AALBORG UNIVERSITET
STUDENTERRAPPORT

Feasibility of participants with chronic non-specific low back pain performing the hip belt squat exercise

Tema: Strength training as treatment for chronic NSLBP

Projektperiode: 01/02/2024-31/05/2024

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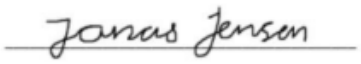
Gruppemedlemmer:



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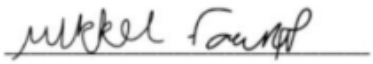

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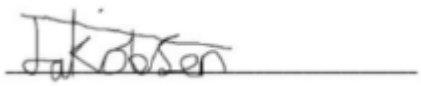

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Introduction: Low Back Pain is a widespread condition, affecting most people at least once in their lives, with annual global costs of $50 billion worldwide. 90% of LBP cases are non-specific, and when it lasts over twelve weeks, it is considered chronic. Treatments include medication, surgery, manual therapy, pain education, cognitive therapy, and exercise, with exercise being the most effective for acute and chronic pain. However, there is no clear evidence favoring one type of exercise over another. Strength training, specifically, is either pooled in the literature or under-researched. The aim of sub-study one was to explore the feasibility of chronic non-specific low back pain (NSLBP) patients using the hip belt squat exercise, their perceptions of it, and any potential benefits. Additionally, the aim of sub-study two was to explore whether progressive strength training enhances the exercise-induced hypoalgesia (EIH) response in healthy individuals over time.
Methods: The participants suffering from chronic NSLBP (n=13) underwent a six-week intervention and the healthy participants (n=16) underwent a four-week intervention of performing the hip belt squat twice a week. Measurements included pressure pain threshold, subjective feeling of pain on a visual analog scale (VAS), muscular strength test, fat mass, fat-free mass, lumbar flexibility, and three questionnaires addressing pain, disability, and quality of life. Ethical approval was obtained (Reference number: N-20230063)
Results: Sub-study one showed high feasibility of the exercise for chronic NSLBP participants. Significant improvements were seen in the majority of acute EIH response ($p=0.003$-0.048) and chronic EIH response before and after the 5RM test ($p=0.003$, 0.023). Chronic pain measured on VAS scores significantly decreased both standing and during movement ($p=0.007$-0.042). Muscular strength and lumbar flexibility also significantly increased ($p\leq0.001$). Sub-study two similarly found significant improvements in acute EIH response ($p=0.002$-0.030) and chronic EIH response post-5RM ($p=0.014$), along with a significant increase in muscular strength ($p\leq0.001$)
Conclusion: Patients with chronic NSLBP showed decreased pain, likely due to the chronic EIH response observed in both sub-studies, indicating that EIH can be enhanced through training. Sub-study one concludes that the hip belt squat exercise is feasible and potentially beneficial for chronic NSLBP patients. Sub-study two found a significant increase in acute EIH response after all but one session and a chronic EIH response after pre- and posttests. A randomized controlled trial is recommended to confirm these findings.

Pre-words on the thesis

Initially, our intention was to conduct a randomized controlled trial (RCT) aimed at exploring whether the utilization of hip belt squats could improve pain, lumbar flexibility, or elevate the overall health quality for individuals suffering from chronic non-specific low back pain. Furthermore, should such an intervention prove to be effective, we then wanted to investigate potential underlying mechanisms, such as the trainability of the exercise-induced hypoalgesia response. Therefore, we also wanted to conduct an additional RCT study consisting of healthy participants to investigate the chronic responses of exercise-induced hypoalgesia.

The process of seeking approval with the scientific ethical committee was started as early as fall 2023. We repeatedly attempted to seek approval, but the process was repeatedly delayed and prolonged by the ethics committee. Consequently, we had to revise the protocol multiple times because they refused to approve it, citing concerns about feasibility and the potential for individuals to sustain injuries while performing hip belt squats. Although the permission came later than expected, we were eventually granted the acceptance to conduct a feasibility study involving both chronic non-specific low back pain- and healthy participants. Reference number: N-20230063.

In the start of April, we tried to obtain permission to add a supplementary protocol including a control group consisting of healthy individuals. Unfortunately, this process encountered unexpected delays, but eventually, the chairman of the ethical committee granted approval on April 30th. However, integrating the control group into the already ongoing study proved to be too late for inclusion in our thesis. The thesis therefore includes individuals with chronic non-specific low back pain in sub-study one, and only an intervention group in sub-study two. Nevertheless, the control group data will be incorporated as supplementary information in our defense of this master's thesis.

Feasibility of participants with chronic non-specific low back pain performing the hip belt squat exercise

Abstract

The aim of sub-study one was to assess the feasibility of hip belt squat training for individuals with chronic non-specific low back pain (NSLBP), and potential benefits. Additionally, the aim of sub-study two was to explore whether progressive strength training enhances the exercise-induced hypoalgesia (EIH) response in healthy individuals over time. The participants suffering from chronic NSLBP (n=13) underwent a six-week intervention and the healthy participants (n=16) underwent a four-week intervention of performing the hip belt squat twice a week. Measurements included pressure pain threshold, subjective feeling of pain on a visual analog scale, muscular strength test, fat mass, fat-free mass, lumbar flexibility, and three questionnaires addressing pain, disability, and quality of life. Ethical approval was obtained (Reference number: N-20230063). Sub-study one revealed high feasibility of the exercise among chronic NSLBP participants. A significant improvement was found in most interventions in the acute EIH response ($p=0.003$-0.048). A significant increase in chronic EIH response was found when comparing measurements taken before and after the pre- and posttest (0.003 and 0.023). The chronic visual analog scale (VAS) scores showed significant decrease when comparing standing VAS scores at pre- and posttest ($p=0.009$ and 0.042), and both VAS scores during movement were significantly decreased ($p=0.007$ & 0.014). Muscular strength was significantly increased post intervention ($p\leq0.001$). Lastly, the lumbar flexibility was also significantly increased ($p=0.001$). Sub-study two found a significant increase in acute EIH response in all but one session (0.002-0.030). A significant increase in the chronic EIH response was found when comparing measurements taken before and after the pre- and posttest (0.014). A significant increase in muscular strength was found ($p\leq0.001$) post intervention. It appears that patients with chronic NSLBP have a positive response in terms of decreased pain. This improvement can be attributed to the chronic EIH response observed in both sub-studies, suggesting that EIH can be developed through training. Therefore, sub-study one concludes that the hip belt squat exercise is feasible and

potentially beneficial for individuals suffering from chronic NSLBP. Sub-study two concludes that there is a significant increase after all but one session in the acute EIH response, and there is a significant increase in chronic EIH response for measurements after the pre- and posttest. However, a randomized controlled trial is recommended to confirm these findings.

Keyword

Strength training, exercise-induced hypoalgesia, pain, rehabilitation, exercise treatment.

Introduction

Low back pain (LBP) is a common musculoskeletal disorder which most people will experience at least once in their lifetime (Lemeunier et al, 2012 & Hoy et al, 2010). A systematic review showed that in 2020 there were 619 million people globally affected by LBP (GBD 2023; World Health Organization). Furthermore, another systematic review estimated that the direct and indirect medical costs related to LBP are more than US$50 billion per annum worldwide (Fatoye et al, 2023). Musculoskeletal disorders such as LBP persist as the primary cause of disability worldwide (GBD, 2016) and represent one of the foremost reasons for seeking primary healthcare (Jordan et al, 2010). A systematic review revealed that 33% of patients experiencing LBP recover within the first three months, but one year later 65% still report ongoing pain (Itz et al, 2013). LBP is defined as pain, muscle tension, or stiffness situated below the costal margin and above the inferior gluteal folds, with or without associated pain radiating to the leg or legs (Hayden et al, 2021a). Approximately 90% of individuals experiencing LBP are diagnosed with non-specific LBP (NSLBP) (World Health Organization), defined as pain not linked to an identifiable, known, or specific pathology (Hayden et al, 2021a & Smith et al, 2014). Chronic LBP is characterized by pain persisting for more than 12 weeks, or recurrent LBP of two episodes within a year, each lasting more than 24 hours, with a pain-free interval of more than 30 days in between (Hayden et al, 2021a). Of those experiencing their initial episode of LBP, 62% will go on to develop chronic symptoms lasting more than one year (Smith et al, 2014).

There are many ways of treating LBP, such as pharmacological interventions or operations (Cashin et al, 2023). A large amount of money is allocated to diverse pharmacological treatments. However, no evidence was found that different types of medication had a significant effect on pain

intensity for both acute- and chronic LBP (Cashin et al, 2023; Jones et al, 2023; O'Sullivan et al, 2020). A study mentions that less than 2% of patients undergo surgery, however almost 30% of the yearly expenses comes from this treatment (Kim et al, 2019). Therapies like injections and surgery are not deemed essential for treating LBP, as evidence suggests their limited efficiency in managing chronic LBP in the long term. They may pose significant risks and result in unhelpful side effects (O'Sullivan et al, 2020). Therefore, first line treatment strategies for LBP, as advised by numerous national guidelines, primarily advocate an approach focusing on non-pharmacological interventions such as manual therapy, pain education, cognitive therapy or exercise (Foster et al, 2018). Manual therapy such as tissue manipulation, acupuncture, or spinal manipulation therapy is common treatments for chronic NSLBP (Thomas et al, 2020; Rubinstein et al, 2012; Baroncini et al, 2022). Tissue manipulation such as massage has shown to ease acute pain but have no effect on chronic pain (Chou et al, 2017). Acupuncture showed immediate effect on pain and function but showed small to no differences long term (Chou et al, 2017). Spinal manipulation has showed in some cases to acutely improve pain and function (Paige et al, 2017) however, spinal manipulation has shown to have the same effect as a simulated spinal manipulation (Loss et al, 2020) and has no statistically significant effect on chronic LBP (Chou et al, 2017).

