Doctoral theses at NTNU, 2018:216

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Norwegian University of
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Doctoral thesis

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ISBN 978-82-326-3222-0 (printed ver.)
ISBN 978-82-326-3223-7 (electronic ver.)
ISSN 1503-8181

NTNU
Norwegian University of Science and Technology
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Printed by NTNU Grafisk senter

Effekter av styrketrening eller generell fysisk aktivitet for pasienter med langvarige rygg- eller nakkesmerter i tverrfagligrehabilitering

Rygg og nakkesmerter regnes som ledende årsaker til nedsatt funksjon for mennesker over hele verden. Per i dag finnes det ingen kur for langvarige rygg og nakkesmerter, men symptomene knyttet til disse lidelsene kan reduseres gjennom forskjellige behandlingsformer. Langvarige rygg og nakkesmerter gir ofte tilleggsplager i form av psykososiale tilleggsplager, og personer med høy grad av psykososiale tilleggsplager henvises ofte til tverrfaglig rehabilitering hvor flere aspekter av symptomene behandles samtidig. Generell fysisk aktivitet inngår ofte som en komponent i tverrfaglig rehabilitering, men det er mulig at effektene av tverrfaglig rehabilitering kan forbedres ved å erstatte denne formen for aktivitet med progressiv styrketrening. Flere studier har vist at progressiv styrketrening kan være en effektiv måte å trene på for å redusere korsryggsmerter og særlig nakkesmerter.

Hovedformålet med doktorgradsarbeidet var å undersøke om progressiv styrketrening med elastiske bånd forbedret smerte-relatert funksjonsnedsettelse mer enn generell fysisk aktivitet i tverrfaglig rehabilitering for personer med langvarige rygg og nakkesmerter. Vi gjennomførte derfor to randomiserte kontrollerte studier i samarbeid med tverrfaglig poliklinikk – rygg-, nakke-, skulder ved St Olavs Hospital i Trondheim. I det ene studiet inkluderte vi pasienter med langvarige korsryggsmerter (ryggstudiet), mens pasienter med langvarige nakkesmerter ble inkludert i det andre studiet (nakkestudiet). Smerte-relatert funksjonsnedsettelse var hovedutfallsmålet i begge studiene. I tillegg gjennomførte vi en studie hvor vi sammenlignet muskelaktivering under trening med elastiske band imot tradisjonelt styrketreningsutstyr (EMG studien).

Deltakere i rygg og nakkestudien ble randomisert til tre uker tverrfaglig rehabilitering med i) generell fysisk aktivitet, eller 2) progressiv styrketrening, og deltakerne ble bedt om å fortsette med sine respektive treningsprogram i 9 uker, slik at den totale intervensjonstiden ble 12 uker. I EMG studien målte vi muskelaktivitet i utvalgte muskler mens deltakerne gjennomførte øvelsene knebøy, strak markløft, nedtrekk og enhånds-roing med både elastiske bånd og med tradisjonelt styrketreningsutstyr. Totalt ble 74 og 59 pasienter inkludert i

henholdsvis ryggstudiet og nakkestudiet. Av disse ble 46 og 31 deltakere fulgt opp ved 12 uker, som var det primære endepunktet. 29 deltakere ble inkludert i EMG studien

Hovedfunnene i denne avhandlingen var at tverrfaglig rehabilitering med progressiv styrketrening med strikk ikke resulterte i større bedring i smerte-relatert funksjonsnedsettelse sammenlignet med tverrfaglig rehabilitering med generell fysisk aktivitet for pasienter med langvarige nakke eller ryggsmerter. Klinikere kan derfor anbefale begge disse treningsformene til pasienter avhengig av deres ønske og interesse. Elastiske band viste seg å være et godt alternativ til tradisjonelt styrketreningsutstyr for øvelsene nedtrekk og enhånds roing. Derimot var tradisjonelt utstyr mest effektivt for å aktivere muskulaturen under øvelsene knebøy og strak markløft. Elastiske band kan likevel benyttes til disse øvelse hvis målet er å aktivere ekstensormuskulaturen i ryggen og hoftene, da aktivering av disse musklene var relativt lik for de to treningsformene.

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Finansieringskilder: KLP – Kommunal Landspensjonskasse, og Gaveforsterkningsmidler fra FYSIOPRIM-prosjektet (2010-2015). FYSIOPRIM var basisfinansiert fra Fysiofondet, med gaveforsterkningsmidler fra Norges forskningsråd.

Ovennevnte avhandling er funnet verdig til å forsvares offentlig
for graden PhD i samfunnsmedisin.
Disputas finner sted i Auditoriet, KA11, Kunnskapssenteret
onsdag 27. juni 2018, kl. 1215

Acknowledgement

This PhD-project was possible through funding by KLP – Kommunal Landspensjonskasse, and the Norwegian Research Council through the FYSIOPRIM project– a research program on physiotherapy in primary care. Performance Health (Akron, OH, USA) provided us with Theraband® elastic bands.

First, I thank my main supervisor, Marius Steiro Fimland for being my mentor, a good friend, and even training partner throughout this journey. You have always been supportive and encouraging, and your scientific guidance has been of invaluable importance for my work. I am also very grateful to my co-supervisors Ottar Vasseljen and Paul Jarle Mork for sharing your expertise, including several valuable discussions, presenting me with challenging questions and for your thorough review of manuscripts.

Further, I would like to thank all the enthusiastic and wonderful people working at the Department of Physical Medicine and Rehabilitation at St. Olavs Hospital. Without this collaboration and your enthusiasm, the project would not have been possible. Special thanks to Janne-Birgitte Bloch Børke, Bitten Kihl Olsen and Ida Berthelsen Reitan who played a crucial role in planning and implementing the study at the clinic, Lars Vikan Rise for leading the booster sessions, and all the physiotherapists managing the interventions. I would also like to thank Øyvind Salvesen for your advice and discussions on statistical topics. Thanks also to all other co-workers for your valuable contributions: Ronny Bergquist, Anne-Therese Tveter, Atle Melleby Kongsvold, Synnøve Fossheim Karlssen, Sigmund Gismervik and Gro Bertheussen.

I would also like to express gratitude to all my colleagues and friends at NTNU - Department of Public Health and Nursing for valuable discussions, motivational input, and social aspects. A special thank you to Lene Aasdahl for consistently being an academic sparring-partner and friend throughout the PhD, and to my office-mate Martin Skagseth for keeping me physically active and entertained throughout the workday.

I thank all participants who volunteered to take part in the studies. None of this work would have been possible without you.

Thank to my dear parents Torill and Jan-Viggo, and my sister Hanne for all your love and support throughout life. Thank you to all the rest of my family and friends who have been there the entire time. A special shout out to all my friends and training partners at Trondheim

Brazillian Jiu Jitsu club for not caring about me getting older and physically deteriorated from sitting all day and pushing me to keep both my body and mind in shape.

Finally, and most of all, I would like to thank my darling Åse who has supported me and had faith in me both throughout the PhD and life in general. Thank you for all your love and encouragement, for being a superb partner in life and a wonderful mother for our kids Leon and Henry. I love you all!

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Resistance training in addition to multidisciplinary rehabilitation for patients with chronic pain in the low back: Study protocol

Contemporary Clinical Trials Communications (2017);6: 115-121.

II. Vegard Moe Iversen, Paul Jarle Mork, Ottar Vasseljen, Ronny Bergquist, Marius Steiro Fimland

Multiple-joint exercises using elastic resistance bands vs. conventional resistance-training equipment: A cross-over study

European Journal of Sports Science. 2017 Sep;17(8):973-982.

III. Vegard Moe Iversen, Ottar Vasseljen, Paul Jarle Mork, Sigmund Gismervik, Gro Falkener Bertheussen, Øyvind Salvesen, and Marius Steiro Fimland

Resistance band training or general exercise in multidisciplinary rehabilitation of low back pain? A randomized trial

Submitted to Scandinavian Journal of Medicine and Science in Sports: Conditionally accepted with minor revisions.

IV. Vegard Moe Iversen, Paul Jarle Mork, Ottar Vasseljen, Marius Steiro Fimland

Resistance training versus general physical exercise in multidisciplinary rehabilitation of chronic neck pain: A randomized controlled trial.

Submitted to Journal of rehabilitation medicine

Abbreviations

ACSM	American College of Sports Medicine
BMI	body mass index
C1	first part of the concentric phase
C2	second part of the concentric phase
CI	confidence interval
CRE	conventional resistance training equipment
CT	computerized tomography
E1	first part of the eccentric phase
E2	second part of the eccentric phase
ERB	elastic resistance bands
FABQ	Fear-Avoidance Beliefs Questionnaire
GPE	general physical exercise
GRC	Global Rating of Change (scale)
HSCL	Hopkins Symptom Checklist
MDR	multidisciplinary rehabilitation
MRI	magnetic resonance imaging
MVC	maximal voluntary isometric contraction
NDI	Neck Disability Index
NPRS	Numerical Pain Rating Scale
ODI	Oswestry Disability Index
PRT	progressive resistance training
RCT	randomized controlled trial
RM	repetition maximum
SD	standard deviation
sEMG	surface electromyography
PSFS	Patient-Specific Functioning Scale
WAI	Work Ability Index

Summary

This thesis is based on the recognition of chronic low back pain and chronic neck pain as being major contributors to disability and suffering worldwide. There is no known cure for chronic neck pain and low back pain, but it is possible to alleviate their symptoms through different management strategies. Individuals with chronic neck or low back pain that comprises a substantial psychosocial impact and who have responded poorly to treatment in usual care often have their pain managed by multidisciplinary rehabilitation in order to target multiple aspects of their symptoms. It is possible that multidisciplinary rehabilitation can be improved by replacing the general physical exercise component of the treatment programme with progressive resistance training. Progressive resistance training refers to a systematic form of strength training that aims to enhance muscular strength, and some studies have suggested that progressive resistance training can be effective in alleviating the symptoms of chronic low back pain and especially chronic neck pain.

The specific aim of the research for this thesis was to investigate whether replacing general physical exercise with progressive resistance training could improve the effects of multidisciplinary rehabilitation. Accordingly, two randomized controlled trials with similar designs were carried out to investigate the effects of replacing general physical activity with progressive resistance training for patients with chronic low back pain (the low back pain study) and patients with chronic neck pain (the neck pain study). Elastic resistance bands were used to provide external resistance in the progressive resistance training exercises in both studies. Additionally, a crossover study was carried out to compare the muscular activation levels, in which surface electromyography (sEMG) with elastic resistance bands (ERB) was compared with training with conventional resistance training equipment (CRE) (the EMG study).

Participants in the low back pain and the neck pain study were randomized to three weeks of multidisciplinary rehabilitation with either general physical exercise or progressive resistance training, and were then instructed to continue with their respective home-based programmes for a further nine weeks. The primary outcome in both studies was pain-related disability. In the EMG study, the muscle activity of relevant muscles was assessed while participants performed squats, stiff-legged deadlifts, unilateral rows, and lateral pulldowns using ERB and CRE.

There were 74 participants in the low back pain study, 59 in the neck pain study, and 29 in the EMG study, but loss to follow-up at 12 weeks resulted in 46 participants in the low back and 31 participants the neck pain study at the 12-week endpoint.

The most important findings of the research presented in this thesis was that replacing general physical exercise with progressive resistance training using elastic resistance bands did not result in reduced pain-related disability for patients with chronic low back pain or chronic neck pain in multidisciplinary rehabilitation. It is unlikely that a lower dropout rate and/or more participants would have altered this main conclusion, since the changes in the main outcome in the groups were almost identical. Thus, clinicians should recommend either of these forms of exercise depending upon the patient's interests and motivation. Lastly, elastic resistance bands were found to be a viable option to conventional resistance training equipment for the exercises unilateral rows and lateral pulldowns, since they induced fairly similar muscle activity during those exercises. Elastic resistance bands induced lower muscle activity for some important muscles during stiff-legged deadlifts and squats compared with CRE, but muscle activity was fairly similar between the modalities for the extensor muscles in the back and hip.

1. Introduction

This aim of this thesis is to contribute to knowledge regarding the management of chronic neck pain and chronic low back pain. Identifying effective ways of managing these conditions can potentially have a tremendous impact worldwide, as they are both extremely common worldwide. Specifically, this thesis examines the effects of replacing general physical exercise (GPE) with progressive resistance training (PRT) in multidisciplinary rehabilitation (MDR). The following section provides the background to my research and the rationale for each of the three studies that form part of this thesis.

1.1 Prevalence and classification

Neck pain and low back pain are the leading causes of disability in most countries worldwide, and the majority of the world's population experiences these conditions at some point in their life (1-3). Further, low back pain is the primary reason for disability among people below the age of 45 years (4). According to the Global Burden of Disease Study, the mean global point prevalences of low back pain and neck pain were c.18% and 14% respectively in 2010 (5, 6). The impact from these conditions are substantial with respect to both individual suffering and the burden on families, communities, businesses, and governments (7). In Norway alone, the annual cost to society has been estimated as approximately NOK 69–73 billion for musculoskeletal problems in general, with low back pain and neck pain being the leading causes (8).

Neck and low back pain are not diseases, but rather patterns of symptoms that can accompany other diseases or pathoanatomical causes. In most cases, the specific cause of the pain is not identified and the patient is diagnosed with non-specific neck pain or non-specific low back pain (5, 6, 9, 10). Thus, the primary aim of clinical diagnosis and diagnostic imaging (e.g. magnetic resonance imaging (MRI) or computerized tomography (CT scan)) is to rule out the rare cases when pain is caused by potentially harmful conditions such as compression fractures, structural injury that requires special care, or malignancy, infections, neurological compromises, or inflammatory arthritis (9-11).

A common view is that in most cases of non-specific neck pain and low back pain, the symptoms disappear with time. However, for a large proportion of those who experience a single episode of neck pain or low back pain, the symptoms will return in episodic relapses

throughout their life (6, 9), and in that sense true remission of the conditions is rare. Still, only a small subset of cases are defined as having chronic pain (i.e. pain lasting > 3months) (12). It is estimated that 15–19% of the European population will develop chronic neck pain (13), and that 5–10% of the population with low back cases will develop chronic low back pain (14).

1.2 The biopsychosocial aspects of chronic pain

The traditional perception of pure biomedical indices as the only way to define a diseases or an illness has been outdated since the introduction of the biopsychosocial model by Engel in 1977 (15). The model aims to incorporate a more complete understanding of a patient's total situation, including their biomedical indices, and the psychological, behavioural, and social aspects of their situation, in order to give a more complete understanding of how the interaction of these aspects affects the patient. The model has been used to understand different health-related conditions, and resulted in a renewed understanding of low back pain following Waddel's landmark article subtitled 'A new clinical model for the treatment of low-back pain' (16). Today, there is consensus on both chronic low back pain and neck pain being complex disorders that comprise biopsychosocial symptoms, including widespread pain, work disability, reduced quality of life, fear-avoidance beliefs, mental symptoms and social withdrawal, and deconditioning (16-20). There is also some evidence for psychosocial factors being associated with the transition from acute low back pain to chronic low back pain (5).

1.3 Treatment of chronic low back pain and neck pain

Currently, there are no known cures for chronic neck or low back pain, but there are different ways of managing the conditions in order to reduce their symptoms (9). Both patients and clinicians may find this situation challenging, and it is important to recognize this because the commercial market is flooded with non-evidence based promises of 'effective treatments' and 'cures'. Thus, an important role of clinicians and health personnel is to guide patients through the numerous treatment options and advise them about interventions (9). In general, it is recommended that patients should be managed with non-pharmacological interventions, including physical exercise, patient education and counselling, acupuncture, mindfulness-based stress reduction, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioural therapy, or spinal manipulation (13, 21-23). However, even these recommended interventions have limited effects on pain and disability, and due to the multidimensional nature of the symptoms related to the conditions it is unlikely that a single

intervention would be is effective for treating the overall problem and therefore combined interventions have been recommended (11, 13, 21, 22). Additionally, patients with poor response to treatment, who have long endured pain, and who have suffered substantial impacts due to their psychosocial symptoms, can be managed by MDR (24, 25).

1.4 Multidisciplinary rehabilitation

MDR is founded on the biopsychosocial model and aims to target the full complexity of a patient's conditions simultaneously by using different treatment modalities. The duration and content of MDR varies, but it usually includes a combination of physical, psychological, educational, and/ or work-related components (24, 26-29). In Norway, the physical exercise component often consists of an introduction to various GPEs and individually tailored programmes that often focus on normalizing the activities of daily living. The psychological component is normally a cognitive behavioural therapy based intervention (29). Cognitive behavioural therapy aims to reduce pain, disability, and distress by assessing and modifying maladaptive and dysfunctional thoughts and behaviour associated with pain (30). The aims of a patient's education are to give assurance and encouragement, reduce their concerns, and increase their engagement in daily-life activities by informing them about relevant topics, such as understanding pain or neck and/or back anatomy.

MDR has been described as 'the state of the art of the management of complex, chronic, non-malignant pain patients' (29). Still, the effects of MDR in cases of chronic low back pain are only modest, and just slightly more effective than usual care with regard to reducing pain and disability (27, 31). There has been much research on the use of MDR for treating chronic low back pain, but less research on its use for treating chronic neck pain, although MDR is commonly used to manage both conditions (25). However, a study by Buchner and colleagues concluded that following MDR, patients with chronic low back pain and chronic neck pain showed similar improvements (26). It should though be noted that the most recent Cochrane review on MDR for chronic low back pain urged for interventions with a view to improving MDR designs, potentially by optimizing the included components (27). Thus, considering that physical exercise can be performed in various ways, and that exercise is considered an important component in the management of both chronic neck pain and back pain, it would be useful to investigated whether replacing the GPE component of MDR with a potentially more potent exercise modality, such as PRT, could lead to improvement in the rehabilitative effects of MDR.

1.5 Exercise for chronic low back and neck pain

Until the 1980s, people with chronic pain were primarily advised to rest, stay in bed, and relax, but since then there has been a change towards minimizing the amount of bed rest and instead advocating physical activity and exercise as core components in the management of all chronic pain (32). Today, physical activity and exercise are recommended treatment components in the guidelines for both chronic low back pain and chronic neck pain (21, 22, 33).

Physical exercise may target cardiovascular fitness, flexibility, muscle strength, or any combination of them (34). The influence of the various exercise modalities on chronic neck pain and low back pain has been extensively investigated, but most reviews state that there is insufficient evidence to conclude that certain types of exercise should be preferred over other types (11, 35, 36). However, results from several studies published since the late 2010s have shown that resistance training interventions are effective in increasing muscular strength, which is especially beneficial in terms of reducing the symptoms of chronic neck pain (37-42). The body of evidence is not as large for chronic low back pain, but some studies have suggested that interventions that are effective in increasing muscular strength can also be effective for reducing symptoms of chronic low back pain (43-45). To appreciate the evidence in support of interventions designed to strengthen muscles by training, it is important to understand the principles of resistance training. Thus, before discussing studies of resistance training for chronic neck pain and low back pain in detail, I first present a brief introduction to the principles of resistance training in the next section.

1.6 Progressive resistance training

Resistance training refers to systematic training designed to increase muscular strength and fitness by training the muscles against external resistance (e.g. free-weights, resistance training machines, and elastic resistance bands). In addition to increasing muscular strength and mass, resistance training has been found to give a wide range of health-related benefits, such as improved cardio-metabolic risk profile, increased bone mass, functional ability, and improved energy and mental health (46, 47).

