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The effect of high-intensity strength training as compared to standard medical care on muscle strength, physical function and health status, in patients with Rheumatoid Arthritis Functional Class II

Meghan Biggs

Pacific University

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The effect of high-intensity strength training as compared to standard medical care on muscle strength, physical function and health status, in patients with Rheumatoid Arthritis Functional Class II

Disciplines

Physical Therapy

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Title: The effect of high-intensity strength training as compared to standard medical care on muscle strength, physical function and health status, in patients with Rheumatoid Arthritis Functional Class II.

Clinical Scenario: The patient who led us to pursue this question is: 53 y.o. female with a diagnosis of Rheumatoid Arthritis (RA) and considered in Functional Class II based on criteria from the American College of Rheumatology (ACR). Medical treatment to date has included a regimen of Humira (adalimumab), low-resistance strength training, and exercises to increase range of motion (ROM). Problems identified include: decreased strength, decreased functional range of motion, and decreased physical ability.

Brief introduction: Rheumatoid Arthritis is a chronic autoimmune condition causing pain, stiffness, inflammation and destruction of joints. Progression of this disease leads to physical limitations and the inability to complete simple activities of daily living (ADLs). RA is typically treated with medications such as: analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs) and disease-modifying antirheumatic drugs (DMARDs). Many patients also receive occupational and physical therapy to help with physical and occupational function. Cardiovascular disease, muscle atrophy and osteoporosis are major concerns in the RA population due to inactivity from the signs and symptoms of the disease. We want to know if there is research supporting positive effects of high-intensity training on muscle strength, health status, and physical function for patients with RA. One of our group members served on the Rheumatoid Team at Providence Portland Physical Therapy and worked with many patients who have RA. There are concerns that high-intensity training could increase pain and decrease function in this population as compared to a standard medicinal regimen with simple ROM exercises [2].

My Clinical question: Is high-intensity strength training better than standard care of Rheumatoid Arthritis in improving muscular strength, health status, and physical ability?

Clinical Question PICO:

Population - The population investigated includes adult patients with medically documented Rheumatoid Arthritis.

Intervention - The intervention this paper will investigate the effectiveness of high-intensity strength training.

Comparison - The intervention will be compared to usual care as overseen by their rheumatologist.

Outcome - Outcomes being measured include differences in muscle strength, physical function and health status as measured by dynamometry, an aerobic test, and health questionnaires, respectively.

Overall Clinical Bottom Line: Based on the results of the outcomes from de Jong *et al.*, Flint-Wagner *et al.*, and Lemmey *et al.*, there is moderate evidence to suggest that an intervention of high-intensity strength training for patients with RA is better than standard care of low-intensity ROM exercises in improving muscular strength and physical ability. However, there is sufficient evidence that this intervention does not improve health status. Outcomes of interest included muscle strength of the knee extensors measured by

dynamometry, aerobic tests such as the 50-foot walk test and standardized bicycle ergometer test and health status evaluated by various forms of the Health Assessment Questionnaire. All three studies indicated significant increases in knee extensor muscle strength from the pretest to posttest; however, only de Jong *et al.* and Lemmey *et al.* reported significant differences when compared to the control group, ($p < 0.05$). de Jong *et al.* found a mean change score of 26.1 ± 60.9 N in their intervention group compared to 9.6 ± 52 N in the control group while Lemmey *et al.* reported a large effect size of 0.34. According to our analyses, 0.34 is actually representative of a small effect size. Lemmey *et al.* did not describe why the effect size range was skewed in the article. Regarding improvement of aerobic tests, all three studies also indicated significant improvement in aerobic function. Mean change scores for the standardized bicycle ergometer test in the study de Jong *et al.* were 8.2 ± 37.1 W and 8.2 ± 37.1 W ($p < 0.05$) for the intervention and control group, respectively. Statistical analyses for the 50-foot walk test in the study by Flint-Wagner *et al.* indicated a mean change score of -1.2 ± 1.6 seconds for the intervention group and 0.8 ± 1.0 seconds for the control group ($p < 0.05$) with a large effect size of 1.34 based on a 95% confidence interval. Lastly, Lemmey *et al.* reported a large effect size of 0.28 using a 95% confidence interval for the 50-foot walk test. According to our analyses, 0.28 is actually representative of a small effect size. Lemmey *et al.* did not describe why the effect size range was skewed in the article. No significant changes were found between any intervention group or control group for all three studies concerning health status via health questionnaires. Overall, it is difficult to generalize the results of this study to our patient at hand. The results and interventions of this study can be applied to her based on the age range and RA functional classification level; however, our patient was not on the same drug regimen as patients in the study by Flint-Wagner *et al.* and all three interventions were conducted in group sessions over a period of 16 weeks to 2 years instead of one-on-one physical therapy sessions. We wanted to incorporate high-intensity strengthening exercises over a more realistic time frame of a typical physical therapy script with one-on-one interactions between the therapist and patient as well as providing a home exercise program. Further research should evaluate the effects of a short-term, six to eight week intervention of individualized, high-intensity strength training for the same outcome measures. Also, more research is needed on the effects of high-intensity strength training on radiographic joint damage for safety and to monitor disease progression. Perhaps results would also differ if patients were treated one-on-one instead of in a group setting. Thus future research should investigate this interaction.

Search Terms: Rheumatoid Arthritis, High-Intensity Strength Training, Exercise Program, and Physical Therapy

Appraised By: Meghan Biggs, SPT & Carrie Yap, SPT
School of Physical Therapy
College of Health Professions
Pacific University
Hillsboro, OR 97123
bigg6649@pacificu.edu, yap8315@pacificu.edu

Rationale for your chosen articles

For the purpose of this evaluation, the articles were searched for using the following databases: Medline (OVID) and PubMed. The PEDro rankings for all three articles were

obtained from the PEDro database.

The articles were chosen based on our patient population and the intervention of high-intensity strength training, which has been a controversial treatment for RA due to the potential issue of increasing joint damage. Through our search, multiple articles regarding RA in smaller joints such as hands and/or feet were found; however, we decided to focus on larger joints, which would affect gross motor skills versus fine motor skills. We also ensured that each article addressed our chosen outcome measures of muscular strength, health status, and functional ability as shown in Table 1., below.

Table 1. A comparison of the population, intervention, comparison group, and outcome measures for the critically appraised topic, de Jong *et al.*, Flint-Wagner *et al.* and Lemmey *et al.* research studies.

