Anders Gjellan
Torstein Haaland

Management of chronic lower back pain through resistance training

Bachelor's Thesis in Human Movement Science
BEV2900 - Spring 2021

Bachelor's project in Human Movement Science
Supervisor: Anne Lovise Nordstoga
May 2021

Bachelor's project

NTNU
Norwegian University of Science and Technology
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Abstract

Background: Low back pain (LBP) is extremely prevalent and a large burden to society as it often leads to disability. One potential rehabilitating approach is resistance training because of the strong link between improved muscular fitness and function. Resistance training could also decrease nociceptive responses and thereby pain in LBP sufferers. We sought to see how full body resistance training would affect muscular fitness and disability caused by LBP.

Methods: Seven studies were found and selected through searches made in Google Scholar, including people with chronic non specific low back pain (CNSLBP). The studies measured LBP related disability through Oswestry Disability Index (ODI) before and after a 12+ week resistance training program. **Results:** All the included studies saw ODI scores improve following the resistance training program compared to baseline measurements. All studies noted improvements in muscular strength as a part of their results. **Conclusions:** Full body resistance training seems to be a promising means of managing LBP related disability and increasing muscular strength in individuals suffering from LBP.

Abstrakt

Bakgrunn: Korsryggsmerter er svært prevalent og er en stor byrde for samfunnet, ettersom de ofte fører til nedsatt funksjonsevne. En potensiell rehabiliteringsmetode er styrketrening på grunn av den sterke sammenhengen mellom muskulær fitness og funksjonsevne. Styrketrening kan også svekke nociceptiv respons og dermed svekke smerte hos de med korsryggsmerter. Vi søkte etter hvordan fullkropp styrketrening ville påvirke muskulær fitness og funksjonsnedsettelse fra korsryggsmerter. **Metoder:** Syv studier som inkluderte personer med kroniske uspesifikke korsryggsmerter ble funnet og valgt gjennom søk i Google Scholar. Studiene målte smerterelatert funksjonsnedsettelse gjennom Oswestry Disability Index (ODI) i forkant og etterkant av et 12+ ukers styrketreningsprogram. **Resultater:** Alle studiene dokumenterte forbedring i ODI-score etter styrketreningsprogrammet sammenlignet med pasientenes utgangspunkt. Alle studiene dokumenterte forbedringer i muskelstyrke som en del av resultatene sine. **Konklusjon**: Fullkropp styrketrening ser ut til å være en lovende behandlingsmetode for å redusere funksjonsnedsettelser relatert til korsryggsmerter og i å øke muskelstyrke hos de med nedre ryggsmerter.

Introduction

Lower back pain (LBP) is a commonly occurring health problem in the world today. It is related to disability and inactivity, and is the most common cause for work-related disability and long-term disability. [1,2] LBP is one of the leading causes of long term disability leave in Norway, and one of the most common reasons for receiving welfare benefits. [3] It is a massive burden not only for those who suffer from LBP, but also for society as a whole. LBP can occur acutely, as in sudden injuries, often with a more defined cause. It does also occur chronically, which is usually defined as experiencing pain and discomfort in the lower back region for at least 3 months. Chronic lower back pain often does not have a clear cause and is thus labeled non-specific, and chronic non-specific lower back pain (CNSLBP) does not have an obvious cure. LBP is also more frequent in those who have previously experienced it, so long term management is important. [4] With a reported lifetime prevalence of 84% for LBP, and a 23% prevalence of chronic low back pain [5], the need to find effective treatments for CNSLBP is clear, especially given that pain medication does not seem to be an effective treatment against CNSLBP.

The pain stemming from LBP often leads to a form of pain related disability amongst those suffering from it. [6] The Oswestry Disability Index and the Roland Morris Questionnaire are both validated questionnaires that attempt to quantify the disability a person may experience from LBP [7] Disability indicators like these help show how LBP may affect the life of sufferers. Other factors associated with pain related disability such as perceived energy levels, motivation and fear of physical activity could be assessed through qualitative measures.