The American College of Sports Medicine (ACSM) has recommended that people in general should engage in resistance training of all their major muscle groups two to three

times per week (46). The muscles can be trained either by performing single-joint exercises, which target specific muscles (e.g. lateral raises), or multi-joint exercises, which are more complex and target several muscle groups (e.g. squats). Both variations have a place in a resistance-training programme, but Ratamess and colleagues have recommended emphasizing multi-joint exercises because they allow for more time-efficient training and are regarded as more effective for increasing overall strength (46).

The effects of resistance training depend on the training intensity, volume, exercises chosen and their order, the length of rest intervals, and the frequency and velocity of the repetitions performed (48, 49). To maximize strength gains and muscular adaptations, the ACSM recommends that resistance training programmes should be designed in accordance with the principles of progressive overload, specificity and periodization (46). Such resistance training is hereafter referred to as PRT (i.e. progressive resistance training).

Progressive overload involves progressively increasing the amount of stress on the muscles during training by increasing external load, increasing number of repetitions while maintaining the load, reducing rest periods between sets, increasing training volume, or altering the tempo of the repetitions (46, 49). *Specificity* refers to the body's adaptation to the specific stimuli to which it is exposed, and in the case of resistance training this refers to the muscles that are involved, the movement patterns, and the nature of the muscle actions (e.g. force application and movement speed) (46, 49). In simple terms, this means that adaptation follows the specific demand placed on the body. Thus, it is crucial to design the training programme in accordance with what one wishes to achieve (e.g. increased maximal strength in a specific exercise). *Periodization* refers to a method of structuring training variables to maximize training adaptations and reduce the risk of overtraining and stagnation and/or setback in training performance (46, 49, 50). Periodization is usually classified as linear or undulating (non-linear). Linear periodization programmes are characterized by sequencing the training period into weekly or monthly blocks of high-volume, low intensity training (i.e. a high number of repetitions and low resistance) in the initial phase of training and progressing toward higher intensity and lower volume throughout the training period. By contrast, undulating or non-linear periodization programmes involve more frequent variations in intensity and volume. Both linear and undulating periodization programmes can be used to increase the strength gains substantially and to overcome plateaus in the training, and there is no clear evidence that either type of periodization is more effective than the other (50).

The ACSM recommends that a resistance training programme for novices should focus on a training intensity with loadings that correspond to a repetition range of 8–12 repetitions maximum (RM) (46). Repetition maximum is defined as the greatest amount of weight that can be lifted for a specific number of repetitions (49). However, it is documented that training with resistance that corresponds to loads as light as 15–25 RM can result in strength gains even for people with moderate resistance training (51). Importantly, RM refers to the use of a weight when a person is not able to perform more than the prescribed number of repetitions. For example, in a training period with loads corresponding to 25 RM, which can be regarded as low intensity, the person training should not be able to perform more than 25 repetitions. Thus, if the person is able to perform 1–2 repetitions more than prescribed, their relative workload should be increased by 2–10%. Additionally, the ACSM recommends the inclusion of both concentric and eccentric movements, and that novices should perform the movements in a controlled manner with slow to moderate movements (46).

1.7 Resistance training for low back pain

There has been some scepticism towards prescribing high-intensity resistance training to populations with chronic pain due to the perceived risk of causing additional pain and injuries in a population that is already suffering (52). However, it is well established that high intensity training is generally well-tolerated by individuals with chronic pain conditions, especially when the training is introduced in a periodized, progressive manner and the exercises are performed in a controlled manner (13, 52). This way of training allows the individual to become acquainted with the exercises and gain a sense of achievement from using a relatively low training load, and then gradually increasing the load.

Most reviews and clinical guidelines for treating chronic low back pain state there is a lack of evidence of clear differences in effect between different exercise regimes (21, 23, 31). However, comparisons of exercise regimes are usually done by collapsing exercises variations into groups, such as cardiovascular exercise interventions versus flexibility interventions versus muscle strengthening interventions. This provides a crude picture that potentially masks the effects of specific exercise interventions. In order for resistance training to be effective, the ACSM recommends adherence to the principles of progressive overload, periodization, and specificity (46). However, most studies that have investigated resistance training for chronic low back pain have been criticized for using ineffective strengthening

interventions with low training intensity, short intervention periods, low training volume, and a lack of progression (43, 52).

A review conducted in 2005 revealed that resistance training was more effective for improving function in patients with chronic low back pain than were aerobic training, mobilizing exercises and coordination exercises, and other specific exercise therapies, namely McKenzie exercise therapy, functional restoration or the David Beck Clinic programme, Cesar therapy, and Mensendieck therapy (53). However, the same review identified stretching interventions as most effective for reducing pain and it should be noted that most of the studies included in the review were of low methodological quality and the authors of the review stated that it was difficult to draw any clear conclusions. It should also be noted that none of the studies that had investigated muscular strengthening (54-60) had adhered to the principles of PRT.

A few studies have investigated the influence on chronic low back pain of resistance training programmes designed in accordance with the principles of PRT (43-45). All of these studies found that PRT resulted in reduction in both disability and pain. The interventions varied from 13 weeks to 16 weeks, with 2–4 sessions per week, and intensity typically progressed from training with loadings corresponding to approximately 50–55% of 1 RM to approximately 75–80% of 1 RM. In one of the studies that included young men and women, PRT was found superior to aerobic training despite the fact that the training time and intensity were matched (43). In addition to differences in training intensity, these studies and several other studies that investigated resistance training for chronic low back pain included exercises targeted all major muscle groups, in contrast to many other studies in which the focus was on strengthening muscles in the core and lumbar area, primarily through back extension and flexion exercises (54-62). In a review published in 2012, Kristensen and colleagues found that resistance training programmes that target the entire body and that are conducted in accordance with the principles of PRT appeared to be favourable for patients with chronic low back pain (52). Additionally, a systematic review and meta-analysis published in 2015, which compared exercise interventions for chronic low back pain, found that the effect was largest for the interventions that used PRT and focused on the whole body (63). By contrast, cardiovascular and mixed exercise programmes were found ineffective for reducing chronic low back pain. The authors suggested that the larger effect sizes associated with whole-body training could be explained by improvements in muscular strength, power, and functional abilities in a wide range of muscles. This corresponds with the recommendations from the

American College of Sports Science (ACSM), which states that healthy adults should engage in resistance training of all major muscle groups in order to attain the maximal benefits from resistance training (46).

Although some studies have demonstrated promising results from effective resistance training interventions, it is important to note that those studies included participants with chronic back pain from the general population through public advertisements (43-45), and their findings cannot be generalized to patients enrolled in MDR as part of their specialized care.

1.8 Resistance training for neck pain

Since the late 2000s, a number of studies and reviews and a meta-analysis have been published that all point to resistance training as an effective way of exercising to alleviate that pain and disability related to chronic neck pain (36-42, 64-66). A recently published Cochrane review concludes that there is moderate quality evidence in favour of resistance training that focuses on strengthening painful muscles in the neck and shoulder area (i.e. targeted resistance training) as part of routine treatment for patients with chronic neck pain (38). The review also concludes that mixed exercise programmes that do not include strengthening exercises seem to be ineffective in reducing chronic neck pain.

In general, resistance training interventions that have proven effective in the treatment of chronic neck pain have been targeted in accordance with the principles of PRT and performed for approximately 20 minutes, 3 times per week, for a minimum 10 weeks. One study even demonstrated that engaging in as little as two minutes of targeted PRT per day for 10 weeks was enough to achieve a significantly reduction in pain (41). It should be mentioned that the evidence is still somewhat conflicting, as another study did not find any difference between intense, targeted resistance training and general physical activity for patients with non-specific neck pain. However, the degree of participants' compliance with the training programme was low and the training was not periodized (67). The primary focus in studies that have investigated resistance training for neck pain has been on targeted training interventions, and a recent meta-analysis found larger effect sizes for targeted resistance training than for whole-body training (64). However, the meta-analysis only included one study in which whole-body resistance training was investigated (68), and the training intensity in that study was very low (30% of 1 RM). Thus, although several studies have investigated the effect of resistance training on chronic neck pain, there has been a lack of studies that

have investigated the effect of whole-body resistance training. As suggested for low back pain patients, it is reasonable to believe that improving overall muscular strength, power, and functional abilities would be beneficial also for patients with chronic neck pain. This would especially be relevant for patients with neck pain who also experience widespread pain. A potential reason why so many studies have investigated targeted resistance training may be that most studies investigating resistance training for individuals with chronic neck pain have recruited working populations, especially office workers, where interventions are often performed in the work environment and have had to be both effective and time-efficient.

In summary, high intensity targeted resistance training appears to be beneficial for treating chronic neck pain, but full-body training has the potential to be more effective because this type of training can lead to increases in strength and functional ability in a wide range of muscles, which is especially relevant for patients with widespread pain.

1.9 Resistance training with elastic resistance bands

Resistance training can be performed with various types of equipment or even without equipment (i.e. bodyweight training). Still, the most popular and recognized equipment for resistance training is CRE (i.e. free-weights and resistance training machines), and it is well documented that these modalities can be used effectively to increase muscle strength (69). However, such equipment can be both expensive and space consuming, and is not always an option in clinical or home-based training settings. For a resistance training intervention to be usable on an extended scale in clinical practice, it should be designed in such a way that makes it possible for it to be performed in small clinics and in homes. A potentially viable alternative to conventional resistance training equipment could be elastic resistance bands (ERB), which are relatively inexpensive, portable, can be used in a wide range of exercises, and can be stored and used in small places if necessary.

There are some differences between elastic resistance band training and conventional resistance training. In contrast to free-weights and machines, in which the external resistance is constant throughout the range full range of motion, elastic bands generate variable resistance, depending on how much they are stretched (elongated) (70). The resistance generated by elastic bands also varies between bands depending on their tensile strength, and it is harder to perform an exercise with a stiffer and thicker band than with a more flexible and thinner band. Resistance from free-weights and machines can easily be quantified (in kilos or

pounds), but it is somewhat more challenging to quantify the resistance generated by elastic bands. Usually, the resistance is indicated by the band's colour or name, but resistance also depends on how much the bands have been pre-stretched and on the user's range of motion. Thus, it is has been advised that the Borg CR10 scale should be used to aid estimations of intensity during training with elastic resistance bands (71). The Borg CR-10 scale is used to measure perceived exhaustion on a scale from 0 (none at all) to 10 (very, very heavy/near maximum) (72, 73). It is permissible to give answers with decimal points (e.g. 8.7), and the score can even be rated higher than 10 (i.e. 12 as an absolute maximum). Additionally, the scale can be used to rate the intensity of pain during exercise.

To reap the benefits of resistance training it is crucial to use training equipment that can generate sufficient muscular overload. Training with ERB training has generally been considered an inferior alternative to training with CRE and had traditionally been performed at low to moderate intensity and with a high number of repetitions (74, 75). However, studies that have used surface electromyography (sEMG) (i.e. a technique for evaluating a recording of the electrical activity generated by the muscles) have found that when intensity was matched through repetition maximum tests, muscular activation appeared similar during training with elastic bands compared with training with free-weights and machines (76-81). Furthermore, a recent meta-analysis concluded that elastic bands were a viable option to conventional resistance training equipment (70).

Most studies that have compared elastic bands with conventional equipment have assessed muscular activation for single-joint exercises, and only a few have looked at differences in muscular activation during multi-joint exercises (79, 81). Considerably heavier resistance can be used in multi-joint exercises because several muscles are involved and the range of motion is often greater than in single joint exercises. Thus, potential differences between the modalities are likely to be more prominent for multi-joint exercises. Sundstrup and colleagues compared lunges (i.e. a variation of squats) performed with elastic bands with lunges performed with dumbbells and with unilateral leg presses done using a machine (82). They concluded that elastic bands were equally effective in inducing muscular activation as the conventional equipment. However, there were some differences in the muscular activation pattern, since elastic resistance was more effective in activating some muscles and conventional equipment was more effective for other muscles. Sundstrup and colleagues attributed this to biomechanical differences in how the exercises were performed. In another study, Calatayud and colleagues found similar muscular activation from bench presses using

free-weights and push-ups with elastic resistance (79). They also demonstrated similar training adaptations following 5 weeks of heavy resistance training with elastic-resisted push-ups or bench presses. However, as push-ups are a heavy type of exercise, even without external resistance the elastic bands would only have provided a small portion of the resistance. Thus, there is still limited evidence for the efficacy of elastic bands for multi-joint exercises.

1.10 Surface electromyography

Surface EMG (sEMG) is commonly used in medical research, ergonomics, sports science, and rehabilitation to quantify muscle activation (83). To understand the concept of sEMG, it is important to understand how the muscles in the human body work. Skeletal muscles are made up of bundles of individual muscle fibres, which are covered by a muscle fibre membrane. Within the muscle fibres are several cylinder-shaped structures called myofibrils, and in turn the myofibrils contain the contractile proteins actin and myosin. When a muscle contracts, it is due to the sliding of actin filaments over the myosin filaments, which cause the muscle to shorten. This process is initiated by pulses of electrical signals (i.e. action potentials) that are sent from motor neurons located in the spinal cord and travel to the muscle fibre membrane, where they activate the contractile machinery in the muscle (84).

sEMG is a representation of the sum of action potentials travelling over the muscle fibre membrane(85). The signal is measured through electrodes attached to the skin over the muscles of interest, and the recorded signal is referred to as the sEMG amplitude. EMG signals can also be assessed by placing the electrodes over the muscles but under the skin (subcutaneous EMG) or by inserting electrodes into the muscle (intramuscular EMG). Intramuscular EMG allows for the detection of signals from small muscles that can be located deep inside the body, and the method allows for recording of single action potentials in selected muscle fibres (86). The choice of EMG method depends on the research question, but sEMG is sufficient when the aim is to record the activation level of superficial muscles (83).

The sEMG signals can be influenced and contaminated by several different factors (83), including the following: (1) thickness and characteristics of the tissue under the electrode; (2) physiological crosstalk, which refers to contributions to the EMG signals from neighbouring muscles; (3) the randomness of the motor neuron firing patterns; (4) electrode placement, as well as movement of the electrodes during testing, which can be a problem especially in dynamic movements where the muscles changes length throughout the

movement; and (5) noise from the equipment (electrodes and amplifiers) and from external electrical environments. It is important to address these concerns when assessing sEMG. The first step to achieve good sEMG signals is to prepare the skin thoroughly where the electrodes are to be attached, by shaving and rubbing the skin with fine sandpaper and then cleansing it with alcohol, as this reduces impedance from the skin (83). It is also important to select suitable electrodes and to secure that both these and the connecting cables are properly attached. Additionally, in most settings, bipolar recordings (i.e. when electrodes are placed in pairs) are preferred over monopolar recordings (i.e. when electrodes are placed singly) because bipolar sEMG signals are less prone to contamination. It is also very important to be careful with the electrode placement, both with respect to where the electrodes are placed on the muscles and how the electrodes are placed in relation to each other in bipolar recordings (86). However, guidelines are available that describe the optimal electrode placements for several muscles (http://seniam.org/sensor_location.htm). A common way of removing noise and artefacts is by filtering the EMG signals. Low-pass filters retain only the data signals with a low-frequency level, whereas high-pass filters retain only the high-frequency data, and a band-pass filter retains data within a predefined frequency range, while a band-stop filter reduces the presence of signals in a specific frequency range (86). Lastly, since the raw EMG signals have both negative and positive components, they are commonly rectified by calculating the root mean squared signal (RMS-EMG). This is done by summing the squared values of the EMG amplitude in a set period and then dividing the sum by the number of records in the period (83). Alternatively, the signal can be processed using average rectified EMG (i.e. by removing all negative phases of the raw EMG or reversing them) (86).

To enable comparison between different muscles and individuals, the EMG amplitude is usually normalized to the EMG amplitude from a maximal voluntary isometric contraction (MVC), and this amplitude is then used as reference for subsequent EMG recordings expressed as $\%EMG_{max}$ (87).

2. Aims of the thesis

The work in this thesis was initiated on the basis of the following premises:

- Chronic low back pain and chronic neck pain have major impacts worldwide.
- The two conditions often comprise complex biopsychosocial symptoms.
- MDR is commonly used to manage patients in order to target several aspects of their symptoms simultaneously
- The effect of MDR can potentially be improved by optimizing the exercise component.
- Resistance training performed in accordance with the principles of progression, overload, and specificity has been suggested as effective for reducing the symptoms of chronic neck pain and chronic low back pain.
- No previous studies have investigated the effect of PRT for patients enrolled in MDR in specialist health care.

The main objective of the research on which this thesis is based was to investigate the hypothesis that PRT is a more effective component in MDR than general physical exercise for patients with chronic neck pain and patients with chronic low back pain. Three separate studies were made, each with specific aims:

1. The low back pain study (Papers I and III) examined whether replacing general physical exercise with progressive resistance training could improve the effect of MDR for patients with chronic low back pain.
2. The neck pain study (Paper IV) examined whether replacing general physical exercise with progressive resistance training could improve the effect of MDR for patients with chronic neck pain.
3. The EMG study (Paper II) evaluated whether elastic resistance bands could be a viable training modality for the multi-joint exercises squats, stiff-legged deadlifts, unilateral rows, and lateral pull downs) used in the PRT interventions in the low back pain study and the neck pain study.

3. Methods

The research was conducted from December 2013 to March 2018 at the Department of Public Health and Nursing, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology (NTNU) in Trondheim, Norway. The work was done in collaboration with the specialized back and neck pain clinic at the Department of Physical Medicine and Rehabilitation, St. Olavs Hospital, Trondheim University Hospital (hereafter referred to as the clinic). Detailed information about the methods is presented in Papers I–IV.

3.1 Design and data collection

3.1.1 The low back pain study (Study 1, Papers I and III)

The low back pain study (Study 1) was a researcher-blinded, randomized controlled trial (RCT) involving patients with chronic non-specific low back pain. Paper I is a protocol article in which the methods and rationale for the study are described in detail, and results of the study are reported in Paper III. The RCT was carried out at the clinic, were participants were randomized to participate in either (1) 3 weeks of MDR, including progressive resistance training with elastic bands at the clinic, and 9 weeks of home-based progressive resistance training, or (2) 3 weeks of MDR, including general physical activity at the clinic and 9 of weeks home-based general physical activity. Baseline data were collected on the first day of the MDR, while follow-up data were collected at 3 weeks and 12 weeks. During the home-based training period, the participants, regardless of group allocation, were offered the opportunity to participate in three supervised booster sessions (see Fig. 1 for time course). The study was registered at ClinicalTrials.gov (registration number: NCT02420236), which is a web-based resource that presents summary information about the study's protocol.

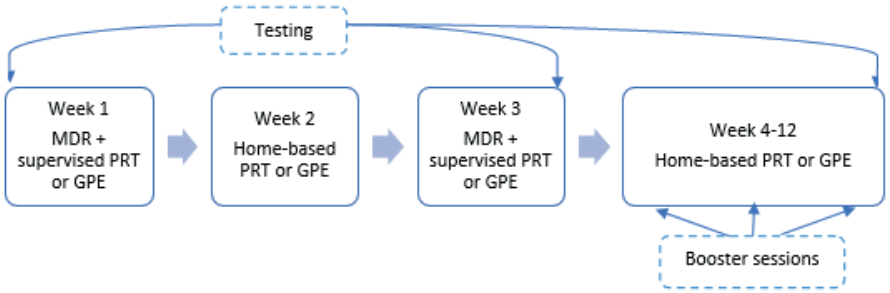

Fig. 1 Time course for participants in the low back pain and the neck pain study

3.1.2 The neck pain study (Study 2, Paper IV)

The neck pain study (Study 2) was a researcher-blinded RCT involving patients with chronic non-specific neck pain. With exception of different study populations and some minor differences in the methods, the design of neck pain study was similar to the design of low back pain study. Participants were enrolled from the clinic and randomized to three weeks MDR with either (1) progressive resistance training or (2) general physical exercise and home-based activity for 9 weeks. Data collection was performed at similar interval as in Study 1, and participants in Study 3 were similarly offered three booster sessions in the home-based period (Fig. 1). The study was registered at ClinicalTrials.gov: NCT02420197.