PICO DETAILS

Population	
CAT	Adult patients with medically documented Rheumatoid Arthritis.
de Jong <i>et al.</i>	RA patients registered in four RA outpatient clinics in the Netherlands
Flint-Wagner <i>et al.</i>	RA patients registered in rheumatologists' offices with infliximab infusion clinics
Lemmey et al	Established, controlled RA
Intervention	
CAT	High Intensity Training
de Jong <i>et al.</i>	RAPIT = Rheumatoid Arthritis Patients in Training
Flint-Wagner <i>et al.</i>	Strength Training, Aerobic exercise and Abdominal Exercises
Lemmey et al	PRT = Progressive Resistance Training
Comparison	
CAT	Standard Medicinal Care
de Jong <i>et al.</i>	Usual Care
Flint-Wagner <i>et al.</i>	Standard Care
Lemmey et al	ROM Exercise
Outcomes Measured	
CAT	Muscle Strength and Endurance
de Jong <i>et al.</i>	Knee extension muscle strength, aerobic fitness standardized ergometer tests, and HAQ,
Flint-Wagner <i>et al.</i>	Muscle strength of knee extensors, timed 50-foot walk test, and HAQ DI
Lemmey et al	Knee extension muscle strength, 50-foot walk test, and MDHAQ

The PEDro scores of de Jong *et al.*, Flint-Wagner *et al.* and Lemmey *et al.* are all within one point of each other, as shown in Table 2. There are several threats to validity in the articles chosen, such as a lack of blinding and concealed allocation. We feel that that these studies are still beneficial in addressing our clinical question due to the interventions performed and the outcomes measured.

Table 2. A comparison of PEDro Scores for Lemmey *et al.*, de Jong *et al.* and Flint-Wagner *et al.* research studies.

	de Jong <i>et al.</i>	Flint-Wagner <i>et al.</i>	Lemmey <i>et al.</i>
PEDro Score	10-Jun	10-May	10-May
Eligibility Criteria	X	X	X
Random Allocation	X	X	X
Concealed Allocation			
Baseline Comparability		X	X
Blind Subjects			
Blind Therapists			
Blind Assessors	X		
Adequate Follow-up	X	X	
Intention-to-treat Analysis	X		X
Between-group comparisons	X	X	X
Point estimates & Variability	X	X	X
Total PEDro Score	7/10	6/10	6/10

- (1) de Jong Z, Munneke M, Zwinderman AH, Kroon HM, Jansen A, Runday KH, van Schaardenburg D, Dijkmans BAC, van den Ende CHM, Breedveld FC, Vliet Vlieland TPM, Hazes JMW. Is a long-term high-intensity exercise program effective and safe in patients with rheumatoid arthritis? Results of a randomized controlled trial. *Arthritis and Rheumatism* 2003 Sep;48(9):2415-2424.
- (2) Flint-Wagner HG, Lisse J, Lohman TG, Going SB, Guido T, Cussler E, Gates D, Yocum DE. Assessment of a sixteen-week training program on strength, pain, and function in rheumatoid arthritis patients. *Journal of Clinical Rheumatology* 2009 Jun;15(4):165-171.
- (3) Lemmey AB, Marcora SM, Chester K, Wilson S, Casanova F, Maddison PJ. Effects of high-intensity resistance training in patients with rheumatoid arthritis: a randomized controlled trial. *Arthritis and Rheumatism* 2009 Dec 15;61(12):1726-1734.

Article: A. Is a long-term high-intensity exercise program effective and safe in patients with rheumatoid arthritis? Results of a randomized controlled trial. *Arthritis and Rheumatism* 2003 Sep;48(9):2415-2424.

Clinical Bottom Line: Based on the results of this study, there is moderate evidence to suggest that for patients with Rheumatoid Arthritis, a two-year long high-intensity exercise program (Rheumatoid Arthritis Patients in Training [RAPIT] program) results in changes in muscle strength and physical ability, when compared to usual care group (UC) of physical therapy. Outcomes of interest included knee extensor muscle strength as measured by dynamometry, a standardized bicycle ergometer test for aerobic fitness and the Health Assessment Questionnaire (HAQ). From baseline to 24 months, the RAPIT group had a greater increase in knee extensor muscle strength (26.1 ± 60.9 N) as compared to the UC group (9.6 ± 52 N), ($p < 0.05$). A significant difference was also found in physical ability, which was measured by a standardized ergometer test. Subjects in the RAPIT group had an increase aerobic fitness (8.2 ± 37.1 W) and patients in the UC group had a decrease in aerobic fitness (-6.7 ± 35.2 W), ($p < 0.05$). Regarding health status, no significant difference was found in HAQ scores between the two groups from baseline to 24 months. Major threats to the internal validity of this study include lack of blinding as well as poor validity of the cycle ergometer test. Overall, a long-term, high-intensity exercise program is not a cost-effective treatment option or feasible alternative due to the amount of time and resources necessary for optimal results. Furthermore, the intervention was conducted as group-based therapy sessions versus individualized therapy sessions. Results of this study cannot be adequately generalized to our patient of interest due to the study design, insufficient information to repeat the exercise protocol, cost of equipment, and the need for a large facility.

Article PICO:

Population— The target population for this study includes patients diagnosed with RA from four outpatient rheumatology clinics in the Netherlands.

Intervention— The intervention investigated by this study is a high-intensity exercise program (the Rheumatoid Arthritis Patients in Training [RAPIT] program).

Comparison— The patients in the intervention program was compared to patients receiving usual care, which consisted of physical therapy if deemed necessary by their attending physician.

Outcomes— Outcome measures of this study include the following: health status, which was assessed the Health Assessment Questionnaire (HAQ); physical ability, which was determined by the standardized ergometer test for aerobic fitness; and muscle strength of knee extensors.

Blinding: In this study, the assessors were blinded to treatment allocation. Additionally, patients were instructed to avoid discussing their treatment allocations with the assessor and were given tips to on how to avoid revealing which group they were allocated. The authors also ensured that all assessments were conducted in a room “as far as possible from the training location.” Because the HAQ is a subjective measure, this poses a significant threat due to potential patient bias.

Controls: The control or UC group received physical therapy only when deemed necessary by their attending physician. Physical therapy treatment included hydrotherapy, therapeutic modalities, and passive and active range of motion exercises. The authors of this study indicated that patients in the RAPIT program also received individual physical therapy treatment when it was necessary in addition to the group based exercise treatment. Thus, any differences can be attributed to the treatment.