Some studies indicate that insufficient muscle strength and low fatigue resistant trunk muscles have played a large role in LBP development as a risk factor, as sufficient muscle strength could be needed to keep the vertebrae aligned to avoid excess disk pressure. [8] Though there is little evidence to support this theory, some studies have investigated if physical fitness levels predict development of LBP. And there is evidence that there is an added risk of developing LBP in those with poor muscular fitness. [9,10] However, some studies have mentioned that the poor muscular fitness associated with LBP is not necessarily a risk factor, but rather a symptom of LBP due to pain related disability. [11] As such, LBP could further worsen muscular fitness and fatigue resistance. [12] It can therefore also occur amongst those with initially good muscular fitness, but lead to deconditioning over time.

Currently there are many rehabilitating interventions being used in CNSLBP management. These interventions involve a multitude of different exercises, using different equipment and varying intensities. However, there is not a clear consensus on how to address CNSLBP. One common rehabilitation intervention for treating those with LBP is resistance training. Resistance training can effectively increase strength and work capacity through externally loading skeletal muscles [13], but it may also be effective in reducing pain sensation, reducing muscle tonus and possibly inducing hypoalgesia [11], which is a general reduction in pain both during and following exercise. Resistance training has also been proven to decrease disability in those with CNSLBP [14], making it a viable treatment that seeks to reduce symptoms while improving muscular fitness in CNSLBP sufferers.

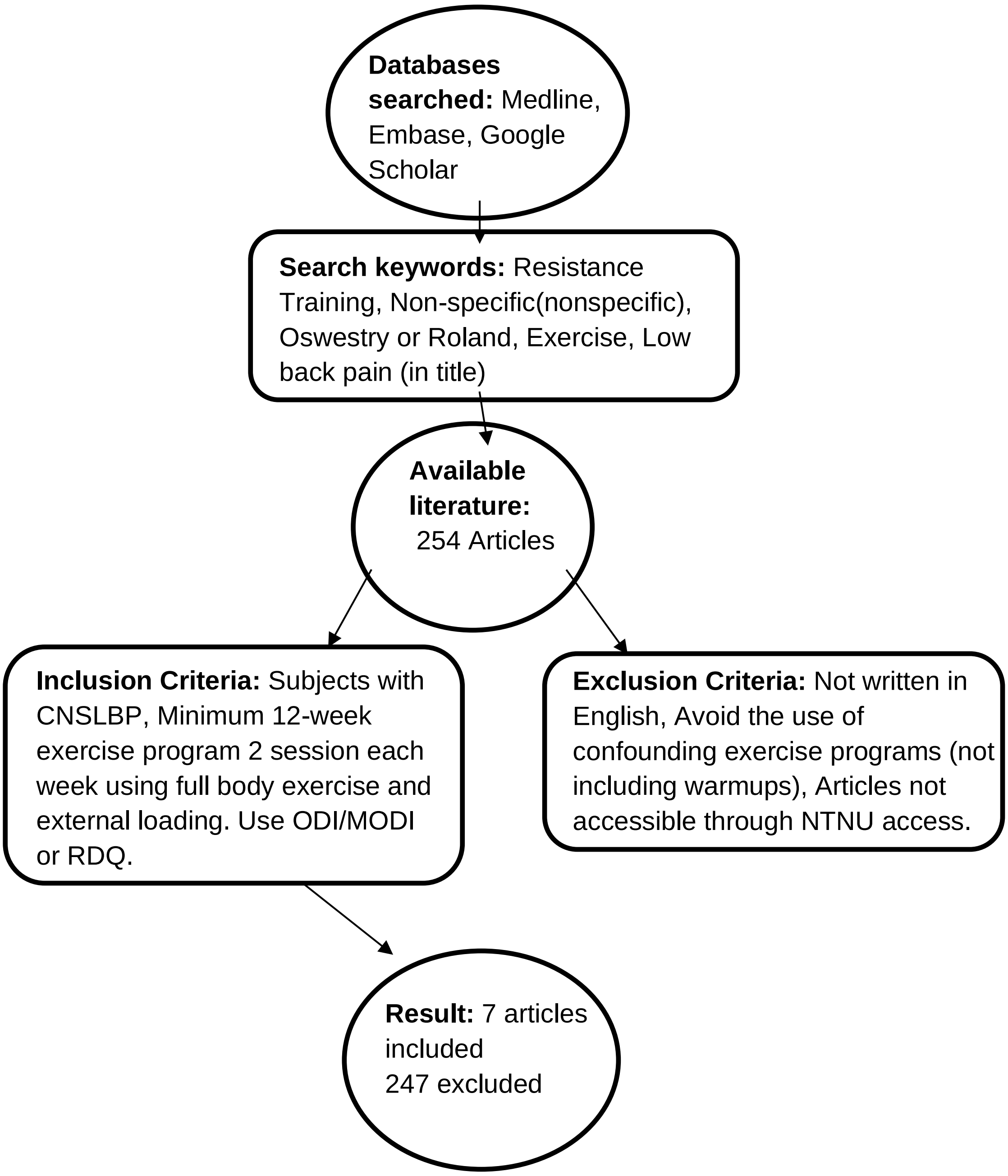
However some questions still remain regarding the effectiveness and practical applications for resistance training. There is uncertainty around which training protocols would be more effective and feasible to use in the general population, as most resistance training based interventions seem to require specific training equipment and supervised follow-up, which might not be available for all [15]. The long term effects of such interventions are also not well documented, as most protocols seem to only include a follow-up at the end of an intervention. It is also uncertain what the exact relationship between resistance training and LBP is, as there is little evidence supporting theories surrounding muscular fitness and LBP development [16].

