Effects of a Group-Based Exercise and Educational Program on Physical Performance and Disease Self-Management in Rheumatoid Arthritis: A Randomized Controlled Study
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Effects of a Group-Based Exercise and Educational Program on Physical Performance and Disease Self-Management in Rheumatoid Arthritis: A Randomized Controlled Study

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Background. Evidence supports the use of educational and physical training programs for people with rheumatoid arthritis (RA).

Objective. The purpose of this study was to evaluate the effects of a group-based exercise and educational program on the physical performance and disease self-management of people with RA.

Design. This was a randomized controlled trial.

Setting. The study was conducted at a rehabilitation center in the Netherlands.

Participants. Thirty-four people diagnosed with RA participated in the study. Participants were randomly assigned to either an intervention group (n=19) or a waiting list control group (n=15).

Intervention. The intervention in this study was an 8-week, multidisciplinary, group therapy program for people with RA, consisting of physical exercise designed to increase aerobic capacity and muscle strength (force-generating capacity) together with an educational program to improve health status and self-efficacy for disease-self-management.

Measurements. The main outcome measures were maximum oxygen uptake ($V_{O2}$max), muscle strength of the elbow and knee flexors and extensors, health status, and perceived self-efficacy. All data were recorded before intervention in week 1, after intervention in week 9, and at follow-up in week 22.

Results. The intervention group showed significant improvement (12.1%) in $V_{O2}$max at week 9 compared with the control group (-1.7%). Although significant within-group changes were found over time for muscle strength of the upper and lower extremities and health status that favored the intervention group, no between-group changes were found regarding these outcomes.

Limitations. An important limitation was the small number of participants included in our study, which may have resulted in a lack of power.

Conclusions. The present group-based exercise and educational program for people with RA had a beneficial effect on aerobic capacity but not on muscle strength, health status, or self-efficacy.
Rheumatoid arthritis (RA) is a chronic, systemic, inflammatory, progressive disease, with joint synovitis as its main manifestation. It is a painful disease, with symptoms that can include joint pain, swelling, increased temperature, morning stiffness, and limited physical functioning. The disease often is accompanied by fatigue and malaise. The symptoms are unpredictable, depending on remission or exacerbation of the disease, and can have a significant effect on the patient’s daily life.

Studies have shown that most people with RA tend to avoid physical activity due to their fear of overstraining themselves or pain exacerbations. Avoidance of activities may result in decreased muscle strength (force-generating capacity) and aerobic capacity, which can lead to further inactivity. Compared with people without RA, people with the disease show significant decreases in muscle strength, muscle endurance, and aerobic capacity. Furthermore, people with RA are at greater risk with regard to cardiovascular morbidity and mortality compared with people who are healthy. Because of the wide range of the consequences, rehabilitation programs should aim at both maintaining physical functioning and teaching people how to deal with the disease and its consequences.

With respect to physical functioning, a growing number of studies show that dynamic exercise training seems to be effective in increasing aerobic capacity and muscle strength of people with RA. More specifically, intensive dynamic training appears to be more effective than isometric training in increasing aerobic capacity and muscle strength. Other studies indicate that moderate- to high-intensity exercise in water can lead to improvements in muscle endurance, muscle strength, and aerobic capacity. It has been reported that physical exercise can improve functional ability, quality of life, and physical and emotional health status. In addition, a study among older adults showed beneficial effects on self-efficacy after high-velocity training and traditional strength training.

Until now, however, there has been little consistency in how these physical training programs are delivered. The activities used vary from aerobic pool exercise to bicycling and walking with different types of strengthening exercises. Furthermore, the frequency and duration of the programs vary between 3 and 5 times per week for as little as 4 to 5 weeks whereas other programs continue for as long as 2 years. The variations in the exercise programs make it difficult to determine which intervention produces the best results. It is important to note, however, that despite these variations, most studies demonstrated no increase in disease activity and joint swelling. Three studies even observed a positive reduced effect on (ie, decrease in) the number of clinically active joints postexercise. Clinical fears that high-intensity exercise may lead to an increase in disease activity and joint destruction are not necessarily justified. On the contrary, the literature supports appropriate exercise as both safe and beneficial for people with RA.

People with RA manage the disease and its consequences every day, which requires their active involvement. The responsibility for this day-to-day disease management is gradually shifting from health care professionals to the individual. Taal et al stated that assisting people with RA to change their behavior in order to improve their self-management of the consequences of the disease is a very important factor in health education. Teaching people how to deal with RA often is incorporated within psycho-educational programs—an umbrella term that may include traditional education or teaching activities and psychological interventions. Prior research on psycho-educational programs has shown that they are capable of reducing pain and improving functional ability, psychological status, coping abilities, and self-management behaviors such as adherence to exercise and medication regimens. Clinically, one of the most frequently used programs is self-management training by laypeople or professionals. This training emphasizes changing behavior by presenting information and assistance in learning and adapting new activities and skills in order to manage the consequences of the disease. Adequate self-management, however, does imply that people are capable of performing the actions required.

An important research-based theoretical construct for helping individuals to develop this capability is called self-efficacy. Self-efficacy is a person’s confidence in his or her ability to perform a task or specific behavior or to change a specific cognitive state successfully, regardless of circumstances or contexts. To maintain improvement in physical performance in daily life, it has been recommended that interventions should include physical activity along with enhancement of

An Educational and Physical Training Program for People With Rheumatoid Arthritis

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self-efficacy with regard to performing those physical activities. In addition, baseline self-efficacy and changes in self-efficacy have been reported to be positively associated with future health status. Educational programs with the intent to improve self-management that are based on this self-efficacy theory should include its 4 sources: mastery performance, vicarious experience, cognitive re-processing, and verbal persuasion.