Randomization: A permuted-blocked randomization with stratification for training center, age (<50 years and >50 years), and sex was used to determine the allocation of patients into the either the UC group or RAPIT program. An administrative assistant performed the allocation of patients and distribution was concealed to the patients, therapists, and assessors. Patients in the UC group had a slightly longer duration of RA, higher frequency of using DMARDs, and more radiographic damage of the hands and feet; however, there was no statistically significant difference. Demographically, more patients in the UC group had paying jobs, which was statistically significant but there was no difference in the amount of time spent at work.

Study: The present randomized clinical control study examined the effects of a two year long, high-intensity exercise program in patients with RA (Rheumatoid Arthritis Patients In Training [RAPIT]) as compared to similar patients receiving usual care (UC) or physical therapy as deemed necessary by their attending physician.

A total of 309 patients with RA were recruited from four outpatient rheumatology clinics in the Netherlands. Patients completed informed consent and met the following inclusion criteria: age 20-70 years, RA according to the American College of Rheumatology (ACR), ACR functional classes I-III, stable DMARD regimen in the past three months, able to cycle, willing to exercise twice a week on a fixed schedule, living regions near a the training/assessment center, no use of a prosthesis on a weight-bearing joint, no cardiopulmonary disorders, no comorbidity causing a shorter life expectancy, no serious psychiatric disease, and the ability to complete a questionnaire. Once the inclusion criteria were met, patients were screened and randomized into the RAPIT program or to UC.

One hundred fifty-eight patients were allocated to the UC group and 151 patients were allocated to the RAPIT program however, 150 from the UC group and 150 from the RAPIT program completed baseline assessments. The UC group received physical therapy, the standard treatment. The RAPIT group participated in exercise sessions conducted twice a week for 1.25 hours per session. The exercise session consisted of bicycle training (20 minutes); an exercise circuit consisting of eight to ten different exercises to improve muscle strength, muscle endurance, joint mobility, and activities of daily living (20 minutes); and a sport or game consisting of badminton, volleyball, indoor soccer, and basketball (20 minutes). Additionally, each session was preceded by a warm-up and followed by a cool-down.

Outcome Measures: Outcome measures investigated by this study included: muscle strength of knee extensors as measured by an isokinetic dynamometer at an angle velocity of 60 degrees/second in Newtons (N), physical function as measured by a standardized ergometer test and health status as measured by a HAQ. Data was recorded at baseline and 24 months. The authors conducted a pilot study in 19 patients and determined intraclass correlations coefficients (ICCs) for aerobic fitness and muscle strength of 0.97 and 0.98, respectively. The authors only reported an MCID of 0.20 in the change in the

HAQ, which was cited in their literature [6].

Study Losses: Prior to patient recruitment, the authors conducted a power analysis based on the change in the HAQ score and performed an intention to treat analysis. For each group, a minimum of 119 patients was needed for significance for a 95% confidence interval ($p < 0.05$). After the randomization process, nine patients refused to participate in the study for unknown reasons. Over the two-year intervention period, five patients from the UC group and 14 patients from the RAPIT program dropped out of the study. In the RAPIT program, ten of the 14 patients withdrew due to a serious comorbidity not related to RA and four withdrew for other reasons. de Jong *et al.* (2003) also reported that 14 other RAPIT patients did not attend the exercise classes regularly but were evaluated at all time points. The median percentage of exercise attendance was 74%. Statistical analyses indicated no difference between those who failed to attend exercise sessions from those who did attend, and also between those who withdrew and those who participated in the study.

Summary of internal validity: The internal validity of this study is fair. A stratified randomization was performed by an assistant to group participants and the assessors were blinded to treatment allocation thus eliminating rater bias. Additionally, the authors conducted a power analysis based on the MCID for HAQ and an intention to treat analysis was performed. Furthermore, the authors conducted a pilot study for reproducibility and determined ICCs for the outcome measures. The therapists were well trained and rehearsed in the study protocol. However, there are potential threats to internal validity. Because the patients were not blinded to treatment, this poses a major threat due to Hawthorne and Rosenthal effects. However, due to the study design, it would be difficult to blind patients. A minor threat to internal validity is potential instrumentation errors. The authors did not state the reliability or validity of instruments used such as the bicycle ergometer test.

Evidence:

Twenty-four months after initiation of the Rheumatoid Arthritis Patients in Training program (RAPIT), de Jong *et al.* completed outcome measurements on both groups. To assess functional ability and health status, subjects completed an aerobic ergometer test and a Health Assessment Questionnaire (HAQ). To assess muscular strength, subjects performed a maximal volitional knee extensor contraction using an isokinetic dynamometer with an angle velocity of 60 degrees per second. These stated measures were used to evaluate changes in groups with respect to time, as shown in Table 5, below. Changes in knee extensor strength were greater in the RAPIT group (26.1 ± 60.9 N) as compared to the Usual Care (UC) group (9.6 ± 52 N), ($p < 0.05$). Sample sizes (n) were not given for each group, therefore effect size and 95% confidence intervals could not be calculated. The RAPIT group increased in aerobic fitness via an ergometer test from baseline to 24 months (8.2 ± 37.1 W), while the UC group decreased in aerobic fitness (-6.7 ± 35.2 W), ($p < 0.05$). Again, de Jong *et al.* did not calculate effect size. Sample sizes (n) were not given for each group; therefore effect size and 95% confidence intervals could not be calculated. There were no significant differences in change of HAQ measures from baseline to month 24 between groups.

Table 5. Between Group Comparison of Muscular Strength, Physical Function and Health Status from baseline to after 24 months of intervention.

	UC (n not given)	RAPIT (n not given)
Change in Knee Extension F (N)	9.6 ± 52	26.1 ± 60.9*
Change in Aerobic Ergometer Test (W)	-6.7 ± 35.2	8.2 ± 37.1*
Change in HAQ score	0.07 ± 0.3	0.00 ± 0.4

*Significantly different from usual care (UC) group at $p < 0.05$

Applicability of study results:

Benefits vs. Costs: de Jong *et al.* studied patients aged 20-70 years of age with Functional Class I-III Rheumatoid Arthritis according to ACR 1987 revised criteria [1] [5]. All subjects were on a stable regimen of DMARDs for three months prior to the study, were able to complete a questionnaire and able to cycle as well as exercise twice weekly. No subjects used a prosthesis, were contraindicated for exercise by cardiopulmonary diseases, had a serious psychological disorder, or had a comorbid condition that could result in a shortened life expectancy. The patient of interest had Rheumatoid Arthritis Functional Class II. She did not participate in any exercise program, had no comorbidities and was on a regimen of Humira (adalimumab).

