

Feasibility of Heavy Slow Resistance Training in patients with subacromial shoulder pain. A single-blind, randomized pilot study.

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Abstract

Background: Subacromial shoulder pain is the most common shoulder diagnosis, and should preferably be treated non-operatively. Previous studies have shown promising results of Heavy Slow Resistance training (HSR) in patellar and Achilles tendinopathy, but few studies have evaluated the effect of HSR for shoulder pain. The purpose of this pilot trial was to evaluate if HSR training is feasible for patients with subacromial shoulder pain, and to compare HSR to traditional supervised exercises. **Methods:** Twenty-two patients with subacromial shoulder pain lasting at least three months were recruited and randomized to HSR (n=11) or traditional supervised exercises (n=11) by computer-generated randomization in blocks of four. Patients received HSR once a week, in addition to home-training twice a week, or supervised exercises twice a week for 12 weeks, in addition to daily home-training. The primary outcome measure was the Shoulder Pain and Disability Index (SPADI). Linear regression analysis was applied to evaluate the between group differences after 12 weeks. Outcome assessors were masked. **Results:** After 12 weeks, patients in both groups had improved significantly from baseline in SPADI score ($P=0.001$) but no group difference was found (mean difference 1.3; 95% CI, -21.9 to 24.5, $P=0.91$). Similar non-significant results between groups were seen for pain in activity and rest, and the DASH score. **Conclusion:** This pilot-study observed similar results of HSR compared to supervised exercises for patients with subacromial shoulder pain and both groups improved significantly from baseline. Only one patient changed from HSR to supervised exercises due to increased pain. Based on this, HSR appears to be a feasible treatment for this patient group, but due to small sample size there is a risk of type II error and studies with larger sample size are required.

Background

Shoulder pain is common in general practice, and a systematic review¹ reported 1–month prevalence from 19-31%. More recent studies have reported that subacromial pain is the most common form of shoulder pain; both in general practice² and secondary care³. Many patients suffer from long lasting pain and reduced function of the shoulder, which is costly for the society⁴. It is therefore crucial to develop good strategies of treatment to these patients.

Subacromial pain syndrome (SAPS), or subacromial impingement syndrome (SIS), is a broad term that covers a variety of underlying pathology that affects tissue of the subacromial space: tendons, muscles and bursa. This includes, but is not limited to, rotator cuff tendinopathy, subacromial bursitis and partial rotator cuff tears. The pain is commonly located on the lateral side of the shoulder and develop over a period of weeks to months. The patients often experience a painful arch on active abduction. The diagnosis is clinical, but it is important to rule out other severe conditions. Guidelines developed by the Dutch Orthopaedic Association⁵ for diagnosis of SAPS recommend using a combination of clinical tests.

There are many treatment options available for patients suffering from subacromial shoulder pain such as physical therapy, analgesics, surgery and shockwave therapy. Review articles have concluded with a significant effect of exercise therapy, and recommend exercises as the first-line treatment^{6,7}. Injection on

of glucocorticoids may be indicated for patients with persistent or recurring pain⁵. Many patients are receiving surgery, even though randomized controlled trials and review articles conclude that supervised exercises yield the same effect as surgery^{8,9,10}.

During the last few years, a new kind of exercise treatment for tendinosis has been tested and it has shown promising results for Achilles tendinopathy and patellar tendinopathy^{11,12}. This new type of exercise, Heavy Slow Resistance (HSR), differentiates from traditional exercise therapy by focusing on heavy weights and slow repetitions. In the study of patellar tendinopathy, the effectiveness of HSR training was similar compared to the traditional eccentric training both in short- and long-term effect. The HSR group reported higher overall satisfaction, and the study suggested a reduction of tendon abnormality and increased collagen turnover¹¹. The authors suggested that HSR training may allow for a longer restitution period between each loading session. In the Achilles trial, the effectiveness of the HSR and eccentric training was similar and HSR group had greater satisfaction after 12-weeks, but not after one year¹². The increased satisfaction reported with this type of exercises may be beneficial for compliance and improve treatment fidelity.

There are a few studies of this type of training, only one recent study from Denmark¹³ has tested the effectiveness of progressive high-load strength training in patients with subacromial pain. The study concluded that high-load strength training is not superior to traditional training for patients with rotator cuff tendinopathy and that further investigation is required.