Currently, full body resistance training in particular seems to be more efficient for reducing disability in those suffering from LBP compared to area specific training due to possibly improving more aspects of function than area isolated training. [14,17] Full body resistance training could activate a larger number of motor neurons than isolated training, possibly leading to improvements in muscular fitness across a greater total cross sectional area. The purpose of this review is to examine the effects a full body resistance training program has on pain related disability and muscular fitness in people with CNSLBP.

Methods

A literature search was carried out on 07.03.2021 and is outlined in the flowchart in figure 1. The primary search was performed in Google Scholar. We also performed an identical search in Medline and Embase, however, it did not result in additional studies. Screening of exclusion and inclusion criteria was initially done by reading the title, and if the title was promising, the abstract was read. The minimum time of 12 weeks was set to ensure that participants had sufficient time to become stronger, and not just see improvements from neuromuscular adaptations through movement patterns alone. A quality assessment was done with the PEDro scale (Appendix A) where applicable.

Figure 1. Flowchart for literature search.



Results

A total of seven studies were included, four of which were randomized control trials. The studies mostly used free weights and machines for external loading and progressively increased the resistance. Only one study opted to use resistance bands as external loading. The seven studies included a total of 390 people, the majority of which were male. (Table 1) Not all the studies used a control group, three used a no-treatment group for control and the study by Iversen [15] used a multidisciplinary biopsychosocial treatment approach as a control group.

All the included studies used the Oswestry Disability Index or a modified version of it to measure disability. These measurements and others were taken at start as a baseline, and again at the end of the intervention in all the studies. Two studies took baseline measurements after a 3-week familiarization phase. None included long term follow up as part of their results.

All of the studies used a form of progressive resistance training in order to increase external loading over time and improve strength levels and work capacity of the participants. All studies included strength improvements as a part of their results. Notably, these results were measured through vastly different strength tests, making them incomparable. Five of the studies utilized tests for measuring back extensor strength [2,14,15,18,19], four used at least one test measuring strength in the lower extremities [12,14,19,20] and four used an upper body pressing movement for assessing general upper body strength. [12,14,18,20] Additionally, Tjøsvoll and colleagues [14] measured improvements in self-perceived energy levels and work capacity through qualitative feedback from the participants.