A significant Cochrane review found that exercise outperforms pain education and cognitive therapy regarding improvement of pain and functional limitations. Nonetheless, their approach to exercise is pooled, encompassing different exercise treatments delivered in different formats, with various duration, frequency, and intensity, which poses a challenge in selecting the most effective exercise type for modulating LBP (Hayden et al, 2021a). Certain forms of exercise may benefit some individuals; however, they could potentially aggravate pain in others. Thus, the intriguing aspect lies in formulating specific training guidelines aimed at improving LBP (Vaegter et al, 2016). Rasmussen et al, 2021 found that three months of strength training decreased pain levels for chronic cancer-related pain indicating that strength training decreases pain levels for individuals with chronic pain (Rasmussen et al, 2021). This is supported by research demonstrating that exercise can lead to a reduction in pain sensitivity among healthy individuals, a phenomenon referred to as exercise-induced hypoalgesia (EIH) (Rice et al, 2019). Aerobic exercise has been demonstrated to evoke the most

notable acute EIH response, whereas resistance training typically elicits a smaller EIH response (Wewege et al, 2021). However, other studies have indicated that resistance training can lead to a decrease in pain sensitivity (Rice et al, 2019 & Naugle et al, 2012). Resistance training often lacks standardization in exercise type, intensity, and volume when investigating the EIH response (Wewege et al, 2021). Additionally, while EIH exhibits an acute response, the potential for chronic improvement over time remains unclear. Therefore, investigating whether the EIH response can be trained over time is of particular interest. Individuals with chronic NSLBP may find benefits of an exercise program, which aims to enhance both physical function and reduce potential worsening of the chronic NSLBP (Foster et al, 2018). This implies that exercise therapy might serve as an effective treatment for chronic NSLBP. However, determining the specific exercises or exercise program for LBP patients can be difficult. The variability in treatment approaches and recommended guidelines, even within the same professions, is various (Madsen et al, 2021). The most common exercise employed in physiotherapy is stabilization exercises. Nevertheless, there is insufficient evidence to assert their superior effectiveness compared to alternative exercises (Smith et al, 2014). Fersum et al, 2009 mentions that there is a lack of evidence supporting one specific treatment intervention for people with chronic NSLBP (Fersum et al, 2009). This illustrates that the available evidence is limited in the use of one specific type of exercise or exercise program superior to others (Hayden et al, 2021b).

De Sousa et al, 2019 revealed significant reductions in back extension strength, lower limb muscle strength, hip abduction/extension strength, and isokinetic knee strength for people with LBP compared to healthy individuals (De Sousa et al, 2019). Meanwhile, Nadler et al, 1998 found that weakness in shortening and stiffness of the muscle in the lumbar and pelvic region contributed to the development of LBP (Nadler et al, 1998). This suggests that individuals with LBP should concentrate their training on increasing strength in knee and hip extension. Research assessing the use of strength training for chronic NSLBP is currently lacking, highlighting the necessity for scientific investigations into the effectiveness of strength training as a treatment for chronic LBP. Strength training exercises aimed at the lower extremity might provide a feasible, effective, and cost-effective treatments for chronic NSLBP. Strength training exercises that address these weaknesses include

lower limb exercises such as squats and deadlifts. However, these kinds of exercises impose a significant strain on the spine and lower back, potentially leading to discomfort for individuals with LBP and making them challenging to perform. Therefore, a variation of these exercises could be beneficial.

Initial data from an affiliated research group indicates that engaging in the hip belt squat exercise may lead to a reduction in stiffness, pain, and an enhancement in functionality among individuals suffering from chronic NSLBP. This exercise removes the load from the deltoideus and upper trapezius and places the load on the hip and legs which removes force transmission through the spine while still having similar muscle activity as the barbell back squat (Gulick et al, 2015). It remains unclear if the hip belt squat exercise is feasible for individuals with chronic NSLBP to perform over time, and what the effect on pain levels are. Furthermore, it is unclear if the EIH response can be trained over time, which could cause a decrease in pain. Therefore, the main purpose of sub-study one is to conduct a feasibility study to investigate if a larger group of people with chronic NSLBP can endure a training period with the hip belt squat exercise, how they perceive the exercise, and if there would be any indications of whether they benefit from it or not. Furthermore, the purpose of sub-study two is to explore whether the EIH response can be enhanced through progressive strength training in a healthy group of people over a period, which may explain the possible decrease in pain levels for the individuals in sub-study one.

Method

Sub-study one was conducted as a feasibility study, aiming to explore the acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited efficacy (Bowen et al, 2010) of chronic NSLBP participants engaging in the hip belt squat exercise. Limited efficacy was assessed on pre- and posttest measures on a visual analog scale (VAS), three additional questionnaires addressing pain, disability, and quality of life, EIH response using pressure pain threshold (PPT), muscular strength (5RM), fat mass (FM), fat-free mass (FFM), and lumbar flexibility. Additionally, participants in sub-study one answered a feasibility questionnaire. Sub-study two involved healthy participants, following a similar protocol assessing only the EIH response using PPT, muscular strength (5RM), FM, and FFM. Both studies received approval from the ethics

committee (Reference number: N-20230063).

In both sub-studies, every participant was obligated to participate in both pre- and posttest assessments. The participants suffering from chronic NSLBP underwent a six-week intervention period, while the healthy participants underwent a four-week intervention period. Throughout this duration, all participants performed the hip belt squat exercise twice a week. Both sub-studies were conducted at Aalborg University, located at Selma Lagerløfs Vej 249.

Participants for sub-study one

Thirteen individuals, with an average age of 37 years (Standard deviation (SD)= ±13.3)) with chronic NSLBP, participated in this study. Among them six were women, aged 35.4 (±14.2), and seven were men, aged 39.1 (±13.1). Each participant received comprehensive information about the study and provided informed consent by signing a declaration, which also were explained verbally to ensure full understanding. For sub-study one the inclusion criteria were men and women aged 18-60 years old who had been experiencing NSLBP for more than twelve weeks. The exclusion criteria were leg pain greater than back pain, neuromuscular disorders, spinal or lower extremity fractures, infections, cancer, osteoporosis, dementia, BMI>35, current substance abuse, former lumbar surgery, persistent pain syndromes other than back pain and inflammatory rheumatic diseases.

The data collected in sub-study one were sex, age, body weight, height, followed by limited-efficacy such as VAS score before and after each session, three questionnaires: Oswestry Disability Index (ODI), the Fear Avoidance Beliefs Questionnaire (FabQ), EuroQOL-5D, PPT measurements before and after each session, muscle strength 5RM test, FM and FM using a dual energy X-ray absorptiometry scan (DEXA) (iDXA, Lunar Prodigy series, GE Lunar, Madison, USA), and a lumbar flexibility test. Furthermore, a logbook for each participant was noted which consisted of each participants repetitions, intensity, and RIR. Lastly a feasibility questionnaire was conducted by the participants to investigate the acceptability, demand, implementation, practicality, adaptations of performing the hip belt squat.

Participants for sub-study two

A total of sixteen healthy individuals, with an average age of 29 years (±4.6) participated, four women aged 25.7 (±1.2), and twelve men aged 30.1 (±4.9). Each participant received comprehensive information about the study and provided informed consent by signing a declaration,

which also were verbally explained to ensure full understanding. For sub-study two the inclusion criteria were healthy men and women aged 18-60 years old. The exclusion criteria were BMI>35 and current substance abuse.

The data collected in sub-study two was sex, age, body weight, height, and measures such as PPT before and after each session, muscular strength 5RM test, FM and FFM using a DEXA-scan at pre-and post-intervention.

Procedure

Questionnaires

During both the pre- and posttests, participants with chronic NSLBP completed a feasibility questionnaire which consisted of six questions ranging from 1= totally disagree to 5=totally agree. Furthermore, they reported their current pain levels using a VAS ranging from 0 indicating "no pain at all" to 10 representing the "worst imaginable pain" while standing and during their self-chosen most painful movement before and after each session.

The participants also answered three questionnaires, which were the ODI, the FabQ, and the EuroQOL-5D for evaluating subjective disability, fear and avoidance beliefs, and health-related quality of life, respectively. ODI score is assessed through ten questions with six possible answers. The first answer gives zero points, the second gives one point and so on. The total score is calculated and defined as: 0-4 = no disability, 5-15 = mild disability, 15-24 = moderate disability, 25-34 = severe disability, and 35-50 = completely disabled (Fairbank & Pynsent, 2000). The total score of FabQ is calculated by summing the scores from the participants answers on a 7-point scale, from 0 strongly disagree to 6 strongly agree, where the higher the score the higher level of fear-avoidance beliefs. Between 0-48 is defined as low levels of fear-avoidance beliefs, between 49-64 moderate levels of fear-avoidance beliefs, and between 65-96 high levels of fear-avoidance beliefs (Waddell et al, 1993). The EuroQOL-5D scores can be depicted as a five-digit number, ranging from 11111 indicating great quality of life to 55555 representing the lowest quality of life. These scores are then transformed into a single utility index, utilizing nation-specific value sets, such as the Danish values set used in the present study ranging from 0-1. Values closer to 0 represent low quality of life (Jensen et al, 2021).