The purpose of the present pilot trial was to evaluate whether HSR training is feasible for patients with subacromial shoulder pain, and to compare HSR to traditional supervised exercises.

Methods

The study was designed as a prospective, randomized single-blind trial with an intervention period of 12 weeks. Patients were recruited from the outpatient clinic at the Department of Physical Medicine and Rehabilitation, Oslo University Hospital, Oslo, Norway. During a regular consultation for shoulder pain, the physicians at the outpatient clinic evaluated eligibility for all patients examined. Patients with SAPS lasting at least three months were eligible. The patients then were referred to a medical student for inclusion of the trial.

The inclusion criteria were pain on one of two isometric tests (abduction or external rotation); positive Hawkins-Kennedy impingement sign; and normal passive glenohumeral range of motion. The exclusion criteria were previous surgery on the affected shoulder; instability; rheumatoid arthritis; clinically considered full thickness tear of the rotator cuff; clinical signs of nerve root symptoms from the neck; patients considered unable to fill out questionnaires in Norwegian or follow the treatment; pregnancy; and injection of cortisone in the affected shoulder in the last six weeks.

The study was approved in the Regional committee for medical and health research ethics (REK) ref: 2017/1277 and was registered in the ClinicalTrials.gov: NCT03317808. The study adheres to the Consort guidelines. All study participants have submitted written approval for participation in the study.

The patients were randomized to one of two different intervention groups (HSR and traditional treatment) by a pc-based block randomization with four in each block. The allocation ratio was 1:1. A research assistant not involved in any other part of the study opened the sealed opaque envelopes and assigned the patients to their respective treatment group. The outcome assessors were masked to treatment allocation. Subjects with bilateral symptoms received treatment for both shoulders, but only the most painful shoulder at baseline was selected for analysis. The patients were informed that they could not receive any other form for physical therapy during this period, but they were allowed to use analgesics.

Heavy slow resistance

The patients in the HSR group received one individual training session each week for 12 weeks, supervised by a physical therapist, at the outpatient clinic at the Department of Physical Medicine and Rehabilitation, Oslo University Hospital. In addition they were instructed to perform the HRS program twice a week at home. Each session consisted of three specific exercises for the shoulder: shoulder flexion, abduction and external rotation. Flexion was performed in supine position, whereas abduction and external rotation were performed in side-lying position. All exercises were performed in both in eccentric and concentric phase. Patients were instructed to use 3 seconds completing each eccentric and concentric phase (i.e. 6 seconds per repetition), as previously described^{11,12}. The exercise equipment used was hand held dumbbells. Patients were also instructed in different stretching exercises if needed (pectoralis stretch, cross-body shoulder stretch, sleeper stretch for internal rotation). For the first three weeks of training, they were given soft tissue treatment in addition. During the 12 weeks the treatment lasted, the number of repetitions gradually decreased; and the load gradually increased. The number of repetitions were: 3 x 15 repetitions in week 1; 3 x 12 repetitions in weeks 2 to 3; 3 x 10 repetitions in weeks 4 to 5; 3 x 8 repetitions in weeks 6 to 8; and 3 x 6 repetitions in weeks 9 to 12. The starting load was approximately the patients' 15-repetition maximum (15RM) and increased to match the decrease in repetitions, or as tolerated, based on shoulder pain. Some pain during, and after, exercise was acceptable, but if the pain lasted to the next day, the load was decreased. The load also decreased if the pain during the exercise exceeded a threshold of 5 on an 11-pointed pain (0-10) Numeric Rating Scale (NRS). To improve compliance the patients were given a training diary to register the number of the training session they completed for each week, and what load they used.

The patients in the HRS group were also informed about the possibility to transfer to the other group, if the treatment was considered ineffective or the pain increased.

Traditional supervised exercises

The patients in the traditional group were given treatment by a physical therapist, conducted one-to-one, twice a week for 12 weeks, in addition to daily home-exercises. This is a program developed by at Ullevål

University Hospital (now Oslo University Hospital) in the 1980s¹³, with a documented effect in earlier studies^{14,15,16}.