Currently, the effectiveness of a program consisting of education to improve disease self-management combined with intensive exercises is not clear. In the present study, we developed a group-based program for people with RA consisting of physical exercise to increase physical performance (ie, aerobic capacity and muscle strength) combined with an educational program to improve disease self-management (ie, self-reported health status and self-efficacy). We called it the “FIT program.” The aim of the present randomized controlled trial (RCT) was to examine the effects of the FIT program on aerobic capacity, muscle strength, self-reported health status, and self-efficacy in a group of people with RA. We hypothesized that the FIT program would have beneficial effects on physical performance and disease self-management in a group of people with RA compared with a waiting list control (WLC) group.

Method
Participants
A rheumatologist referred people diagnosed with RA to the rehabilitation department if they had complaints concerning their physical performance or if they experienced problems with the daily management of their illness. Referred participants were independent and living at home. They did not include residents of nursing homes.

To participate in the study, participants had to have a medical diagnosis of RA according to the American College of Rheumatology (ACR) criteria and had to be between 18 and 66 years of age. Participants were excluded if they had: (1) severe disease activity (Disease Activity Score [DAS-28] > 5.1), (2) cardiac or pulmonary diseases resulting in restrictions in their ability to follow a physical exercise program, (3) a Steinbrocker classification of functional capacity ≥ 3, (4) no stable medication for the RA, and (5) intra-articular injections during the time of the study. The DAS-28 includes a global assessment of 28 tender joint counts, a general health assessment using a visual analog scale, and an assessment of the erythrocyte sedimentation rate (ESR) (Tab. 1).

An explanation about the purpose and content of the study was given to each eligible participant. Referred individuals who did not want to participate in the study were able to follow the FIT program in a non-study group.

A total of 39 individuals were referred for this study. Thirty-four individuals (87%) returned a signed informed consent form, and 5 individuals decided not to participate for...
a variety of reasons. Twenty-four women and 10 men with a mean age of 48 years (SD=11.3, range=23–65) were included in the study and randomly assigned to either the intervention group (n=19) or the WLC group (n=15). The mean age of the participants was 45 years (SD=11.9) in the intervention group and 51.8 years (SD=9.4) in the WLC group. The majority of the participants in both groups were female (12 women in the intervention group and 12 women in the WLC group). Duration of RA was 9.7 years (SD=14.0) in the intervention group and 5.9 years (SD=7.2) in the WLC group. Mean DAS-28 score was 2.9 (SD=1.1) in the intervention group and 3.1 (SD=0.9) in the WLC group, indicating low disease activity for both groups. No significant differences in participants’ characteristics were found between the intervention group and the WLC group, indicating that the groups were comparable (Tab. 2).

Randomization
After checking the inclusion and exclusion criteria, participants were accepted for the study and listed. Due to the low rate of referrals, an unintended long period between the referral and the start of the intervention occurred. Due to this delay, we decided, for ethical reasons, to limit this period to a maximum of 3 months and start a study group when we had accrued enough qualified participants. The participants then were randomly assigned to groups. Presuming younger people often are more healthy than older people and men have more muscle strength than women, we stratified the participants to have an equal distribution by sex and age in each group. Cutoff

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Complete functional capacity with ability to carry on all usual duties without handicaps</td>
</tr>
<tr>
<td>Class II</td>
<td>Functional capacity adequate to conduct normal activities despite handicap of discomfort or limited mobility of 1 or more joints</td>
</tr>
<tr>
<td>Class III</td>
<td>Functional capacity adequate to perform only a few or none of the duties of usual occupation or of self-care</td>
</tr>
<tr>
<td>Class IV</td>
<td>Largely or wholly incapacitated, with patient bedridden or confined to wheelchair, permitting little or no self-care</td>
</tr>
<tr>
<td>DAS-28</td>
<td>High disease activity: DAS-28 &gt;5.1</td>
</tr>
<tr>
<td></td>
<td>Moderate disease activity: 3.2 &lt;DAS-28 ≤5.1</td>
</tr>
<tr>
<td></td>
<td>Low disease activity: DAS-28 ≤3.2</td>
</tr>
</tbody>
</table>

**Table 1.**
Steinbrocker Classification of Functional Capacity in People With Rheumatoid Arthritis and Disease Activity Score (DAS-28) Cutoff Scores

**Table 2.**
Participant Characteristics at Baseline for the Intervention and Waiting List Control (WLC) Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention Group (n=19)</th>
<th>WLC Group (n=15)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y), X (SD)</td>
<td>45 (11.9)</td>
<td>51.8 (9.4)</td>
<td>.06</td>
</tr>
<tr>
<td>Sex, female/male (n)</td>
<td>12/7</td>
<td>12/3</td>
<td>.28</td>
</tr>
<tr>
<td>Duration of RA in years, X (SD)</td>
<td>9.7 (14.0)</td>
<td>5.9 (7.2)</td>
<td>.67</td>
</tr>
<tr>
<td>DAS-28 score, X (SD)</td>
<td>2.9 (1.1)</td>
<td>3.1 (0.9)</td>
<td>.94</td>
</tr>
<tr>
<td>Current treatment</td>
<td></td>
<td></td>
<td>.36</td>
</tr>
<tr>
<td>NSAID</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>DMARD</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>NSAID + DMARD</td>
<td>13</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Biological + DMARD</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>No medication</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

* Comparisons between intervention and WLC groups based on Mann-Whitney U tests and chi-square tests. RA=rheumatoid arthritis, DAS-28=Disease Activity Score, NSAID=nonsteroidal anti-inflammatory drug, DMARD=disease-modifying antirheumatic drug.
age was defined depending on the age of people listed. An independent researcher randomly assigned participants to either the intervention group or the WLC group by drawing sealed tickets. The WLC group was allowed to enter the FIT program for rehabilitation after the study period. Four groups enrolled in the program over a 2-year period.