All of the exercise groups showed a significant reduction in disability following the exercise intervention. The average improvement was 40%. The lowest reduction in disability was found in the resistance band group used by Iversen and colleagues at 19% improvement, alongside two of the groups from Kells study that saw improvements of 20% and 21%. Most of the other training groups saw improvements ranging between 36%-52%, [2,12,14,18,20], although the greatest improvements were measured in the study by Welch (76%), and one exercise group from Verbrugghe and colleagues (66%). The results seemed to favour resistance training with relatively heavy loads for the limbs alongside high training volume for trunk stabilizers such as abdominals and spinal erectors. All of the studies that included strength improvements as a part of their results also saw their participants getting stronger following the training.

Quality assessment of the RCTs through the PEDro scale (Appendix A) showed poor results for internal validity. The three studies co-authored by RT. Kell [12,18,20] all scored the same, as they all generally were carried out in the same manner. Eligibility criteria were clearly stated and allocation was random, however no mention of blinding of neither researcher or participants were stated. Due to dropouts, key outcomes were measured in less than 85% of initial participants. Iversen [15] scored better by blinding the researchers completing the statistical analysis, otherwise it scored the same as the previously mentioned studies.

Table 1 Studies included in the review.

Study (Year)	Partici-pants	Exercise Mode	Control	ODI Changes	Weekly sessions	Duration (Weeks)	Main Findings
Kell and Asmundson (2009) [18]	N=9 6M/3F	Free- weights Machines PRT Body- weight Loading: 52%-72% of 1RM	Retain current activity	Baseline 40,4 End 24,2	3	16	The use of PRT protocol similar to one used with athletes reduced disability in people suffering from CNSLBP more so than an Aerobic training protocol. The control group retaining their current activity level saw no significant change from baseline testing and after the 16 week trial. The PRT group also saw significantly increased strength and low back endurance.
Kell et al 2011 [12]	N=179 119M 60F	Free- weights, MachinesPRT Body- weight Loading: 50%-83% of 1RM	Stop all resistance training	Baseline (2d)39,8 (3d) 40,1 (4d)42,5 End (2d)31,8 (3d) 31,6 (4d)27,1	2,3,4 (3 groups, with different protocols)	13	Following Kell 2009, the use of a 4 day/week exercise split saw significantly larger improvements in disability and strength in a similar set of participants. Compared to the 2 and 3 day/week exercise splits. The control had no significant changes from baseline to testing after the trial.
Jackson et al 2011 [20]	N=30 30M	Free- weights, MachinesPRT Body- weight Loading: 55%-79% of 1RM	Retain current activity	Baseline ME 43,1 OE 44,7 End ME 23,2 OE 21,4	4	16	Following Kell 2009 & 2011, they showed the PRT protocol could also improve disability and strength in recreationally active adults suffering from CNSLBP. With significantly reduced disability at the 16 week mark than at baseline.

Welch et al 2015 [19]	N=30 19M 11F	Free- weights Machines Body- weight PRT Loading: 5 repetitions at 6/7RM	No control group	Baseline 22,9 End 5,4	3	16	Free weight resistance training reduced disability from baseline to follow-up after the intervention. The participants also saw a significant improvement in back extension endurance with a mean improvement of 18%.
Iversen et al. 2018 [15]	N=46	Bands. PRT Loading: 60-80%	Biopsycho-social treatment	Baseline 28,1 End 22,7	3	12	Resistance band training significantly reduced disability and increased strength in participants following a 12 week intervention. Resistance band training alone was not better than general exercise as part of a multidisciplinary biopsychosocial rehabilitation for those with CNSLBP.
Tjøsvoll et al 2020 [14]	N=20	Free- Weights PRT Loading: 50%-90% of 1RM	No control group	Modified ODI Baseline 8,4 End 5,3	4	16	PRT with free weights using heavy compound exercises showed reductions in disability along with improved strength and pain self-efficacy
Verbrugghe et al 2020 [2]	N=76	Machines Body- weight PRT Loading: 80% + of 1RM	No control group	Modified ODI Baseline (1) 22,8 (2) 20,0 (3) 20,0 (4) 21,6 End (1) 7,8 (2) 14,6 (3) 12,4 (4) 12,2	2	12	4 groups used a HIT resistance training exercise mode on machines paired with different combinations of additional training. All groups improved disability and strength in those suffering from LBP.