The following paragraph is a description of the training regimen by the developer Bøhmer¹⁴ “The first session included gathering of medical history as well as bilateral inspection of alignment, including scapula and the glenohumeral joint. Movement pattern, the immediate co-contraction, and timing of the scapula and the arm were observed during elevation to obtain a functional diagnosis for individual guidance of treatment. The principal treatment focus was on relearning of normal movement patterns, which could then be transferred to daily activities. The initial aim was to unload the stress on the rotator cuff and subacromial structures. This phase entailed awareness of posture and the use of manual techniques for tense muscles, and elastic rubber band for relaxed repetitive movements, exercises for periscapular muscles, and a vertically fixed sling. The focus in the next phase was to increase the eccentric force when the patient was lowering the arm in standing position. The patients received immediate feedback from and correction by the physical therapist. Subsequently, endurance exercises with gradually increasing resistance were performed.”

Outcomes

The primary outcome was change in the Shoulder Pain and Disability Index (SPADI) score¹⁷. The SPADI score is a self-report questionnaire with twelve questions regarding the last week divided into two dimensions: five questions for pain and eight questions for disability of the shoulder. Each dimension accounts for 50% of the overall score. The questions are answered by marking on a visual analogue scale, which are later converted to scores from 0 to 10. 0 = no pain/problem, 10 = worst possible pain/so difficult I needed help. The total SPADI score is calculated into a number between 0 and 100, with 100 meaning worst pain and disability. The questionnaire is concluded to be reliable and acceptable for assessing Norwegian-speaking patients with subacromial shoulder pain, with 19.7 being the smallest detectable change (SDC)¹⁸.

Secondary outcomes were the Disabilities of the Arm, Shoulder and Hand (DASH) score¹⁹, pain in activity and rest last week and shoulder function last week. DASH is also a self-report questionnaire that contains of 30 questions regarding dysfunction of the shoulder the last week, five work-related questions and five sport- and instrument-related questions. The scores for all items are then used to calculate a scale score ranging from 0 (no disability) to 100 (most severe disability).

DASH is previously evaluated, SDC reported at 11.8, and is recommended to measure outcome in patients with shoulder pain in Norway²⁰.

Pain on activity and at rest last week were all measured on an 11 point Likert-type scale: 0= no pain/problem, 10= worst possible pain/impossible to complete. Answers were converted in the same way as the SPADI questions. Besides, the shoulder function the last week was evaluated with two questions: “Can you carry a 5kg shopping bag” and “Can you take something down from a high shelf?”

Outcomes were evaluated at baseline and at the end of the 12-week intervention. The patients completed a written questionnaire and underwent a physical examination at both time points. The baseline questionnaire was however, more comprehensive and included sociodemographic and clinical factors such as sex, age, marital status, education, work and sick leave, duration of symptoms, self-efficacy and outcome expectations.

Statistical analysis

This study is a pilot study; therefore a calculation of sample size was not performed. IBM SPSS version 25 was used for all statistical analyses. A medical student completed the clinical evaluation and to avoid bias, this person was blinded during the study and the analyses. Terms used and given in the results are mean, standard deviation (SD), numbers, percentages, odds ratio (OR) and 95% confidence intervals (CI).

The analyses were completed by the intention-to-treat principle. Descriptive statistics was used to estimate mean (with SD) baseline and demographic characteristics and to estimate the mean (with SD) primary and secondary outcome scores at baseline and at the 12-week follow up.

Linear regression analysis adjusting for baseline SPADI was applied with the SPADI score at 12 weeks as the dependent variable to evaluate the between group differences for the patients who received HSR vs. the patient who received supervised exercises. The same analysis was also applied for the secondary outcomes.

To estimate effect of treatment by the SPADI score, 19.7¹⁸ points (SDC) on the SPADI score was used as the smallest detectable change between baseline and 12-week follow up. Likewise, 11.8 points²⁰ on the DASH score was used as the smallest detectable change. Binary logistic regression was used to compare the number of patients achieving SDC in the two groups and the OR (95%) was calculated.

Paired sample t-test was used to evaluate the change in outcomes, not divided by groups.

Results

Twenty-five patients were assessed for eligibility, and 22 patients were included in the study between October 16, 2017 and September 20, 2018. Figure 1 is a flowchart that shows the inclusion, exclusion and dropout throughout the trial. Eleven patients were randomly assigned to the HSR group, and 11 to the traditional group. In both of the groups one person failed to complete, and did not show up for the 12-week follow-up. Ten patients (91%) in each group followed up. In addition, one person changed from HSR to supervised exercises due to increased pain.