3.1.3 The EMG study (Study 3, Paper II)

The EMG study (Study 3) was a crossover study, designed to investigate whether elastic resistance bands could be a viable training modality for the multi-joint exercises in the PRT programme prescribed in Study 1 and Study 3. Participants in the study took part in two familiarization sessions and two test sessions, in which EMG data were collected during dynamic squats and deadlifts (Session 1) and unilateral rows and pulldowns (Session 2). Two single-joint exercises used in the PRT interventions – flies and reversed flies – were evaluated, but the results are presented in a separate article that is not included in this thesis (88).

3.2 Participants

All participants included in the studies received oral and written information about the studies and all gave written consent to participate. Important baseline characteristics of the participants are presented in Table 1.

Table 1 Baseline characteristics of participants

Disability status	Low back pain study (n = 74)	Neck pain study (n = 59)	EMG study (n = 29)
Age (years), mean (SD)	45 (12)	46 (10)	25±3
Women (%)	57	68	41
BMI, kg/m^2, mean (SD)	29.5 (5.3)	26.0 (4.5)	23.0 (3.0)
Disability, 0–100	30.4 (11.4)	35.4 (10.3)	N/A
Worst low back back/neck pain in last two weeks, 0–10; mean (SD)	6.8 (2.0)	6.3 (2.1)	N/A
Additional pain sites, mean (SD)	1.9 (2.2)	3.5 (3.9)	N/A

Participants in both the low back pain study and the neck pain study were recruited from the clinic. A physician screened patients referred to the clinic for eligibility during their first consultation at the clinic, and eligible patients were invited to participate in the study. Based on sample calculations, the aim was to include 100 participants in each of the studies. However, the slow recruitment rate and upcoming changes in routines at the clinic meant we had to stop the inclusion of patients before the desired number of participants had been reached. In total, 99 patients with chronic low back pain were included and randomized in the low back pain study, while 74 patients with chronic neck pain were included in the neck pain study (Fig. 2). Due to early dropouts, baseline data were collected from 74 participants in the low back pain study and 59 participants in the neck pain study, and were included in the analyses (see Table 1). Additionally, 34 patients were included in reference group for the low back pain study, and 39 patients were included in reference group for the neck pain study, to assess the generalizability of the results. Participants in the reference groups were those who had participated in the MDR programmes but had been excluded from study participation or had declined to participate.

Participants in the EMG study were recruited via public advertisement in Trondheim. In total, 30 healthy participants (men and women) were included in the study, but one woman

dropped out prior to testing, leaving 29 participants in the study. The participants were healthy and had a mean age of 25±3 years

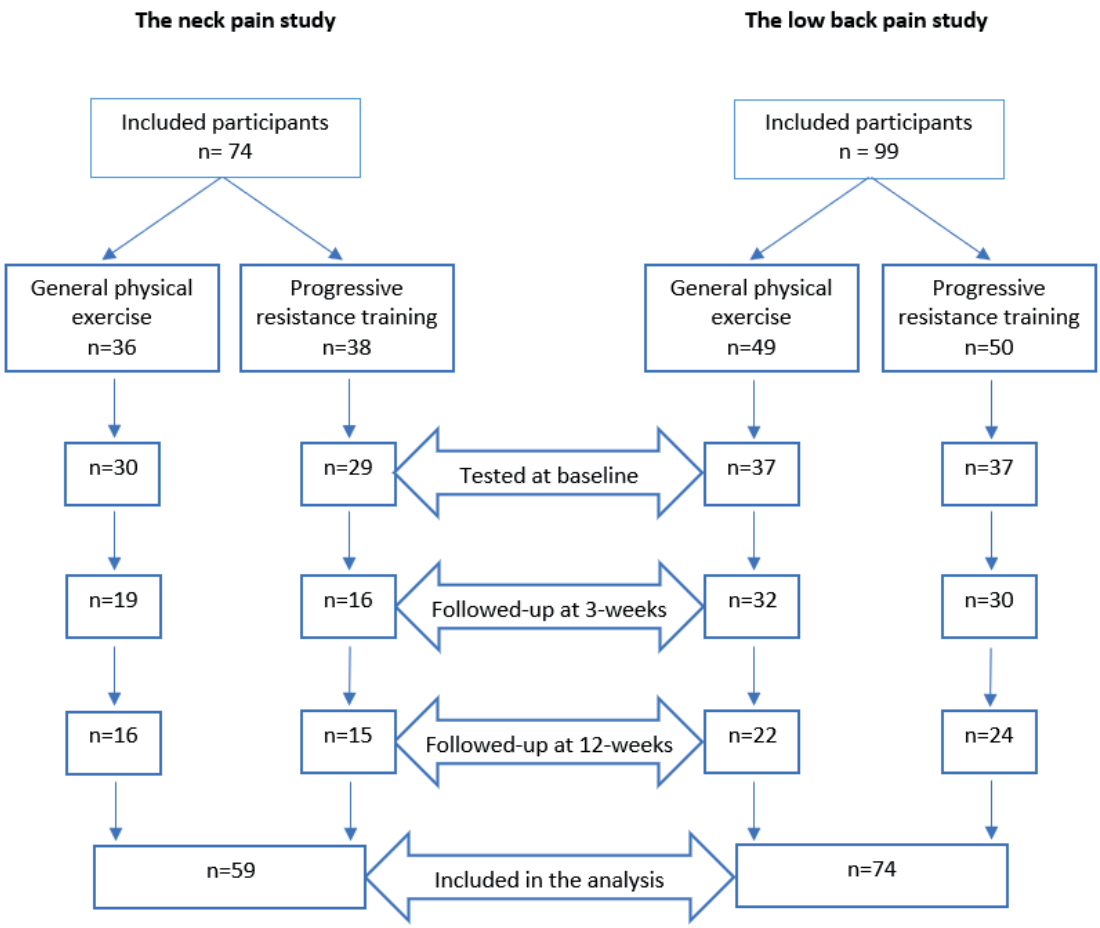

Fig. 2 Participant flow in the neck pain study and the low back pain study

3.3 Interventions in the low back pain study and the neck pain study

In this section, I present key points of information about the interventions in both the low back pain study and the neck pain study (see Papers I, III, and IV for detailed information).

3.3.1 Multidisciplinary rehabilitation

- All participants received MDR.
- MDR was provided at the clinic.

- MDR was extended over three weeks.
- The MDR programme was based on the intervention presented in a study by Hellum and colleagues, who conclude that MDR should be considered before surgical intervention for patients with chronic low back pain and lumbar disc degeneration (89).
- MDR included consultation with physicians, physiotherapists, and social workers, in addition to: exercise; group discussions; patient education covering themes such as understanding low back and neck pain symptoms, spine anatomy, understanding pain, stress management, work participation, physical activity, and individual goal-settings; and group-based sessions with a psychologist.
- The groups consisted of ≤ 10 patients.
- There were three main components in the MDR programme: (1) to encourage patients to return to work; (2) to give patients an understanding of the spine as a robust structure that does not suffer harm when the patient engages in daily-life activities; and (3) to reduce fear-avoidance behaviour, such as avoiding bending the back or turning the head.

3.3.2 General physical exercise

- GPE was the usual exercise component at the clinic.
- GPE included activities such as endurance training, ball games, body awareness, stretching, circle training, walks, relaxation techniques, and low-intensity resistance exercises. Moderate–heavy resistance training was not included during the intervention period.
- Home-training programmes were individually tailored, and often focused on normalizing activities in daily living. The programmes were based on the participants' interests and the clinicians' recommendations, and therefore varied considerably.
- Two examples of the home-based programmes are: (1) Walk to work every day instead of taking the bus, do some housework/gardening every day, participate in yoga classes once per week, and do some floor exercises every evening. (2) Play football once per week and walk the dog for minimum of 30 minutes every day + do different mobility exercises.

3.3.3 Progressive resistance training

- PRT sessions were held three times per week, using ERB
- PRT was supervised in Weeks 1–3 and in home-based training in Weeks 4–12
- The PRT programme was based upon the ACSM's recommendations for training novices (46, 69).
- The PRT exercises included stiff-legged deadlifts, flies, unilateral rows, reversed flies, unilateral shoulder abductions, and lateral pulldowns (Fig. 3).
    - Squats were included as an additional exercise in the low back pain study.
    - Neck flexion and neck extension were included as additional exercises in the neck pain study.

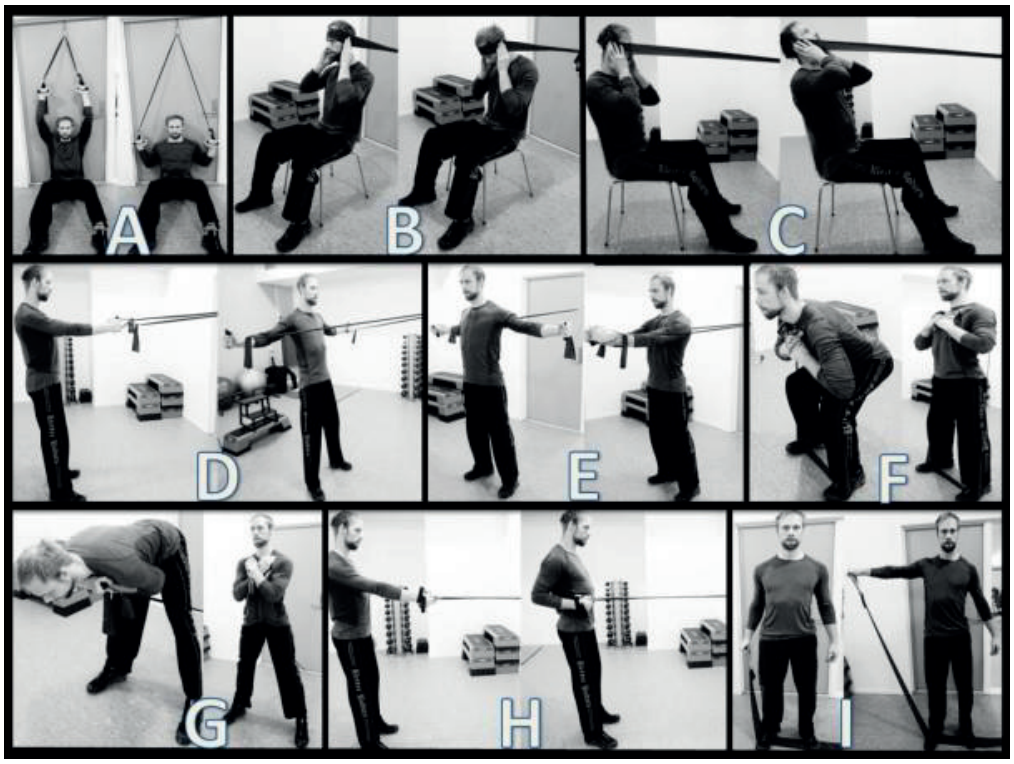

Fig. 3 The elastic resistance band exercises: (A) lateral pulldowns, (B) neck extension, (C) neck flexions, (D) reversed flies, (E) flies, (F) squats, (G) stiff-legged deadlifts, (H) unilateral rows, and (I) shoulder abductions

The PRT programme had a linear periodization with 15–20 repetitions in Weeks 1–2, 12–15 repetitions in Week 3–5, 10–12 repetitions in Weeks 6–8, and 8–10 repetitions in Weeks 9–12, and was characterized as follows:

- The number of repetitions was prescribed in interval ranges, due to the properties of elastic resistance.
- All sets were performed until muscular failure
- The training load was increased when participants were able to do more repetitions than prescribed, or if they rated the training sets as lighter than 7 on the Borg-CR10 scale.
- The exercises were similar to those used in previous studies that had shown positive results for patients with chronic neck pain (39, 90, 91) or low back pain (43-45).
- The participants had to record all training sessions in a diary (see Fig. 4 for an example).
- If the participants experienced worsening of their symptoms following an exercise, they were variously instructed to (1) reduce resistance, (2) reduce movement velocity, (3) reduce range of motion, or (4) avoid the exercise for a minimum of three sessions.

Week 9 – 8-10 reps

Day 1 Date:

Exercise:	Set 1		Set 2		Set 3		Borg CR10
	Repetitions	Band(s) colour	Repetitions	Band(s) colour	Repetitions	Band(s) colour	
Stiff-legged deadlifts							
Flies							
Unilateral rows							
Reversed flies							
Lateral pulldown							
Shoulder abduction							
Neck flexion							
Neck extension							
Comments							

Fig. 4 Example of a training diary from the neck pain study

3.3.4 Booster sessions

- Three group-based booster sessions were offered to all participants during the home-based training period.
- The booster sessions were held at the clinic and held by the same therapists as had delivered the exercise components in the MDR programme.
- For the PRT group, the booster sessions were used to improve technique and adjust resistance, as well as to improve adherence and compliance with the PRT programme.
- For the GPE groups, the booster sessions were used to adjust the individual programmes and to motivate the patients to stay physically active.

3.4 Familiarization sessions and repetition maximum tests (the EMG study)

- The participants engaged in two familiarization sessions to learn the exercises and establish the resistance that should be used during sEMG evaluations.
- The first familiarization session was dedicated to familiarizing the participants with the performance of the exercises with elastic resistance bands.
- The second familiarization session was dedicated to familiarizing the participants with the performance of the exercises with conventional resistance training equipment.
- An experienced trainer instructed participants in proper form and technique.
- An Olympic barbell with free weights was used for the CRE version of squats and stiff legged deadlifts, a pulley apparatus (IT9125, Impulse Fitness, Newbridge, Midlothian, Scotland) was used for the unilateral rows, and a pulldown apparatus (PL 9002 Lat pulldown, Impulse Fitness) was used for the lateral pulldowns.
- TheraBand® elastic bands with resistance ranging from light to very heavy (colours: yellow–gold) were used for the ERB exercises.
- 10 RM tests were performed for each exercise when participants were able to perform the exercise with the correct technique.
- The participants rated their perceived level of exhaustion on the Borg CR-10 scale immediately after completion of the 10 RM tests.

3.5 Outcomes

3.5.1 The low back pain and the neck pain study

3.5.1.1 Self-reported questionnaires and data

In the low back pain study and the neck pain study, the participants completed a set of self-reported questionnaires at all tests points: at baseline (start of MDR), at three weeks (end of MDR), and at 12 weeks (end of home-based training period). Additionally, the participants included in the reference groups completed the baseline questionnaire.

3.5.1.1.1 Disability and pain

The primary outcome in both the low back pain study and the neck pain study was change in diagnosed specific disability from baseline to 12 weeks. Disability related to low back pain was measured with the Oswestry Disability Index (ODI) in the low back pain study (92), while the Neck Disability Index (NDI) – a modified version of the ODI – was used to measure disability related to neck pain in the neck pain study (93). Both the ODI and the NDI include 10 items related to daily living activities. The scores were calculated as a per cent score: 0–20% = minimal disability, 21–40% = moderate disability, 41–60% = severe disability, 61–80% = crippled, 81–100% = bed bound or symptoms exaggerated. Scores were excluded from the analysis if more than two items were missing. Minimal clinically important change has been suggested as a score of 7 on the NDI and 9.5 on the ODI, on a 0–100 scale (94, 95).

The Numerical Pain Rating Scale (NPRS) was used to assess the intensity of neck pain and low back pain (96, 97). The participants were asked to rate their current pain and their worst pain in last two and four weeks on a scale from 0 to 10, were 0 indicated no pain, 1–3 indicated mild pain, 4–6 indicated moderate pain, and 7–10 indicated severe pain. In addition to neck and low back pain intensity, pain in other parts of the body in the last four weeks was assessed on a scale of 0–11 with use of patient pain drawings (98).

The Patient-Specific Functioning Scale (PSFS) was used to evaluate limitation in a patient-specific activity due to low back or neck pain (99). The score ranged from 0 (no problems performing the activity) to 10 (unable to perform the activity). Whereas limitation can be rated for several activities, the reliability of the PSFS is best for the first activity reported (100).

3.5.1.1.2 Psychosocial factors

Symptoms of anxiety and depression were assessed with the Hopkins Symptom Checklist-25, (HSCL-25) which contains 25 items scored from 0 (not bothered at all) to 4 (extremely bothered). The total score was calculated by averaging all answered questions. We used a cut-off value of 1.75 to indicate mental disorder (101).

Health-related quality of life was assessed with the EQ-5D-5L (102), a questionnaire that covers the five-dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Questions about each dimension are answered using a score ranging from 0 (no problems) to 5 (extreme problems). The scores were converted to a summary index, using the EQ-5D-5L Crosswalk Index Value Calculator (Version 2) with the value set based on the Danish populations values (103).

The Fear-Avoidance Beliefs Questionnaire (FABQ) was used to assess fear-avoidance behaviour (104). The questionnaire is divided into two subscales: the first scale covers 5 items related to physical activity, and the second scale covers 11 items related to work-related issues. Items are scored on a scale from 0 to 6, giving a maximum score of 24 for physical activity and 42 for work-related issues, where higher scores indicate more fear avoidance behaviour. Questionnaires with missing values were excluded.

A single item from the Work Ability Index (WAI) was used to assess participants work ability: 'current workability compared with the lifetime best' (105). The item is scored on a scale from 0 (completely unable to work) to 10 (work ability at its best). Although the index originally consists of 7 items, the aforementioned single item can be used as a simple indicator for measuring work ability status and progress of work ability.

In the low back pain study, the Global Rating of Change (GRC) scale was used to assess the participants' self-rated experience of improvement following treatment (106). Scoring was done on a 1–7 scale (1 = feeling very much improved, 2 = feeling much improved, 3 = feeling slightly improved, 4 = feeling no change, 5 = feeling slightly worse, 6 = feeling much worse, 7 = feeling very much worse).

3.5.1.2 Objective measurements and recordings

3.5.1.2.1 Muscular strength and pressure pain threshold

Muscular strength was assessed through MVCs (see Papers I, II, and IV for detailed information). In short, a force transducer was used to measure force during MVC of the back

extensors in the low back pain study (Fig. 5) and lateral shoulder abduction MVC in the neck pain study (Fig. 6). Force data were recorded and analysed using the computer program Musclelab software (Version 10.3.26.0, Ergotest Technology AS, Langesund, Norway). In the low back pain study, grip strength was assessed using a hand-held dynamometer (JAMAR hydraulic hand dynamometer, model J00105) (Fig. 7). In the neck pain study, the pressure pain threshold of the tibialis anterior muscle was measured with a handheld dynamometer (Lafayette manual muscle testing system, model 01165) (Fig. 8).