N= amount, M= male, F= female, PRT = Progressive resistance training, RM=Repetition maximum, HIT High Intensity Training, LBP = Low back pain, CNSLBP = Chronic non-specific low back pain, ODI= Oswestry disability index, Numbers indicate different training groups. Xd = X day/week. ME = middle age exercises, OE = Old age exercises.

Discussion

All of the included studies found that resistance training interventions reduced symptoms of disability from baseline to follow-up after 12+ weeks of exercise. The studies using a no treatment control group found significantly different results between control and intervention. [12,18,20] In contrast, the biopsychosocial control group outperformed the resistance band group in the study by Iversen and colleagues [15] Furthermore, all of the studies found that all the participants got physically stronger. [2,12,14,15,18–20] As such, this indicates that there may be a link between improvements of physical strength and disability stemming from CNSLBP. It also possibly suggests that by following a strength training program one could reduce the disability symptoms stemming from CNSLBP through improving their physical condition.

Both the changes in strength and disability varied across the studies, possibly indicating that different exercise protocols were more effective than others. It is also possible that participants would respond differently to the exercises performed. Due to a lack of standardized strength testing for LBP patients, the strength improvements were measured using different tests. Some of the test results could be improved by increased skill and motor learning such as on the deadlift one repetition maximum, whereas others, such as isometric back extensions, cannot be improved as much through skill and motor learning alone. This makes it impossible to compare the changes in strength reported in the included studies. No conclusions about which protocol is the most effective should therefore be drawn, and tailoring the exercise protocol based on the individual's need is likely the most important aspect for a successful exercise intervention. However, it does seem that a combination of free weights and machine based training could be the most effective approach based on the results.

Full body resistance training could be useful for reducing disability associated with CNSLBP as it aims to improve muscular fitness and general function. As resistance training improves strength and fatigue resistance of the skeletal muscles, it could serve as the main driver for reducing disability, because of the strong link between muscular fitness and improved function. [8,13] Resistance training can improve muscle strength and work capacity by externally loading skeletal muscles. Full body resistance training in particular would recruit more overall motor neurons, resulting in neuromuscular adaptations and strength increases across a greater total cross sectional area. This is in line with our findings, which showed that resistance training can be effective in increasing the muscular strength and work capacity in people with CNSLBP while simultaneously reducing disability. [12,14,18] This suggests that resistance training can be utilized in a successful manner to reduce disability even in those suffering from CNSLBP.

An explanation for the positive effect of resistance training on pain is the possibility of exercise induced hypoalgesia, resulting in a diminished perception of pain to normally painful stimuli during, and for a short time after performing the exercise. [11] It could thereby decrease the responsiveness of nociceptive neurons during and following exercise, resulting in an ease of perceived pain during the execution of exercises. By experiencing less pain during resistance training, patients could experience positive changes in their own perception of pain in relation to physical activity. This could serve as an abruption to the negative feedback loop and fear often associated with pain related disability and decreased physical fitness [12].

LBP sufferers often struggle with poor muscular fitness and perform worse in several tests that measure low back function and strength. [8] Additionally, those who have lower levels of physical fitness are more likely to develop LBP. [9] The trait most associated with LBP is poor endurance of the back extensors. This possibly correlates to a lower work capacity for performing regular everyday tasks that require a certain level of back extension strength, endurance and stability, such as bending over and picking up items. Implementing exercises that target these specific problems along with improving overall muscular fitness of other important body parts could therefore be effective in improving function both during and after a LBP rehabilitating program. Tjøsvoll and colleagues discussed how exercises that mimic the movement patterns used in everyday activities like the back squat and deadlift could improve several important aspects of disability in those suffering from CNSLBP while increasing work capacity [14].

All the studies used in this review used different tests for measuring strength improvements. This would make these results very difficult to compare. Similarly, comparing the changes in disability may be challenging, as all the groups had different baseline measurements. This could lead to different levels of relative changes in outcome measurements. Furthermore, the different initial levels of disability could impact the ability to perform the program properly. Though it seems that heavier loading and the use of free weights and machines is favorable, it is possible that baseline measurements and initial physical fitness amongst study participants could play a large role in differentiating results, as improvements seemed to be greater in groups where disability scores were worse at baseline, the only exception being the resistance band group used in Iversen. [15] Additionally, two of the studies performed baseline measurements after a 3 week familiarization phase [12,20], which could result in better baseline measurements than if they had performed the measurements before the familiarization. However, all these studies showed positive results in terms of both increases in strength increases and reduced disability, indicating that each intervention could be effective in its own way.

