensity level for 20 minutes in succession was significantly greater in the IT than in the GT group at all follow-up time points (mean difference between groups 1.0, 1.1, 1.1 and 0.9 days a week, respectively) and over the total follow-up period ($p=0.001$). The change in the number of days on which patients were physically active at a moderate intensity level declined in both groups after 3 months, with the overall decline between 3 and 12 months reaching statistical significance in the IT group ($p=0.02$).

A per-protocol analysis, comparing the 35 patients in the IT group who had a high schedule usage rate with all the patients in the GT group showed that the differences between the two groups in favor of the IT intervention increased (Tables 2 en 3). Excluding the patients in both groups who underwent surgery during the study did not cause any major changes in the reported outcome measures (data not shown).

The results regarding changes in physical activity according to the activity monitor are shown in Table 4. No statistical differences between the IT and the GT groups were found with respect to the changes in the general activity score, the peak amplitude or the number of peaks found during the 3 days of analysis.

In general, the improvement of functional ability and quality of life was greater in the IT than in the GT group (Table 5), with none of the differences reaching statistical significance, except for a greater improvement of the RAQoL in favor of the IT group at 9 months. There were no statistical differences in changes of the RAND-36 physical and mental summary scales, nor of the DAS28-score between the groups.

Table 3. Baseline and change scores regarding the number of days per week on which patients with RA were physically active on a moderate intensity level for 30 minutes accumulated or on a vigorous intensity level for 20 minutes in succession in a randomized clinical trial comparing two Internet-based physical activity programs*

	IT group all	IT group schedule users	GT group	Difference between change in IT group all and change in GT group, mean; effect size (95% CI) †	Difference between change in IT group schedule users and change in GT group, mean; effect size (95% CI) †
Number of days per week of moderate activity for 30 minutes accumulated					
Baseline, mean (IQR)	2.0 (3.0)	2.0 (3.0)	3.0 (4.0)		
3 months	1.7 (1.12, 2.23) ‡	1.5 (0.70, 2.27) ‡	1.0 (0.35, 1.58) ‡	0.7; 0.3 (-0.1, 0.7)	0.5; 0.2 (-0.2, 0.6)
6 months	1.6 (1.03, 2.22) ‡	1.9 (1.01, 2.70) ‡	0.5 (-0.07, 1.04)	1.1; 0.5 (0.1, 0.8) ‡	1.4; 0.6 (0.2, 1.0) ‡
9 months	1.2 (0.64, 1.69) ‡	1.8 (1.04, 2.49) ‡	0.5 (-0.10, 1.08)	0.7; 0.3 (-0.1, 0.6)	1.3; 0.6 (0.1, 1.0) ‡
12 months	1.1 (0.58, 1.61) ‡	1.9 (1.17, 2.54) ‡	0.7 (0.06, 1.28) ‡	0.4; 0.2 (-0.2, 0.5)	1.2; 0.5 (0.1, 0.9) ‡
$P_{overall}$ for all time points#				p=0.051	p=0.011‡
Number of days per week of vigorous activity for 20 minutes in succession					
Baseline, mean (IQR)	0 (1.0)	1.0 (1.0)	0 (1.0)		
3 months	1.8 (1.35, 2.21) ‡	2.1 (1.47, 2.76) ‡	0.8 (0.41, 1.14) ‡	1.0; 0.6 (0.3, 1.0) ‡	1.3; 0.8 (0.4, 1.3) ‡
6 months	1.4 (0.98, 1.80) ‡	2.2 (1.47, 2.88) ‡	0.3 (0.06, 0.52) ‡	1.1; 0.7 (0.4, 1.1) ‡	1.9; 1.3 (0.9, 1.8) ‡
9 months	1.6 (1.13, 2.10) ‡	2.8 (2.16, 3.47) ‡	0.5 (0.22, 0.76) ‡	1.1; 0.7 (0.3, 1.0) ‡	2.3; 1.6 (1.1, 2.1) ‡
12 months	1.3 (0.84, 1.74) ‡	2.5 (1.86, 3.14) ‡	0.4 (0, 0.72)	0.9; 0.5 (0.2, 0.9) ‡	2.1; 1.3 (0.9, 1.7) ‡
$P_{overall}$ for all time points#				p=0.001‡	p<0.001‡

* Values are the mean (95% CI) change from baseline values unless indicated otherwise. IQRs are expressed as the net result of 75th percentile minus 25th percentile]). See Table 1 for additional definitions.