The pressure pain threshold measurements

The EIH response was evaluated in both studies using PPT measurements conducted before and after each session. This

assessment consisted of three measurements with a 30-second interval between, utilizing a slope of 30 kPa and a cutoff at 1000 kPa. A mean value was derived from these measurements. The measurements were performed with the participants seated, targeting a point on the medial deltoid located three fingers down from the acromion on a direct line towards the olecranon. The test was performed using a pressure algometer (Somedic SenseLab AB, Norra Mellby, Sweden), where the participants were instructed to press the button whenever the pressure sensation changed from a feeling of pressure to a feeling of pain.

Muscular strength test

Participants in both studies performed a 5RM test on the hip belt squat exercise (rogue, Columbus Ohio, USA Rogue) both pre- and post-intervention. This was done to assess the intensity of the intervention and to compare muscular strength pre- and post-intervention. Prior to determining the 5RM, participants received a demonstration of the hip belt squat exercise and instructions on how to perform the movement. During the 5RM test and the following sessions, Repetition in Reserve (RIR) was utilized to indicate and control the intensity of the intervention. Finding the 5RM involved three warm-up sets at progressively increasing submaximal intensities, the first set of ten repetitions, the second set of seven repetitions (10 RIR), and the third set of five repetitions (6-8 RIR). The following sets consisted of five repetitions with increased intensity until the 5RM was determined with 1 RIR to ensure close to maximal effort. The pause between each set was based on the RIR value. A RIR of >7 corresponded to a 1-minute pause, RIR between 4-6 was a 2-minute pause, and RIR ≤3 was a minimum of 3 minutes pause (Miranda et al, 2007). The 5RM test and the following interventions would be stopped or reduced in intensity if the participant experienced too much pain, if they reached muscular failure or the execution of the exercise was not acceptable.

Flexibility test

For the flexibility test, participants were directed to perform a sit and reach test (Lee & Kang, 2016), seated on the floor with their backs against a wall and legs extended. They were then instructed to reach forward as far as possible while keeping their hands on the ground. If they experienced excessive back pain preventing them from assuming the seated position, their score would be recorded as zero.

Duration of intervention

Both sub-studies consisted of two training sessions per week, with a minimum rest period of 48 hours between sessions

(Monteiro et al, 2019). The duration of the intervention was six weeks for sub-study one, and four weeks for sub-study two. Throughout each session, participants were required to complete three warm-up sets consisting of ten, seven, and five repetitions at increasingly sub-maximal loads. Afterwards three working sets of five repetitions were performed starting at 90% of their 5RM found in the pre-test. If the RIR exceeded three, the intensity was increased and if it was RIR zero the intensity was decreased. The pause of each set was similar to the protocol mentioned above.

Statistical Analysis

IBM SPSS Statistics Data Editor version 29 was used to investigate the data. For both sub-studies a paired t-test was used to investigate the difference between pre- and posttest results, as well as before and after each session, with a significance level of 0.05. The assumptions of the use of a paired t-test were assessed. No significant outliers were detected in the differences between the related groups in any of the measures. The normal distribution was investigated using a Shapiro-Wilk test. If the variables were not normally distributed a nonequivalent test (wilcoxon test) was utilized. Furthermore, a one-way ANOVA test within subjects was used to assess if there was a significant difference in the acute EIH over the duration of the intervention. The assumptions of the use of a one-way ANOVA test were assessed.

Results

In sub-study one, ten participants suffering from chronic NSLBP successfully completed the trial. Three participants were unable to continue due to personal circumstances, while another participant sustained a knee injury in another activity not related to the study prior to the post-test assessment. This participant was unable to perform the two last training sessions and the 5RM test during the post-test evaluation. Instead, an estimation of their 5RM using the Brzycki formel (Brzycki, 1993) was used. The participants completed every training session except one participant, who missed one session. In sub-study two, fifteen healthy participants completed the trial, while one participant dropped out during the intervention due to knee pain after a run unrelated to the study. All participants completed all training sessions except one participant who missed one session.

Sub-study one results

Feasibility Questionnaire

The feasibility questionnaire was performed by all participants in sub-study one (n= 10) and the results can be seen in

figure 1. When asked if they had a great experience with the hip belt squat exercise (a), 100% totally agreed. Regarding feeling comfortable and safe while performing the exercise (b), 90% totally agreed and 10% agreed. As for whether they wish to incorporate the exercise in their future workouts (c), 80% totally agreed and 20% agreed. Regarding the continued use of the exercise in the future (d), 70% totally agreed, 20% agreed and 10% answered either or. Concerning if it was easy for them to implement the exercise in their workouts (e), 60% totally agreed and 40% answered either or. Regarding the opportunity to perform the exercise in their workouts (f), 20% totally agreed, 10% agreed, 30% answered either or, 30% disagreed, and 10% totally disagreed.

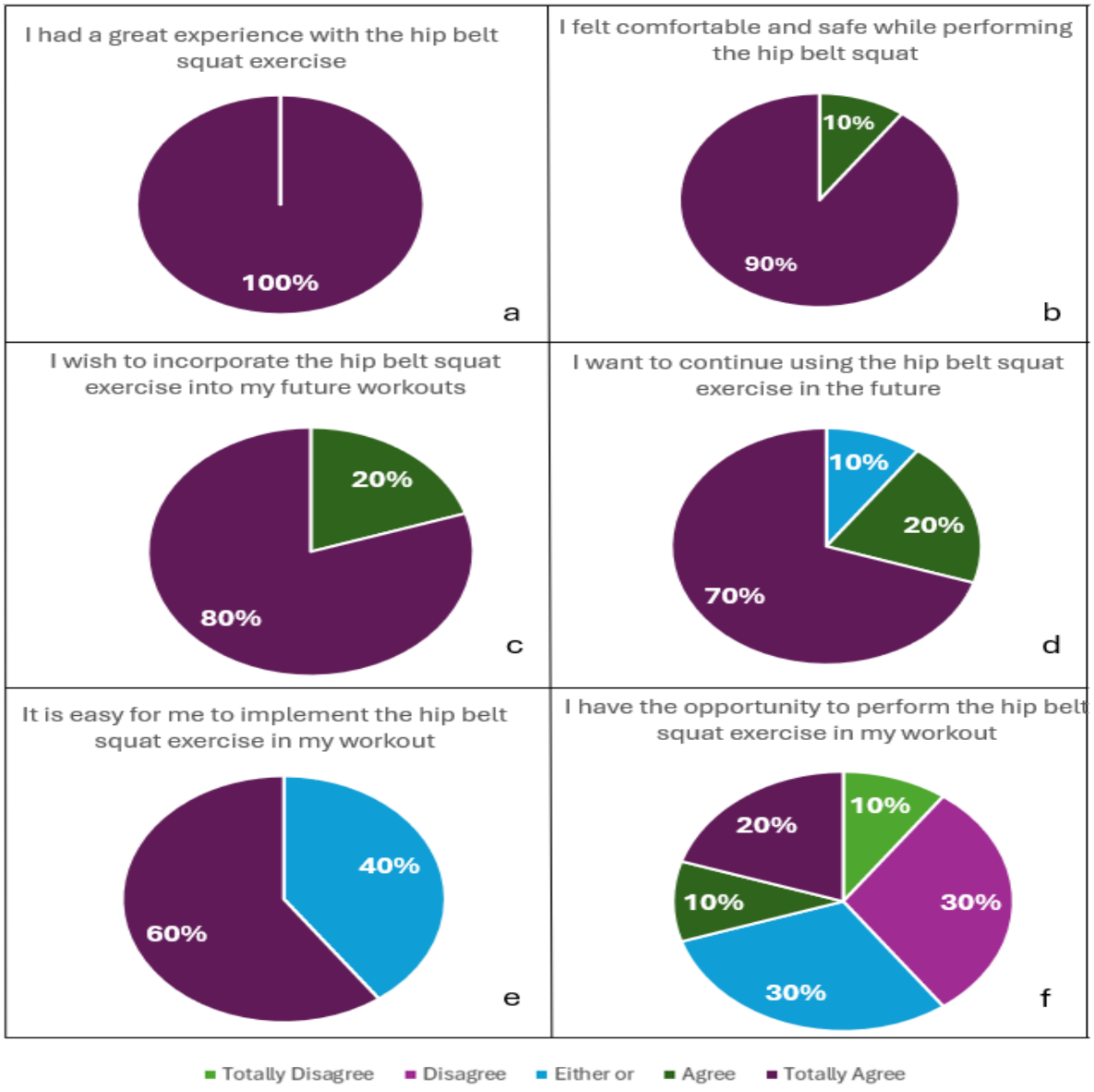

Figure 1 displays the feasibility questions along with the corresponding percentage responses for each question.

Acute VAS

In sub-study one the participants were asked about their VAS score both standing and during movement, before and after each session. The numeric VAS score showed a tendency to be lower post sessions. This was, however, only significantly decreased in session 2, 3, 6 in a standing position (p=0.004-0.041) as seen in chart 1, and during movement in all except three sessions (p=0.002-0.049) as seen in chart 2.