**Blinding**

All outcome assessors were blinded to group allocation for all participants. The assessors were not involved in the intervention. The DAS-28 score was determined by a nurse practitioner experienced in rheumatology. Two physical therapists examined the bicycle ergometry and handheld dynamometry results under standard conditions. The health care professionals who delivered the program were aware that participants were taking part in the study. All data were collected at the rehabilitation department of the University Medical Center Groningen (UMCG).

**Intervention: The FIT Program**

The FIT program was carried out in an outpatient setting at the rehabilitation center of UMCG. Participants in the intervention group followed an 8-week, multidisciplinary, group rehabilitation program, consisting of a physical exercise part and an educational component. The physical exercise part was conducted in group sessions and consisted of a muscle exercise circuit and bicycle training once a week for 60 minutes, sports once a week for 60 minutes, and aqua jogging twice a week for 30 minutes. The total amount of time each participant spent exercising was 3 hours per week on 2 separate days. All physical exercises were supervised by physical therapists experienced in guiding people with RA.

The muscle exercise circuit included 8 different fitness devices: leg press, leg extension, leg curl, rowing, chest press, abdominal trainer, back trainer, and En Tree pulley device. This isokinetic muscle exercise circuit was performed once a week at 40% to 60% of 1 repetition maximum, and the load was gradually increased by 5% a week. Each training session consisted of 3 sets of 20 contractions. In case of pain or other physical complaints, the load was temporarily decreased. The bicycle training started at 60% of the age-predicted maximum heart rate using the Karvonen formula: training heart rate = HRrest + [(HRmax − HRrest) × 60%], where HRmax is 220 − age and HRrest is resting heart rate. The training intensity was increased weekly depending on the participants’ individual performance. The training lasted about 10 to 20 minutes once a week. The sports consisted of different activities, such as badminton, table tennis, bowls, unihockey, and circuit training, so that participants became acquainted with different kinds of sports. We anticipated that the experience of different sports activities would lead to adoption of such activities after the intervention. Aqua jogging was included because this kind of endurance training minimizes joint stress.

The major goal of the education sessions was to increase participants’ knowledge concerning different aspects of their disease and its consequences, such as pain, fatigue, sleeping disorders, limited functional ability, and psychological distress. A secondary goal was to improve participants’ insight into their disease and activity management. The educational part consisted of a weekly 60-minute session. A multidisciplinary group of health care professionals consisting of a psychologist, a physical therapist, an occupational therapist, a dietitian, and a social worker gave specialist-oriented advice about how to handle the consequences of RA. Special attention was paid to adjusting each patient’s activity level to his or her actual energy level. Further information was given about body sensations, sports, food and energy, pain, fatigue, emotional changes, sleeping disturbances, and daily routine. People were invited to discuss these items together. They also were instructed to monitor their daily activities at home and to discuss them in the next session.

The primary goal of the physical exercise program was to increase aerobic capacity and muscle strength in order to improve overall physical performance. A secondary goal was to increase participants’ confidence in handling their rest-activity balance. The physical part of the program also purposefully incorporated the 4 methods of improving self-efficacy: (1) mastery experiences, (2) verbal persuasion, (3) vicarious experience, and (4) cognitive processing of physiologic and affective states. Mastery of performance was incorporated by adapting and gradually increasing the physical elements of the program so that every participant could do the training and perceive his or her individual success. Therapists gave feedback and encouragement to the participants on their actual performance and decision making in knowing when to stop or keep exercising. They gave participants an opportunity to watch how others performed and to discuss their own and others’ experiences and decision making regarding exercise. Finally, therapists taught participants to recognize that not all symptoms from exercise, such as tiredness, muscle discomfort, breathlessness, and so on, are dangerous.

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Outcome Measures

Outcome variables were measured in the intervention and WLC groups at the start of the FIT program (T0, week 1), at the end of the FIT program (T1, week 9), and 13 weeks after the FIT program had ended (T2, week 22).

Physical performance (aerobic capacity and muscle strength).

To assess aerobic capacity, participants used a cycle ergometer. Aerobic capacity was determined using the Åstrand-Rhyming ergometry test. This test measures maximum oxygen uptake (V\textsuperscript{\circ}O\textsubscript{2max}, in mL/min/kg), the standard index of cardiorespiratory fitness. The starting workload for participants on the cycle ergometer was based on their condition, age, and sex. The pedaling frequency was a standard 50 rpm, and the exercise load was increased by 25 W every minute until the heart rate reached 120 bpm. At this intensity, the load was considered adequate to continue the test protocol. Participants had to sustain cycling for about 6 minutes, and the heart rate was recorded every minute. The mean heart rate of the fifth and sixth minutes was registered. With the given workload, the observed heart rate, and the participants’ weight, the V\textsuperscript{\circ}O\textsubscript{2max} (in mL/min/kg) can be established using the Åstrand-Rhyming nomogram.\textsuperscript{41,42}

Muscle strength was assessed using a handheld dynamometer (Microfet\textsuperscript{1}). Maximal voluntary isometric muscle strength of the elbow flexors, elbow extensors, knee flexors, and knee extensors was tested and recorded 3 times for each muscle group. All tests were performed bilaterally. Elbow flexion and extension were measured with participants in a supine position. Knee flexion and extension were measured with participants sitting on a table. Each participant was directed to push as hard as possible against the dynamometer and hold the contraction for 4 seconds, at which point the tester told the participant to relax.\textsuperscript{43} The mean value of 3 measurements was computed. In addition, a sum score of the mean values of the upper-extremity (UE) and lower-extremity (LE) flexors and extensors on both sides was computed and used in the analyses.