The results of this study were that changes in knee extensor strength were greater in the RAPIT group (26.1 ± 60.9 N) as compared to the Usual Care (UC) group (9.6 ± 52 N), ($p < 0.05$). The RAPIT group increased in aerobic fitness via an ergometer test from baseline to 24 months (8.2 ± 37.1 W), while the UC group decreased in aerobic fitness (-6.7 ± 35.2 W), ($p < 0.05$). There were no significant differences in change of HAQ measures from baseline to month 24 between groups.

de Jong *et al.* conducted a power analysis based on the change in the HAQ score and performed an intention to treat analysis. For each group, a minimum of 119 patients was needed for significance for a 95% confidence interval ($p < 0.05$). Over the two-year intervention period, five patients from the UC group and 14 patients from the RAPIT program dropped out of the study. In the RAPIT program, ten of the 14 patients withdrew due to a serious comorbidity not related to RA and four withdrew for other reasons.

There were baseline characteristic differences between the groups which included the UC group having been diagnosed with Rheumatoid Arthritis for a longer period time, greater use of DMARDs, and greater damages of hands and feet via radiographs as compared to the RAPIT group.

The RAPIT group received twice weekly 1.25 hour sessions for 24 months lead by Rheumatologists. It is unknown where the sessions were held. They performed a warm-up and cool-down in addition to twenty minutes of bicycle training at 70-90% of maximum heart rate (HRmax) and a Rate of Perceived Exertion (RPE) of 4-5, 20 minutes of an exercise circuit (8-15 repetitions of 8-10 exercises) and 20 minutes of various sports/games (badminton, volleyball, indoor soccer, basketball). The RAPIT group received a much greater interaction and training. If the PRT program is applied to our patient it will result in a

greater time and cost of intervention as compared to usual care for rheumatoid arthritis.

It is interesting to note that, during the 24-month study, a percentage of subjects in the UC group (55%) and RAPIT group (34%) were treated individually by physical therapists. The median cumulative time spent in physical therapy in the RAPIT group (5.4 hours) was less than the UC group (8.2 hours) over the 24-month period, ($p < 0.001$).

Feasibility of Treatment: The RAPIT program can only be completed as a group therapy design due to the 20 minutes of various sports/games (badminton, volleyball, indoor soccer, basketball) portion of the program. Each of the biweekly sessions takes more than 1.25 hours to complete. This is a large commitment for both therapists and patients if the RAPIT program is conducted for 24 months as de Jong *et al.* described.

de Jong *et al.* (2003) reported that 14 RAPIT patients did not attend the exercise classes regularly but were evaluated at all time points. The median percentage of exercise attendance was 74%. Statistical analyses indicated no difference between those who failed to attend exercise sessions from those who did attend, and also between those who withdrew and those who participated in the study. Having the ability to convert this program into a home exercise program completed at a gym with only minimal sessions with a therapist and high compliance would be ideal but is not very feasible.

The physical therapists that measured all outcomes received training both prior to the study beginning and one year into the study. Therapists must be comfortable with leading bicycle training, exercise circuits and sports including badminton, volleyball, indoor soccer and basketball to complete this protocol. The strength training exercises were not sufficiently explained and the progression of the bicycle training and exercise circuit portions of the RAPIT program that can be too complicated for someone without an exercise training or therapy background. Equipment needed to complete the program includes a stationary bicycle, gym equipment to complete and exercise circuit and sufficient equipment and space to play badminton, volleyball, indoor soccer and basketball.

Summary of External Validity: The study by de Jong *et al.* had fair external validity but numerous threats to internal validity greatly decreased our ability to use results to influence future treatments for the patient of interest. All subjects included were diagnosed with Rheumatoid Arthritis. The subjects were randomly allocated, and the assessors were blinded to treatment allocation. Additionally, patients were instructed to avoid discussing their treatment allocations with the assessor and were given tips to on how to avoid revealing which group they were allocated. The authors also ensured that all assessments were conducted "as far as possible from the training location." Because the HAQ is a subjective measure, this poses a significant threat due to potential bias. The authors did not state inter-rater or intra-rater reliability for measurements, which could have affected the measured outcomes. The reliability of the instruments and outcome measures used were not validated, which also poses major threats to both the bicycle ergometer test and dynamometry measurements. A power analysis was performed to determine sample size and to account for potential dropouts. This study can be applied to our clinical patient based on age, functional class, and drug regimen. However, this study cannot be applied to patients with comorbidities or prostheses, the RAPIT protocol and amount of time needed on behalf of the patient and therapist is not feasible, and geographical differences make it difficult to generalize to a larger population.

Article: Flint-Wagner HG, Lisse J, Lohman TG, Going SB, Guido T, Cussler E, Gates D, & Yocum DE. Assessment of a sixteen-week training program on strength, pain, and function in rheumatoid arthritis patients. *JCR*. 2009;15(4):165-171

Clinical Bottom Line: Based on the results of this study, there is weak evidence to suggest that for patients with Rheumatoid Arthritis, a 16-week long intervention of high-intensity individualized strengthening program results in changes in muscle strength, physical function, and health status, when compared to usual care as overseen by their rheumatologist. Outcomes of interest included knee extensor muscle strength as measured by dynamometry, a 50-foot timed walk test and the Health Assessment Questionnaire Disability Index (HAQ DI). From baseline to week 16, the strength-training group had an increase in knee extensor muscle strength with a mean strength change of $46.4\% \pm 35.2\%$ ($p < 0.05$); however, comparisons could not be made between the strength-training group and the control group due to insufficient information. The strength training group had an increase in physical function as described by a decrease in time for the 50-foot walk test (-1.2 ± 1.6 sec) as compared to the control group who increased their time, thus showing a decrease in physical function (0.8 ± 1.0 sec), ($p < 0.05$). Additionally, further analysis for the timed 50-foot walk indicated a large effect size of 1.38 using a 95% confidence interval (0.40 to 2.37 CI). Regarding health status, no significant difference was found in HAQ DI scores between the two groups. Major threats to the internal validity of this study include lack of blinding, baseline differences between the control group and strength training group, and not enough statistical power. Overall, a high-intensity individualized strengthening program is not a cost-effective or feasible treatment option due to the amount of time and resources necessary for optimal results. Results of this study cannot be adequately generalized to our patient of interest due to differences in drug regimens.