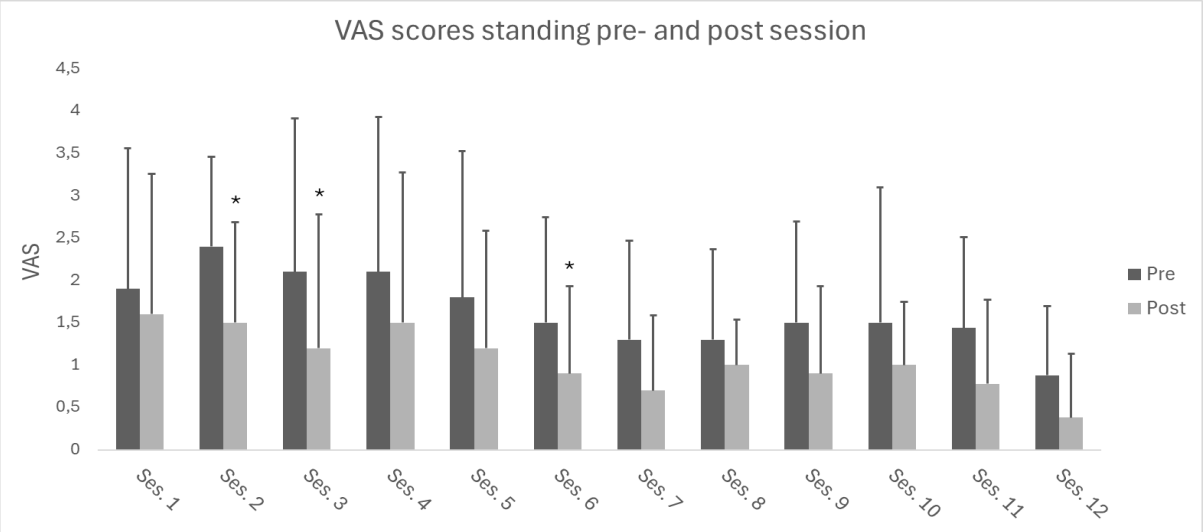

Chart 1 illustrates the VAS score in a standing position pre and post each training session. The ∗-symbols indicate that there is a significant decrease in the reported VAS-score after the session (p <0.05). Ses = session.

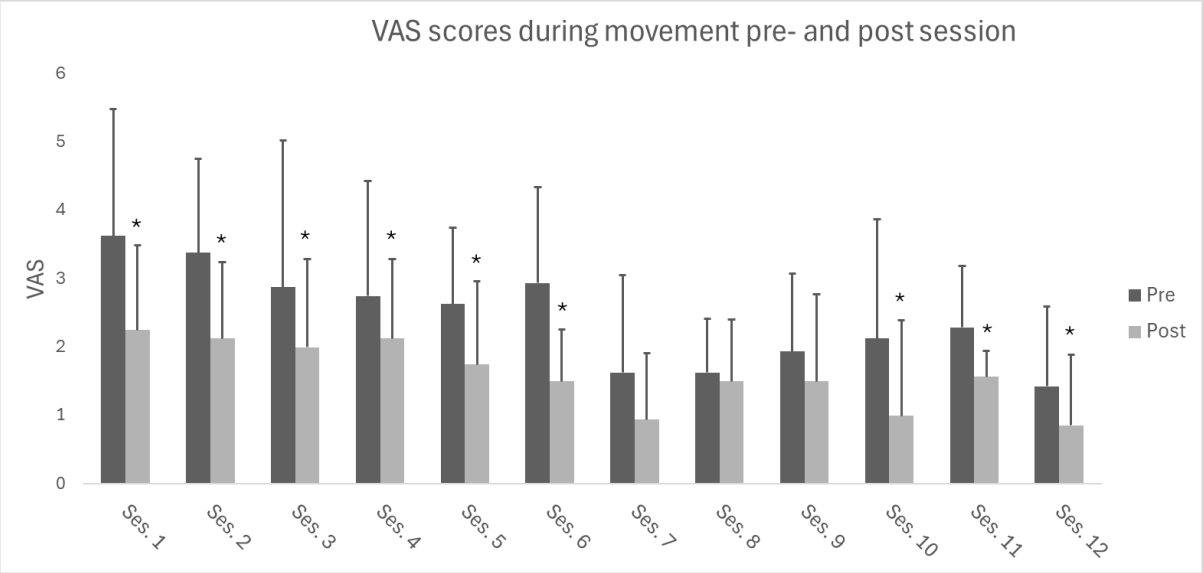

Chart 2 illustrates the VAS score during movement pre- and post each session. The ∗-symbols indicate that there is a significant decrease in the reported VAS-score after the session (p <0.05). Ses = session.

Chronic VAS

In sub-study one the participants were asked about their VAS score both standing and during movement before and after the pre- and posttest. As seen in chart 3, a significant decrease in the standing VAS score was found when comparing measurements taken before the pretest (2.10 ±1.59) and measurements taken before the posttest (0.80 ±1.13 (p=0.009) effect size (ES)=0.94). A significant difference in VAS score standing was found when comparing measurements taken after the pretest (1.89 ±1.53) and measurements taken after the posttest (0.56 ±0.72 (p=0.042), ES=0.59).

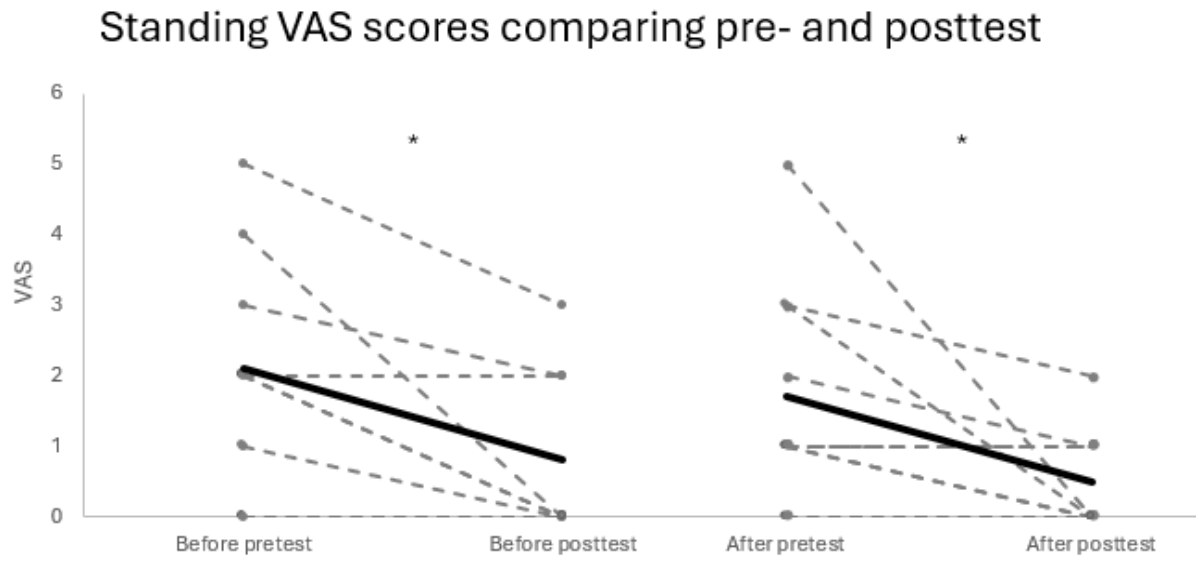

Chart 3 the dashed lines illustrate the VAS score standing before and after the 5RM test, at pre- and posttest. The thick highlighted black line shows the mean VAS scores at the pre- and posttest. The ∗-symbols indicates that there is a significant decrease in the reported VAS-score after the intervention (p <0.05).

As seen in chart 4, a significant decrease in VAS score was found when comparing VAS score during movement before the pretest (3.78 ±1.85) and before the posttest (1.56 ±1.59 (p=0.007), ES=1.27). A significant decrease was also found in VAS score during movement when comparing VAS score after the pretest (2.63 ±1.40) and after the posttest (1.00 ±1.07 (p=0.014), ES=1.27).

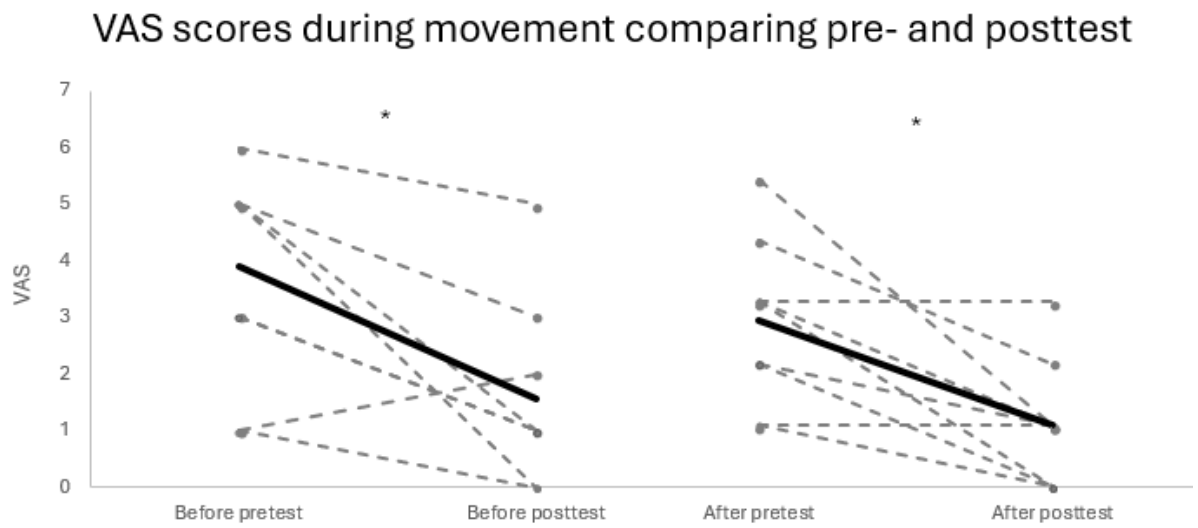

Chart 4 The dashed lines illustrate the VAS score during movement before and after the 5RM test, at pre- and posttest. The thick highlighted black line shows the mean VAS scores at pre- and posttest. The ∗-symbols indicate that there is a significant decrease in the reported VAS-score after the session (p <0.05).