Table 1 shows the baseline characteristics of the patients, both overall and according to the treatment group. There were no significant differences between the two groups at baseline. Mean age in the HSR group was 8.7 years younger than the supervised exercise group, but the groups are not significantly different (CI: -18.8 to 1.5, p=0.09).

The overall mean change of the SPADI after 12 weeks was 20 (95% CI; 8.9 to 31.3, $P=0.001$). The group difference of the SPADI score was not significant (mean difference 1.3, 95% CI; -21.9 to 24.5, $P=0.91$), table 2. Out of all the patients that completed the 12-weeks follow-up ($n = 20$), 5 (50%) in the HSR group and 3 (30%) in the supervised exercise group had an improvement in the SDC of at least 19.7 points (OR 1.03, 95% CI; 0.86 to 1.23, $p=0.51$).

The group difference in DASH was not significant (mean difference 0.38, 95% CI; -16.8 to 17.0, $p=0.96$), table 2. Six patients (60%) in the HSR group, and 5 patients (50%) in the supervised exercise group achieved a reduction in the DASH score greater than the SDC of 11.8 points (OR 1.04, 95% CI: 0.97 to 1.10, $p=0.28$).

In accordance with the SPADI and DASH scores, the remaining of the secondary outcomes displayed in table 2 shows no significant mean group difference.

Discussion

The purpose of this pilot study was to evaluate the feasibility of HSR exercise for patients with shoulder impingement syndrome, compared to a traditional exercise treatment.

This study found no significant differences between the two treatments in either the primary or the secondary outcome measures, but both groups had a reduction in pain on activity and at rest, and a reduction in the SPADI and DASH score. These results are similar to that of Ingwersen et al¹³ and Maenhout et al²¹, who did not find difference in effectiveness between a heavy loaded group compared to a traditional exercise group. In accordance with previous studies this suggests that the type of exercise may not be important.

On the other side, each patient is different, and may benefit from individualised treatment. Exercise type may be specified for each patient individually. This is previously discussed briefly by other authors^{13,22,23}. The results of the current study suggest that different treatment methods may have a positive effect.

One patient crossed over from the HSR group to the traditional group because of increased pain and problems in performing the exercises. The HSR exercise regimen may be difficult to perform, and especially for the patients reporting a high pain intensity at baseline. Future studies with a larger number of participants may answer which patients that may benefit from HSR exercises.

The study on Achilles tendinopathy¹² demonstrated higher patient satisfaction among the group with HSR compared those that received eccentric training. The overall time requirement each week were significantly higher for the patients in the eccentric group compared to the HSR group, and the authors explained this to be a possible reason for the difference. The patient satisfaction was not evaluated in our study.

Study limitations

The current study has several limitations. The sample size was small, which makes it difficult to detect differences between groups and there is a risk of type II error. Due to this project being a pilot study and a part of a project thesis for a medical student the time frame for inclusion of patients was limited. However, pilot studies may be an important part of developing a strategy of treatment²⁵.

Secondly, the follow-up was short. The long-term effect of the exercise interventions is not evaluated in this study.

Thirdly, the study did not include a no treatment group. The traditional treatment has shown significant results from earlier^{14,15,16}, but in this current study, it is not possible to decline the possibility of natural regression to have contributed to the overall improvement regarding pain and function.

In addition, the mean age in the HSR group was 8.7 years younger than the supervised exercise group, which might have affected the results even though the groups were not significantly different

Conclusion

This pilot-study observed similar results of HSR compared to supervised exercises for patients with subacromial shoulder pain and both groups improved significantly from baseline. Only one patient changed from HSR to supervised exercises due to increased pain. Based on this, HSR appears to be a feasible treatment for this patient group, but due to small sample size there is a risk of type II error and studies with larger sample size are required..

List Of Abbreviations

DASH	-	Disability of Arm and Shoulder
HSR	-	Heavy Slow Resistance training
NRS	-	Numeric Rating Scale
SAPS	-	Subacromial Pain Syndrome
SIS	-	Subacromial Impingement Syndrome
SPADI	-	The Shoulder Pain and Disability Index

Declarations

Ethics approval and consent to participate

The study approved in the Regional committee for medical and health research ethics (REK) ref: 2017/1277. All study participants have submitted written approval for participation in the study.