Article PICO:

Population— The target population for this study included 24 patients between ages 29 to 75 years who were diagnosed with rheumatoid arthritis (RA) and receiving infliximab infusions by their rheumatologist.

Intervention— The intervention investigated by this study was a high-intensity, individualized strengthening program consisting of strength training, aerobic exercise, abdominal exercises, and stretches.

Comparison— The control group ($n=8$) received standard care for their medical diagnosis of Rheumatoid Arthritis by their rheumatologists.

Outcomes— The outcome measurements of interest include: muscular strength of knee extensors, a timed 50-foot walk, and a Health Assessment Questionnaire Disability Index (HAQ DI). These measurements were taken at baseline and week 16 of the study.

Blinding: Flint-Wagner *et al.* did not state if any party was blinded. This was one of the

major threats to the internal validity of this study as there are many biases (patient, therapist, and researcher) that could have affected the outcome measures. Because the HAQ DI is completely subjective, knowing what type of treatment the other group received could skew these outcome measures. It would be very difficult to blind the subjects in that one group completed a high intensity training program while the other received only standard medical care.

Controls: The control group (n=8) who were aged 49.0 ± 12.6 years received standard medical care by their rheumatologist. In addition to standardized care, the treatment group (n= 16) who were aged 52.2 ± 12.6 years received an individualized, high-intensity strengthening program. Any differences between groups will be attributed to the intervention alone.

Randomization: Subjects of this study were assigned into treatment groups via simple randomization with a 2:1 ratio of strength training to control group. At baseline the control group had a greater average peak torque of their left and right legs as compared to the strength-training group ($p < 0.05$).

Study: This randomized clinical control study investigated the effects of a 16-week, high-intensity, individualized, strength training program in infliximab-treated patients with RA compared to similar patients who only received infliximab treatment and standardized care by their rheumatologist.

Flint-Wagner *et al.* screened 100 patients at rheumatologists' offices in the Boise, ID area and 30 of them participated in their randomized clinical trial. The study included patients over 18 years of age with Rheumatoid Arthritis Functional Class I or II based on the American College of Rheumatology (ACR) criteria. All subjects were being seen at rheumatologists' offices with infliximab infusion clinics in Boise, ID. Patients had begun treatment with infliximab for ≥ 4 months and received no other biological therapies at the time of the study. Patients had no medical history of comorbid conditions and had not exercised ≥ 150 minutes per week in the three months preceding the study. Subjects of this study were assigned into treatment groups via simple randomization with a 2:1 ratio of strength training (n=16) to control group (n=8).

The Strength Training (ST) group (n=16) underwent 75 minute session, 3 times weekly. The sessions were composed of the following:

1. Walking warm-up
2. Strength training (either Theraband and body weight, Theraband and weight machines, or dumbbells and weight machines) 6-8 repetitions/2 sets of:
 - a. Leg press
 - b. Leg curl
 - c. Hip abduction
 - d. Hip adduction
 - e. Calf raise
 - f. Incline press
 - g. Rowing
 - h. Hammer curl
3. Aerobic exercise
4. Abdominal Exercise
5. Cool Down Walk

6. Static Stretching

Outcome measures: Flint-Wagner *et al.* measured muscular strength of subjects' knee extensors, a timed 50-foot walk and had subjects complete a HAQ. The strength of patients' knee extensors was measured by the gold standard of isokinetic dynamometry while performing a leg press. Three maximum voluntary contractions (MVCs) at a fixed velocity of 60 degrees per second were averaged to find the peak torque. Each subject completed two sets of three MVCs and the higher of the peak torque averages were used. These measurements were taken at baseline, week 8 and week 16 of the study. The researchers did not report any inter or intra-rater reliability measures. A MCID was only stated for HAQ as being -3.2 and -0.5 [3] [4]. MCID qualifications for knee extensor force and the 50-foot walk test were not listed in the article and literature to date is inconclusive of an exact value.

Study Losses: There were a total of six subjects who did not complete the study. Their non-completion was reported to be due to complications from medical conditions unrelated to the study.

Summary of internal validity: The lack of blinding, differences of groups at baseline and lack of a power analysis calculation contribute to the study's fair rating of internal validity. Not blinding the subjects, therapists or assessors opens up this study to Hawthorne and Rosenthal effects as well as rater biases. At baseline, the control group had a greater average peak torque of their left and right legs as compared to the strength-training group ($p < 0.05$). Leg strength of the control group was only stated for baseline characteristics and therefore no discussion can even be made comparing the change in groups with respect to knee extensor strength. The lack of a power analysis is a threat to this study in that the study may not have detected present significant differences.

Evidence: Sixteen weeks after initiation of the strength-training program, Flint-Wagner *et al.* completed outcome measurements on both groups. To assess muscular strength, subjects performed a three repetition maximum (3RM) on a leg press, a measure of knee extensor strength. To assess physical function and health status, subjects completed the 50-foot walk test and a Health Assessment Questionnaire (HAQ). These stated measures were used to evaluate changes in groups with respect to time, as shown in Table 3. Changes in knee extensor strength in the strength training group increased from baseline to week 16 ($46.4 \pm 35.2\%$) but this could not be compared to the control group as only baseline measures were given, ($p < 0.05$). The strength training group had a greater decrease in 50-foot walk time from baseline to week 16 (-1.2 ± 1.6 seconds) as compared to the control group (0.8 ± 1.0 seconds), $p < 0.05$. Effect size for 50-foot walk time was not given by the authors and was therefore calculated to be 1.38 with a 95% confidence interval of (0.40-2.37). There were no significant differences in HAQ measures between groups from baseline to week 16.

Table 3. Between Group Comparison of changes in Muscular Strength, Physical Function and Health Status from baseline to completion of intervention program at 16 weeks.

	Control (n=7)	ST (n=15)	Effect Size	95% Confidence Interval
Change in Knee Extension F (%)	Data not given	46.4 ± 35.2**	N/A	N/A
Change in 50-foot walk time (sec)	0.8 ± 1.0	-1.2 ± 1.6*	1.38 (Large)	0.40 to 2.37
Change in HAQ score	-0.1 ± 0.40	-0.4 ± 0.40	N/A	N/A

*Significantly different from control group at $p < 0.05$.