Questionnaires

Participants in sub-study one answered three questionnaires addressing pain, disability, and quality of life. FabQ showed a significant difference between pretest (27.60 ±18.42) and posttest (20.60 ±14.41 (p=0.050) ES=0.43). ODI showed no significant difference between pretest (8.50 ±3.92) and posttest (7.40 ±4.03 (p=0.264), ES=0.42). EuroQOL showed no significant difference between pretest (0.69 ±0.20) and posttest (0.74 ±0.24 (p=0.518), ES=0.33).

Acute EIH response

In sub-study one, the numeric number of the PPT values was shown to be higher post training in every session. However, this increase in the acute EIH response was only significant in eight sessions as seen in chart 5 (p=0.003 to 0.048) for participants suffering from chronic NSLBP. The within-subjects effect ANOVA test for participants with chronic NSLBP showed no significant difference over time when comparing PPT measurements taken before each session with each other (F (3.608, 32.476) = 1.776, P=0.163) and after each session with each other (F (3.036, 27.328) = 2.495, P=0.080).

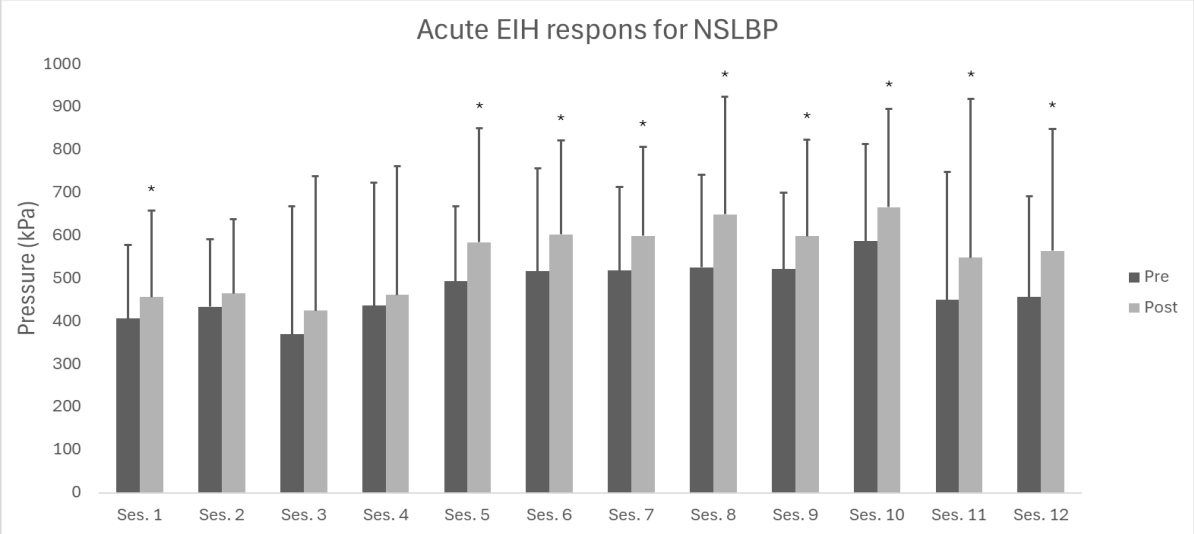

Chart 5 shows the acute EIH response for participants with chronic NSLBP. The ∗-symbol indicate that there is a significant increase in EIH response after the sessions (p <0.05). Ses = session

Chronic EIH response

In sub-study one, a significant increase in EIH response was observed between measurements taken before the pretest (392.3 ±180.9kPa) and measurements taken before the posttest (605.9 ±198.9kPa (p=0.003), ES=1.16) for participants suffering from chronic NSLBP. A significant difference was also found between measurements taken after the pretest (417.8 ±242.7kPa) and measurements taken after the posttest (655.8 ±240.5kPa (p= 0.023), ES=0.58) for participants suffering from chronic NSLBP as seen on chart 6.

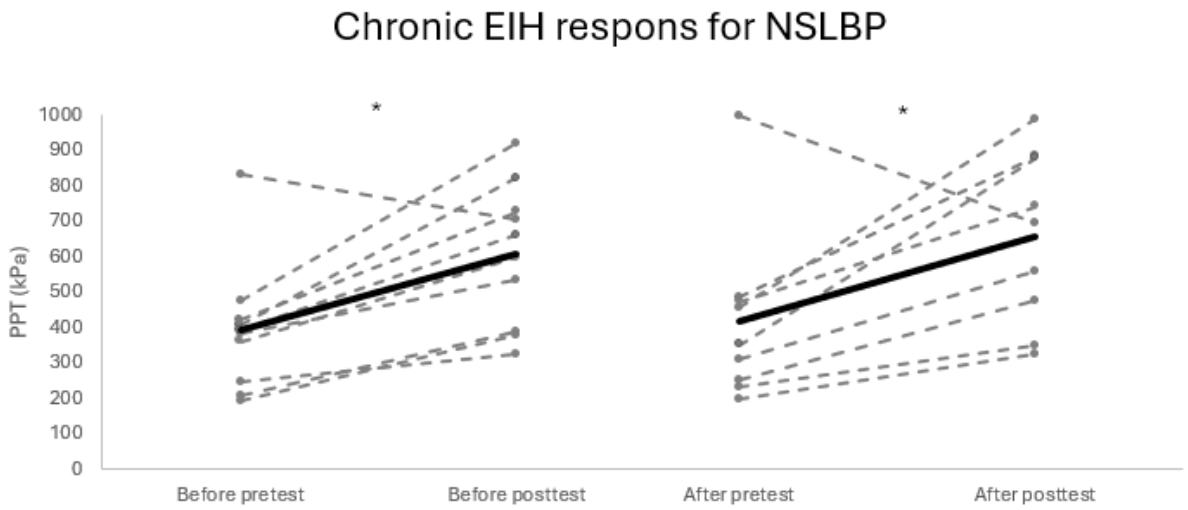

Chart 6 The dashed lines illustrate each participant with chronic NSLBP PPT values before the 5RM test at pre-and posttest, and PPT values after the 5RM test at pre-and posttest. The thick highlighted black line showcases the mean difference from pre-to posttest. The ∗-symbols indicate that there is a significant increase in the chronic EIH response post intervention (p <0.05).

Muscular strength

In sub-study one a statistically significant increase in muscular strength was found from the pretest (63.0 ±30.4kg (mean ±SD)) to the posttest (89.7 ±39.7kg (p≤ 0.001), ES= 0.74) in chronic NSLBP participants as seen on chart 7.

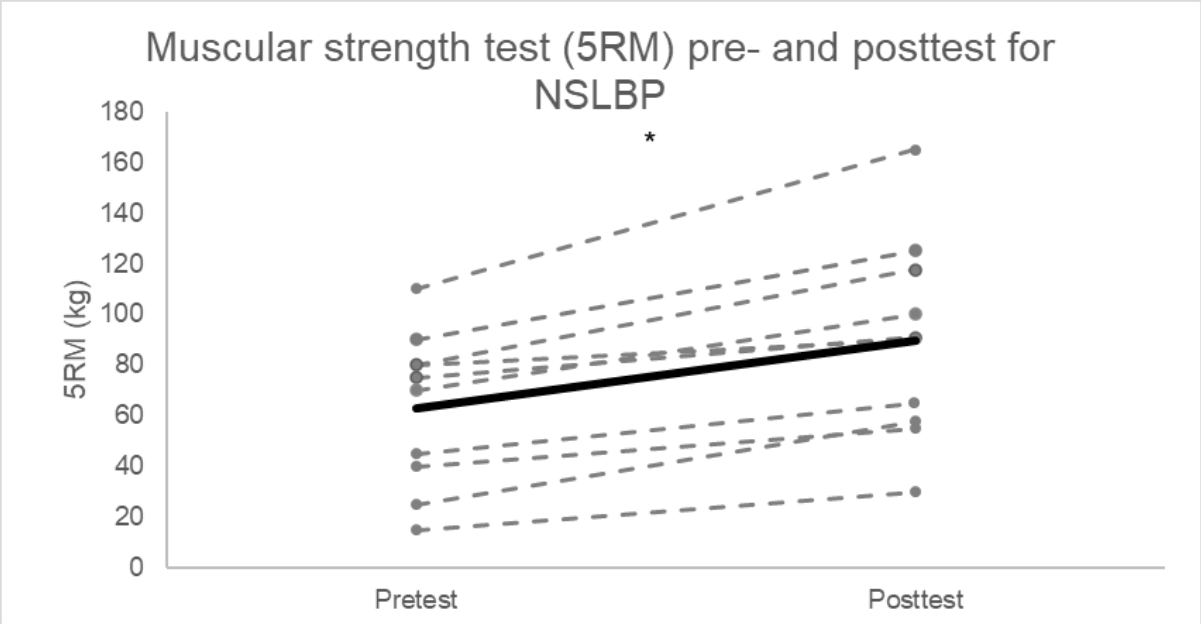

Chart 7 The dashed lines illustrate each participant in sub-study one's muscular strength in a 5RM test. The thick highlighted black line showcases the mean difference between pre- and posttest. The ∗-symbol indicates that there was a significant increase in muscular strength post intervention (p <0.05).

Body composition

In sub-study one, no significant difference in FM was found from the pretest (22.36 ±8.75kg) to the posttest (21.95 ±8.75kg (p=0.108), ES=0.04) for participants with chronic NSLBP. No significant difference in FFM was found from the pretest (53.84 ±10.04kg) to the posttest (54.07 ±10.06kg (p=0.226), ES=0.01) for participants with chronic NSLBP.