To understand if the resistance training interventions were what caused the change in disability, the studies need to be internally valid. To understand the effectiveness of each intervention in the general population, the participants need to be representative of the population as a whole. Only four of the included studies were randomized control trials, though all scored poorly on the PEDro scale (Appendix A) indicating low levels of internal validity. The score did not affect how we viewed the studies, as we also included studies which could not be rated. The inability to adequately blind therapists and participants, and conceal the allocation in exercise interventions could make this tool more useful in other contexts than exercise interventions. However, we do know that in all of the studies, the participants were not performing resistance training before the study began, and after completing the program they all improved their symptoms to a significant degree.

Work related physical activity was not controlled for in any of the included studies. This could cloud results as physically taxing labour causes added stress on the body which could impair recovery from the resistance training sessions. However, it seems that resistance training protocols were what caused the change, as the control groups receiving no treatment saw negligible changes. The lack of distinction between people in manual labour and those in office environments may act as a limitation for applying the same exercise protocols to both populations. Though it seems that using a resistance training protocol could be effective in managing disability caused by CNSLBP in the general population, there may be room for more research aimed at the part of the population that works in manual labour, given that work related heavy lifting is a known risk factor for LBP development that could interfere with resistance training. Understanding how resistance training could affect those with physically taxing jobs could help guide future treatment for this segment of the population.

Disability is often multifactorial. This suggests that several of the factors associated with disability would possibly not be taken account for through quantitative measurements. Though the studies in this review noted strength improvements and reduced disability, there could have been immeasurable factors that could have affected the results and baseline measurements. Therefore, qualitative feedback from participants could be important for highlighting improvements that would have not been measured through quantitative measures like the Oswestry Disability Index. In this review, the study by Tjøsvoll and colleagues [14] was the only study that utilized qualitative feedback from participants for this added benefit. Here, improvements in training motivation, self perceived energy and relationship with physical activity were noted, all of which could have affected baseline measurements and end results. For an added benefit, qualitative feedback could also reflect participants' own perception of the intervention, such as the ease of execution for the exercises that were performed or fear of physical activities.

The lack of long term follow-up in the included studies made disclosing whether participants continued with resistance training following the intervention impossible. Preventing deconditioning following a rehabilitation program is not well documented in the setting of LBP. Deconditioning could increase the prevalence of different risk factors associated with LBP development and is theorized to be a risk factor itself. [9,10] The importance of motivation amongst the participants of a study could therefore be very important, as less motivated individuals likely would become inactive after completing such a program, whereas motivated participants could be more likely to continue training to a certain degree. All participants of the study made by Tjøsvoll reported that they wanted to continue training after completing the program, which could mean the supervision and training protocol were effective in motivating those with CNSLBP to exercise more. Participants of the study also reported a positive experience exercising together in smaller groups of 3-5 individuals, which made the training environment more social while still receiving adequate supervision and feedback. A biopsychosocial approach with qualitative feedback in a similar setting could therefore be valuable in future research.

Many of those suffering from CNSLBP could be unfamiliar with resistance training and may therefore be in need of guidance and supervision. This could affect the results of a resistance training based intervention as supervision could help people perform exercises and load more effectively and correctly relative to interventions that rely on the study participants doing it by themselves. In this review, several of the studies implemented supervision and guidance as a part of their protocols, which could affect the outcomes. However supervised exercise protocols could be less effective for the general population as resources are limited, and as such protocols which require minimal resources may be advantageous. Out of the studies used in this review, four implemented in-person supervision, two of which used close supervision, as in guiding the participants through every session while giving instructions on technique and loading. The two studies that did not implement in-person supervision gave out written and verbal instructions ahead of the program. Though it is hard to compare different levels of supervision and how it possibly affected the results of each study, results seemed to be better in the groups that used supervision. As such, the use of supervision could help explain some of the differences in outcomes.