** Significantly different from baseline at $p < 0.05$.

Applicability of study results:

Benefits vs. Costs:

The study included patients with with Functional Class I or II Rheumatoid Arthritis (Based on ACR criteria) having treatment with infliximab for ≥ 4 months and receiving no other biological therapies at the time of the study. Patients had no medical history of comorbid conditions and had not exercised ≥ 150 minutes per week in the three months preceding the study. Our patient of interest had Rheumatoid Arthritis Functional Class II. She did not participate in any exercise program, had no comorbidities and was on a regimen of Humira (adalimumab).

The results of this study were that the strength training group decreased their 50-foot walk time from baseline to week 16 more than the control group ($p < 0.05$). Though the strength training group increased their leg extensor strength from baseline to week 16, no between group comparison can be made due to the lack of week 16 data provided for the control group. There were a total of six subjects who did not complete the study, though their non-completion was reported to be due to complications from medical conditions unrelated to the study and no adverse events to treatment were described. The strength training group received 75 minute sessions 3 times per week for 16 weeks. Due to this, the strength training group received greater time and cost of intervention.

Feasibility of Treatment: The strength training program is best suited for a group therapy design. Each of the three sessions per week were 75 minutes long which is a large time commitment for both therapists and patients if conducted as Flint-Wagner described. Average attendance of the strength training sessions was $82.0\% \pm 10.6\%$ which is very high. Being able to convert this program into a home exercise program completed at a gym with only minimal sessions with a therapist would be ideal but is not very feasible. No additional training must be done for therapists to complete this protocol. Though the strength training exercises were sufficiently explained, the progression of the strength training program that can be too complicated for someone without an exercise training or therapy background and requires access to a gym. The equipment needed to complete the program includes therabands, weight machines, dumbbells and either space to complete aerobic exercising or a treadmill. These items can be provided by a therapist (theraband) and can be found in a typical workout facility (dumbbells, weight machines, treadmill).

Summary of External Validity: The study by Flint-Wagner *et al.* had fair external validity and the numerous threats to internal validity greatly decreasing our ability to use results to influence future treatments for the patient of interest. All subjects included were diagnosed with Rheumatoid Arthritis. Our patient was within the age range of the control and strength training group and was within the functional class level of the subjects in the

study. Additionally, the study subjects and our patient were on different treatment regimens to control their RA.

Article: Lemmey AB, Marcora SM, Chester K, Wilson S, Casanova F, Maddison PJ. Effects of high-intensity resistance training in patients with rheumatoid arthritis: a randomized controlled trial. *Arthritis and Rheumatism* 2009 Dec 15;61(12):1726-1734.

Clinical Bottom Line: Based on the results of this study, there is moderate evidence to suggest that for patients with Rheumatoid Arthritis, a 24-week intervention of high-intensity progressive resistance training (PRT) results in changes in muscle strength, health status, and functional ability, when compared to low-intensity range of motion (ROM). Outcomes of interest included knee extensor muscle strength as measured by dynamometry, Multidimensional Health Assessment Questionnaire (MDHAQ), and a 50-foot walk test. From baseline to week 24, the Progressive Resistive Training (PRT) group had a significant increase in knee extensor muscle strength and significant decrease in time for the 50-foot walk test ($p < 0.05$); however, mean change scores could not be calculated due to insufficient information. Additionally, further analysis by Lemmey *et al.* for knee extensor muscle strength and the 50-foot walk test indicated large effect sizes of 0.34 and 0.28, respectively, using a 95% confidence interval. According to our analyses, 0.34 and 0.28 actually represent small effect sizes. Lemmey *et al.* did not describe why the effect size ranges were skewed in the article. Regarding health status, no significant difference was found in MDHAQ scores between the two groups. Major threats to the internal validity of this study include lack of blinding, poor inter-rater and intra-rater reliability, and poor validity of instrumentation. Overall, a high-intensity individualized strengthening program is not a cost-effective, beneficial treatment option or feasible alternative due to the amount of time and resources necessary for optimal results. Results of this study cannot be adequately generalized to our patient of interest due to the extensive amount of time needed to achieve these results using their exercise program and it would be difficult to receive reimbursements from insurance companies.

Article PICO

Population— The study included patients from The Gwynedd Rheumatology Department at Gwynedd Hospital, Bangor, UK. Subjects were ≥ 18 years old, diagnosed with RA Functional Class I or II, on < 10 mg/day of corticosteroids and whose drug therapy had been stable for 3 months preceding the study.

Intervention— The intervention investigated by this study is a progressive resistance-training (PRT) program to restore muscle mass, physical function, and ability to perform habitual physical activity.

Comparison— The control group ($n=15$) completed low-intensity range of motion (ROM) exercises twice weekly without causing muscle hypertrophy.

Outcomes— The outcome measurements of interest included: knee extensor strength, timed 50-foot walk test, and the Multidimensional Health Assessment Questionnaire (MDHAQ).

Blinding: Lemmey et al did not blind patients, therapists, or examiners. This poses a significant threat to the study due to subjective outcome measures that were utilized such as the MDHAQ.

Controls: The control group received low-intensity ROM exercises to be performed twice a week at home at an intensity that would not elicit muscle hypertrophy. To monitor compliance, patients were required to keep a daily diary and report any adverse effects. Patients were also phoned every two weeks. The treatment group also performed low-intensity ROM exercises as a 10-minute warm-up prior to PRT sessions and a 10-minute cool-down following PRT interventions twice a week. The authors did not state how long or how often the control group performed ROM exercises during each session, thus it is unclear if differences between groups can solely be attributed to the intervention. At baseline, there were no differences between the two groups.

Randomization: After meeting the inclusion and exclusion criteria, 36 patients were randomized by stratified random allocation to either a control group (n=15), which consisted of low-intensity ROM exercises, or the intervention group (n=13), which consisted of PRT in addition to the ROM exercises. Age, sex, and estrogen status were used as the stratified variables. Of the 36 eligible patients, only 28 completed the baseline assessments and began training. There were no differences between groups at baseline for age, sex, disease duration, current disease activity and medication, or estrogen status.

Study: This was a randomized clinical control study that compared the efficacy of a high-intensity PRT program in restoring muscle mass and function in patients with RA in comparison to low-intensity ROM exercises.