Disease self-management (self-reported health status and self-efficacy).

Self-reported health status of the participants was assessed using the Dutch version of the Arthritis Impact Measurement Scales-2 (Dutch-AIMS2).\textsuperscript{27,44-46} The AIMS2 is a self-administered, arthritis-specific questionnaire.\textsuperscript{47-49} The Dutch-AIMS2 questionnaire contains 77 items measuring 12 areas of health status, which represent 5 dimensions: physical functioning, psychological functioning, symptoms, social interaction, and role functioning. Responses are recorded on a 5-point scale ranging from “all days” to “no days” or from “always” to “never.” All responses were recoded and calculated to a 0 to 10 scale. Scores were modified according to the number of comorbidity complaints, as was recommended in the Dutch-AIMS2 manual. A low score indicates better health. Previous studies have shown the internal consistency of the Dutch-AIMS2 questionnaire to be “sufficient to good,” with a Cronbach alpha value between .66 and .89.\textsuperscript{27,44,45} The World Health Organization defines health as a state of physical, psychological, and social well-being.\textsuperscript{50} Therefore, and due to our low number of participants, we used only the dimensions on physical functioning, psychological functioning, and social interaction in the analyses, as these are the most important measures for quality of life.

Self-efficacy was assessed with the Dutch version of the Arthritis Self-Efficacy Scale (ASES).\textsuperscript{23,27,51} The ASES contains 3 subscales: self-efficacy pain (5 items related to coping with pain, \( \alpha = .76 \) for internal reliability), self-efficacy function (8 items related to physical function, \( \alpha = .88 \)), and self-efficacy other symptoms (6 items related to coping with other symptoms, such as depression, fatigue, and frustrations, \( \alpha = .77 \)). A 5-point ordinal scale is used, ranging from “totally disagree” (1) to “totally agree” (5). A higher score refers to higher self-efficacy. We decided to combine all of the disease symptoms for analyses. We computed a mean score of 11 items (ie, 5 items for self-efficacy pain and 6 items for self-efficacy other symptoms). The self-efficacy scale for function was analyzed separately.

Data Analysis

Statistical analyses were performed using Statistical Package for the Social Sciences, version 14.0.\textsuperscript{52} The Student t and chi-square tests were used to assess differences in baseline sociodemographic and medical characteristics between the intervention and WLC groups. Normality of the data was assessed by plotting and using the Shapiro-Wilk test.\textsuperscript{52} Because of non-normal distributions, Friedman analyses of variance (ANOVs) were used to assess changes over time, taking into account T0, T1, and T2. The Friedman ANOVA can be used when a regular ANOVA cannot be performed based on violations of its assumptions such as normality. The Friedman ANOVA is based on ranked data.\textsuperscript{52} In addition, Mann-Whitney U tests were used to assess between-group changes on delta scores at T1 and T0. The significance level for all statistical tests was set at \( P<.05 \). To determine the clinical relevance of the

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\textsuperscript{1} HOGGAN Health Industries Inc, 12411 South 265 West, Draper, UT 84020.

\textsuperscript{2} SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.
An Educational and Physical Training Program for People With Rheumatoid Arthritis

The flow of participants in the study is shown in the Figure. One participant dropped out of the program and withdrew from the study. Another participant refused to fill in the questionnaires at T1 and did not show up at T2.

Effects of the FIT Program on Physical Performance

Aerobic capacity. Some \( \dot{V}O_2\max \) data (n=4 in the intervention group and n=2 in the WLC group) could not be collected because of specific participant conditions at the different testing time points. Four participants did not reach the necessary heart rate to estimate the \( \dot{V}O_2\max \). One participant had hypertension, and another had knee problems. The Mann-Whitney \( U \) test showed highly significant differences in \( \dot{V}O_2\max \) scores between the intervention group and the WLC group at T1 (\( P=.002 \)). This effect remained statistically significant after Bonferroni corrections (Tab. 3). The Friedman ANOVA showed highly significant changes in \( \dot{V}O_2\max \) over time within the intervention group (\( P=.009 \)) (Tab. 4). Within the WLC group, no significant changes over time were found (\( P=.24 \)) (Tab. 4). After intervention, the magnitude of improvement in \( \dot{V}O_2\max \) was 12.1\% in the intervention group and 1.7\% in the WLC group. The ES for \( \dot{V}O_2\max \) (0.35) indicated a small positive change (Tab. 3).

Upper-extremity muscle strength. The Mann-Whitney \( U \) test showed no significant differences in change scores for UE muscle strength between the intervention group and the WLC group at T1 (\( P=.16 \)). A Friedman analysis of muscle strength of the UEs showed significant changes over time within the intervention group (\( P=.035 \)). No significant changes over time were found within the WLC group (\( P=.82 \)). After intervention, muscle strength of the UEs improved by 5.1\% in the intervention group. The ES for UE muscle strength (0.15) indicated a trivial change. Muscle strength of the UEs in the WLC group decreased by 0.8\%.

Lower-extremity muscle strength. Lower-extremity muscle strength data for 1 participant in the WLC group are missing because knee problems prevented testing. Mann-Whitney \( U \) tests showed no significant differences in change scores for LE muscle strength between the intervention group and the WLC group at T0 and T1 (\( P=.21 \)) (Tab. 3). Friedman analyses on muscle strength of the LEs showed highly significant changes over time within the intervention group (\( P=.003 \)), but none within the WLC group (\( P=.61 \)). Effects remained statistically significant after Bonferroni corrections. After intervention, muscle strength of the LEs improved by 12.9\% in the intervention group and by 3\% in the WLC group. The ES for LE muscle strength (0.43) indicated a small positive change.