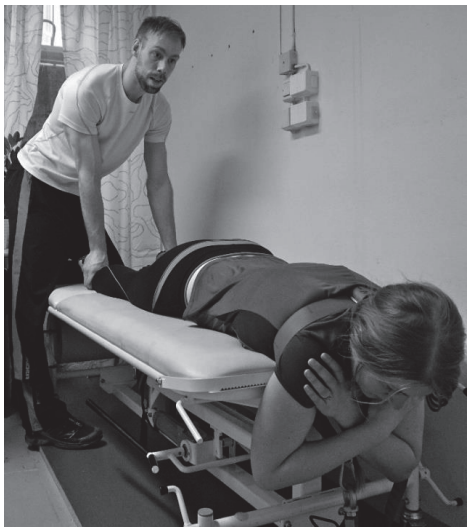

Fig. 5 Back extension strength test

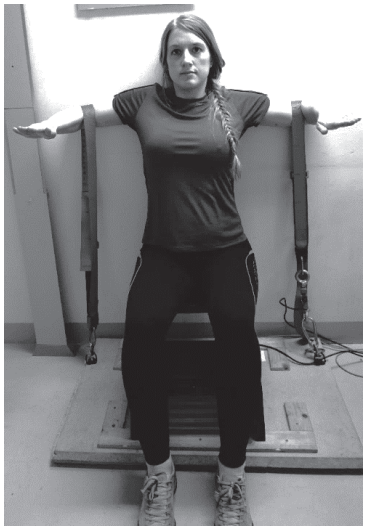

Fig. 6 Lateral shoulder abduction strength test

Fig. 7 Grip strength test

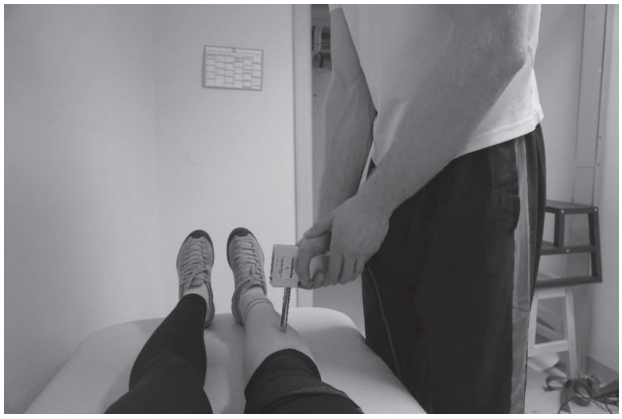

Fig. 8 Pressure pain threshold test

In the neck pain study, neck flexion (Fig. 9 A) and neck extension (Fig. 9 B) MVC were measured using a hand-held dynamometer (Lafayette manual muscle testing system, model 01165). The procedure is not described in detail in Paper IV because it has been described in depth in another article (107), and the procedure is therefore only briefly described here. Neck flexion was performed with participants sitting on a stool, with their back and head against the wall and their feet on the ground during testing. The test leader stood in front of each participant holding the dynamometer against the participant's forehead, directly above the eyebrows. The participant was then instructed to nod their head and to try to bring their chin down to their chest with maximal force. Each participant moved their head 2–3 cm out from the wall before the movement was stopped by the counterweight from the dynamometer.

Neck extension was performed with each participant lying on their stomach on a bench with their arms down by their side. The test leader then held the dynamometer against the midpoint of an imaginary line between the participant's ears. Each participant lifted their head slightly up from the bench before it was stopped by the dynamometer, and then performed the MVC. Both the torso and lower body were in contact with the bench during testing. During testing of neck flexion and extension, the dynamometer was set to start recording when the force reached 10 N and continued to record the force for 5 seconds while the participant performed MVCs. Each test was performed three times with one-minute pauses between them. Immediately after each test, the participant was asked to indicate pain intensity and how hard they had pushed themselves using the BORG-CR10 scale. The highest test values were used in the analysis.

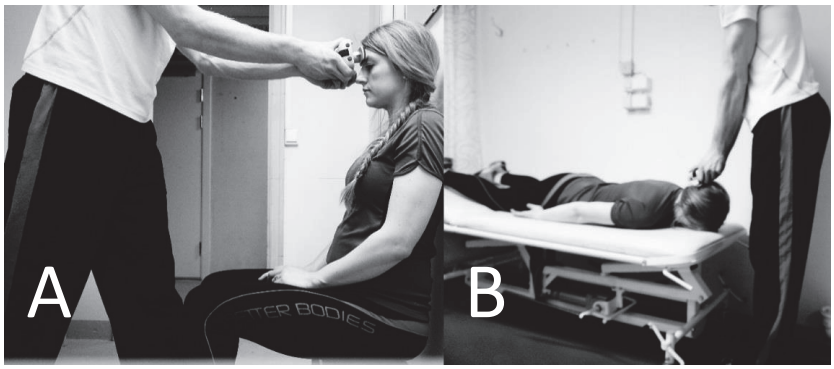

Fig. 9 Neck strength tests: (A) neck extension strength test, (B) neck flexion strength test

3.5.2 The EMG study

3.5.2.1 Surface electromyography

Disposable electrodes (25 mm inter-electrode centre to-centre distance) were attached to relevant muscles and EMG was recorded during dynamic squats and stiff-legged deadlifts (Test Session 1), and unilateral rows and lateral pulldowns (Test Session 2). At the beginning of each test session, EMG was recorded during MVCs of all the relevant muscles. These recordings were used to normalize the recordings from the different tests. Thus, all results were reported as percentages of the muscles' maximal EMG activity. Following the MVCs, each participant performed the exercises (i.e. either squats and deadlifts or rows and

pulldowns) with elastic resistance bands while EMG was recorded, and then the exercises were performed again using conventional resistance training equipment. Three repetitions were performed for each exercise, using identical set-ups as in the 10 RM test.

During EMG recordings, we used a pre-amplifier (common mode rejection ratio of 100 dB) to reduce external noise, a fourth-order Butterworth bandpass filter (8–600 Hz) to filter the signals, and a hardware circuit network to convert the filtered EMG signals (frequency response of 0–600 kHz, averaging constant of 100 ms, and total error of ±0.5%). The root mean square signal was then sampled at 100 Hz with a 16-bit A/D converter (AD637). A linear encoder was used to synchronize movement with the EMG recordings, and the movement data were used to divide the EMG recordings from each repetition into four different phases: first part of the concentric phase (C1), second part of the concentric phase (C2), first part of the eccentric phase (E1), and second part of the eccentric phase (C2).

3.6 Statistical analysis

Statistical analysis was performed with STATA (Version 13.1 for Windows, StataCorp LP, USA), and graphs were made in Origin Pro. Unless otherwise stated, the variables were analysed using mixed effects linear analysis with multilevel modelling, and participant identity was always included as a random effect. This model of analysis used all available data, and did not require imputation of missing data (108). The data were checked with histograms and with QQ-plots, to check for normality of distribution, which resulted in log-transformation of all variables in the EMG study.

In the low back pain study and the neck pain study, between-group differences for each of the primary and secondary outcomes were analysed separately. The relevant outcome was set as the dependent variable, while the effects of group and time were set as fixed effects. In accordance with recommendations for baseline adjustments in randomized controlled trials in which treatments were compared over time(109), we constrained the group means so that they were equal at baseline. Thus, in the analysis, we included the following levels: baseline, 3 weeks PRT, 3 weeks GPE, 12 weeks GPE and 12 weeks PRT (Fig. 10).

The study design enabled direct comparison of group means at the different time points.

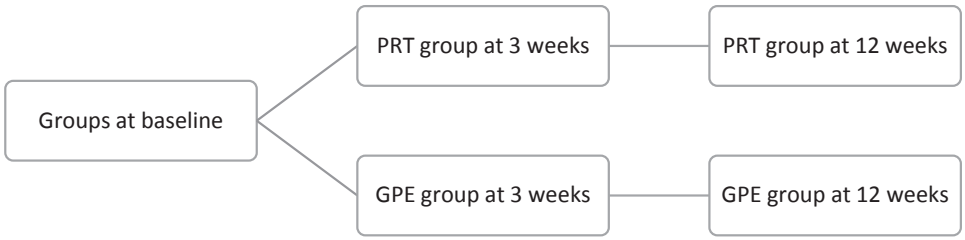

Fig. 10 Levels included in the analysis

Differences in the baseline characteristics of participants included in the studies and in the reference groups were assessed with t-tests or Fisher's exact tests, as appropriate. Due to a considerable loss to follow-up at 12 weeks in both studies, we also compared baseline characteristics for participants who were followed up and participants who were lost to follow-up.

In the low back pain study, the outcome GRC scale was dichotomized and analysed with multilevel mixed effect logistic regression. Additionally, per-protocol and sensitivity analyses were performed for the study reported in Paper III (Study 1) in order to investigate whether respectively completing more than 60% of the training sessions and increasing back extension strength above median affected differences in change in the primary outcome.

In the EMG study (Study 3), we investigated differences in muscular activation between training with elastic and conventional resistance. All muscles were analysed separately. The normalized EMG value was set as the dependent variable, while contraction phase and training modality, as well as their interaction term, were included as fixed effects. Post hoc analyses were performed in cases when overall differences or interaction effects were discovered, to investigate where the differences were located in the movement. Differences in perceived exhaustion, assessed with the BORG CR10 scale, between performing the exercises with elastic and conventional resistance was investigated with pared t-tests. The significance level was set at $p < 0.05$ for the main analysis, and at $p < 0.01$ for the post hoc analysis.

4. Summary of the main results

In this section, I present a summary of the main results from the three studies (see Papers II–IV) for more details).

4.1 The low back pain study

The objective of the study was to compare the effects of PRT with ERB and GPE both as part of and as an extension of an MDR programme for patients with chronic low back pain.

Of the 74 participants in the cohort, 61 were followed up at 3 weeks and 46 at 12 weeks. There were no between-group differences in the improvement in the primary outcome ODI from baseline to 12 weeks. From a baseline mean of 30.4 (95% CI: 27.7, 33.0)], the general exercise group improved to 21.1 (95% CI: 17.0, 25.3), while the progressive resistance training group improved to 22.7 (95% CI: 18.7, 26.7). The general physical exercise group demonstrated a moderately larger improvement on the PSFC compared with the PRT group, with a mean difference of 1.4 (95% CI: 0.1, 2.7), p = 0.033. There were little or no differences in between-group changes for the remaining outcomes (see Table 2 in Paper II).

Per-protocol and sensitivity analysis demonstrated that no additional benefit from PRT was measured using the ODI when more than 60% of training had been completed, and no favourable effects of increased strength.

We did not observe any differences between participants who were lost to follow-up and participants who were followed up at 12 weeks. Also, participants in the RCT were similar to the participants in the reference group (n = 34) at baseline, except that more participants in the RCT reported to be sick listed.

4.2 The neck pain study

In the neck pain study, we assessed the effects of replacing GPE with PRT in a MDR programme and an extension of the programme, for patients with chronic neck pain.

A total of 59 participants were tested at baseline, 34 were test at 3 weeks, and 31 were tested at 12 weeks. There was no differences in baseline characteristics in the study participants compared with the reference group participants (n = 39).

The PRT and GPE groups demonstrated similar improvements in the primary outcome NDI from baseline to 12 weeks. Shoulder abduction strength increased more in the PRT group than the GPE group. At 3 weeks, the GPE group had improved more than the PRT group in the physical activity subscale of the FABQ, but there was no difference between the groups at 12 weeks.

The PRT group improved by 1.2 and 1.0 points compared with the GPE group in worst neck pain the last two and four weeks respectively, but these results did not reach statistical significance ($p = 0.068$ for both results).

4.3 The EMG study

The objective of the EMG study was to compare EMG activation during multi-joint exercises performed with elastic resistance and conventional resistance. In total, 29 participants were included in the study.

In squats, conventional resistance was the favoured modality in overall activation in vastus medialis, vastus lateralis, and rectus femoris. Interaction effects (modality and contraction phase) were found in all muscles, and post hoc analyses showed higher activation from conventional resistance in C1, E1, and E2 for rectus femoris and vastus medialis, and C1 and E2 for vastus lateralis and erector spinae, and higher activation from elastic resistance in E1 for gluteus maximus, semitendinosus, and biceps femoris.

In stiff-legged deadlifts, conventional resistance was the favoured modality in overall activation in all muscles, with the exception of rectus femoris. Interaction effects were found in erector spinae, gluteus maximum semitendinosus, biceps femoris, and obliquus externus. Post hoc analyses demonstrated higher activation from conventional resistance in C1 and E2 for erector spinae, gluteus maximus, semitendinosus, and obliquus externus, and in C1, C2 and E2 for biceps femoris.

In lateral pulldowns, conventional resistance was the favoured modality in overall activation in latissimus dorsi, bices brachii, deltoideus posterior, and pectoralis major, while elastic bands were the favoured modality in overall activation in obliquus externus. Interaction effects were shown in all muscles except for latissimus dorsi and deltoideus medius. Post hoc analysis demonstrated higher activation from conventional resistance in C1 and E2 for latissimus dorsi, biceps brachii, and pectoralis major, and C1 for deltoideus

posterior, deltoideus anterior, and trapezius descendens. ERB produced higher activation in all phases for obliquus externus and E2 for deltoideus anterior.

In unilateral rows, conventional resistance was the favoured modality for overall activation in latissimus dorsi, deltoideus posterior, deltoideus medius, biceps brachi, obliquus externus, and trapezius descendens. Interaction effects were demonstrated in latissimus dorsi, deltoideus posterior, biceps brachii, erector spinae, obliquus externus, and pectoralis major. The post hoc analyses demonstrated higher activation from conventional resistance in C1 and E2 for latissimus dorsi and deltoideus posterior, in C1 and E1 for obliquus externus, in C1 for deltoideus medius and biceps brachii, and in E2 for pectoralis major.

Analysis of the Borg-CR10 scale scores showed higher reporting of perceived exhaustion using conventional resistance (mean score 7.7) compared with elastic resistance (mean score 6.8). Similarly, the exhaustion scores were higher for squats with conventional resistance (mean 7.5) compared squats with elastic resistance (mean 6.9).

5. Discussion

The primary aim of the research on which this thesis is based was to investigate whether PRT using ERB should be favoured over GPE in MDR of chronic neck pain and chronic low back pain. Since randomized controlled trials are the best designs to establish causality between an intervention and an outcome, two randomized controlled trials (i.e. the low back pain study and the neck pain study) with parallel designs were carried out to test the hypothesis that PRT is more effective than GPE in reducing pain-related disability. Additionally, a crossover study (i.e. the EMG study) was carried out to assess the viability of using elastic resistance bands as a training modality for the multi-joint exercises prescribed in the randomized controlled trials.

The most important finding in both the low back pain study and the neck pain study was that PRT was not a more effective component in MDR than GPE for alleviating pain-related disability.

The most important finding in the EMG study was that elastic resistance bands could be used as a viable alternative to conventional resistance training equipment for the exercises lateral pulldowns and unilateral rows. Conventional resistance training equipment was more effective in activating the prime moving muscles in squats (i.e. quadriceps muscles: vastus medialis, vastus lateralis, and rectus femoris) and stiff-legged deadlifts (gluteus maximus and hamstring muscles: semitendinosus and biceps femoris), but elastic resistance bands provided largely similar activation of the gluteus maximus and erector spinae in squats and erector spinae in stiff-legged deadlifts. Thus, elastic-resisted squats and stiff-legged deadlifts can be used to strengthen the extensor muscles in the back and hip.

In-depth discussions of the individual results are presented in Papers II–IV. In the following discussion, I elaborate upon the findings across the different studies, the methodological considerations, and clinical relevance of the findings.

5.1 Reflections on the results

5.1.1 The exercise interventions

Previous studies have suggested that progressive resistance training can be an effective way of exercising for people with chronic low back pain (52, 63), and especially for those with

chronic neck pain (36, 37). However, the results from the research done for this thesis suggest that PRT was not more effective than GPE for patients with moderate to severe chronic neck pain and chronic low back pain who were enrolled in MDR in specialized health care. Several reasons may explain why we were unable to demonstrate similar favouring of PRT, with the most important being differences in the study populations and that exercise was given as part of MDR in the three studies (discussed in detail in Papers III and IV).

An important aspect of how the results in the low back pain study and the neck pain study are understood relates to the implementation of the PRT intervention: Did the studies truly investigate the effects of effective strength training? The PRT intervention provided in the low back pain study and the neck pain study was primarily based upon interventions used in previous studies that had identified PRT as effective for reducing neck pain and low back pain. Additionally, the intervention was designed in accordance with the ACSM's recommendations for resistance training for novices. Further, we included exercises that targeted all major muscle groups in a time-efficient manner. We conferred with the physiotherapists at the clinic to get their opinions on which exercises they considered were suitable for the relevant group of patients, and then we conducted a small pilot study in which we tested the exercises in the relevant patient group.

To ensure that the resistance band exercises could be considered viable resistance training exercises, we reviewed the literature to see whether they had been compared with training with conventional resistance training equipment. In general, the literature suggested that elastic resistance bands were a viable option for single-joint exercises (70), including shoulder abductions (76), while there was limited evidence for multi-joint exercises. Thus, the EMG study was initiated to compare the muscular activation for squats, stiff-legged deadlifts, unilateral rows, and lateral pulldowns. Additionally, flies and reversed flies with elastic resistance bands were investigated and found a feasible alternative to conventional resistance training equipment (88). Since neck flexion and extensions (two of the exercises in the neck pain study) are less common exercises, we were not aware of a gold standard way of performing them with conventional resistance training equipment, and therefore the exercises were not evaluated for elastic bands. Additionally, due to the involvement of small and/or deep muscles in both neck flexion and extension, sEMG measurements would not have been very useful. However, these exercises were included on the basis of findings from previous studies that demonstrated reduced cervical strength in individuals with chronic neck pain (110-113). As already stated, the results of the EMG study suggested that elastic resistance

band could be used as a viable modality for the exercises of interest, despite the fact that conventional resistance was clearly more effective for squats and stiff-legged deadlifts. However, as elastic resistance was found effective in targeting the erector spinae during stiff-legged deadlifts and both the erector spinae and the gluteus muscles during squats, the exercises were considered useful for the target population in the low back pain and the neck pain study. To summarize, I am confident that the PRT programme was designed in a way that was effective for increasing muscular strength, although ideally the ERB programme should have been compared with a similar programme using conventional equipment in an independent RCT.

Although the PRT programme was designed to be effective for increasing strength, few or no between-group differences in strength gains were observed in the different muscular strength tests, with the only significant difference being that PRT was slightly more effective for improving shoulder abduction strength (effect size: 0.23). The lack of difference in strength gains can probably largely be accounted for by: (1) poor adherence to the PRT programme, (2) participants training with lower intensity than prescribed, (3) participants in the GPE group engaging in resistance training during the home-based training period, and (4) discrepancy in strength gains in the trained exercises and the tests used to assess muscular strength. With respect to the latter point, adaptations to strength training are generally considered to be task-specific, meaning that participants in the PRT group might have increased their strength in the trained exercises, without improving their MVCs (46, 48, 114).

With regard to adherence to the training, it is important to note that most of the training was home-based. It has previously been suggested that between 50% and 70% of patients with chronic low back pain are non-adherent to prescribed home-based exercise programmes (115). For workers with neck pain, it has been found that group-based training at workplaces resulted in higher compliance and a reduction in the symptoms of neck pain compared with those who did home-based training (116). Thus, it is possible that the participants in our studies would have benefitted more from closer follow-up during a home-based training period. It has also been suggested that psychosocial impacts can affect adherence to physical training (117), which relevant for the populations in the low back pain study and the neck pain study. Finally, it should be mentioned that in interviews with participants from the PRT groups in the low back pain study, participants reported they had trained with varying intensity: some reported they had trained with high intensity (as prescribed) throughout the entire training period, while others characterized their training as

lower intensity movement training than intensive resistance training. Data from the interviews have not yet been systematized or analysed, but the reporting of varying training intensity still supports that the external loading during training might have been too low in some cases.