A total of 36 patients composed of men and women over the age of 18 years were randomized into the PRT group or the control group by stratified randomization. The sample size was determined by a power analysis for Appendicular Lean Mass (ALM). Patients were recruited from the Gwynedd Rheumatology Department and met the following criteria: diagnosed with RA, considered in functional class I or II, having no cognitive impairments, drug therapy must be stable for the past 3 months, on <10 mg/day of corticosteroids, free of cachectic diseases, free of any medical conditions impairing ability to participate in high-intensity exercise, not taking any anabolic supplements, not currently participating in intense physical training, and not pregnant.

Of the 36 patients that were recruited, 28 attended baseline assessments and participated in the study. The control group (n=15) was instructed to perform low-intensity ROM exercises twice a week, to keep a training diary for compliance and to report any adverse effects, and to maintain their normal habitual physical activity and diet. The PRT group (n=13) trained twice a week for 24 weeks under the supervision of three exercise physiologists. The PRT program (n=13) included 3 sets of 8 repetitions at a load 80% of patient's 1-repetition max (1-RM) with 1-2 minutes rest between sets for the following exercises: leg press, chest press, leg extension, seated rowing, leg curl, triceps extension, standing calf raises, and bicep curl. To reduce muscle soreness, during the first week, patients performed only 1 set of exercises and during the second week, patients performed 2 sets. Additionally, during weeks 1-4, patients performed 15 repetitions per set at 60% 1-

RM and during weeks 5 and 6, 12 repetitions per set at 70% of their 1-RM before progressing to 70% 1-RM in weeks 7-24. Each patient's 1-RM was reassessed every 4 weeks. PRT sessions were preceded by a 10-minute warm and followed by a 10-minute cool-down of low-intensity ROM exercises.

Outcome measures: Lemmey *et al.* measured muscle strength of the knee extensors at a fixed joint angle of 90 degrees using an isokinetic dynamometer, timed 50-foot walk test, and MDHAQ. Measurements were recorded at baseline and after the 24-week training period. The authors failed to mention the reliability and validity of their outcome measures within the study. Thus, measurements can only be taken at face validity. MCIDs were not reported and has not been reported in the literature.

Study losses: After recruiting 36 patients, three from the control group and five from the PRT group were unable to complete baseline assessments and did not participate in the interventions. There were no study losses reported following baseline. Despite the loss of patients, no difference was found at baseline between the groups.

Summary of internal validity: The internal validity of this study is fair. Lemmey *et al.* allocated patients to either the control or intervention group via randomization. A power analysis was calculated for sample size according to the primary outcome measure Lemmey *et al.* was interested in, Appendicular Lean Mass (ALM). This was calculated to be five subjects per group. Lemmey *et al.* recruited a total of 36 subjects to account for study losses. However, the lack of blinding of the patients, therapists, and examiners poses a major threat to the internal validity of this study due to Hawthorne and Rosenthal effects as well as rater bias. Furthermore, the authors did not state inter-rater or intra-rater reliability. Thus, it is unclear if there are differences between the various raters who performed the tests and this raises major concerns to the study's internal validity. The reliability of the instruments and outcome measures used were not validated, which also poses minor threats to the study. The instruments used were not reportedly calibrated to the appropriate setting and use of the MDHAQ versus the standard HAQ can only be assumed to be a valid measure.

Evidence: Twenty-four weeks after initiation of the progressive resistive training program (PRT), Lemmey *et al.* completed outcome measurements on both groups. To assess muscular strength, subjects performed a maximal volitional isometric knee extensor contraction using an isokinetic dynamometer with a fixed joint angle at 90 degrees. To assess physical function and health status, subjects completed the 50-foot walk test and a Multidimensional Health Assessment Questionnaire (MDHAQ). These stated measures were used to evaluate changes in groups with respect to time, as shown in Table 4 below. There were no significant differences from baseline to 24 weeks in any of the measures for the ROM group. Changes in knee extensor strength were greater in the PRT group ($81 \pm 145\text{N}$) as compared to the ROM group ($21 \pm 180\text{N}$), ($p < 0.05$). Lemmey *et al.* calculated effect size to be 0.34 for knee extensor strength changes. The PRT group had a greater decrease in 50-foot walk time from baseline to week 24 (-1.56 ± 2.78 seconds) as compared to the ROM group (-0.14 ± 5.71 seconds), ($p < 0.05$). Effect size was given as 0.28 for 50-foot walk time between groups. There were no significant differences in MDHAQ measures from baseline to week 24 in either group.

Table 4. Between Group Comparison of Muscular Strength, Physical Function and Health Status changes from baseline to twenty-four weeks of intervention.

	Range of Motion ROM (n=15)	Progressive Resistive Training PRT (n=13)	Effect Size
Knee Extension Force Pre-Test (N)	308 ±131	323 ± 79	0.34
Knee Extension Force Post-Test (N)	329 ±123	404 ± 122*	
50-foot walk time Pre- Test (sec)	10.03 ± 3.78	9.33 ± 2.40	0.28
50-foot walk time Post- Test (sec)	9.89 ± 4.28	7.77 ± 1.40*	
MDHAQ score Pre-Test	0.575 ± 0.619	0.914 ± 0.680	N/A
MDHAQ score Post-Test	0.575 ± 0.590	0.817 ± 0.691	

*Change from Pre-Test to Post-Test significantly different from control group at $p < 0.05$.

Applicability of study results:

Benefits vs. Costs: Lemmey *et al.* studied patients over 18 years of age with Functional Class I or II Rheumatoid Arthritis. All subjects were on a stable anti inflammatory and/or antirheumatics therapy for the past three months and, if on corticosteroids, on a stable dosage of less than 10mg per day. No subjects were pregnant, taking anabolic drugs or supplements, had cachectic disease or a disease where high intensity training is contraindicated, were cognitively impaired, or had undergone regular high intensity training. The patient of interest had Rheumatoid Arthritis Functional Class II. She did not participate in any exercise program, had no comorbidities and was on a regimen of Humira (adalimumab).

The results of this study were that the control group showed no significant differences from baseline to 24 weeks in any of the stated measures. Changes in knee extensor strength were greater in the PRT group (81 ± 145 N) as compared to the ROM group (21 ± 180 N), ($p < 0.05$). The PRT group had a greater decrease in 50-foot walk time from baseline to week 24 (-1.56 ± 2.78 seconds) as compared to the ROM group (-0.14 ± 5.71 seconds), ($p < 0.05$). There were no significant differences in MDHAQ measures from baseline to week 24 in either group.