Lumbar flexibility

A statistically significant increase in lumbar flexibility was found from the pretest (88.3 ±10.6cm) to the posttest (96.2 ±10.5cm (p=0.001), ES=0.74) for participants suffering from chronic NSLBP.

Sub-study two results

Acute EIH response

In sub-study two, the numeric number of the PPT value is shown to be higher post training in every session as seen in chart 8. Nearly all training sessions exhibited a significant increase in acute EIH response post-session (p=0.002 to 0.030) for healthy participants, except for session seven (p=0.170). The within-subjects effect ANOVA test for healthy participants showed no significant difference over time when comparing PPT measurements taken

before each session with each other (F (2.710, 37.933) = 2.067, P=0.126) and after each session with each other (F (2.280, 31.920) = 1.410, P=0.259).

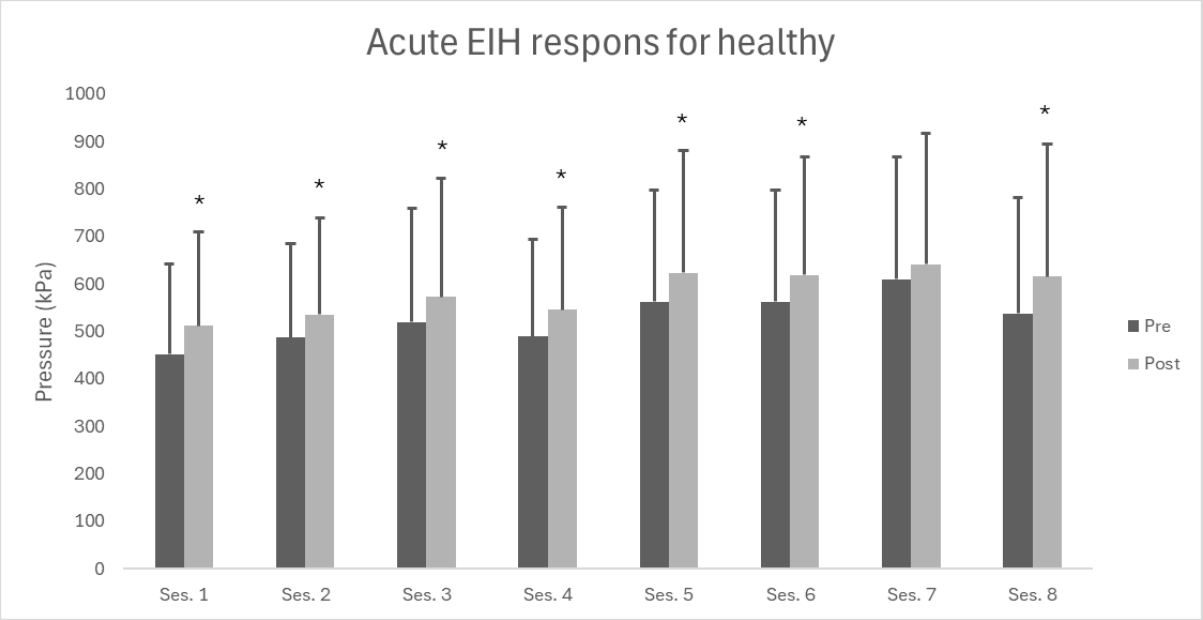

Chart 8 shows the acute EIH response for healthy participants following a strength training session. The ∗-symbols indicate that there is a significant increase in the acute EIH response after the session (p <0.05). Ses = session

Chronic EIH response

In sub-study two, no significant difference was found when comparing measurements taken before the pretest (482.4±168.6kPa) and measurements taken before the posttest (538.5±232.1kPa (p=0.161), ES=0.27), for healthy participants. However, a significant increase in EIH response was observed when comparing measurements taken after the pretest (494.5±187.3kPa) and measurements taken after the posttest (595.8±263.7kPa (p=0.014), ES=0.44) for healthy participants as seen in chart 9.

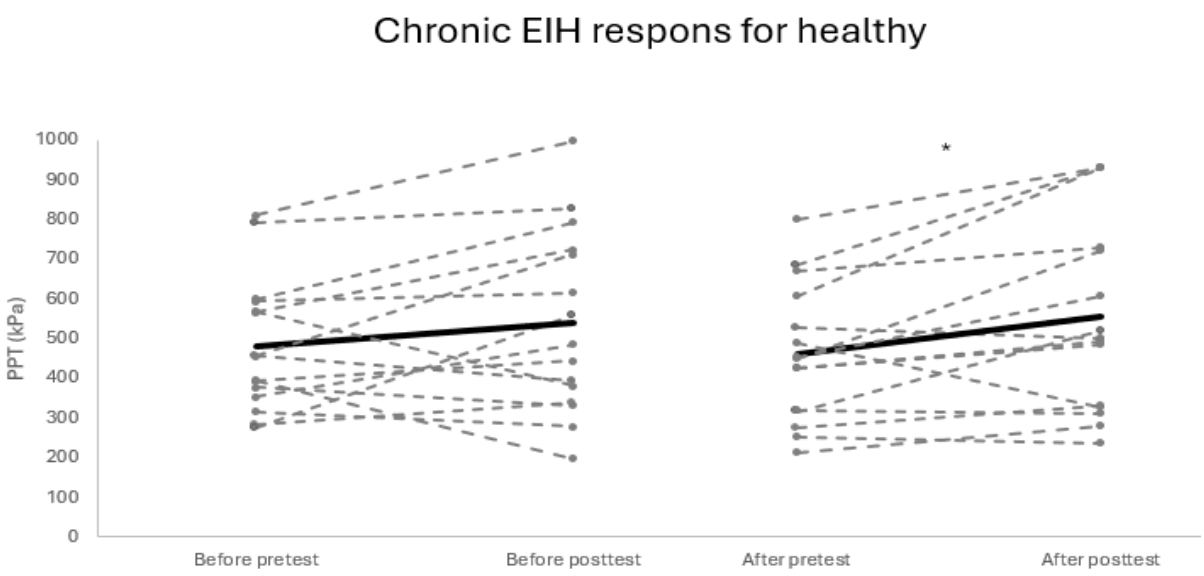

Chart 9 The dashed lines illustrate the average PPT values across all healthy participants. The thick highlighted black line shows the mean of the chronic EIH response. The ∗-symbol indicates that there is a significant increase in the chronic EIH response post intervention (p <0.05).

Muscular strength

In sub-study two a significant increase in muscular strength was found from the pretest (93.4±39.6kg) to the posttest (113.4±40,0 (p≤ 0.001), ES=0.50) for healthy participants as seen in chart 10.

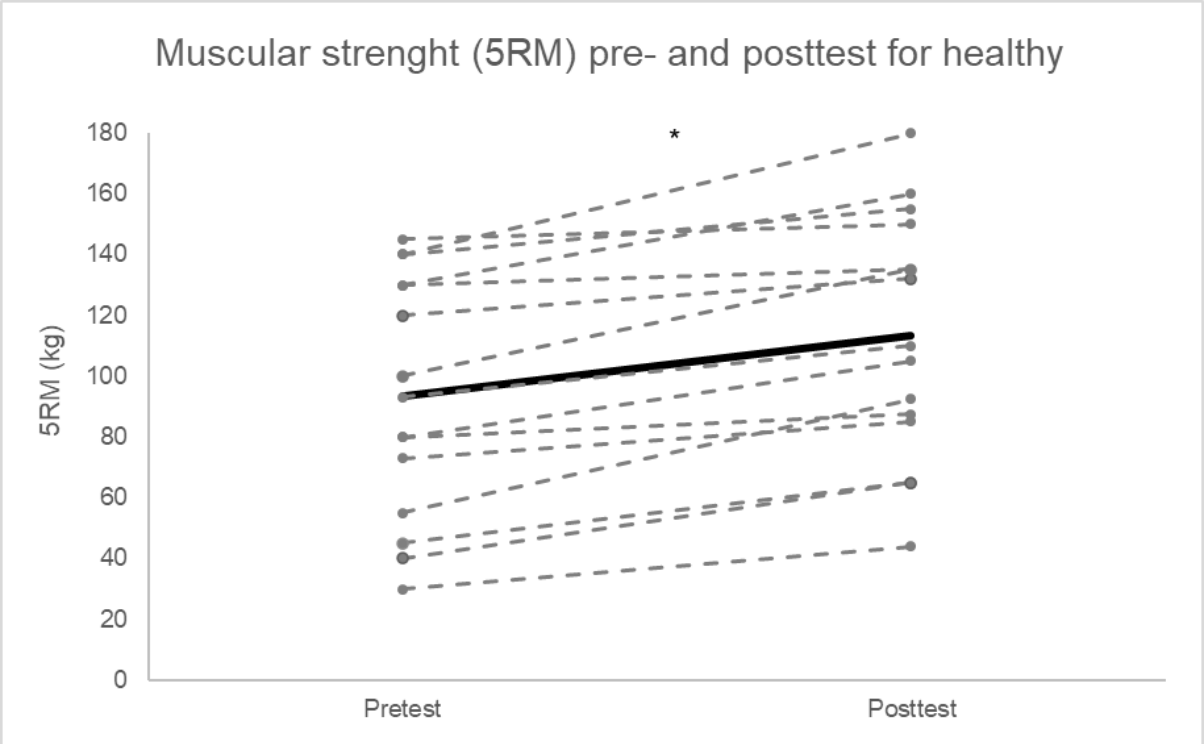

Chart 10 The dashed lines illustrate each healthy participant's muscular strength in a 5RM test. The thick highlighted black line showcases the mean difference between pre- and posttest. The ∗-symbol indicates that there is a significant increase in muscular strength post intervention (p <0.05).