Consent for publication

Not applicable.

Availability of data and material

The datasets generated and analysed during the current study are available from the first author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

There was no external funding of the trial.

Author's contributions

EK supervised the clinical evaluation, contributed to the design of the study and writing of the manuscript. HHFH is the medical student that performed the clinical evaluation of the patients at the inclusion and 12-week follow-up, analysed and interpreted the patient data and contributed in writing of the manuscript. MBJ and KBE contributed to the design of the study, developed the HSR method, treated the patients and contributed in writing of the manuscript. JIB contributed to the design of the study and writing of the manuscript. CR contributed to the design of the study, analysed the data and contributed in writing of the manuscript.

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Tables

	Total (N=22)	HSR (N=11)	Supervised exercise (N=11)
Age (years), mean (SD)	46.4 (12)	41.8 (10.8)	50.5 (12)
Sex (female)	13 (59%)	7 (63.6%)	6 (54.5%)
Marital status (Single)	7 (31.8%)	5 (45.5%)	2 (18.2%)
Education			
Completed junior high school	2 (9.1%)	0	2 (18.2%)
University/college	11 (50%)	6 (54.5%)	5 (45.5%)
Duration of symptoms			
3-6 months	4 (18.2%)	2 (18.2%)	2 (18.2%)
6-12 months	3 (13.6%)	2 (18.2%)	1 (9.1%)
12-24 months	6 (27.3%)	3 (27.3%)	3 (27.3%)
≥ 24 months	9 (40.9%)	4 (36.4%)	5 (45.5%)
Earlier received physical treatment	18 (81.8%)	10 (91%)	8 (72.7%)
Earlier received injections of corticosteroids*	7 (31.8%)	3 (27.3%)	4 (46.4%)
Consumption of analgesics			
Daily	6 (27.3%)	1 (9.1%)	5 (45.5%)
Weekly	9 (40.9%)	6 (54.5%)	3 (27.3%)
Self-efficacy (1-7), mean (SD) **	4.1 (1.2)	4.3 (1.2)	3.9 (1.2)
Outcome expectations (1-7), mean (SD) ***	4.6 (1.3)	4.3 (1.5)	4.9 (1.1)
Full- or part time work	16 (72.7%)	9 (81.8 %)	7 (63.6%)
Bilateral shoulder pain	8 (36.4%)	4 (36.4%)	4 (36.4%)
Worst shoulder pain in right shoulder ****	12 (54.5%)	9 (81.8%)	3 (18.2%)

Table 1: Baseline characteristics of patients

* Injection received at least 6 weeks earlier than the inclusion. ** Combined score of 4 questions; 1=easy, 7=impossible. *** Combined score of 3 questions; 1=much worse, 7=much better. **** The patients were asked to determine their worst shoulder.

	HSR	Supervised exercise	Group difference in treatment effect after 12 weeks	P-value
SPADI, baseline	53.9 (21)	52.5 (23.8)		
SPADI, 12-week follow-up	33 (31.2)	33.3 (26.5)	1.25 (-21.9 to 24.46)	0.91
*Pain in activity, baseline	7 (1.2)	6.2 (1.8)		
*Pain in activity, 12-week follow-up	4.5 (3.1)	4.2 (3.0)	0.40 (-2.4 to 3.1)	0.77
*Pain in rest, baseline	4.2 (1.9)	4.4 (3.0)		
*Pain in rest, 12-week follow-up	3.3 (3.0)	2.1 (2.1)	-1.33 (-3.39 to 0.74)	0.19
*Able to carry a 5g groceries bag, baseline	4.7 (3.2)	3.9 (3.1)		
*Able to carry a 5g groceries bag, 12-week follow-up	3.6 (3.5)	2.9 (2.8)	0.496 (-3.5 to 2.5)	0.73
*Able to take something down from a high shelf, baseline	5.8 (3.0)	5.5 (3.2)		
*Able to take something down from a high shelf, 12-week follow-up	3.6 (3.7)	3.4 (3.3)	-0.26 (-3.59 to 3.1)	0.87
DASH, baseline	41.3 (14.1)	41.2 (20)		
DASH, 12-week follow-up	26.2 (22.7)	26.4 (20.7)	0.38 (-16.8 to 17)	0.96

Table 2: Mean (SD) scores at baseline and the 12-week follow-up regarding primary and secondary outcomes, and difference in treatment effect after 12 weeks, from linear regression analysis.