Effects of the FIT Program on Disease Self-Management

Self-reported health status. The Mann-Whitney \( U \) test on change scores for physical health at T1 between the intervention group and the WLC group narrowly missed significance (\( P=.07 \)) (Tab. 3). A Friedman analysis of within-group changes over time showed significant improvement within the intervention group (\( P=.05 \)) (Tab. 4). No significant changes over time were found within the WLC group (\( P=.23 \)). After intervention, the magnitude of improvement was −34\% in the intervention group and −9.3\% in the WLC group. The ES for physical health was −0.60, which indicated a moderate positive change.

The Mann-Whitney \( U \) test on change scores for psychological health at T1 between the intervention group and the WLC group showed no significant between-group differences (\( P=.4 \)). Friedman analyses showed no significant changes over time within the intervention group (\( P=.10 \)) and within the WLC group (\( P=.13 \)). After intervention, the magnitude of improvement was −13.7\% in the intervention group and 3.6\% in the WLC group. The ES for psychological health was −0.20, which indicated a small positive change.

Mann-Whitney \( U \) tests on change scores for social interaction showed no significant differences between the intervention group and the WLC group at T0 and T1 (\( P=.6 \)). Friedman tests on social interaction showed no significant changes over time within the intervention group (\( P=.55 \)) and group.
Number of referrals meeting entry criteria: n=39

Losses:
- Impairment due to trauma: n=1
- Not able to follow the program: n=1
- Personal reasons: n=3

Total number of participants included: n=34

Randomization

Intervention group, assessment at week 1 (T0) (n=19)

Losses:
- Withdrew from rehabilitation and study: n=1

Assessment at week 9 (T1) (n=18)

Losses:
- Withdrew from study, lack of motivation: n=1

Assessment at week 22 (T2) (n=17)

Analyzed T0-T1: n=18
Excluded from analysis:
- \( \text{VO}_2\text{max} \): n=3 (due to not reaching the necessary heart rate)
- AIMS2 and ASES: n=1 (refusal to fill in questionnaires)

Analyzed T0-T1-T2: n=17
Excluded from analysis:
- \( \text{VO}_2\text{max} \): n=4 (due to hypertension and not reaching the necessary heart rate)

WLC group, assessment at week 1 (T0) (n=15)

Assessment at week 9 (T1) (n=15)

Losses:
- Withdrew from study, lack of motivation: n=1

Assessment at week 22 (T2) (n=15)

Analyzed T0-T1: n=15
Excluded from analysis:
- \( \text{VO}_2\text{max} \): n=2 (due to knee problems and not reaching the necessary heart rate)
- Muscle strength, LE: n=1 (due to knee problems)

Analyzed T0-T1-T2: n=15
Excluded from analysis:
- \( \text{VO}_2\text{max} \): n=2 (due to knee problems and not reaching the necessary heart rate)
- Muscle strength, LE: n=1 (due to knee problems)

Figure.
Flow of participants through the study. WLC=waiting list control, \( \text{VO}_2\text{max} \)=maximal volume of oxygen uptake, Dutch-AIMS2=Dutch version of the Arthritis Impact Measurement Scales-2, ASES=Arthritis Self-Efficacy Scale, LE=lower extremity.
Table 3.
Effects of the FIT Program on Physical Performance, Measures of Aerobic Capacity, Upper-Extremity (UE) and Lower-Extremity (LE) Muscle Force, Perceived Health Status, and Perceived Self-Efficacy at Baseline and Postintervention, With Between-Group Changes, Percentage of Change, and Effect Size, for the Intervention and Waiting List Control (WLC) Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Participants Analyzed</th>
<th>Baseline (T0, Week 1)</th>
<th>Post-intervention (T1, Week 9)</th>
<th>Delta (T1−T0)</th>
<th>P (Between-Group Changes, Mann-Whitney U Test, Δ Intervention Group−Δ WLC Group)</th>
<th>Percentage of Change T0−T1</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical performance</td>
<td>Vo₂max (mL/kg/min)</td>
<td>Intervention group (n=15)</td>
<td>31.52 (10.17)</td>
<td>35.34 (11.33)</td>
<td>3.82 (3.86)</td>
<td>.002&lt;sup&gt;b&lt;/sup&gt;</td>
<td>12.1</td>
</tr>
<tr>
<td>Muscle strength, UE (N)</td>
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<td>−0.48 (1.90)</td>
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<td>−12.8</td>
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<td>ASES (intervention group, n=17; WLC group, n=15)</td>
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<td>Intervention group (n=17)</td>
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<td>0.34</td>
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<td>Function</td>
<td>Intervention group (n=17)</td>
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<td>7.2</td>
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<td>0.10 (0.38)</td>
<td>2.4</td>
<td>0.13</td>
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</tbody>
</table>