Lemmey *et al.* recruited a total of 36 subjects. Three subjects from the control group and five from the PRT group were unable to complete baseline assessments and did not participate in the interventions. There were no study losses reported following baseline. No baseline characteristic differences were found between the groups.

The PRT group received 24 weeks at 2 sessions per week of training lead by exercise physiologists at a local fitness center. They performed 10 minutes of warm-up and cool-down in addition to 3 sets of 8 repetitions of eight resistance exercises with 1-2 minutes of rest between sets. Lemmey *et al.* did not indicate total time spent per session with each patient. Both groups recorded their activity in a training diary. The control group subjects were talked to on the phone once every two weeks and performed range of motion (ROM) exercises twice weekly after instruction by exercise physiologists. The PRT group received a much greater interaction and training with the exercise physiologists. If the PRT program is applied to our patient it will result in a greater time and cost of intervention as compared to instructing her in a home based range of motion exercise (ROM) program.

Feasibility of Treatment: The PRT program is best suited for a group therapy design. Each of the twice weekly sessions were not given a specific duration of time but most likely would take more than 30 minutes. This is a large commitment for both therapists and patients if the PRT program is conducted for 24 weeks as Lemmey *et al.* described. Average attendance of the PRT sessions was 73% as compared to the control group reporting 54% compliance via training journal. Having the ability to convert this program into a home exercise program completed at a gym with only minimal sessions with a therapist and high compliance would be ideal but is not very feasible. No additional training must be done for therapists to complete this protocol. Though the strength training exercises were sufficiently explained, the progression of the strength training program that can be too complicated for someone without an exercise training or therapy background and needing access to a gym. The ROM exercise program was not described in any detail, therefore would be difficult to replicate. The equipment needed to complete the program included a multi-stack resistance exercise machine that can be found at most exercise facilities.

Summary of External Validity: The study by Lemmey *et al.* had fair external validity and the numerous threats to internal validity greatly decrease our ability to use results to influence future treatments for the patient of interest. All subjects included were diagnosed with Rheumatoid Arthritis. Our patient was within the age range and RA Functional Class level of the ROM and PRT groups. Though the subjects were randomly allocated, no party was blinded to the allocation. The authors did not state inter-rater or intra-rater reliability for measurements, which could have affected the 50-foot walk time outcomes. The reliability of the instruments and outcome measures used were not validated, which also poses major threats to both the 50-foot walk time and dynamometry measurements. The use of the MDHAQ versus the standard HAQ can only be assumed to be a valid measure. A power analysis was performed to determine sample size and to account for potential dropouts.

Synthesis/Discussion

The purpose of this analysis is to compare of the effect of high-intensity strength training to standard medical care on muscle strength, functional ability and health status, in patients with Rheumatoid Arthritis (RA) Functional Class II. Specific outcome measures included muscle strength of the knee extensors, aerobic tests such as the 50-foot walk test and standardized ergometer test as well as the Health Assessment Questionnaire. The three studies that were presented all had similar outcomes and we are able answer our clinical question. The studies that we have found fit our patient based on age, functional RA classification, current physical ability or functional level, and our outcome measures. However, we were unable to find studies that focused on individualized, short-term high-

intensity strength training that would apply to a typical physical therapy prescription of six to eight weeks.

All three studies demonstrate “fair” internal validity when reviewing their PEDro scores with ratings of 7/10, 6/10, and 6/10 for de Jong *et al.*, Flint-Wagner *et al.*, and Lemmey *et al.*, respectively. de Jong *et al.* earned fair rating due to blinding of the assessors, power and intention to treat analyses, inter-rater and intra-rater reliability. Nevertheless, the authors did not cite validity or reliability of the cycle ergometer test and though they attempted to control for blinding, they were unable to blind the patients and therapists. Flint-Wagner *et al.* earned the fair rating due to lack of blinding, differences between groups at baseline, and lack of a power analysis. Lemmey *et al.* also earned a fair rating due to lack of blinding, inter-rater and intra-rater reliability, and the inability to cite validity of the MDHAQ.

Increases in knee extensor muscle strength were determined from baseline to posttest measurements within the treatment groups for all three studies, ($p < 0.05$). However, only de Jong *et al.* and Lemmey *et al.* reported greater increases in knee extensor strength in treatment groups as compared to control groups, ($p < 0.05$). Flint-Wagner *et al.* did not report a group comparison for this measure, thus we do not know if there were any significant differences between treatments. The lower extremity muscle exercises used in the interventions to increase muscle strength were similar in the studies by Flint-Wagner *et al.* and Lemmey *et al.* but it is unknown what specific exercises were used by de Jong *et al.*, which affects the ability to apply their treatment to our patient. All measurements in each study were recorded via isokinetic dynamometry.

Additionally, in all three studies, intervention groups were found to have greater increases in aerobic testing from baseline to the end of the intervention as compared to the control groups, ($p < 0.05$). The only difference in methods between the studies is the use of a standardized bicycle ergometer test for aerobic function by de Jong *et al.*

Regarding health status, all three studies also had identical results in that there were no significant improvements found between the intervention group and the control group. However, it is important to note that the three authors used different variations of the Health Assessment Questionnaire (HAQ). de Jong *et al.* used the standard HAQ while Flint-Wagner *et al.* used the HAQ Disability Index (HAQ DI) and Lemmey *et al.* used the Multidimensional HAQ (MDHAQ). The use of the various assessments may affect the ability to adequately compare these tests to each other. Because there were no differences for this outcome measure, we believe this is a minor issue. Furthermore, studies cited by all three authors indicated similar results regarding a lack of change in health status.

Based on the analysis of the three studies, we believe there is moderate evidence to support the use of high-intensity strength training over standard medicinal care in treating patients in RA Functional Class II. Research demonstrated increases in muscle strength for the knee extensors and physical ability represented by aerobic test scores. However, the intervention does not change patients' health status as evaluated by various forms of the HAQ. Overall, we believe that though this treatment is moderately effective, the amount of time and the use of a group-based intervention make this treatment difficult to generalize and apply to our patient. The risk of potential damage to various bone joints stills needs to be clarified by further research. de Jong *et al.* was the only study amongst the three articles that found no significant increases or further damage over a period of 2 years, $p < 0.05$.

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