† Mean difference between change in the Individualized Training group and change in the General Training group (intention to treat analysis) and between change in the Individualized Training group schedule users and in the General Training group all (per protocol analysis). Schedule users = the 35 patients in the IT group who had a high (75-100%) schedule usage rate. Effect size (95% CI) = difference in change score from baseline between Individualized Training group and General Training group divided by pooled SD of change scores.

‡ p<0.05 IT group vs. GT group.

By linear mixed-effects model (test for interaction between group and time).

Table 4. Results of 3 activity parameters as measured by the activity monitor (Actilog V3.0) in patients with RA*

	IT group	GT group	Difference between change in IT group and change in GT group, mean; effect size (95% CI)†
General physical activity score‡			
Baseline, median (IQR)	72.0 (33.5)	79.0 (25.8)	
6 months	−3.0 (−9.3, 3.4)	−7.3 (−13.3, −1.3)§	4.3; 0.2 (−0.2, 0.5)
12 months	0.3 (−7.1, 7.6)	1.7 (−5.1, 8.5)	−1.5; −0.1 (−0.4, 0.3)
$P_{overall}$ for all time points#			p=0.46
Peak amplitude‡			
Baseline, median (IQR)	163.0 (48.0)	167.5 (25.0)	
6 months	2.2 (−6.9, 11.3)	−4.5 (−13.6, 4.6)	6.7; 0.2 (−0.2, 0.5)
12 months	−1.7 (−10.4, 7.0)	2.8 (−6.0, 11.6)	−4.5; −0.1 (−0.5, 0.2)
$P_{overall}$ for all time points#			p=0.06
Number of peaks found			
Baseline, median (IQR)	22.0 (8.0)	24.0 (7.0)	
6 months	0.6 (−0.8, 1.9)	−1.1 (−2.9, 0.8)	1.6; 0.3 (−0.1, 0.6)
12 months	0.6 (−0.9, 2.0)	−0.9 (−2.5, 0.7)	1.5; 0.2 (−0.1, 0.6)
$P_{overall}$ for all time points#			p=0.34

* Values are the mean (95% CI) change from baseline values unless indicated otherwise. IQRs are expressed as the net result of 75th percentile minus 25th percentile. See Table 1 for additional definitions.
† Mean difference (95% CI) between change in the IT group and change in the GT group. Effect size (95% CI) = difference in change score from baseline between IT group and GT group divided by pooled SD of change scores.
‡ Expressed as the number of accelerations per 5-min period.
§ $p<0.05$ IT group vs. GT group.
# By linear mixed-effects model (test for interaction between group and time).

Discussion

This study demonstrates that in patients with RA, an Internet-based physical activity intervention with the provision of individually tailored supervision, exercise equipment and group contacts is more effective with respect to the proportion of patients who report meeting physical activity recommendations than an Internet-based program without these additional elements. No differences were found with respect to the total amount of physical activity as measured with an activity monitor. There were no sustained differences between the two programs regarding functional ability and quality of life.

Table 5. Functional ability, quality of life and disease activity in patients with RA participating in a randomized clinical trial comparing two Internet-based physical activity programs*