Tjøsvoll and colleagues [14] utilized close supervision and qualitative feedback from participants regarding the rehabilitation program as a whole. As they used relatively complex and heavily loaded movements, they took the participants' opinions on ease of execution into account. Several of the participants reported difficulties in performing the exercises and that they saw supervision and guidance as necessary. The Welch study group [19], which saw the greatest reduction in disability, also relied on close supervision, as technique and biomechanical components of the back squat were evaluated. Though both of these study protocols saw great improvements in both strength and disability of participants, they would probably be too complex to perform for the general population and require large amounts of resources.

Kell and Asmundson [18] used supervision through all of their training sessions, but to a lesser degree than those previously mentioned. Verbrugghe and colleagues [2] also used moderate supervision in all their protocols. It was mostly used to help and manage the loading on exercises and not technical execution. A common factor in both of these studies is the lack of complex exercises, possibly making the need for supervision less pronounced. They performed similarly to the closely supervised studies, possibly suggesting that close supervision is not necessary in specific settings and with less complex exercises that still seek to improve full body muscular fitness.

The three studies that did not utilize supervision still gave participants instructions on how to perform exercises and load management. Kell [12] used three groups with different training volumes and the most promising protocol was used in Jackson [20]. They used the same tests for measuring strength and disability. The 4 days/week group from Kells results did not differ much from the results from Jackson though they were slightly worse. The resistance band group used in Iversen [15] was left mostly to their own with a few sessions to improve motivation and check technique. They saw the lowest reduction in pain related disability compared to other exercise groups, but whether this is due to lack of supervision or the implementation of exercise bands instead of free weights is not clear.

None of the studies in this review included any long term follow up of participants, only short term follow up at the end of each intervention. LBP in general appears to be a recurring problem, and those who have previously experienced LBP are more likely to experience it again. [4,21] Long term follow ups could therefore be beneficial for understanding the lasting effects of these interventions and motivation amongst participants, as well as long term adherence to exercise. This is an area future research could focus on, to understand long term management of CNSLBP.

The use of full body resistance training to aid management of CNSLBP is very promising, though there is still room to know more about how to use it in a broad population. Possibilities for future research is to focus on less use of supervision throughout the training period. It is possible that no supervision could limit exercise selection severely, so some level of supervision might still be needed. Increased autonomy might also impact long term adherence to regular exercise following the intervention period, and as such, long term follow up is also needed. Qualitative feedback should also be taken into account in order to find an optimal schedule for supervision, ease of execution for certain exercises and to measure factors that are not easily quantified. Lastly there is still room to learn more about how those with CNSLBP who have physically taxing jobs respond to resistance training.

Conclusion

Our results show that full body resistance training can be effectively used to reduce disability while improving muscular fitness in people with CNSLBP. It seems that interventions which used heavier loading and a mix of free weight and machine exercises saw the best improvements. However, more research could be done to evaluate how to optimally use resistance training based interventions in a broad population. Specifically we can still learn more about long term effects in management of CNSLBP, how supervision affects adherence, and how patients who work physically taxing jobs respond to these kinds of interventions.

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Appendix A

PEDro scale

1.	eligibility criteria were specified	no ❑ yes ❑ where:
2.	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ❑ yes ❑ where:
3.	allocation was concealed	no ❑ yes ❑ where:
4.	the groups were similar at baseline regarding the most important prognostic indicators	no ❑ yes ❑ where:
5.	there was blinding of all subjects	no ❑ yes ❑ where:
6.	there was blinding of all therapists who administered the therapy	no ❑ yes ❑ where:
7.	there was blinding of all assessors who measured at least one key outcome	no ❑ yes ❑ where:
8.	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ❑ where:
9.	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ❑ yes ❑ where:
10.	the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ❑ where:
11.	the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ❑ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999

Notes on administration of the PEDro scale:

All criteria	**<u>Points are only awarded when a criterion is clearly satisfied</u>**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

NTNU
Norwegian University of
Science and Technology