<sup>a</sup> Vo₂max = maximal volume of oxygen uptake, Dutch-AIMS2 = Dutch version of the Arthritis Impact Measurement Scales-2, ASES = Arthritis Self-Efficacy Scale.
<sup>b</sup> Significant after Bonferroni correction.
Table 4.
Effects of the FIT Program on Physical Performance, Measures of Aerobic Capacity, Upper-Extremity (UE) and Lower-Extremity (LE) Muscle Force, Perceived Health Status, and Perceived Self-Efficacy at Baseline, Postintervention, and Follow-up, With Within-Group Changes Over Time, for the Intervention and Waiting List Control (WLC) Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Participants Analyzed</th>
<th>Baseline (T0, Week 1)</th>
<th>Postintervention (T1, Week 9)</th>
<th>Follow-up (T2, Week 22)</th>
<th>P (Within-Group Changes Over Time, Friedman ANOVA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical performance</td>
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<td></td>
</tr>
<tr>
<td>V̇O₂max (mL/kg/min)</td>
<td>Intervention group (n=13)</td>
<td>32.15 (10.58)</td>
<td>36.31 (11.61)</td>
<td>34.67 (11.62)</td>
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<td>25.55 (6.36)</td>
<td>26.86 (5.99)</td>
<td>.24</td>
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<td>Muscle strength, UE (N)</td>
<td>Intervention group (n=17)</td>
<td>678.24 (268.13)</td>
<td>728.58 (224.65)</td>
<td>698.12 (242.01)</td>
<td>.04</td>
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<td>WLC group (n=15)</td>
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<td>659.08 (223.67)</td>
<td>675.89 (207.56)</td>
<td>.82</td>
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<tr>
<td>Muscle strength, LE (N)</td>
<td>Intervention group (n=17)</td>
<td>831.57 (270.39)</td>
<td>973.38 (233.26)</td>
<td>932.25 (248.62)</td>
<td>.003&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>WLC group (n=14)</td>
<td>853.64 (368.79)</td>
<td>879.26 (276.34)</td>
<td>909.38 (229.28)</td>
<td>.61</td>
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<td>Health status (Dutch-AIMS2) (intervention group, n=17; WLC group, n=15)</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Physical health</td>
<td>Intervention group (n=17)</td>
<td>1.95 (1.22)</td>
<td>1.27 (1.05)</td>
<td>1.41 (1.26)</td>
<td>.05</td>
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<td></td>
<td>WLC group (n=15)</td>
<td>1.51 (1.14)</td>
<td>1.37 (1.05)</td>
<td>1.39 (1.08)</td>
<td>.23</td>
</tr>
<tr>
<td>Psychological health</td>
<td>Intervention group (n=17)</td>
<td>2.47 (1.78)</td>
<td>2.12 (1.58)</td>
<td>2.34 (2.06)</td>
<td>.10</td>
</tr>
<tr>
<td></td>
<td>WLC group (n=15)</td>
<td>2.21 (1.27)</td>
<td>2.29 (1.31)</td>
<td>1.95 (1.12)</td>
<td>.13</td>
</tr>
<tr>
<td>Social interaction</td>
<td>Intervention group (n=17)</td>
<td>3.74 (1.86)</td>
<td>3.26 (1.37)</td>
<td>3.61 (1.76)</td>
<td>.55</td>
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<tr>
<td></td>
<td>WLC group (n=15)</td>
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<td>2.52 (1.24)</td>
<td>2.71 (1.30)</td>
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<tr>
<td>Pain + other symptoms</td>
<td>Intervention group (n=17)</td>
<td>3.12 (0.95)</td>
<td>3.54 (0.88)</td>
<td>3.49 (0.96)</td>
<td>.08</td>
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<tr>
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<td>WLC group (n=15)</td>
<td>3.34 (0.80)</td>
<td>3.63 (0.85)</td>
<td>3.56 (0.81)</td>
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<tr>
<td>Function</td>
<td>Intervention group (n=17)</td>
<td>4.03 (0.84)</td>
<td>4.32 (0.74)</td>
<td>4.24 (0.89)</td>
<td>.06</td>
</tr>
<tr>
<td></td>
<td>WLC group (n=15)</td>
<td>4.21 (0.73)</td>
<td>4.31 (0.87)</td>
<td>4.24 (0.69)</td>
<td>.46</td>
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</tbody>
</table>

<sup>a</sup>V̇O₂max=maximal volume of oxygen uptake, Dutch-AIMS2=Dutch version of the Arthritis Impact Measurement Scales-2, ASES=Arthritis Self-Efficacy Scale.
<sup>b</sup>Significant after Bonferroni correction.
within the WLC (P=.60) (Tab. 4). After intervention, the magnitude of improvement was −12.8% in the intervention group and −25.8% in the WLC group. The ES for social interaction was −0.29 for the intervention group and −0.49 for the WLC group, which indicated a small change (ie, improvement for both groups).

Perceived self-efficacy. Mann-Whitney U tests (T0−T1) showed no significant differences in change scores for self-efficacy pain and other symptoms between the intervention group and the WLC group (P=.47) (Tab. 3). Friedman analyses on self-efficacy pain and other symptoms showed no significant changes over time in the intervention group (P=.08). In the WLC group, no significant changes were found over time (P=.58) (Tab. 4). After intervention, the magnitude of improvement was 13.5% in the intervention group and 8.4% in the WLC group. The ES for self-efficacy pain and other symptoms was 0.46, which indicated a small positive change.

Mann-Whitney U tests (T0−T1) showed no significant differences in the change scores for self-efficacy function between the intervention group and the WLC group (P=.24). Friedman analyses showed nearly significant changes in self-efficacy function over time in the intervention group (P=.06). The WLC group showed no significant changes over time (P=.46). After intervention, the magnitude of improvement was 7% in the intervention group and 2.4% in the WLC group. The ES for self-efficacy function was 0.37, which indicated a small positive change.