	IT group	GT group	Difference between change in IT group and change in GT group, mean; effect size (95% CI)†
Functional ability by MACTAR score			
Baseline	51.0 (4.0)	50.0 (4.0)	
6 months	2.4 (0.5, 4.4)‡	3.4 (1.5, 5.3)‡	−1.0; −0.1 (−0.4, 0.2)
12 months	4.2 (2.5, 6.0) ‡	2.5 (0.2, 4.7)‡	1.8; 0.2 (−0.1, 0.5)
$P_{overall}$ for all time points#			p=0.32
Functional ability by HAQ score			
Baseline	0.75 (1.13)	0.75 (0.75)	
3 months	0.02 (−0.06, 0.10)	−0.01 (−0.07, 0.06)	0.02; 0.08 (−0.26, 0.42)
6 months	−0.04 (−0.12, 0.04)	−0.03 (−0.10, 0.03)	−0.01; −0.02 (−0.35, 0.30)
9 months	−0.05 (−0.12, 0.02)	−0.03 (−0.11, 0.05)	−0.02; −0.06 (−0.40, 0.27)
12 months	−0.09 (−0.16, −0.01)‡	−0.04 (−0.11, 0.04)	−0.05; −0.15 (−0.47, 0.18)
$P_{overall}$ for all time points#			p=0.41
Quality of Life by RAQoL score			
Baseline	10.0 (10.2)	10.0 (9.5)	
3 months	−1.1 (−2.15, 0)	−0.4 (−1.10, 0.28)	−0.7; −0.2 (−0.5, 0.2)
6 months	−1.0 (−2.06, 0.04)	−0.5 (−1.33, 0.28)	−0.5; −0.1 (−0.4, 0.2)
9 month	−2.0 (−2.92, −0.98)‡	−0.3 (−1.18, 0.58)	−1.7; −0.4 (−0.8, −0.1)‡
12 months	−1.3 (−2.35, −0.34)‡	−0.6 (−1.37, 0.24)	−0.8; −0.2 (−0.5, 0.1)
$P_{overall}$ for all time points#			p=0.12
Quality of Life by RAND-36 score: *Physical summary scale*			
Baseline	52.8 (40.1)	54.4 (42.8)	
3 months	1.6 (−2.0, 5.2)	4.6 (1.1, 8.1)‡	−3.0; −0.2 (−0.6, 0.1)
6 months	3.2 (−0.1, 6.5)	4.1 (0.3, 7.9)‡	−0.8; −0.1 (−0.4, 0.3)
9 months	6.4 (2.6, 10.1)‡	2.4 (−1.7, 6.6)	3.8; 0.2 (−0.1, 0.6)
12 months	4.9 (1.1, 8.7)‡	4.0 (0, 8.1)‡	1.2; 0.1 (−0.3, 0.4)
$P_{overall}$ for all time points#			p=0.08
Quality of Life by RAND-36 score: *Mental summary scale*			
Baseline	75.1 (26.2)	73.0 (30.5)	
3 months	1.1 (−2.8, 5.0)	3.9 (0.4, 7.5)‡	−2.8; −0.2 (−0.5, 0.2)
6 months	1.9 (−2.0, 5.8)	3.3 (−1.1, 7.7)	−1.5; −0.1 (−0.4, 0.2)
9 months	1.3 (−2.7, 5.2)	−2.0 (−6.9, 2.9)	3.3; 0.2 (−0.2, 0.5)
12 months	−0.2 (−4.8, 4.3)	0.8 (−2.9, 4.5)	−0.9; −0.1 (−0.4, 0.3)
$P_{overall}$ for all time points#			p=0.38
Disease activity by DAS28 score			
Baseline	3.5 (2.3)	3.3 (2.1)	
6 months	−0.3 (−0.5, −0.1)‡	−0.4 (−0.6, −0.1)‡	0.1; 0.1 (−0.2, 0.4)
12 months	−0.4 (−0.6, −0.1)‡	−0.5 (−0.7, −0.2)‡	0.1; 0.1 (−0.3, 0.4)
$P_{overall}$ for all time points#			p=0.63

* Values are the mean (95% CI) change from baseline values unless indicated otherwise. IQRs are expressed as the net result of 75th percentile minus 25th percentile. See Table 1 for additional definitions.

† Mean difference (95% CI) between change in the IT group and change in the GT group. Effect size (95% CI) = difference in change score from baseline between IT group and GT group divided by pooled SD of change scores.

‡ $p<0.05$ IT group vs. GT group.

By linear mixed-effects model (test for interaction between group and time).

Our findings confirm the results of earlier studies on the effectiveness of programs in which the promotion of daily physical activity for patients with arthritis played a major role. The People with Arthritis Can Exercise (PACE) program (14), developed by the Arthritis Foundation in the US, appeared to have positive effects on psychosocial status and physical functioning in patients with arthritis. In patients with osteoarthritis physical activity programs including the use of a pedometer (15) or individual physical activity counseling (16) were also shown to be effective. Due to the absence or the use of different measures of physical activity in the above-mentioned studies, a direct comparison with the outcomes of the present study is not possible.