Due to the limited differences in strength gains, we performed some additional analyses in the low back pain study. However, these analyses did not demonstrate any additional improvement for the participants who had reported the most improvements in strength, or for the participants who had completed more than 60% of the prescribed PRT sessions. This finding supports the main finding of PRT not being more beneficial than GPE for the study population. No additional analyses were performed in the neck pain study, due to the low number of participants.

Both the PRT group and GPE group appeared to show improvements in most outcomes from baseline to 12 weeks, but due to the lack of a control group that did not participate in MDR, we were unable to draw any conclusions about the direct effect of either the MDR programme or the different exercises. Furthermore, it is important to recognize that patients with chronic pain (especially widespread pain) are prone to developing sedentary lifestyles, which in turn can lead to lifestyle-related health risks and even excess risk of mortality (118). Considering that exercise can have positive impacts on symptoms of chronic neck pain and low back pain, I wish to stress the importance of prescribing exercise for these patients. Considering that no major differences in improvement were observed between the PRT and the GPE groups in either of the studies and that exercise can be beneficial for both chronic neck pain and low back pain, I would encourage clinicians to advise patients to try different ways of exercising and then work together with their patients to design a training programme that the patients are comfortable with and motivated to engage in, in order to improve adherence and compliance. Finally, for patients who are interested in engaging in strength training but do not want to join a fitness club, the PRT programme followed in the three studies could be a suitable alternative.

5.1.2 Similarities in low back and neck pain

The mean improvement in the primary outcome – pain-related disability – was similar for both the PRT group and the GPE group in both studies (Studies 1 and 2); approximately 25% improvement in disability, effect sizes in the range 0.68–0.82 within groups. This finding is interesting, as there has been limited research on MDR for chronic neck pain, whereas MDR is a well-established method for managing chronic low back pain. Thus, the findings support

the few studies that have suggested that that MDR results in similar improvements for patients with chronic neck pain and chronic low back pain (26).

Given the similarities in both the interventions and findings across the studies, it is appropriate to reflect upon differences and similarities between the included patient populations. Previous findings from a large epidemiological study from Denmark suggested that, due to the many common risk factors and characteristics of chronic neck pain and chronic low back pain, these conditions should be regarded as the same conditions, regardless of whether the pain is primarily manifested in the lumbar, thoracic, or cervical regions (119). The Danish study was based upon data from the general population of Denmark, while the patients included in our studies were recruited from a hospital outpatient back and neck pain clinic, and the findings from the Danish study could not be generalized to our study populations.

In our studies, patients were enrolled in the MDR programme for neck pain or low back pain based upon which of the conditions they had been referred to the clinic for, in combination with what the physician's at the clinic recommended during the initial screening session. However, participants in both studies reported additional pain sites at baseline: approximately 40% of the patients in the neck pain study reported back pain, and approximately 40% of the participants in the low back pain study reported neck pain. A master's thesis on baseline data for the populations in the neck pain study and the low back pain study shows that there were no major differences in health characteristics at baseline between the patients included in the two studies (120). The main differences were a slightly higher body mass index (BMI) for patients with low back pain and that more patients in the neck pain study reported a high number of pain sites. Considering the overlapping symptoms and the similar improvements, it can be suggested that that patients referred for specialized health care due to chronic neck pain and chronic low back pain should potentially receive similar treatment. The abovementioned findings reflect the experiences of the health personnel at the clinic, and today, the clinic operates with mixed groups of patients, providing the same MDR programme to low back pain patients and neck pain patients.

The results from our studies indicate some potentially small differences in how the patients with neck pain and low back pain responded to PRT compared with GPE. In the neck pain study, there was a tendency towards PRT being more beneficial for changes in pain from baseline to 12 weeks. In the same study, the improvement in worst pain in the last two weeks

and four weeks was respectively 1.2 and 1.0 points better for the PRT group than the GPE group, which were close to statistically significant. This was not the case in the low back pain study. The findings are thus somewhat in line with a rapidly growing body of evidence that suggests PRT is especially effective for reducing neck pain (36, 37, 39-42). However, as the findings were not statistically significant, they should be interpreted with caution, and it should also be noted that a reduction of minimum 2 points in pain (NRS) has been proposed as the minimal change considered clinically important for chronic pain (121). However, considering the major impact of chronic neck pain on a global level, a difference of 1 point on the NRS for pain should not be neglected as a potential addition to the effect of usual MDR, especially considering that our patients had responded poorly to treatment in their primary care. Part of the rationale for recommending MDR to patients with chronic low back pain has been based upon a 1-point improvement in pain (0–10) compared with customary care (24).

5.2 Methodological considerations

5.2.1 Validity of the low back pain study and the neck pain study

Clinical research is performed with intention of being able to draw inferences from the study to real-world clinical settings. However, drawing inferences from the results of a study raises questions about the validity of the results, which means whether the study has been performed and reported in a way that minimizes potential systematic errors in the results and the inferences (i.e. bias) or, put more simply, whether the results can be trusted. The validity of the results is usually divided into internal and external validity (generalizability) (122). Internal validity concerns the way the research is done, the interpretation and the conclusions drawn from the study, and whether these are supported by the findings from the study. External validity concerns the generalizability of the findings from the study to the world outside the study setting. Importantly, internal validity is considered a precondition for external validity. Studies with poor validity can potentially lead to ineffective or even harmful interventions being perceived as effective or that a potentially effective intervention is disregarded (123). There are several types of bias, but violation of the validity in clinical trials mainly involves selection bias, performance bias, detection bias, attrition bias, and reporting bias (123), all of which are discussed in the following section. It should also be mentioned that confounding, which refers to a phenomenon whereby the association between an

independent and a dependent variable is affected by a confounding variable, can be a problem in several studies, but is generally not considered a major concern in RCTs, due to the randomization.

Selection bias refers to distortion in how participants are selected and enrolled in the study. In theory, the RCT design minimizes selection bias due to the randomization. However, selection bias can occur in RCTs if the randomization is not performed correctly, such as when the recruiters know or are able to guess the allocation sequence and selectively enrol participants into the study based upon knowledge of the upcoming treatment allocation (124). In our studies, the physicians who had recruited the patients potentially could have considered one of the interventions as more beneficial for the patients and therefore include the patients at a time point that ensured randomization to that specific intervention. However, since a concealed allocation procedure was used and since the randomization was performed using a programme from a third party (the Unit for Applied Clinical Research, Norwegian University of Science and Technology) with unknown block sizes, there was a very low risk of selection bias. However, since the studies involved participants with chronic pain, it is possible that those who chose to participate were either those with the most problems or those who had had a poor response to previous treatment and were most eager to try something new. Potentially, this could have resulted in a selection bias, and therefore to address this potential problem we included a reference group was included in both the neck pain study and the low back pain study. These groups consisted of patients in the MDR programme who had declined to participate in the study or had been excluded from study participation, and the analysis revealed that there was little difference between participants in the study and the reference groups. This finding gives a strong indication that that the participants included in the study were representative of the patient population at the clinic, although the possibility of selection bias also in the reference groups cannot be entirely excluded.

Performance bias concerns differences in how the intervention is provided to the groups and their exposure to factors other than the intervention of interest. Thus, performance bias relates to the blinding procedure. Due to the nature of our studies, it was impossible to blind both the participants and the therapists. However, we had regular meetings with the therapists to ensure that the interventions were performed according to the protocol. Additionally, when the studies were completed, interviews were conducted with the therapists' who had delivered the interventions. While the data from the interviews have yet to be analysed and published, some of the statements by the therapists can shed light on the

discussion of performance bias and are therefore included here. First, the therapists generally reported that they had adhered to the protocols for the two different exercise interventions and they dismissed the possibility that one group had received more attention or ancillary treatment. However, there had been some rotations of staff at the clinic during the intervention period, and some of the therapists reported they had introduced strengthening exercises to a few of the participants in the GPE group. This only concerned a very small portion of the participants in the GPE group, and none had been provided with several exercises or systematic training programmes. Thus, the risk of the introduced strengthening exercises influencing the results was low. Regarding the inability to blind participants, it is important to note that PRT was not favoured over GPE when participants were asked to participate, but that the study aimed to compare the two different interventions. Additionally, it should be mentioned that in the interviews with participants in the low back pain study, the majority said that they had been unaware that there were two different interventions.

Detection bias concerns biased assessment of the outcomes. In both the low back pain study and the neck pain study, test leaders and researchers were blinded to group allocation, and strict procedures were maintained to preserve masking throughout the entire study period. Participants were thoroughly instructed not to reveal their allocation during testing and they were reminded on this at the beginning of each test session. Additionally, strict protocols were followed during testing, and standardized verbal information and feedback were provided during all tests. With regard to analysis, group allocation was not revealed until all analyses had been completed. Additionally, all health-related outcomes were analysed prior to the analysis of muscular strength in order to minimize the risk that the researcher could guess which groups had received PRT and which had received GPE.

Attrition bias concerns systematic differences in dropouts between groups. Loss to follow-up was a major issue in both the low back pain study and the neck pain study. We observed a dropout rate of 53.5% and 58.1% from inclusion to 12 weeks in the low back pain study and the neck pain study, respectively. However, it is important to note that several of the dropouts happened prior to baseline testing and this rate was similar for both the GPE group and the PRT group. It can therefore be argued that the actual dropout rate from the respective studies was 37.8% and 47.5%, as these percentages reflect those who answered the baseline questionnaire but were lost to follow-up at 12 weeks. Potentially, the early dropouts could have introduced bias to the studies if their reason for dropping out was based on the group they had been allocated to. However, the early dropout rate was similar for the PRT

group and the GPE group in both studies. Some of the dropouts at 12 weeks were explained by time conflicts or disease and/or sickness, but most dropouts remained unexplained because we were unable to contact the participants. A potential reason for the considerable loss to follow-up at 12 weeks is that participants had to come to the clinic for the test whenever they were running errands. By contrast, they were already at the clinic during the baseline and the 3-weeks test because they were participating in the MDR programme at that time. An important aspect of the loss to follow-up is that the rate was similar for the GPE group and the PRT group, and there were no differences in the baseline characteristics of those who dropped out and those who completed their participation in the study. Thus, it is unlikely that the loss to follow-up affected the results in other ways than a reduction of statistical power. Regarding statistical power, the a priori power calculations suggested that 100 participants, including 20 dropouts, were necessary to evaluate the primary outcomes in the low back pain study and the neck pain study. However, we were unable to reach the desired number of participants in the neck pain study, due to the slow recruitment rate and upcoming changes at the clinic. Lastly, attrition bias was to some extent accounted for in the statistical analyses. Approximately 82% and 60% of the participants measured at baseline in the low back pain and the neck pain study was measured at least two times. The mixed linear models, which were used to assess outcomes in all three studies, used all available data and were less sensitive to missing data than other statistical models. However, such models rely on data being missing at random, which we are unable to assess.

Reporting bias concerns systematic differences in reported and unreported findings. One strength of our studies is that outcomes have been reported in accordance with the predefined outcomes registered at ClinicalTrials.gov, and that a study protocol was published for the low back pain study. Additionally, the RCTs (Papers III and IV) have been reported in accordance with the CONSORT statements (125), and the study protocol (Paper I) adhered to the SPIRIT 2013 checklist (126).

With regard to *other issues* concerning validity, one of the main concerns regarding the internal validity in the low back pain study and the neck pain study is whether the studies truly investigated the effects of resistance training, as discussed in depth in Section 5.1.1. Furthermore, there was always some potential for misinformation from the physical tests as well as recall bias in the data from the self-reported questionnaires, but due to the RCT design there is no reason to believe that this would have differed systematically between the two groups.

The low back pain study and the neck pain study included patients enrolled in an MDR programme in specialized health care, and it is reasonable to assume that the included participants constituted a good representation of patients enrolled in the MDR programmes at the clinic. However, the findings of the two studies cannot be generalized to the population referred to MDR in general or to people with chronic neck and back pain in general.

5.2.2 Validity of the EMG study

In the EMG study a crossover design was used to compare EMG activity in training with CRE and ERB. The design minimized confounding, since the participants acted as their own controls and increased statistical power due to the paired analyses resulting in fewer participants being required (122). In total, 29 participants were included in the EMG study, which resembled the number of participants included in previous studies that compared EMG activation during training with ERB and CRE (76, 77, 79, 82). When two training modalities are compared, this should ideally be done under exactly same test conditions and with totally uncontaminated sEMG signals. However, as it is impossible to achieve such conditions, the goal in the EMG study was to make the test conditions as equal as possible for both modalities.

Potentially, several factors could have affected the internal validity of the EMG study. First, there are several potential sources for information bias in EMG studies in general, due to contamination of the EMG signals, as presented in the background section (1.10). While recommended measures were taken to provide quality EMG signals, there was always the possibility of some contamination of the results. One strength of the EMG study is that sEMG was assessed for elastic resistance and conventional resistance in the same sessions without removing the electrodes between the sessions. Thus, there is little reason to suspect that potential contamination of the signals would have differed between the exposures. Additionally, the sEMG amplitudes were normalized to MVCs, which allowed for comparison of activation levels between the different modalities (87).

The sEMG data were collected at a facility where other people were training, and therefore, for logistical reasons, the order of the testing was not randomized. The conventional resistance training exercises were performed before the elastic resistance band exercises. Potentially, this could have resulted in participants becoming fatigued before they performed the equivalent exercises with elastic resistance bands. However, as the participants only performed 3 repetitions with 10 RM loadings, and the time between the two equivalent CRE

and ERB exercises was close to 1 hour, it seems unlikely that the activation levels would have been substantially affected.

A potential bias in the results can be related to the 10 RM tests using ERB. As discussed in Paper II, it is challenging to determine exact RMs with ERB, and there is a possibility for the resistance used for the ERB not being truly matched to the resistance used for the CRE. In the worst case, this might have resulted in a slight underestimation of the muscular activation levels for exercising with ERB. However, matching resistance through RM testing has been done in several previous studies(77, 79, 82), and currently there is no known methodologically sound procedure to match the resistance between ERB and CRE. As recommended, we used the BORG-CR10 scale to assess the potential mismatch in the loadings (70, 76). The BORG scale results demonstrated that the participants had found it harder to perform the stiff-legged deadlifts and the squats when using CRE compared with when using ERB, which may indicate that the loads were not truly matched. Alternatively, the results may indicate that the participants perceived CRE as heavier than the ERB exercises.

There was some discrepancy in how the exercises were performed between the modalities, and it is likely that the choice of set-up influenced the results and increased the discrepancy in muscular activation between modalities. However, the aim of the study was not to make the ERB exercises as similar as possible to the CRE exercises, but rather to compare the muscle activation between common CRE and ERB exercises, as these were implemented in the training programme in the low back pain study and the neck pain study. A pilot study of the exercises revealed that making exercises as similar as possible was experienced as unnatural and would therefore not allow for a valid comparison. For instance, in the conventional pulldown exercise the body is faced towards the point of resistance (i.e. the machine) but experiences from the pilot study revealed three problems with performing elastic pulldowns in a similar way: (1) it was harder to prevent cheating (swaying and ‘crumpling’ of the torso), (2) it was more challenging to make participants move their arms in a correct manner (i.e. in the coronal plane), and (3) distance to the anchor point resulted in a different force vector, since the elastic bands were pulled down and back instead of straight down, thus making the exercise less similar to the exercise done in a machine.

Finally, it should be noted that although sEMG is a popular tool for assessing muscular activation, sEMG only represents an estimate of the neural activation and not the actual activation of the muscles. Thus, in a recent article, the authors suggest that it is ambiguous to state that sEMG measures muscle activity, and perhaps the terms ‘muscle excitation’ or ‘myoelectric activity’ are preferable (127). Additionally, no measures of

muscular morphology were assessed in the EMG study, and the possibility of other muscular adaptations (e.g. increased cross-sectional area of the muscle fibres, or changes in muscle architecture and muscle fibre type(128)) cannot be excluded.

With regard to generalizability, the participants in the EMG study were healthy young men and women, and the results cannot be directly generalized to other populations.

5.3 Conclusions and clinical implications

The low back pain study has contributed knowledge to the field of exercise interventions used in MDR for chronic low back pain, and specifically the use of PRT compared with GPE, while the EMG study has contributed knowledge regarding the use of elastic bands as a training modality.

The conclusions drawn from the research done for this thesis are summarized as follows:

- Replacing GPE with PRT in MDR did not result in reduced pain-related disability for patients with moderate to severe chronic low back pack or chronic neck pain.
- Despite the reduction in statistical power resulting from the loss to follow-up, the changes in the primary outcomes were virtually identical in the exercise groups and it is highly unlikely that a larger study would result in a change in the primary outcome.
- Clinicians should advise either of these exercises (PRT or GPE) based on the patient's interests and motivation, in order to improve adherence to and compliance with the exercise programme.
- The ERB training programme presented in this thesis is a viable alternative to CRE training, although the latter should be preferred for squats and stiff-legged deadlifts for optimal activation of some prime mover muscles.
- PRT may be slightly better than GPE in MDR for improving neck pain, but this needs to be verified in a larger RCT.

5.4 Future studies and unanswered questions

A considerable amount of data was collected during the low back pain study and the neck pain study, and since performing such studies is both time-consuming and demanding for both the researchers and the participants, the collected data should be thoroughly investigated. Thus, there are plans for future studies using the same data from the low back pain and neck

pain studies. First, we are planning a more in-depth study of the similarities and differences in the characteristics of patients with chronic neck pain and chronic low back pain, which will be an extension of the master's study that investigated baseline characteristics (120). This is expected to shed more light on the similarities in the conditions and contribute to knowledge of patients enrolled in MDR. Additionally, considering the similarities in the populations in the neck pain study and the low back pain study and the overlapping treatments that were provided, it would be possible to pool the populations, to enhance statistical power, and to investigate potential associations between increased strength and improvement in health-related outcomes. Finally, interviews were conducted with a selection of participants from the PRT groups in the low back pain study and with the therapists who delivered the interventions, and we plan to use these data to elaborate upon the feasibility of using elastic resistance bands for PRT in both clinical and home-based settings.

During testing of low back pain, MVC strength data were collected with intention of assessing maximal strength, which was in focus in the low back pain study, as well as the rate of force development. For neck pain patients, it has been suggested that rapid force development is more inhibited than the maximal force capacity (129), and it has been demonstrated that PRT results in a more profound improvement in rapid force development than in maximal strength (129, 130). A reduced capacity to develop rapid force in the muscles of the low back has been demonstrated in women with chronic low back pain (131). Thus, it would be interesting to investigate whether participants in the PRT group in the low back pain study improved their rapid force-generating capacity more than did the GPE group, despite the fact that no significant between-group differences were observed in maximal strength.

Individuals respond differently to training, and it would therefore be useful to have increased knowledge of which participants show improvements following different exercise regimes. Thus, future studies should include enough patients to enable subgroup analysis, in order to investigate which patients might benefit the most from the different exercise variations. Further, multicentre studies would be useful to enhance generalizability, and ensure a faster recruitment rate.

Finally, there is quite a large body of evidence indicating that ERB provide similar EMG activity as CRE for single-joint exercises, whereas the evidence base for multi-joint exercises is much smaller. Thus, potential future studies investigating the usability of ERB

should focus on multi-joint exercises and ideally also aim to compare the effect of training with ERB compared to CRE with respect to muscular strength gains and adaptations.