Body composition

In sub-study two no significant differences in FM were found from the pretest (21.1±9.6kg) to the posttest (20.8±8.8kg (p= 0.452), ES=0.10) for healthy participants. No significant difference in FFM was found from the pretest (62.3±12.5kg) to the posttest (62.8±12.7kg (p=0.131), ES= 0.03) for healthy participants.

Discussion

The main purpose of this feasibility study was to see if individuals with chronic NSLBP could endure hip belt squat training, how they perceive the exercise, and if there would be any indications of whether they benefit from it or not. The results of sub-study one indicates that hip belt squat training is acceptable and comfortable for individuals with chronic NSLBP to perform and that they want to continue performing the exercise. The numeric PPT values seemed to be higher after each session and was significantly higher in eight out of twelve sessions. There was a significantly higher chronic EIH response when comparing measurements taken before and after the pre- and posttest. The VAS scores tended to be lower after each session, with significant reductions in three sessions standing, and nine sessions during movement. The chronic VAS scores had a significant decrease both standing and during movement, when comparing VAS scores from before and after the pre- and posttest. The results of the FabQ questionnaire showed a significant improvement post intervention. Although, the ODI and EuroQoL scores tended to improve post intervention, the improvements were not statistically significant. Furthermore, a significant increase was found in muscular strength, with no changes in FM or FFM. Additionally, the secondary aim of this study was to investigate whether the EIH response could be enhanced through progressive strength training over time for healthy individuals. Sub-study two found a significant improvement in acute EIH response after all sessions except one. For chronic EIH response, there was a significant increase in the measurements taken after the pre- and post-test. However no significant increase was found between measurements taken before the pre- and posttest. Furthermore, a significant increase was found in muscular strength, with no changes in FM or FFM.

Discussion of feasibility

The hip belt squat proved to be an acceptable exercise for individuals with chronic NSLBP. This exercise removes the load from the deltoideus and upper trapezius and places the load on the hip and

legs which remove force transmission through the spine (Gulick et al, 2015), making it comfortable for individuals with LBP to perform. Furthermore, the results suggest that the participants want to keep performing the hip belt squat exercise. This may be due to the participants experiencing less LBP, as indicated by the decrease in VAS scores which could be caused by the increase in the EIH response. When asked if they wanted to incorporate the exercise into their training program, 70% agreed. However, only 20% had the opportunity to continue performing the exercise. This suggests that most people lack access to the necessary equipment making it hard to keep performing.

Conducting feasibility studies often involves exploring whether something can work in practice, thereby paving the way for implementation of a larger study. When developing a feasible intervention, there are three primary questions that should be asked: Can it work, does it work and will it work (Bowen et al, 2010). Previous literature has confirmed that exercise is the preferred treatment for chronic NSLBP (Hayden et al, 2021a; Foster et al, 2018). This agrees with the present feasibility study which indicates that strength training may help participants with chronic NSLBP. The limited efficacy found in the present study with increased muscular strength, better flexibility, a significant decrease in FabQ score, and overall, VAS scores post intervention may help prove that the intervention used in the present study, can- and does work on participants with chronic NSLBP and may be beneficial in the participants real life contexts. The intervention was administered to both male and female participants with chronic NSLBP across various age groups ranging from 22 to 62 years old. Additionally, the participants remained engaged for six weeks, suggesting that the intervention could potentially co-exists with their weekly routine.

This aligns with the findings of Tjøsvoll et al, 2020, who demonstrated that periodized resistance training is a viable method for individuals with chronic NSLBP. In their study, participants followed a full-body program, including squats, bench press, deadlift, and Pendlay row, twice a week for 16 weeks. The results from the present study, combined with the more demanding training regimen used in Tjøsvoll research, suggest that strength training programs are feasible for individuals with chronic NSLBP (Tjøsvoll et al, 2020).

VAS scores

During the six weeks training intervention in the present study there was a significant improvement in VAS scores for both

standing and during movement before and after the pre- and posttest. These results agree with a study by Elfving et al, 2016 who found that when looking at mean VAS scores there was a significant improvement following a four-week training intervention (Elfving et al, 2016). This improvement in the VAS scores indicates that participants with chronic NSLBP experienced a reduction in overall pain following the intervention. The chronic increase in EIH could be a reason the VAS scores decrease during the intervention. A significant increase in EIH was found when comparing measurements taken before the pre- and posttest, which indicates an overall improvement in pain sensitivity which could mean a reduction in pain perception.

The overall decrease in VAS score aligns with the findings of Hayden et al, 2021a, who concluded that exercise is more effective in reducing pain for people with LBP than cognitive and manual therapy (Hayden et al, 2021a). Previous research by Chou et al, 2017 and Paige et al, 2017 indicated that while manual therapy improved acute pain, it did not significantly impact long-term outcomes (Chou et al, 2017; Paige et al, 2017). The present study found a tendency that there was an improvement in acute pain across all sessions, however the improvement was only significant in three sessions in the standing VAS scores and nine sessions during movement.

Several participants engaged in various forms of training before the trial, which they believed contributed positively to their overall pain. However, upon incorporating the hip belt squat exercise, they experienced greater pain relief. This could be attributed to the exercise acceptability and comfort, as indicated by the feasibility questionnaires results. Such factors may have facilitated higher-intensity training of the lower extremities, or a different way of training compared to exercises that load the spine. This may allow participants to perform more intense muscular contractions, which may modulate the chronic EIH response as indicated in the present study, which may lead to greater pain reduction.

ODI

The mean ODI score in the present study was not significantly different post intervention, indicating that participants remained in the same category of "mild disability" both before and after the intervention. This lack of significant change suggests that the intervention did not have a notable impact on overall disability. However, a closer examination of individual cases show that one participant had a positive shift from "moderate disability" to "mild disability"

and two participants went from "mild disability" to "no disability" post intervention, suggesting a potential improvement in their functional capacity. This may show that there is some variability in the individual response where the mean score does not reflect the changes for some participants. The present study indicates a lower pain level, a chronic EIH response and a tendency for ODI to be lower, which may advocate that a longer intervention would prove a significant difference and therefore a significantly lower disability for the participants.

A study by Suh et al, 2019 found a significant improvement in ODI post six-week intervention for four groups with participants suffering from chronic LBP (flexibility exercise, walking exercise, stabilization exercise, stabilization and walking exercise) (Suh et al, 2019). The participants who attended the study by Suh et al, 2019 had a mean age of 54.81 (±15.69), whereas the mean age in the present study was 37 (±13.3). This difference in age between the studies could potentially influence the outcomes differently. It is plausible that participants in the present study were already more physically active, which might have influenced the results. Notably, a participant aged 62 in the present study transitioned from “moderate disability” to “mild disability”, suggesting a potential age-related effect on ODI outcomes post activity. This observation indicates the possibility that older participants might show better ODI improvements compared to younger participants which may be because of their different activity level. Furthermore, the study by Suh et al, 2019 had higher pretest ODI score of all four groups: 38 (±21.1), 28.1 (±12.8), 31.4 (±13.2), and 30.4 (±12.9) (Suh et al, 2019) than the present study 8.50 (±3.92). The lack of significant improvement in the ODI score found in the present study indicates that a higher baseline disability may allow for greater improvement, potentially leading to different results.

FabQ

The FabQ questionnaire investigated the participants fear and avoidance behaviors, with a focus on participants beliefs regarding how physical activity and work influence their pain (Waddell et al, 1993). The present study found a significant decrease in the FabQ score. This indicates a reduction in fear and avoidance behaviors after a strength training intervention with the hip belt squat exercise. A study by Marshall et al, 2022 found no difference in FabQ score post a twelve-week intervention of yoga, physical therapy and education for participants with chronic LBP (Marshall et al, 2022). Which may indicate that a

strength training intervention is superior to yoga, physical therapy and education regarding the fear and avoidance beliefs. The reduction in pain levels combined with the significant increase in chronic EIH response may be one of the reasons the participants have less fear and avoidance beliefs.

EuroQOL-5D

The present study revealed no disparity in the EuroQOL-5D scores, suggesting that participants' health-related quality of life remained unchanged. However, the pretest score of 0.69 (SD ±0.20) indicates that participants already had a relatively satisfactory quality of life before the intervention, leaving limited scope for noticeable improvement.

***The* acute EIH response**

The present study indicates that an acute EIH response happens after a single bout of strength training. The mechanisms responsible for this are poorly understood. The EIH response involves multiple analgesic mechanisms, including both opioid and nonopioid systems. The most acknowledged hypothesis is that exercise triggers the release of endogenous opioids contributing to pain modulation (Koltyn et al, 2014). This may indicate that strength training improves the activation of these endogenous systems. However, a study by Rice et al, 2019 mentions that the ability to activate the endogenous pain inhibitory system is reduced for individuals experiencing chronic pain (Rice et al, 2019). This contrasts with the findings of the present study, which observed a significant improvement in PPT values after strength training in nine out of twelve sessions. This suggests that, despite the chronic pain experienced by participants in sub-study one, their response was similar to that of the healthy participants in sub-study two. This could be explained by the baseline ODI score of 8.5 categorized as “mild disability" and an average VAS score of 2.1 standing, both being on the lower end of the spectrum. If the chronic pain levels had been higher before the trial, the acute EIH response might have shown more variance.