So far, no studies regarding the use of Internet to promote physical activity in patients with arthritis are available. Studies in healthy adults demonstrated the effectiveness of Internet-based physical activity interventions consisting of an interactive website plus weekly e-mail messages (17), 3 tailored electronic newsletters (35) or weekly e-mail messages (36). Another study found no differences with respect to reported physical activity between a printed versus a website version of a physical activity intervention in healthy people (37). In patients with type 2 diabetes, McKay (19) demonstrated the potential of an 8-week Internet-based personalized physical activity program including online personal counseling and support. Two other studies among healthy adults that used more conventional methods to enhance physical activity, reported their physical activity outcomes in similar terms as our study (38;39). In comparison with these studies, in which the increase of the proportion of patients meeting the physical activity recommendations ranged between 19% and 23%, our results seem to be fairly favorable.

In our study, a decline in the proportion of patients meeting the physical activity recommendation after three months was found, especially in the IT group. Other studies have reported decreasing compliance with exercise or physical activity programs as well (40;41). Suggested strategies to improve and maintain compliance include developing more theory-based physical activity interventions, promoting self-regulatory skills, and utilizing phone contacts for home-based activity programs (42). In parallel with the declining compliance with physical activity recommendations, the usage of the website decreased. Declining website usage over time has also been reported in other studies which were aimed at influencing health-related behavior by means of a website (19;43). More interactive website features, incentives and news letters are some of the suggested tools to stimulate regular use (19;43).

In our study, physical activity was measured both by a questionnaire and by an activity monitor. It is known that people filling in questionnaires tend to over-report physical activity and

underestimate sedentary pursuits such as watching television (44). Although we used a control group for comparison, an overestimation of the amount of physical activity in the IT group more than in the GT group cannot be totally ruled out, due to the high demand characteristics of the IT intervention. In our study, the results regarding self-reported physical activity did not run parallel with those of the activity monitor in neither of the groups. One source of discrepancy may be related to the fact that the activity monitor cannot record activities involving water, such as swimming. Since swimming is a rather popular activity among patients with arthritis, an underestimation of the total amount of physical activity as measured with the activity monitor could have occurred. Moreover, a period of 5 days (yielding only 3 full registration days) may have been too short. However, in other studies in which activity monitors were used, similar discrepancies with questionnaires were found (45;46), even if activity monitors were worn for periods as long as 12 days (24). The discrepancy between the total amount of physical activity as reported by patients and that recorded with a physical activity monitor points at the need for more research into outcome measurement of physical activity.

In this study, improvements in functional ability and quality of life were greater in the IT group than in the GT group; however, the differences did not reach statistical significance. It could be hypothesized that the sample size was too small to detect any treatment effect; however as the absolute differences were small, their clinical relevance could still be doubtful. Overall, improvements in functional ability and quality of life were small in both groups, a finding that could be related to the fact that there were relatively high baseline values in both groups, leaving little room for improvements. Since the promotion of physical activity is in part targeted at influencing long-term health benefits, such as the prevention of cardiovascular diseases, diabetes mellitus and osteoporosis, it is questionable whether clinical effectiveness regarding functional ability and quality of life was to be expected. In fact, to demonstrate the long-term health benefits of physical activity interventions, studies should encompass a long follow-up period and probably use other outcome measures.

The results of our study show that delivering a home-based physical activity program by means of the Internet with the provision of individualized supervision, is a promising intervention strategy to promote physical activity in patients with RA. Although it is generally acknowledged that advising adults with arthritis to become more physically active should be a fixed element in the management of this condition (12), others have reported that a considerable number of patients did not receive such advice (47). It appears that the rheumatologist might play an

important part in the education on physical activity (48). However, it was found that advice alone is not enough to increase physical activity levels of patients with arthritis (47) and in that respect the use of Internet and e-mail could be used for sustained individual guidance and reinforcement. Although the present study only included patients who had a computer with Internet access, so that the results cannot be generalized to all patients with arthritis, nowadays almost half of the arthritis population has access to the Internet and this proportion seems to be growing (49;50). Our results suggest that future research should further explore the optimal strategy for the use of Internet and e-mail communication for promoting physical activity and maintaining or improving participants' compliance with these programs over time. Moreover, cost-effectiveness analyses of Internet-based physical activity interventions are urgently needed to determine the surplus value for daily practice.

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