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Paper 1

Contemporary Clinical Trials Communications 6 (2017) 115–121

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Resistance training in addition to multidisciplinary rehabilitation for patients with chronic pain in the low back: Study protocol

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ARTICLE INFO

Keywords:
Musculoskeletal disorders
Disability evaluation
Low back pain
Chronic pain
Resistance training
Exercise

ABSTRACT

Introduction: Chronic low back pain (LBP) is a major health problem worldwide. Multidisciplinary rehabilitation and exercise is recommended for the management of chronic LBP. However, there is a need to investigate effective exercise interventions that is available in clinics and as home-based training on a large scale. This article presents the design and rationale of the first randomized clinical trial investigating the effects of progressive resistance training with elastic bands in addition to multidisciplinary rehabilitation for patients with moderate to severe chronic LBP.

Methods and analysis: We aim to enroll 100 patients with chronic LBP referred to a specialized outpatient hospital clinic in Norway. Participants will be randomized equally to either; a) 3 tion including whole-body progressive resistance training using elastic bands – followed by home-based progressive resistance training for 9 weeks, or b) 3 weeks of multidisciplinary rehabilitation including general physical exercise – followed by home-based general physical exercise for 9 weeks. Questionnaires and strength tests will be collected at baseline, weeks 3 and 12, and at 6 and 12 months. The primary outcome is between-group changes in pain-related disability at week 12 assessed by the Oswestry disability index. Secondary outcomes include pain, work ability, work status, mental health, health-related quality of life, global rating of change, general health, and muscular strength and pain-related disability up to 12 months of follow-up.

Discussion: This study will provide valuable information for clinicians working with patients with chronic LBP.

Trial registration: ClinicalTrials.gov, number NCT02420236.

1. Introduction

Low back pain (LBP) is a leading cause of reduced quality of life and disability worldwide [1,2]. Current guidelines advocate physical exercise in the management of chronic LBP, without recommending any particular exercise modality [3]. Some recent studies indicate that progressive resistance training (PRT) may have a particularly positive effect on pain and disability in patients with chronic LBP [4–7] and other types of musculoskeletal pain [7,8].

Preferably, a training intervention should be easy to implement in clinical practice and as home-based training. Elastic resistance bands are relatively inexpensive, safe, easy to use, portable and require little space, and could therefore represent an attractive and feasible alternative to free weights and training machines for PRT interventions. Studies have shown that the muscular activation level is similar for several resistance training exercises using elastic bands compared to conventional resistance training equipment [9]. However, we are not aware of any randomized clinical trial (RCT) investigating the effect of PRT using elastic bands for patients with chronic LBP.

Chronic LBP often entails a bio-psycho-social symptom picture, i.e., widespread pain, work disability, reduced quality of life, fear-avoidance beliefs, mental symptoms and social withdrawal [10,11]. Thus, multidisciplinary rehabilitation (MDR) approaches are commonly used for dealing with this disorder [12–15]. However, studies seeking to identify effective exercise components of MDR are lacking.

This paper comprises the study protocol for an RCT investigating effects of PRT in addition to MDR for patients with moderate to severe chronic LBP. Our hypothesis is that PRT combined with MDR reduces

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http://dx.doi.org/10.1016/j.conctc.2017.04.001
Received 13 December 2016; Received in revised form 29 March 2017; Accepted 8 April 2017
Available online 12 April 2017

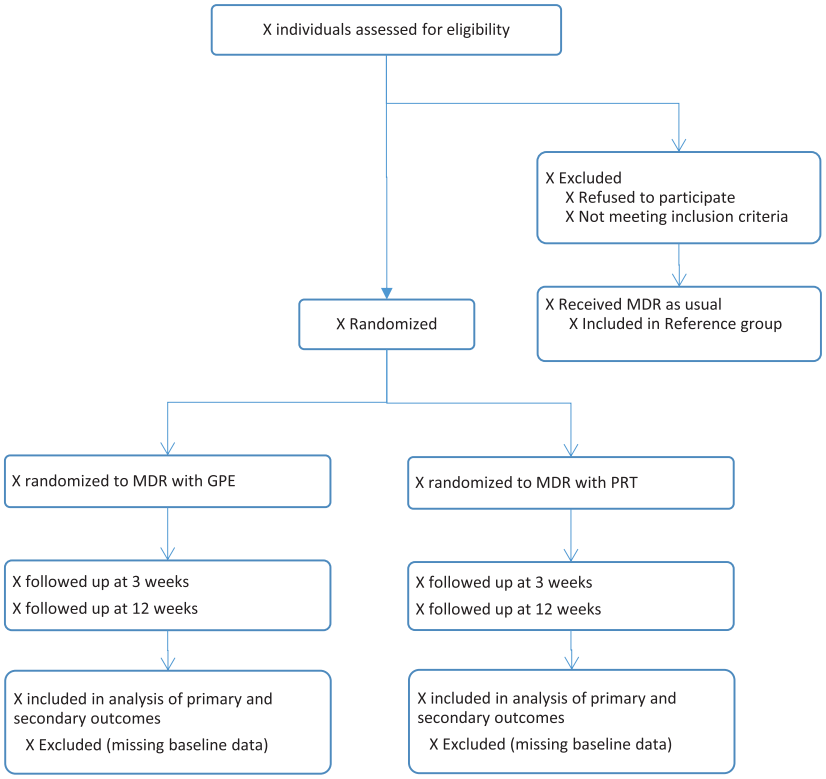

Fig. 1. Patient flow. Included patients are randomized to multidisciplinary rehabilitation (MDR) with progressive resistance training (PRT), or MDR with general physical exercise (GPE). Outcomes will be assessed at baseline, after 3 and 12 weeks, and 6 and 12 months.

pain-related disability more than MDR with general physical exercise (GPE).

2. Methods and design

2.1. Project context

The study is carried out in a specialized outpatient hospital clinic. The MDR program is provided by the Department of Physical Medicine and Rehabilitation, St. Olavs Hospital, Trondheim University Hospital, Norway. Patients will be recruited from the clinic.

2.2. Design

The study is a single-blinded RCT (researchers), involving patients with chronic LBP. Participants will be randomized to participate in i) 3 weeks MDR including PRT at the clinic and 9 weeks home-based PRT, or to ii) 3 weeks MDR including GPE at the clinic and 9 weeks home-based GPE. Three supervised booster sessions will be offered to all participants during the home-period. The study design is presented in Fig. 1. The study protocol adheres to the SPIRIT 2013 checklist [16], and results from the RCT will be published in accordance with the CONSORT statements [17].

2.3. Inclusion and exclusion criteria

Inclusion criteria: 1) Referred to the clinic for LBP, 2) Chronic ($\geq$3 months) or recurrent ($\geq$2 periods with duration $\geq$ 4 weeks in the past year) non-specific LBP, 3) Strongest LBP in the last two weeks $\geq$ 4 on numerical rating scale (0–10), and 4) 16–70 years of age. Exclusion criteria: 1) Severe somatic condition (e.g., cancer, inflammatory rheumatic disease, severe osteoporosis), 2) Psychiatric condition that severely impairs group functioning, 3) Insufficient comprehension of Norwegian language to participate in group sessions and fill out questionnaires, 4) Awaiting surgery of lumbar spine, 5) Alcohol or drug abuse, 6) Ongoing compensation claim or applying for disability pension due to LBP, 7) Engaged in high-intensity resistance training on a regular basis for the last six months, and 8) Contra-indications for high-intensity resistance training (e.g., shoulder complications severely limiting the ability to conduct the training program or where existing shoulder training protocols are advised).

2.4. Recruitment of participants

Patients referred to the outpatient clinic due to LBP will first undergo an ordinary routine clinical examination by a physician. In addition to the formal inclusion and exclusion criteria of the study, physicians performing the clinical examination will also consider whether the participants will benefit from MDR based on the clinical history and motivation of the patient, and whether sufficient treatment has been attempted in primary care. Recruitment and interventions will take place in the period 12/2014 to 01/2017.

1. The physician informs eligible participants about the study and hands out an envelope containing written information about the study and the consent form. Participants can call or e-mail the project leader for supplementary information.
2. Patients get a minimum of three days to consider the invitation

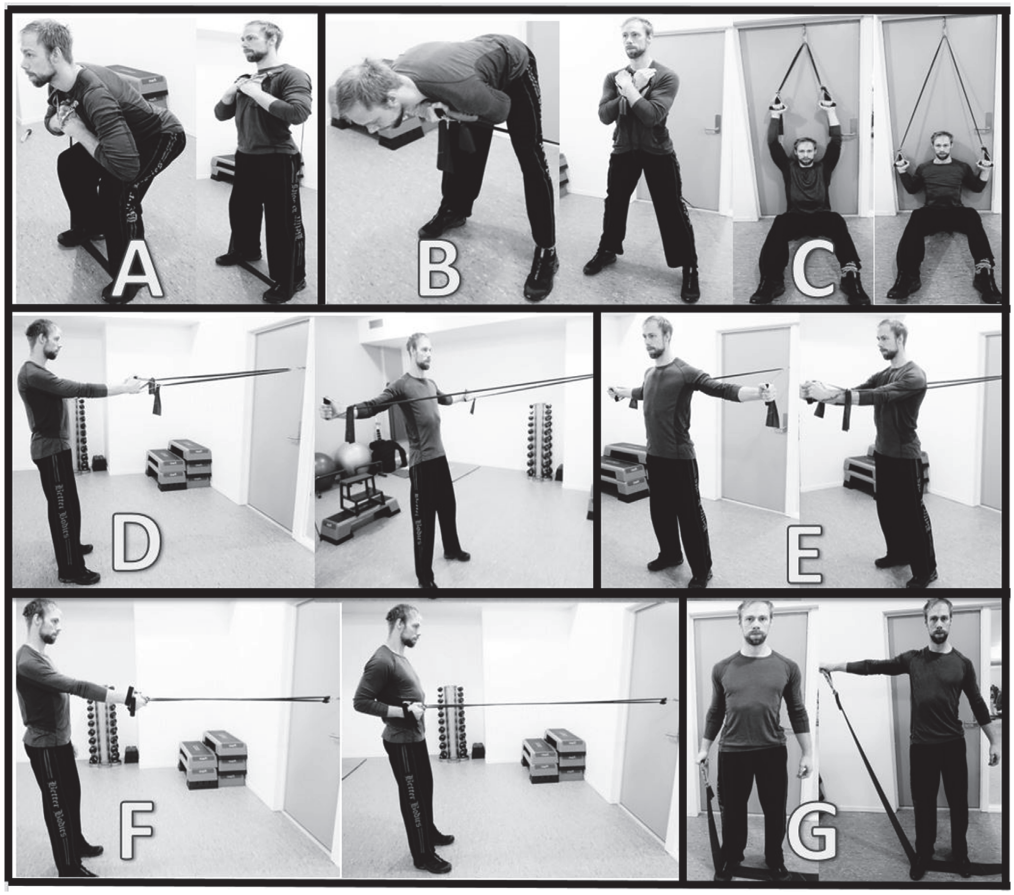

Fig. 2. Illustration of the strength exercises. Squats (A), stiff-legged deadlifts (B), lateral pulldown (C), reversed flies (D), flies (E), unilateral rows (F), lateral raise (G).

before they receive a call from a secretary at the clinic and are asked if he/she would like to participate. Those who want to participate provide oral consent.
3. Patients providing oral consent are consecutively included and randomized.
4. Participants are required to fill in a written consent form before baseline testing.

The MDR groups include up to 10 patients, and are organized so that every other group is an intervention and a comparative group. Patients scheduled to participate in the MDR program at the clinic, but are excluded from or are unwilling to participate in the study, will be asked to complete a baseline questionnaire during their first day at the clinic. Patients willing to participate in the reference group are required to fill in a written consent form.

2.5. MDR at the clinic

The MDR program will be carried out as usual within the study period - five full rehabilitation days in week one and three. There are no sessions in week two, but during this week, the patients are encouraged to apply what they have learned in week one. The teams delivering the MDR program consist of physiotherapists, physicians, social workers, and psychologists.

The MDR programs include individual consultations with physicians and social workers in addition to lectures, patient reflections and discussions. Themes covered are back anatomy, understanding of pain, coping with stress, exercise, psychosocial aspects related to living with pain, making plans and setting goals for work participation, and leisure time, etc. Additionally, there are sessions with physical activity which consist of GPE in the comparative group, and primarily PRE in the intervention group.

2.6. General physical exercise (comparative group)

Participants in the comparative group receive four sessions of GPE in week one and five sessions in week three. The sessions include circle-training, low-intensity resistance exercises, endurance training, ball games, body awareness, stretching, and relaxation techniques. Patients are encouraged to continue to stay physically active at home and are provided a home-training program upon completion of MDR. The program contains exercises and recommendations based upon the patient's interests and individual needs, along with the physiotherapist's recommendations. Participants will be summoned to participate in three supervised booster sessions at two, five, and seven weeks after completion of the MDR. These sessions will be used to adjust the individual program and to motivate the patients to stay physically active.

2.7. Progressive resistance training (intervention group)

In the intervention group, three of the regular weekly physical activity sessions at the clinic are replaced with PRT. These sessions aim to familiarize patients with using elastic resistance bands and to learn proper execution of the different resistance exercises. After completing the MDR, patients will continue with PRT at home three times per week for nine weeks (12 weeks in total). Three supervised booster sessions will be held at similar time intervals as in the comparative group. Improving technique, adjusting resistance and maintaining adherence and compliance will be the main objective of these sessions.

The PRT program will be carried out in accordance with the guidelines described by the American College of Sports Medicine [18], and recommendations for introducing resistance training for persons with musculoskeletal pain [7]. The program is sequenced into four periods (weeks 1–2, 3–5, 6–8, and 9–12). The training load will be increased progressively so that 15–20 repetitions is performed in the first period and 8–10 repetitions in the last period, corresponding to about 50% and 75–85% of one repetition maximum– i.e. the maximum weight that can be lifted in one repetition with proper execution of the exercise. The training load will be increased when the person is able to do 1–2 repetitions more than prescribed. External resistance will be applied using Theraband® Elastic bands (colours: yellow-gold). Bands can be combined in order to increase resistance. Since many LBP patients experience pain from several other sites [19,20], and often have low general muscular fitness [7,21,22], the program consist of exercises for the whole body in order to improve general muscle strength and physical functioning – i.e., squats, stiff-legged deadlifts, flies, unilateral rows, reversed flies, unilateral shoulder abduction and lateral pulldown (see Fig. 2). Similar resistance training exercises have previously been used in studies showing positive results for chronic musculoskeletal pain [4–6,23–25]. Physiotherapists at the clinic were involved in the development of the training programs.

Participants are requested to record all PRT sessions in a training diary (Fig. 3). The Borg CR-10 scale [26] is used to record perceived exertion, as it provides an adequate reflection of resistance training effort [26].

2.8. Training adjustments

In case of acute worsening of symptoms during a specific exercise, the participants will be instructed to: (i) reduce load in the specific exercise, (ii) reduce movement velocity, (iii) reduce range of motion, and (iv) avoid the specific exercise for at least three sessions [27,28]. Participants can contact a physiotherapist at the clinic if they have questions about symptom progression and/or the training schedule. All deviation from the prescribed training schedule is to be recorded in the training diary.

2.9. Outcomes

Outcomes will be measured at baseline, weeks 3 and 12, and at 6 and 12 months.

2.9.1. Primary outcome

- Between group differences in LBP-related disability from baseline to 12 weeks, assessed by the Oswestry disability index [29,30].

2.9.2. Secondary outcomes

- Oswestry disability index (at three weeks and 6 and 12 months)
- Intensity of LBP at each test session, last two weeks, and last four weeks is assessed by the 11-point Numerical pain rating scale [31].
- Pain sites in the last month is assessed using pain drawings [32].
- Workability is assessed with the single item “current workability compared with the lifetime best” from the Workability index [33].
- Anxiety and depressive symptoms is assessed using Hopkins symptom checklist [34].
- Health-related quality of life is assessed using EQ-5D-5L [35].
- Fear-avoidance beliefs using the fear-avoidance beliefs questionnaire [36].
- Functional capacity will be assessed using the patient specific function scale [37,38].
- Patient-rated efficacy of the treatment is assessed using the Global rating of change scale [39] – a seven point scale ranging from “feeling very much improved” to “feeling very much worse”.
- Grip strength and low back strength (see strength tests)

2.9.3. Additional measures

- Sex (male/female).
- Marital status (married/live-in partner, single, divorced).
- Height (measured to the nearest 0.1 cm using a wall mounted stadiometer).
- Body weight (measured to the nearest 0.1 kg, using the Bosch personal scale PPW33000)).
- Education level (primary school/middle school, high school, higher education).
- Level of leisure time physical activity is assessed by three questions [40]: 1)” How frequently do you exercise?” (never, less than once a week, once a week, 2–3 times per week, almost every day), 2) “How long does each session last?” (less than 15 min, 16–30 min, 30 min to an hour, more than 1 h), and 3) “If you do such exercise as

Week 1 – 15-20 repetitions

Day 1 Date:

Exercise	Set 1		Set 2		Borg CR10
	Repetitions	Elastic band colour	Repetitions	Elastic band colour	
Squats					
Stiff-legged deadlifts					
Flies					
Unilateral rows					
Reversed flies					
Lateral pulldowns					
Lateral rise					
Comments					

Fig. 3. Example of the training diary. Participants are instructed to fill in number of repetitions performed, colour of the elastic bands used, and the Borg CR10 rating immediately after finishing the last set of an exercise.

frequently as once or more times a week: How hard do you push yourself?" (I take it easy without breaking into sweat or losing my breath, I push myself so hard that I lose my breath and break into sweat, I push myself to near exhaustion.) Index score

- Work status and social security benefits status with response options: Employment status (full-time employee, part time employee [stated in percent employed], unemployed, retired, student, other, line of work [specify]), Social security benefits (reported sick [stated in percent and duration], work assessment allowance, disability pension [stated in percent and duration], other, not relevant).
- Patient-rated health status is assessed through the question "How is your health at the moment?", with response options poor, not so good, good, very good [41].
- Use of analgesics assessed by the two questions "Have you used analgesics for your back pain the last week" (yes/no), and "Have you used any other medications during the last week" (yes/no), "If yes, which kind of analgesics do you use".
- Duration of current LBP: < 3months, 3–6 months, 1–2 years, and > 2 years.
- Previous history of LBP is assessed by two items "When did you first experience pain of the same character as you have today in the back, which lasted more than a week" (Never experienced pain like this before, less than a year ago, 1–5 years ago, 6–10 years ago, > 10 years ago) and "LBP recurrence" (Never experienced pain like this before, ≤once per year, two to three times per year, > three times per year).
- Description of work is assessed by the question "If you have had paid or unpaid employment, how would you describe your job?", with response options: work that mostly involves sitting (ex: desk work, assembly worker); Work that requires much walking (e.g.: clerk, light industry worker, teacher); Work that requires much walking and lifting (e.g.: mail carrier, nurse, construction worker); heavy physical labor (e.g.: forester, farmer, heavy construction worker).

2.10. Strength tests

Low back strength (Fig. 4) is assessed through maximal voluntary isometric contractions (MVCs) of the back extensors. Participants are instructed to lie on their stomach on a bench with their arms hanging over the edge, and the armpits pressed against the end of the bench. A rigid strap is fastened around the participants' torso from armpit to armpit. The strap is attached to a force transducer on the platform. Four back extensor MVCs, with 1-min rest intervals will be performed. Force is increased in a gradual manner in the first two contractions and in an explosive manner in the two last contractions. Maximal force is to be held for 3 s in all trials. The test leader is pressing the participant's legs down during the test. Maximal force (N) and rate of force development (N/s) are measured by a force transducer and analyzed using Musclelab software (version 10.3.26.0, Ergotest Technology AS, Langesund, Norway). The highest maximal force value of the four tests, and the highest rate of force development score for the two explosive tests will be used in the analysis.