Disease activity. Post hoc analyses regarding disease activity (DAS-28) showed no significant differences in change scores for disease activity between the intervention group (mean Δ=−0.30, SD=0.94) and the WLC group (mean Δ=−0.95, SD=0.85) at T1. Friedman analyses showed significant improvements in disease activity over time in the WLC group (ie, at T0: mean=3.1, SD=0.9; at T1: mean=3.1, SD=1.0; and at T2: mean=2.7, SD=1.1) (P=.01). No significant differences in disease activity over time were found in the intervention group (ie, at T0: mean=3.0, SD=1.0; at T1: mean=2.7, SD=1.1; and at T2: mean=2.7, SD=1.4) (P=.5). Post hoc power analysis based on the found ES of 0.35 for V\textsubscript{O}\textsubscript{2max} revealed that a group of 57 patients would be needed to have a power of 0.8.

Discussion
Our hypothesis that the FIT program, a combination of physical training and self-management education, would improve physical performance, perceived health status, and self-efficacy components was partially confirmed. The present study showed that the FIT program is capable of producing significant beneficial effects on aerobic capacity but not on muscle strength, self-reported health status, or self-efficacy among people with RA. Effect size calculations, however, indicated small to moderate clinically relevant changes in 7 of the 8 outcomes studied in the intervention group compared with only 2 out of 8 variables in the WLC group. Furthermore, although the WLC group showed no changes over time in V\textsubscript{O}\textsubscript{2max}, UE and LE muscle strength, and perception of physical health status outcomes, the intervention group showed significant improvements in all 4 of these parameters. In addition, there was a small trend within the intervention group toward improvement in psychological health, self-efficacy for function, and handling pain and other symptoms.

Aerobic Capacity
Our hypothesis that the FIT program would improve physical performance was confirmed for aerobic capacity. The significant differences in improvements in V\textsubscript{O}\textsubscript{2max} between the intervention and WLC groups indicates that the program had beneficial effects on aerobic capacity, even after Bonferroni corrections. Improvement in V\textsubscript{O}\textsubscript{2max} may occur, however, only if the frequency, intensity, and duration of the training are sufficient to provide an adequate stimulus. Given that the FIT program participants exercised on 2 separate days per week with an intensity of 60% to 70% of their HR\textsubscript{max} and for a duration of 40 to 90 minutes, it seems that the FIT program, as applied in our study, provides a sufficient amount of physical stimulus to improve aerobic capacity, although the frequency per week did not correspond to the given recommendation. In the intervention group, the change in V\textsubscript{O}\textsubscript{2max} indicates that, when compared with age-based reference values of people who are healthy, women improved from poor to average and men improved from low average to high average. In addition, the ES found indicated a small but clinically relevant change, which may enable people with RA to perform more-strenuous physical activities and, ultimately, might contribute to a decrease in cardiac morbidity and mortality.

Our results are in line with a systematic review that reported beneficial effects of exercise on aerobic fitness in people with RA. In the present study, the magnitude of the change was 12.1% for the intervention group compared with a decrease of −1.7% in the WLC group. In previous studies, improvements in aerobic capacity varied from 4% to 33%. These varieties may be due to differ-
ences in the duration of the training. Compared with other studies, our intervention was relatively short. A program with a length of 8 weeks can result in an increase in VO2max if an adequate frequency (twice a week), duration (40–90 minutes), and intensity of the exercise program (55%–90% HRmax) are provided.

**Muscle Strength**

Our hypothesis that the FIT program would improve physical performance was not confirmed as far as muscle strength is concerned. No significant difference in UE or LE muscle strength was found between the groups. However, we did find an improvement of 12.9% in LE muscle strength for the intervention group and an ES that indicated a small but clinically relevant change of 0.35. The latter finding may enable people to perform functional tasks such as walking, stair climbing, and so on more easily. The lack of a between-group effect on muscle strength may have been due to the lower frequency of the muscle strength training and the shorter duration of the program (ie, muscle strength training took place only once per week). Previous studies suggest that a training frequency of at least 2 to 3 times per week is needed to improve muscle strength.

In this study, we assumed that the combination of fitness, bicycle training, aqua jogging, and sports would compensate for the lack of more-frequent specific muscle training. Our results, however, suggest that sport activities and aqua jogging contribute more to aerobic capacity than to muscle strength. These results are not in line with a systematic review on the effects of dynamic exercise therapy that reported positive effects on both aerobic capacity and muscle strength in people with RA. However, the changes over time found in our study were consistent with previous studies that reported an increase of 16.8% in muscle strength after a 12-week intensive dynamic exercise program with a frequency of 3 times a week and variable improvements of 8% to 25% for different muscle groups that were found after a 21-week strength and endurance training program with a frequency of 1.5 times a week. Taking into account that improvements in both studies were larger than in our study and that the durations of the programs were longer and the frequencies were higher, it seems that to improve muscle strength, the duration and frequency of the exercise program should be increased over those offered by the FIT program.

**Self-Reported Health Status**

Our hypothesis that the FIT program would improve disease self-management was not confirmed. The interpretation of the results regarding perceived health status and self-efficacy is ambiguous. For all dimensions, we found no significant differences between the participants in the FIT program and those in the WLC group. However, there seemed to be a consistent pattern for changes that occurred within the groups. This pattern included non-significant baseline differences between the intervention group and the WLC, with the intervention group having the worst scores on perceived health status and self-efficacy, and an equal level of functioning at follow-up. The within-group changes found in the intervention group may be attributed to a regression to the mean or to an effect of the intervention. In the latter case, the lack of a between-group effect may have been due to a lack of power because of the small number of participants.