*These eight questions were answered on an 11-point (0-10) Likert scale. 0 = easy, 10 = impossible

Figures

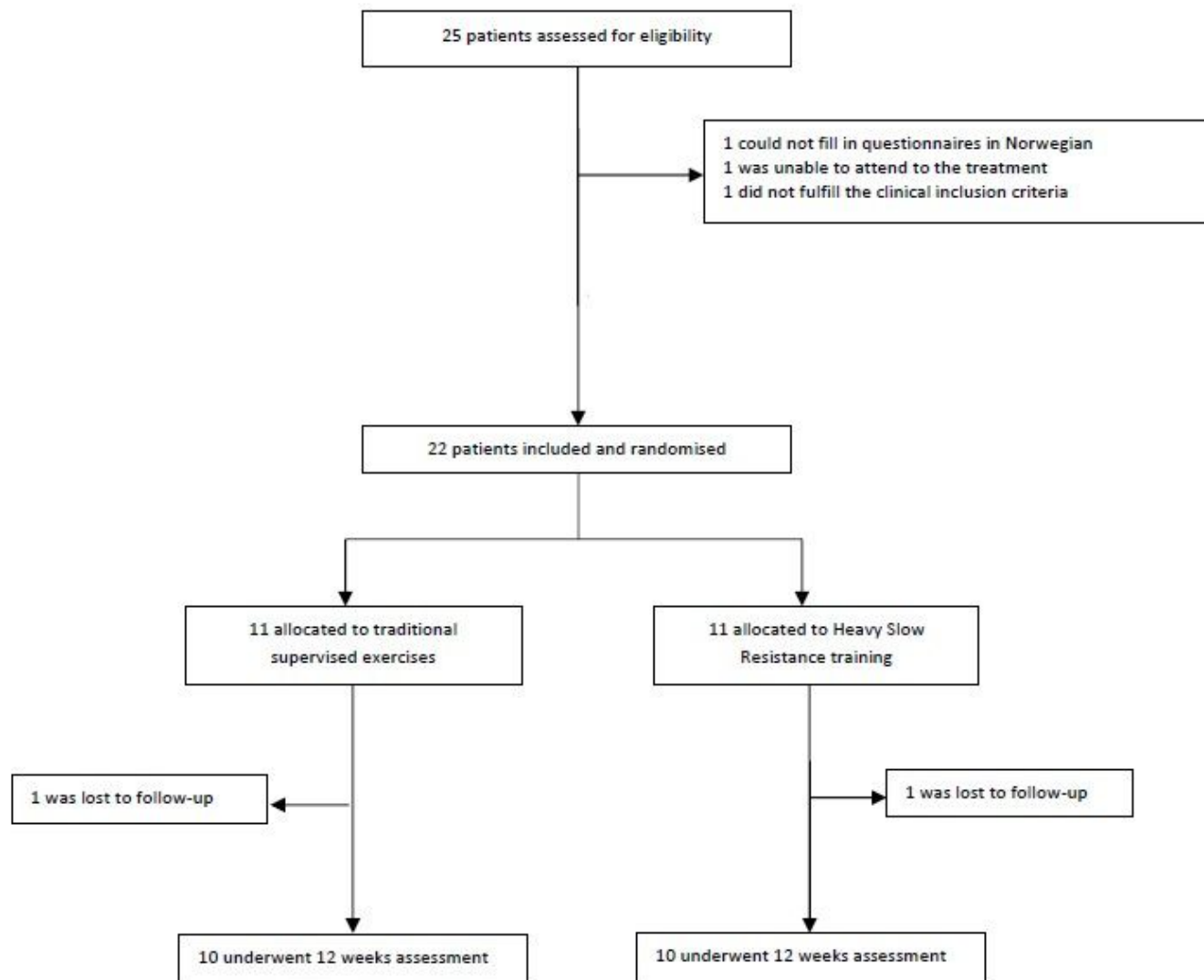


Figure 1

flow chart

Supplementary Files

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