Handgrip strength (Fig. 5) of the dominant hand is assessed using a hand dynamometer (JAMAR hydraulic hand dynamometer, model J00105). The second narrowest handle position will be used [42]. During testing, subjects sit on a stool with their back against the wall, the upper arm hanging down alongside the body and a 90° flexion in the elbow. Subjects are instructed to squeeze the dynamometer as hard as possible and continue to squeeze until the force starts to decline. Two tests are performed with 1-min rest intervals. A third test is performed if the second test is < 10% different from the first test. The highest value will be used in the analysis.

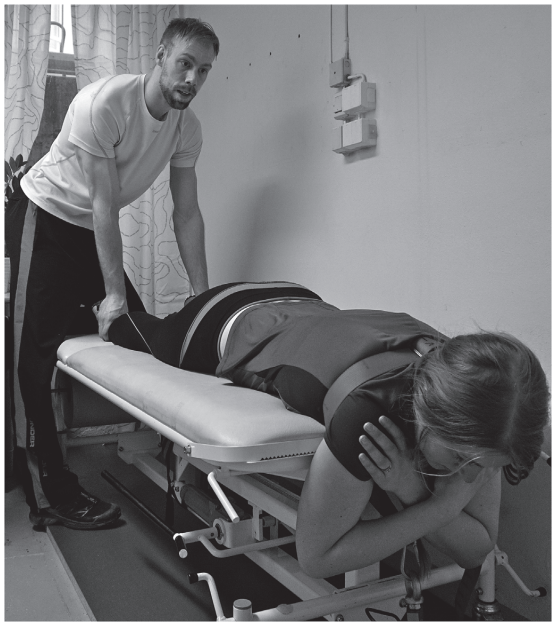

Fig. 4. Setup for maximal voluntary contraction of the back extensors.

Fig. 5. Setup for the grip strength test.

2.11. Compensation and lotteries

Participants will be compensated for travel expenses, and a lottery with prizes will be included to stimulate participation and compliance.

2.12. Sample size

The sample size calculation is done for the mixed linear model described in the Statistical analysis section. With 80 participants (40 in each arm) we will have 80% power to detect a difference of 5 points (0–100) between the groups (alpha level = 0.05), assuming that the marginal standard deviation for ODI is 9 points (based on previous studies [43,44] and unpublished data from the present study population) and that the correlation between baseline and the 12 weeks test, within participants, is 0.5. A ~20–25% dropout rate was expected based on a previous study on patients in the present clinic [45], and studies employing resistance training interventions for chronic LBP patients [4,46]. Thus, we aim to enroll 100 participants.

2.13. Randomization and blinding

Block randomization with unknown block sizes is performed using a web-based program delivered by the Unit for Applied Clinical Research, Norwegian University of Science and Technology. Due to the nature of the study, it is impossible to blind the participants, and the health personnel at the clinic. However, test leaders and researchers conducting the analysis will be unaware of group allocation.

2.14. Data management

All data acquired from objective tests and questionnaires are coded with an identification code, and plotted in excel files stored on a secure network station. Identifying information about the participants, including the signed consent form, is stored in locked filing cabinets kept behind locked doors throughout the study period. All authors have access to the data.

2.15. Statistical analysis

Effect analysis will be performed in accordance with the intention-to-treat principle and per protocol. Effect-differences between groups for the primary outcome will be assessed with mixed linear models. The effect of time and treatment will be included as a fixed effect with levels 'baseline', '12 weeks PRT' and '12 weeks GPE'. Due to randomization, there will be no systematic difference between the groups at baseline. Participant ID will be included as a random effect to account for repeated measurements. Effect differences for secondary outcomes will be assessed with mixed linear models or with multilevel, mixed logistic regression, as appropriate. Per-protocol analysis of the primary outcome will be performed for participants completing more than 60% of the planned PRT sessions.

3. Discussion

Current guidelines recommend physical exercise in the management of chronic LBP, without emphasizing any particular exercise modality [3] This will be the first RCT to assess the effects of resistance training in addition to MDR for patients with chronic LBP.

A limitation is that study participants and therapists could not be blinded. Another limitation is that the same physiotherapists are group leaders of both the PRT and GPE groups, thus a carry-over effect could occur (e.g. by introducing aspects of high-intensity resistance training to the comparative group). However, clear procedures for management of the groups have been made. Since it is voluntary to participate in the study, it is possible that study participants could differ from the ones who do not wish to participate. However, patients included in MDR, but who refuse to participate or are excluded from the study are asked to fill in a questionnaire to assess the generalizability of the results.

A challenge with home-based training interventions is to ensure high compliance and adherence to the prescribed training program [47,48]. In order to increase the likelihood of sufficient adherence and compliance we have included an intensive introduction phase, regular follow-ups to reinforce motivation, and use of training diaries to increase commitment, as recommended [48,49].

In summary, this RCT will provide important knowledge which can improve the future treatment of patients with moderate to severe chronic LBP. The strength training intervention is low-cost, safe, portable, and easy to implement in rehabilitation facilities and as home-training on a large scale. The results will be published in international peer-reviewed journals and presented at national and international conferences.

Authors' contributions

VMI, MSF, OV and PJM conceived the initial idea of the study. All authors contributed in developing the study design and/or training program. VMI wrote the first draft of the article and coordinated the writing of the article. ØS participated in the power calculations and planning of statistical analyses. All authors critically reviewed the manuscript, and approved the article.

Funding

These studies are funded by KLP – Kommunal Landspensjonskasse, and Norwegian Research Council through the FYSIOPRIM project– a research program on physiotherapy in primary care. Performance Health (Akron, OH, USA) provided Theraband® elastic bands for this study. None of the funders had/have any saying in developing the study design, data collection and analysis, decision to publish or preparation of this manuscript or future manuscripts.

Conflict of interest

None declared.

Ethical approval

The studies were approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (no.: 2014/1157).

Acknowledgements

Thanks to employees at St. Olavs Hospital – Department of Physical Medicine and Rehabilitation, Trondheim, Norway, for their enthusiasm and effort in the project. Special thanks to Bitten Kihl Olsen for assistance with recruitment and randomization, Lars Vikan Rise for managing booster sessions, Synnøve Fossheim Karlsen and Atle Melleby Kongsvold for assistance with testings, and to all patients participating in the project.

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Paper 2

European Journal of Sport Science

ISSN: 1746-1391 (Print) 1536-7290 (Online) Journal homepage: http://www.tandfonline.com/loi/tejs20

Multiple-joint exercises using elastic resistance bands vs. conventional resistance-training equipment: A cross-over study

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To cite this article: Vegard M. Iversen, Paul Jarle Mork, Ottar Vasseljen, Ronny Bergquist & Marius S. Fimland (2017) Multiple-joint exercises using elastic resistance bands vs. conventional resistance-training equipment: A cross-over study, European Journal of Sport Science, 17:8, 973-982, DOI: 10.1080/17461391.2017.1337229

To link to this article: http://dx.doi.org/10.1080/17461391.2017.1337229

Published online: 19 Jun 2017.

European Journal of Sport Science, 2017
Vol. 17, No. 8, 973–982, https://doi.org/10.1080/17461391.2017.1337229

Multiple-joint exercises using elastic resistance bands vs. conventional resistance-training equipment: A cross-over study

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Abstract
Previous studies indicate that elastic resistance bands (ERB) can be a viable option to conventional resistance-training equipment (CRE) during single-joint resistance exercises, but their efficacy has not been established for several commonly used multiple-joint resistance exercises. Thus, we compared muscular activation levels in four popular multiple-joint exercises performed with ERB (TheraBand®) vs. CRE (Olympic barbell or cable pulley machines). In a cross-over design, men and women ($n = 29$) performed squats, stiff-legged deadlifts, unilateral rows and lateral pulldown using both modalities. Multilevel mixed-effects linear regression analyses of main and interaction effects, and subsequent *post hoc* analyses were used to assess differences between the two resistance-training modalities. CRE induced higher levels of muscle activation in the prime movers during all exercises ($p < .001$ for all comparisons), compared to muscle activation levels induced by ERB. The magnitude of the differences was marginal in lateral pulldown and unilateral rows and for the erector spinae during stiff-legged deadlifts. In squats the quadriceps femoris activations were substantially lower for ERB. The differences between ERB and CRE were mostly observed during the parts of the contractions where the bands were relatively slack, whilst the differences were largely eliminated when the bands became elongated in the end ranges of the movements. We conclude that ERB can be a feasible training modality for lateral pulldowns, unilateral rows and to some extent stiff-legged deadlifts, but not for the squat exercise.

Keywords: *Resistance training, electromyography, cross-over studies, strength, skeletal muscle*

Highlights
- Elastic resistance bands are relatively inexpensive, versatile and portable, but their efficacy are not well established in several common multiple-joint resistance exercises.
- Elastic resistance bands are a viable option to conventional resistance training equipment for the exercises lateral pull-downs and unilateral rows, as they generally induced similar muscular activations for these exercises.
- Elastic resistance bands induced lower muscular activity for some of the prime movers in the stiff-legged deadlifts and squats.

Introduction

Resistance training induces several health benefits and is recommended for the general population (Garber et al., 2011; Williams et al., 2007) and can be beneficial for persons with musculoskeletal disorders (Kristensen & Franklyn-miller, 2012; Van Eerd et al., 2015). Resistance-training exercises can be categorized as single- or multiple-joint exercises. Multiple-joint exercises (e.g. squat) are generally considered more beneficial than single-joint exercises (e.g. knee extension) as they stimulate several muscle groups, increases overall muscular strength with fewer exercises and more closely resemble activities of daily living (Kraemer & Ratamess, 2004; Ratamess et al., 2009; Schoenfeld, 2010).

It is well documented that resistance training involving conventional resistance-training equipment (CRE) such as free-weights and resistance-training machines is effective in achieving strength gain (Ratamess et al., 2009). Elastic resistance bands (ERB)

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could potentially be used as a feasible alternative for resistance training at smaller outpatient clinics and at home as they are versatile, portable, require little space and relatively cheap.

Studies have found ERB to be similarly effective in activating muscles compared to CRE during single-joint resistance exercises when relative loadings were matched (Aboodarda, Hamid, Muhamed, Ibrahim, & Thompson, 2013; Aboodarda, Page, & Behm, 2016; Aboodarda, Shariff, Muhamed, Ibrahim, & Yusof, 2011; Andersen et al., 2010; Brandt et al., 2013; Jakobsen et al., 2012, 2014; Sundstrup, Jakobsen, Andersen, Jay, & Andersen, 2012). However, we are only aware of two studies investigating muscle activity during multiple-joint exercises with ERB (Calatayud et al., 2015; Sundstrup et al., 2014). Calatayud et al. (2015) found that performing push-ups with ERB provided similar muscular activity in the chest- and shoulder muscles as the bench press. Sundstrup et al. (2014) reported that performing lunges with ERB produced higher muscle activity in the gluteus maximus, hamstrings and erector spinae, but lower activation levels in the quadriceps than lunges with dumbbells and leg press in a training machine.

Despite promising indications, the viability of ERB is not established for several commonly used multiple-joint resistance exercises. In this study we evaluated the muscular activation level in four commonly used multiple-joint exercises: squats, stiff-legged deadlifts, lateral pulldown and unilateral rows – using ERB vs. CRE.

Methods

Study design

In a cross-over design, we evaluated muscular activation levels by electromyography (EMG) in multiple-joint exercises using ERB vs. CRE. EMG data were collected in two successive sessions; for lateral pulldown and unilateral row in session 1, and for squats and stiff-legged deadlifts in session 2. In addition to the primary muscles of interest, we also recorded EMG from several ancillary muscles as multiple-joint exercises activate several muscle groups. All CRE exercises were performed first (3–5 minutes break between exercises) and then ERB exercises were conducted. The corresponding ERB exercise was performed almost an hour later than the CRE exercise. All experimental sessions were separated by at least three days, and participants were instructed to refrain from strength training three days prior to each session. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (no. 2014/1157), and were in accordance with the Helsinki declaration.

Participants

Thirthy healthy persons were recruited for the study, but one woman dropped out between the familiarization sessions and the testing sessions due to lack of time. Thus, 17 men (means ± SD) 25 ± 3 years, height 180 ± 7 cm, weight 75 ± 12 kg, body mass index (BMI) 23 ± 3 and 12 women 25 ± 2 years, height 168 ± 7 cm, weight 60 ± 7 kg, BMI 21 ± 2 completed the study. All participants provided written informed consent prior to engaging in the study.

Exercise equipment

To provide resistance with ERB, TheraBand® elastic bands with resistance ranging from light to very heavy loading (colours: yellow-gold) were used. ERBs were 2 meters, but the actual length used (grip on ERBs and distance to anchor point) was fine tuned for each subject in each exercise to find the correct resistance. When necessary to increase loading, two or more bands were combined. Bands were pre-stretched and never elongated more than 300% of resting length, as recommended by the manufacturer.

To provide CRE, a 20 kg Olympic barbell with free-weights, an adjustable pulley (IT9125, Impulse Fitness, Newbridge, Midlothian, Scotland) and a pulldown machine (PL 9002 Lat pulldown, Impulse Fitness) were used.

Familiarization and matching of relative resistance loading

Two familiarization sessions were used for practicing and testing strength levels prior to the experimental testing sessions. ERB were used in the first familiarization session while CRE were used in the second session. Exercises were demonstrated and thoroughly instructed by the test leader. When a participant was able to execute an exercise correctly, a 10-repetition maximum (RM) test was performed (full dynamic movemements) to match the resistance loadings used for CRE and ERB. The 10-RM loadings were determined within three to five attempts. Individual set-ups were recorded and replicacted during EMG-testing. This included stance, grips, resistance loadings used in CRE, number and colours of ERBs, distance to the anchor points for ERB (pre-stretch). Postures and correct execution of technique were visually controlled. Exercises were conducted in the following order: squats, stiff-legged deadlift, lateral pulldown and unilateral row. Rating of perceived

exhaustion was recorded after each 10-RM test, using the BORG CR10 scale (Shinichiro, Shinya, Fujisawa, & Domen, 2013).

Resistance exercises

Exercises were performed using two seconds for the concentric phase and two seconds for the eccentric phase of the movement. A metronome, set to 60 beats per minute, controlled the pace. The exercises are illustrated in the online figure.

Squats. CRE was provided by an Olympic barbell resting on the participant's trapezius and shoulders. Elastic resistance was applied by standing on the ERB(s) and pulling each end over the shoulder, holding them on the front side of the chest. The exercise was performed with a shoulder-width stance, and started in the standing position. Participants descended to a 90° knee angle, and returned to the initial position to complete one repetition. Primary muscles of interest were the superficial quadriceps muscles (vastus lateralis, vastus medialis and rectus femoris). Gluteus maximus and the erector spinae were considered important supporting muscles.

Stiff-legged deadlifts. CRE was provided by holding a barbell with a shoulder-width overhand grip, and the arms hanging down close to the body. Elastic resistance was provided by anchoring the ERB(s) to a wall-bar (7 cm from the ground), pulling the ERB (s) between the legs and holding each end close to the chest. A shoulder-width stance was used. Participants bent their knees slightly and kept their back straight, pushing the hips back and lowering the upper body down as deep as possible while maintaining a neutral spine position, and return to the starting position to complete one repetition. Shoulders were pulled back during the whole movement. Primary muscles of interest were erector spinae, gluteus maximus, semitendinosus and biceps femoris.

Lateral pull-downs. CRE was provided by a pulldown machine using a bar attached to a cable. The grip width corresponded to twice the bi-acromial distance. The participant was seated with the thighs under a fixed pad, pulling the bar down to the top of the chest, before returning the bar until the arms were fully extended. Elastic resistance was provided by attaching the ERB(s) around the highest bar in a wall-bar, with handles connected to each end of the ERB(s). The participant was seated on the floor with the back against the wall-bar, holding the handles with the palms pointing forward and arms fully extended, and pulling the handles down to shoulder height. The handles were then returned until the arms were fully extended. The primary muscle of interest was latissimus dorsi. Biceps brachii was considered an important supporting muscle.

Unilateral rows. CRE was provided by a cable pulley apparatus. The pulley handle was adjusted to participant's elbow height, while standing. The participant held the handle with the dominant arm, took a step back to ensure that the cable was taut, and placed the non-dominant foot in front of the other and the non-dominant arm on the hip. With upright posture and starting with a straight arm, the participant pulled the handle towards the body until it was lateral to the trunk. The handle was then returned until the arm was fully extended. The participant maintained an erect posture and did not rotate the trunk. Elastic resistance was provided by attaching ERB(s) around the bar in the wall-bar closest to the participant's elbow height. One handle was connected to the ERB(s). The execution of this exercise was otherwise equal to CRE. Primary muscles of interest were latissimus dorsi and deltoideus posterior. Deltoideus medius and biceps brachii were considered important supporting muscles.

Electrode placement and data recording

Disposable electrodes (Blue Sensor, M-00-S, Ambu A/S, Ballerup, Denmark) were attached to the muscles of interest (25 mm inter-electrode center-to-center distance) unilaterally on the side corresponding to the participant's dominant hand. In session one, erector spinae, biceps brachii, deltoideus anterior, deltoideus medius, deltoideus posterior, trapezius descendens, latissimus dorsi, obliquus externus and pectoralis major were recorded. In session two, rectus femoris, vastus lateralis, vastus medialis, biceps femoris, semitendinosus, erector spinae, gluteus maximus and obliquus externus were recorded. Electrodes were placed in accordance with the SENIAM guidelines (http://www.seniam.org), except for those on the latissimus dorsi as no guidelines were available for this muscle. These electrodes were placed approximately one cm lateral to the inferior border of the scapula in the presumed underlying direction of the muscle fibres (Lehman, Buchan, Lundy, Myers, & Nalborczyk, 2004). The skin was gently shaved and cleaned with alcohol prior to electrode placement to minimize resistance between the electrodes (Hermens, Freriks, Disselhorst-Klug, & Rau, 2000).

EMG signals were recorded through shielded wires to the EMG system (MuscleLab 4020e, Ergotest

Technology AS, Langesund, Norway). In order to reduce external noise a pre-amplifier with common mode rejection ratio of 100 dB was used. The signal was filtered with a fourth-order Butterworth band-pass filter (8–600 Hz). Finally, a hardware circuit network converted the filtered EMG signals (frequency response of 0–600 kHz, averaging constant of 100 ms, and total error of ±0.5%). The root mean square signal was then sampled at 100 Hz with a 16-bit A/D converter (AD637).

Normalization of EMG recordings

At the start of each test session, two maximal voluntary isometric contractions (MVCs) were conducted for each of the muscles which were to be monitored in that session in order to induce a maximal EMG response. The MVCs for the erector spinae and all the quadriceps muscles were performed in accordance with suggested procedures (Konrad, 2005), while MVCs for the remaining muscles were standardized based on test set-ups used in our lab. Each MVC lasted five seconds and participants were instructed to gradually increase to maximum force. Standardized verbal encouragements were given. One minute of rest was given between the two MVCs, and the trial with the highest average one second EMG activity epoch was used to normalize the EMG recordings of the resistance exercises.