**Physical Health**

Although we found that the intervention group had a relatively large improvement (−34%) in perception of their physical health, the between-group effect on physical health narrowly missed significance. The ES for physical health status, however, indicates a clinically relevant moderate change, which may indicate an increase in patients’ estimation of their physical performance in daily life. The lack of significant difference in perceived physical health between the intervention group (ie, −34%) and the WLC group may have resulted because the WLC group also showed an improvement of −9.3% over time. We believe that one explanation for the WLC group’s improvement in this area might have been the fact that this group had a physical assessment (ie, Åstrand-Rhyming ergometry test) that might have induced a feeling of safety to engage in physical demanding activities at home, leading to an increase in performance and thus to better self-reported physical health status. We did not take these possible effects into account in our study. Moreover, post hoc analyses showed a significant reduction in disease activity in the WLC group over time, which probably led to better physical health. Finally, because the length of time patients had been taking their current medication prior to the study was not registered, we could not determine potential effects of medication on disease activity and physical health. For future research, we recommend recording the duration of anti-rheumatic drug therapy.

**Psychological Health and Social Interaction**

We found no significant differences in change in psychological health status and social interaction between the intervention group and the WLC group, indicating a lack of beneficial effect of the FIT program on these variables. The lack of effect on social interaction may have been caused by the unexpected improvement of
An Educational and Physical Training Program for People With Rheumatoid Arthritis

−25.8% in the WLC group at T1. The latter improvement may have been due to chance or to reduced disease activity that might have led to an increase of social interactions.

Few other studies with exercise training have used health status as an outcome measure. Two of them reported results that were in line with the results of our study. One study comparing aerobic training with range-of-motion exercises showed significant effects on the AIMS physical functioning and psychological functioning dimensions of the aerobic exercise group after 12 weeks of training.15 A study of the effects of a long-term, high-intensity exercise program showed significant improvements with regard to functional ability and emotional status between the intervention group and the usual care group after 24 months.10 Another study comparing high-intensity and low-intensity training showed no significant differences, however, on the AIMS psychological functioning dimension between the intervention groups.12 Based on these studies, it seems there is some evidence that high-intensity training may contribute to better health status, but it remains unclear what level of intensity and duration are needed to create such an effect.

A review on the effects of psychoeducational programs with regard to health status and psychological status for people with RA showed that such programs can reduce pain and depressive symptoms and improve self-efficacy, coping abilities, and self-management behaviors, including exercise adherence.24 Another review reported significant effects of patient education on functional disability.26 Results with regard to functional ability were reported after a 6-week educational program, although no effects on psychological and social aspects were found.27 Thus, educational programs affect functional ability and health status of people with RA, but the lack of a between-group effect in our study indicates that our program was not successful.

Self-Efficacy
This study revealed no greater improvement in self-efficacy for those who participated in the FIT program compared with those who did not, whereas other single-group comparison and control group design studies of group-based educational programs have shown significant effects on self-efficacy.20,21,25,34 Although our FIT program participants showed improvements in all of the self-efficacy scales over time and ES calculations in the intervention group indicated small positive changes, the lack of a between-group effect in our study means that the self-efficacy elements in the FIT program were insufficient. The educational part of our program was based on giving information. It was supposed to provide opportunities for vicarious experiences, verbal persuasion, reinterpretation of symptoms, and mastery performance.31 Although the information on body sensations and how to handle the rest/activity balance was used during the fitness, sports, and aqua jogging components, the program did not include other important self-management components such as individual goal setting, action planning, and contracting.

Effect of the FIT Program on Disease Activity
Post hoc analyses showed no significant differences in change scores for disease activity between the intervention group and the WLC group. However, significant reductions in disease activity over time were found in the WLC group. As the length of time patients had been taking their current medication prior to the study was not registered, we could not determine the potential effects of medication on disease activity. It is possible that more participants in the WLC group compared with those in the intervention group started with their anti-rheumatic medication shortly before the beginning of the study. For future research, we would advise always taking the duration of anti-rheumatic drug therapy into account. Because disease activity in the WLC group improved, it is likely that participants felt better and were more active in daily life. These changes might have had a positive influence on their physical performance and health status. Although the improvement in disease activity in the WLC group might have negatively biased some of the statistical outcome results, the lack of changes in the intervention group underscores the fact that intensive training has no negative effects on disease activity. This finding is in line with the findings of previous studies,8–10,15,19 which supports the use of intensive exercise programs for people with RA.

Limitations
An important limitation in our study was the small number of participants included. As our starting point we chose an RCT design with a WLC group and an intervention group. Unfortunately, the number of participants in both groups was rather small, which may have induced a lack of power.

Conclusions
The present study showed significant improvements in aerobic capacity (V̇O2max) of participants in a multidisciplinary intervention for people with RA using the FIT program protocol compared with a WLC group. No beneficial effects were found for muscle strength, self-reported health status, or self-efficacy. Within-group analyses over time, however, showed significant
improvements in UE and LE muscle strength and perceived physical health and a trend of improvements in self-efficacy for symptoms and function in the intervention group, whereas no changes over time were found in the WLC group. Of clinical importance is the finding that the FIT program had no negative impact on disease activity.

The results of this study indicate that the FIT program is a safe and feasible rehabilitation program to improve the aerobic capacity of people with RA. Because people with RA show a significant decrease in aerobic capacity and have a higher risk of cardiovascular morbidity, we recommended that physical training should be incorporated into the standard care for this population. To achieve larger improvements in muscle strength, the training parameters should be specified according to the recommendations concerning frequency, duration, and intensity. To achieve improved self-efficacy within a physical training program, greater emphasis on specific components of self-efficacy training is needed.

References


An Educational and Physical Training Program for People With Rheumatoid Arthritis


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Ineke Breedland, Corinne van Scheppingen, Martha Leijsma, Nienke P. Verheij-Jansen and Ellen van Weert

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