The current research investigating the ideal dosage of physical activity required to produce EIH response is lacking (Koltyn et al, 2014). Studies on resistance training often lack standardization in exercise type, intensity or volume when investigating EIH response (Wewege et al, 2021; Hayden et al, 2021a). The present study employed strength training comprising three warm-up sets at submaximal increasing loads and three work sets, each consisting of five repetitions at 90% of the 5RM. This protocol demonstrated consistent

effectiveness in producing an acute EIH response in healthy individuals.

***The c*hronic EIH response**

While it is proved that the acute EIH response happens after a single bout of resistance training, the potential for chronic improvements is unclear and remains uncertain (Wewege et al, 2021). The present study results suggest that individuals with chronic NSLBP experience a significant improvement in chronic EIH response for measurements taken both before and after the pre- and posttest. This suggests an overall improvement in general pain sensitivity, likely influenced by psychological factors and that the EIH response can be trained over time. Individuals enduring chronic pain typically exhibit heightened pain sensitivity compared to those without pain (Phillips et al, 2022). This higher sensitivity often involves psychological aspects such as fear avoidance and catastrophizing, which can affect the perception of pain (Sturgeon and Zautra, 2013). The significant improvement in the FabQ questionnaire found in the present study suggests that these psychological aspects may have less impact after the posttest, potentially leading to a reduction in pain sensitivity. Furthermore, individuals with chronic pain have a decreased ability to activate the endogenous pain inhibitory system (Rice et al, 2019) which could affect the EIH response. However, the present study shows that the training intervention alleviates these psychological factors among individuals with chronic NSLBP, consequently enhancing their pain tolerance both before and after training.

The chronic EIH response was significant when comparing measurements taken after the pre- and posttest. This observation indicates that strength training may enhance the chronic EIH response, and that it can be trained for participants with chronic NSLBP. A Randomized controlled study (RCT) by Rasmussen et al, 2021 has shown that pain levels improve after three months of strength training for individuals with chronic cancer-related pain but return to baseline levels after three months without training (Rasmussen et al, 2021). This indicates that exercise can modulate the EIH response and that it is present for individuals suffering from chronic pain and that exercise is the reason for the lower pain levels.

No significant difference was found in the chronic EIH response for healthy participants in measurements taken before the pre- and posttest. The participants in the present study had more than average strength training experience, which could indicate that the individuals in the present study had already reached the maximum

extent of EIH and thus had maximized their pain sensitivity. However, the significant improvement found in the chronic EIH response after sessions indicates that the EIH response is trainable. This may be explained by the nervous system's ability to adapt and change in response to various stimuli. Strength training is also known to cause adaptive changes in the nervous system (Sale, 1988), where neural pathways responsible for pain modulation may also undergo changes, which could result in a more effective EIH response. Furthermore, the ability to activate the endogenous pain modulatory systems may be improved following resistance training, which includes the release of endorphins and other neurochemicals associated with pain relief (Santos & Galdino, 2018).

Muscular strength

The results of the present study indicate that a training intervention with an intensity of 90% of the 5RM and gradually increasing the intensity between sets of five repetitions with 1-3RIR was effective in enhancing muscular strength, for both chronic NSLBP- and healthy participants. Schoenfeld et al, 2021 found that training with high intensities (80-100% of 1RM) and low volume (between one or five repetitions) optimizes maximal muscular strength (Schoenfeld et al, 2021). Therefore, the increase in muscular strength was expected as this approach was adapted in the linear periodization employed in the present study. However, it is important to acknowledge the potential influence of familiarization with novel exercises. The hip belt squat exercise used in this intervention was new to most of the participants, which may have contributed to initial increase in strength through neuromuscular adaptation and skill acquisition. Research shows that individuals experience rapid improvements in strength during the initial stages of a new form of resistance training, primarily due to the process of familiarization, motor learning and skill acquisition (Hughes et al, 2018). Therefore, the observed increases in strength could be attributed to participants becoming more proficient in executing the hip belt squat exercise over the course of the intervention.

Body composition

The present study indicates that neither six- or four- weeks intervention with participants performing the hip belt squat exercise was proficient to show any significant change in FM and FFM. The primary factors known to induce hypertrophic responses include mechanical tension, muscle damage, and metabolic stress (Krzystofik et al, 2019), which all are anticipated to occur during the performance of the hip belt squat in the present study.

However, even with these factors occurring Damas et al, 2018 found that genuine hypertrophy typically occurs after eighteen sessions of resistance training (Damas et al, 2018). This suggests that extending the intervention beyond the current four and six weeks might show more significant outcomes.

Furthermore, volume is shown to influence hypertrophic gains (Schoenfeld et al, 2021). Schoenfeld et al, 2021 found that moderate repetitions (eight to twelve) and moderate intensity (60-80% of 1RM) were preferred to optimize hypertrophic gains (Schoenfeld et al, 2021). This agrees with Smilos et al, 2003, who observed that a muscular hypertrophy protocol around 75% of 1RM for ten repetitions increased the hormonal response for growth hormone significantly more than a strength training protocol around 88% of 1RM for five repetitions which still showed a small but significant effect on growth hormone response (Smilios et al, 2003). This illustrates that moderate intensity and higher volume optimizes muscle hypertrophy more than training with high intensities for low volume as used in the present study.

Flexibility

The lumbar flexibility test was only performed in sub-study one. The results showed a significant improvement in lumbar flexibility post intervention (7.99±5.60cm (p=0.003)). This was an expected development as resistance training has been shown to improve flexibility (Alizadeh et al, 2023; Delvaux et al, 2020; Nelson & Brandy, 2004). Strength training consists of an eccentric part of the exercise which involves lengthening of the muscle tendon unit, which provides a higher resistive force or loads (Hahn. D, 2018; Hollander et al, 2007), which may provide a greater stimulus for increasing flexibility. When performing eccentric contractions, the resistive force causes microtears in the muscle fibers that when repaired can lead to increased muscle length and elasticity. The increased flexibility could be compared with their reduced VAS score following the intervention, suggesting that pain might have been a contributing factor to the limited flexibility.

Limitations

Due to complications with the application to the scientific ethical committee the protocol had to change multiple times. This resulted in a feasibility study design rather than a RCT study which was the initial intention. Since there is no control group involved in the current study design it is not possible to infer causality in the EIH response, VAS score, muscular strength, and flexibility. However, since most of the

participants with chronic NSLBP expressed that they have been experiencing pain for more than twelve months, and previously had tried different treatment options, the results suggest that this training intervention had a positive effect.

Without a control group, it is challenging to distinguish whether the observed effects are due to the specific intervention or other influencing variables. Additionally, participants might experience change in their VAS scores simply due to a placebo effect, where the belief in the intervention's efficiency impacts their pain perception. Although the chronic EIH response has shown similar results to the decrease in VAS scores, suggesting that the placebo effect might not be the sole reason, it cannot be conclusively determined that the intervention alone caused the reduced pain levels. Therefore, it remains unclear if the decreased pain is directly attributed to the intervention or other factors. Further investigation through RCT studies is needed to investigate this effect more conclusively.

The PPT measurements during the intervention were executed by five different trial managers. This could influence the reliability of the results since it can be difficult to perform the measurements identical to one another even though a precise description of the measuring point was given. Therefore, some variation in the Chronic EIH response could be explained by the fact that it was not the same trial manager performing all PPT measurements throughout the entire intervention. However, PPT measurements performed before and after each training session were always performed by the same trial manager, which should result in an accurate measurement of acute EIH.

In the present study, participants underwent PPT measurements three times before and after each session, potentially impacting the validity of the data. This repetitive process might have led to a training-induced adaptation or familiarity among participants with the measurements, potentially influencing their responses to the applied pressure. Therefore, the observed changes in pain perception may not reflect true alterations. However, the correlation observed between the decreased VAS scores and the improved EIH responses suggests that this method did not induce an adaptation and that there is a chronic EIH response post intervention.

Conclusion

In conclusion the results of the present study demonstrated that hip belt squats are a feasible exercise form for chronic NSLBP patients. This is displayed by the feasibility questionnaire, which showed that the exercise was acceptable, comfortable and that they wanted to continue performing it. Additionally, the limited efficacy of the intervention showed increased EIH response, decreased VAS, and increased muscular strength. Therefore, the present study concludes that the performance of the hip belt squat exercise is feasible and indicates that it could be beneficial for individuals suffering from chronic NSLBP. However, the present study provides data indicating that this specific exercise improves both acute and chronic pain as well as function for participants with chronic NSLBP.

Furthermore, the present study found that strength training modulates an acute EIH response for healthy individuals. The present study did not find any significant difference in chronic EIH response between measurements taken before the pre- and posttest for healthy participants. However, a significant increase in the chronic EIH response was observed between measurements taken after the pre- and posttest, indicating an enhanced EIH response following the intervention. However, to fully conclude this, a RCT study is necessary.

Practical application

The present study did not have a control group, which means that the effects of this intervention cannot be fully concluded. Nonetheless, evidence suggests that the hip belt squat exercise is both feasible and potentially beneficial for chronic NSLBP patients. Consequently, the study's relevance extends to researchers considering larger RCT studies to further investigate these findings. Involving patients with more severe LBP, greater disability, and older individuals to determine if the intervention would have the same effect. However, the present study indicates that it would likely have a positive effect.

Over time, such findings could show relevance in managing clinical guidelines for the treatment of chronic NSLBP. Additionally, the current study may be pertinent to individuals who incorporate training methods to alleviate pain. It suggests the need for further investigation into whether pain sensitivity can be modified through training over time, thereby, being a possible treatment for chronic pain.

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