EMG and movement recordings

The EMG recordings were collected while the participants performed three repetitions, using 10-RM loading, for each of the exercises. Prior to each CRE exercise, a warm-up set of 50% of the 10-RM loading was performed. A linear encoder (100 Hz sampling frequency, 0.075 mm resolution; ET-Enc-02, Ergotest Technology AS, Langesund, Norway) synchronized with the EMG data was used in order to detect movement and identify the different lifting phases. The string of the encoder was attached to a finger on the participants' dominant hand during all exercises.

EMG and motion analysis

EMG data were analyzed using MuscleLab v8.13 (Ergotest Technology AS, Langesund, Norway). The 10–90% range of motion for each contraction phase was used in the analyses, and the time window for each of the concentric and eccentric phases was divided into two phases according to the movement amplitude – i.e. concentric phase one (C1) and two (C2), and eccentric phase one (E1) and two (E2). Three repetitions were performed for each exercise where the mean EMG activity for each of the four phases (C1, C2, E1 and E2) was calculated as follows: for the concentric phases, repetition two and three were averaged and used for analyses, while repetition one and two were averaged and used for the eccentric phases, as it was difficult to determine the exact start and stop for concentric contraction one and eccentric contraction three, respectively. The averaged EMG results were then normalized by the maximal EMG recordings from the MVCs, and are reported as a percentage of the maximal EMG activity.

Statistical analyses

Statistical analyses were conducted in STATA/IC 13.1 for windows (StataCorp LP, USA). The overall difference between resistance modalities (ERB and CRE) and interaction between resistance modalities and contraction phases for each muscle in all exercises were assessed using multilevel mixed-effects linear regression models. Normalized EMG was the dependent variable, while contraction phase and resistance modality as well as their interaction term were used as fixed effects, and participant identity as a random effect (allowing participants to start out differently). If a main effect or interaction effect was discovered, we performed *post hoc* analyses to determine where the differences were located. Significance level (two-tailed) was set to $p < .05$ for the main effect and interaction effect, while $p < .01$ was considered significant for the *post hoc* analyses considering the number of tests performed. Furthermore, all EMG variables as well as regression residuals were visually inspected for normality of distribution, using qq-plots and histograms, resulting in log-transformations of all variables. For presentation of results, the variables were back-transformed to simplify interpretation.

We used a forward approach to search for confounders, meaning that we started with simple regression models without any adjustments, and then adding relevant covariates (i.e. sex, gender and age) to see if the regression coefficients changed. Covariates were considered confounders if the regression coefficient changed more than 10%.

Paired *t*-tests were used to check for differences in perceived exertion (Borg CR10 scale) between modalities and $p < .05$ was considered statistically significant.

Results

No confounding effects of sex, BMI or age were observed. Thus, we did not adjust for baseline characteristics.

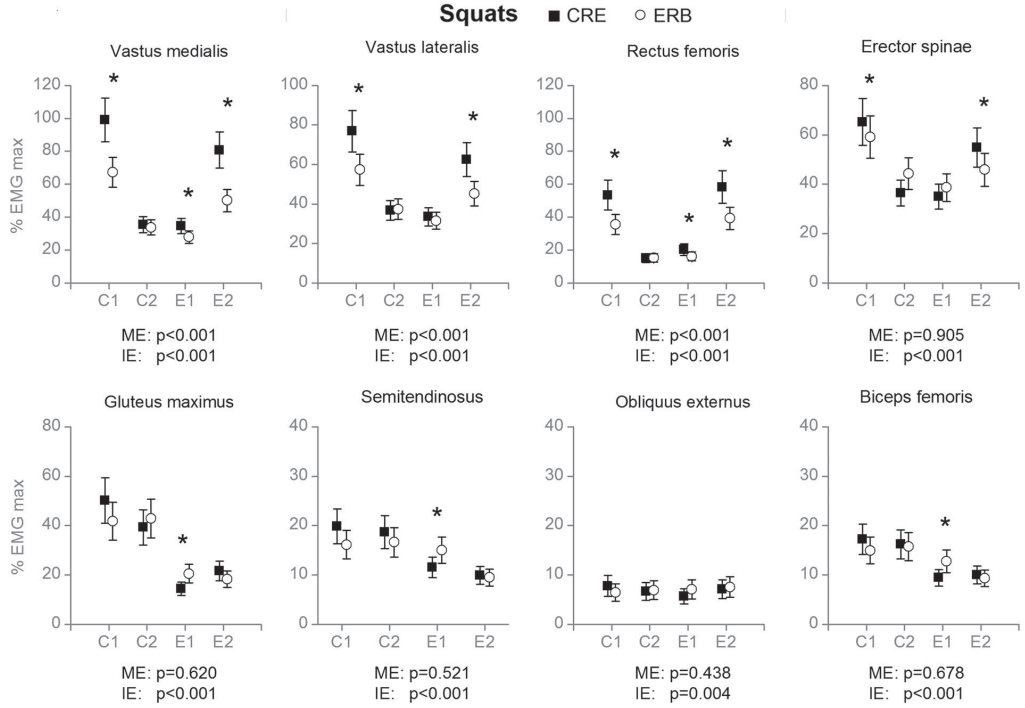

Figure 1. Normalized EMG activity (% EMG max) during squats with CRE vs. ERB. *p*-values for main effect (ME) of exercise modality, and interaction effects (IE) between exercise modality and contraction phases are presented. Asterisk indicate difference between exercise modalities ($p < .01$). Note different scaling of the *y*-axes. Values are means with 95% CI. C1 and C2: concentric phase one and two. E1 and E2: eccentric phase one and two.

For the squat exercise (Figure 1), significant main effects of training modality in favour of CRE were found for vastus medialis, vastus lateralis and rectus femoris. Interaction effects between exercise modality and contraction phases were displayed in all muscles. *Post hoc* analysis showed significantly higher muscle activation with CRE in C1, E1 and E2 for vastus medialis and rectus femoris, C1 and E2 for vastus lateralis and erector spinae. ERB produced higher activation in E1 for gluteus maximus, semitendinosus and biceps femoris.

For the stiff-legged deadlifts (Figure 2), significant main effects of modality were found in favour of the CRE exercise for all muscles except rectus femoris. Interaction effects were observed in all muscles except for the quadriceps muscles, i.e. vastus medialis, vastus lateralis and rectus femoris. *Post hoc* analysis showed significantly higher muscle activation with CRE in C1 and E2 for erector spinae, gluteus maximus, semitendinosus and obliquus externus, and in C1, C2 and E2 for biceps femoris.

For the lateral pulldown (Figure 3), significant main effects of modality were observed in favour of CRE for latissimus dorsi, biceps brachii, deltoideus posterior and pectoralis major, while there was a main effect in favour of ERB for the obliquus externus. Interaction effects between exercise modality and contraction phase were displayed in all muscles except for latissimus dorsi and deltoideus medius. *Post hoc* analysis showed higher muscle activation with CRE in C1 and E2 for latissimus dorsi, biceps brachii and pectoralis major, and C1 for deltoideus posterior, deltoideus anterior and trapezius descendens. ERB produced higher activation in all phases for obliquus externus and E2 for deltoideus anterior.

For the unilateral row (Figure 4), significant main effects of modality in favour of CRE were displayed for latissimus dorsi, deltoideus posterior, deltoideus medius biceps brachii, obliquus externus and trapezius descendens. Interaction effects were displayed for latissimus dorsi, deltoideus posterior, biceps brachii, erector spinae, obliquus externus and pectoralis major. *Post hoc* analysis showed significantly higher muscle activation with CRE in C1 and E2 for latissimus dorsi and deltoideus posterior, C1 and E1 for obliquus externus, C1 for deltoideus

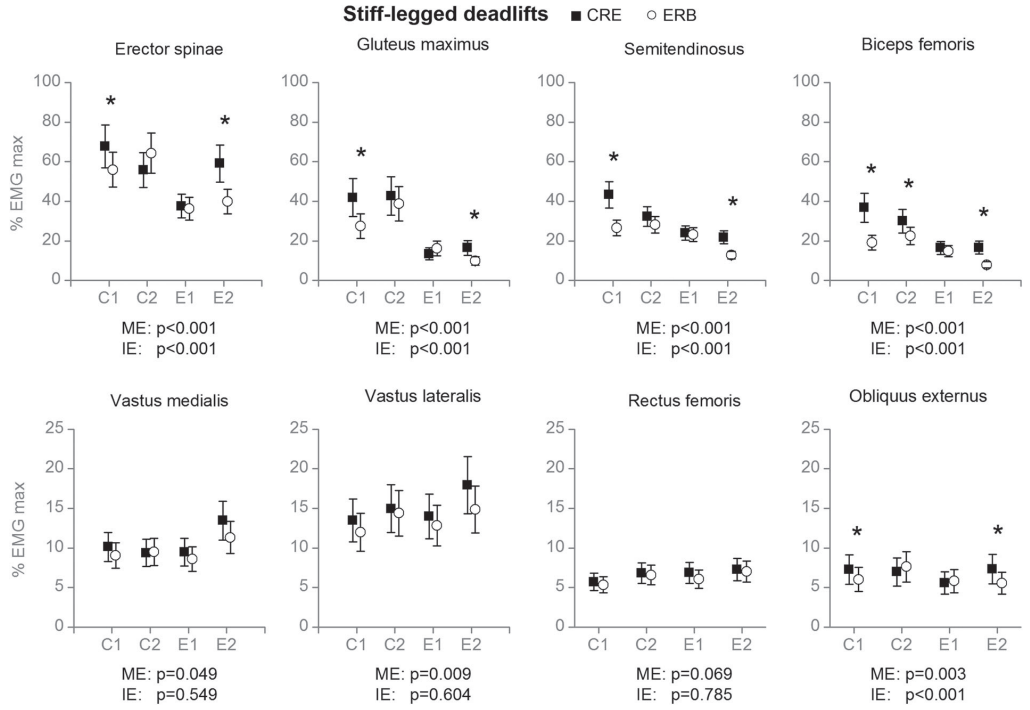

Figure 2. Normalized EMG activity ((% EMG max) during stiff-legged deadlifts with CRE vs. ERB. *p*-values for main effect (ME) of exercise modality, and interaction effects (IE) between exercise modality and contraction phases are presented. Asterisk indicate difference between exercise modalities ($p < .01$). Note different scaling of the *y*-axes. Values are means with 95% CI. C1 and C2: concentric phase one and two. E1 and E2: eccentric phase one and two.

medius and biceps brachii, and E2 for pectoralis major.

Rating of perceived exertion following the 10-RM tests of all exercises is presented in the online table. A significantly higher score was reported for stiff-legged deadlifts with CRE (7.7 vs. 6.8, $p = .024$). A trend for higher score was observed for squats with CRE (7.5 vs. 6.9, $p = .92$).

Mean (SD) loadings used in the CRE exercises were for men: 76.9 (14.4) kg in squats, 67.6 (23.3) kg in stiff-legged deadlifts, 50.5 (9.5) kg in lateral pulldown, and 31.8 (8.0) kg in unilateral rows, and for women: 50.6 (11.5) kg in squats, 51.5 (13.5) in stiff-legged deadlifts, 33.8 (8.3) kg in lateral pulldown, and 23.8 (5.1) kg in unilateral rows.

Discussion

This is the first study comparing ERB with CRE for several commonly used multiple-joint exercises. We found that ERB overall provided marginally lower muscle activation levels relative to CRE for the prime movers in lateral pulldown and unilateral rows, somewhat lower for stiff-legged deadlifts and considerably lower for squats. The differences between ERB and CRE were mostly observed during the parts of the contractions where the bands were relatively slack, whilst the differences were largely eliminated when the bands became elongated at the end range of the movements.

The findings for lateral pulldown and unilateral rows are partially consistent with findings by Calatayud et al. (2015) who reported that push-ups performed with ERB were equally effective to bench press in activating the prime movers (pectoralis major and deltoideus anterior). However, as push-ups is a relatively heavy bodyweight exercise, the ERB component would account for a smaller fraction of the total resistance than in our study which could explain the difference between Calatayd et al. and our study. Nevertheless, as the overall magnitude of the differences was quite small for all prime movers in both lateral pulldown (11–15%) and unilateral row (11–13%), ERB can likely be a viable training modality for these exercises.

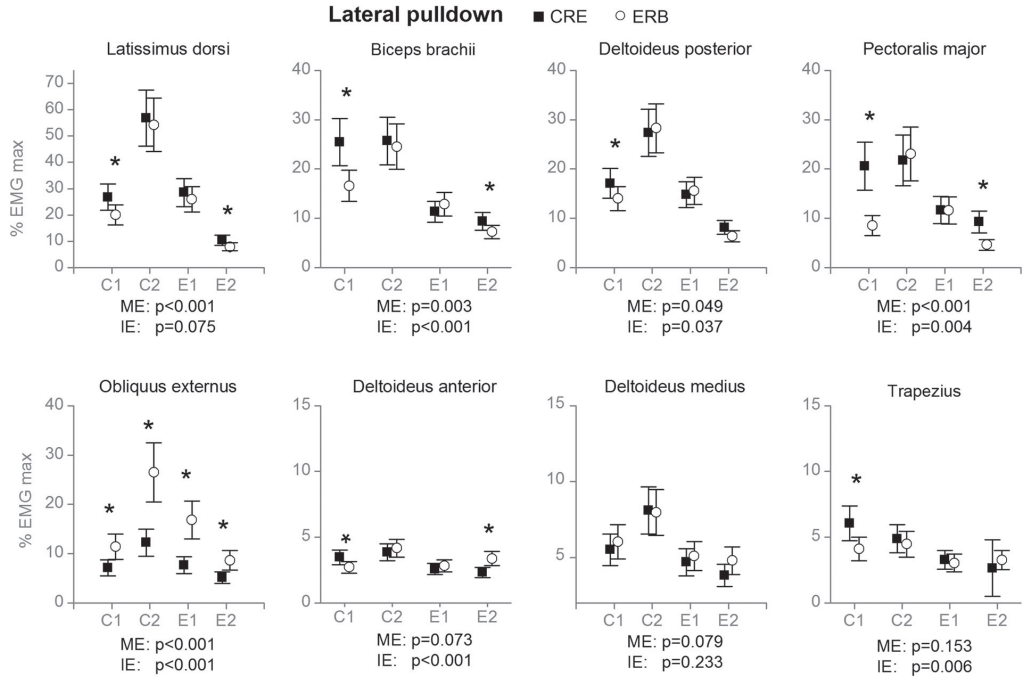

Figure 3. Normalized EMG activity (% EMG max) during lateral pulldown with CRE vs. ERB. *p*-values for main effect (ME) of exercise modality, and interaction effects (IE) between exercise modality and contraction phases are presented. Asterisk indicate difference between exercise modalities ($p < .01$). Note different scaling of the *y*-axes. Values are means with 95% CI. C1 and C2: concentric phase one and two. E1 and E2: eccentric phase one and two.

Our findings of inferior activation of the primary movers during stiff-legged deadlifts and particularly squats with ERB are consistent with the findings by Sundstrup et al. (2014) who reported lower activation of the prime mover (quadriceps muscles) with ERB- vs. CRE lunges and unilateral leg press. Still, Sundstrup et al. concluded that ERB was a viable option, as ERB induced higher or similar activation of other important muscles (gluteus, erector spinae and hamstring muscles). Partly in line with this, ERB and CRE induced similar activation levels for important supporting muscles during squats in our study (i.e. gluteus maximus and erector spinae). Nevertheless, the substantially lower quadriceps activation with ERB suggests that CRE should be preferred for squats. Additionally, CRE should be the favoured training modality for stiff-legged deadlifts, but depending on the goal of training, ERB could be utilized as a viable option in this exercise since the magnitude of the difference in erector spinae activation was relatively small (11%).

Differences in EMG between ERB and CRE in our study were generally observed when ERBs were least elongated (C1 and E2) while activation levels were quite similar in the end ranges. This is probably a direct consequence of the difference in tensile force throughout the range of motion with ERB, whereas CRE provided constant external resistance. Other studies investigating ERB multiple-joint exercises did not investigate activation levels related to elongation of the ERB (Calatayud et al., 2015; Sundstrup et al., 2014). However, our finding corresponds with studies on single-joint exercises (Aboodarda et al., 2013; Jakobsen et al., 2012, 2014). From a practical perspective, it could be useful to perform ERB exercises with a considerable pre-stretch to reduce the difference in external loading throughout the range of motion, when this is feasible (e.g. unilateral row). However, there is limited opportunity for manipulating the amount of pre-stretch in exercises where the height of the person is the limiting factor (e.g. squat).

Contrary to the upper-body exercises, it appeared challenging to reach high activation levels for some important muscles with ERB in stiff-legged deadlifts and particularly squats. For stiff-legged deadlifts, in particular, there were differences in the execution of CRE and the comparative ERB exercise. While the

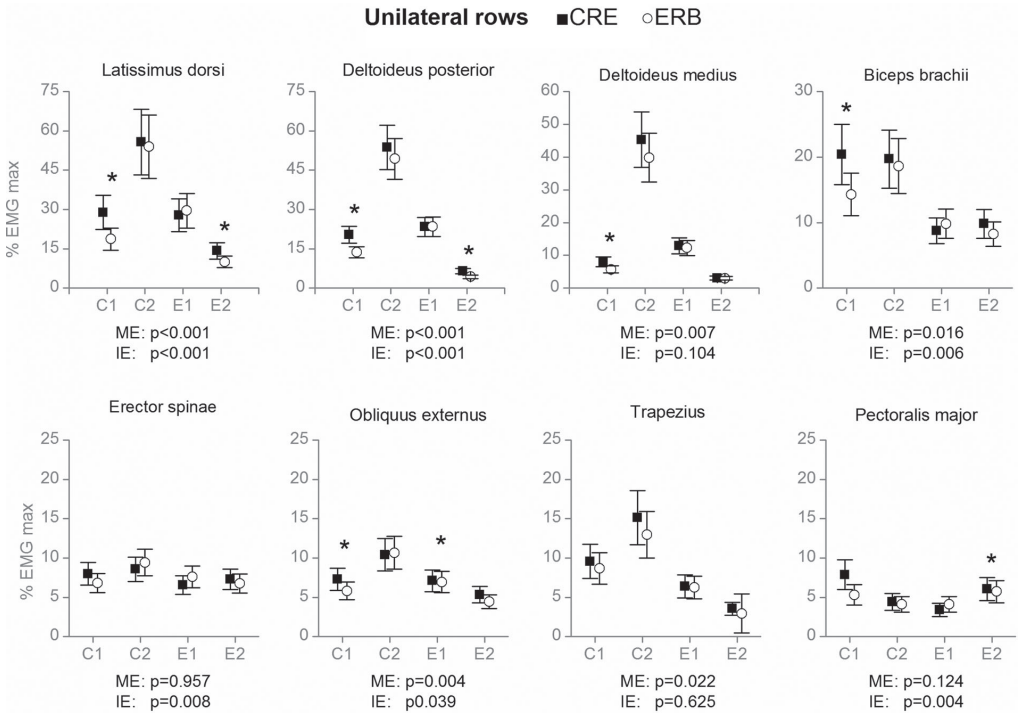

Figure 4. Normalized EMG activity (% EMG max) during unilateral rows with CRE vs. ERB. *p*-values for main effect (ME) of exercise modality, and interaction effects (IE) between exercise modality and contraction phases are presented. Asterisk indicate difference between exercise modalities ($p < .01$). Note different scaling of the *y*-axes. Values are means with 95% CI. C1 and C2: concentric phase one and two. E1 and E2: eccentric phase one and two.

weighted barbell provided a gravitational downward pull, the ERB was attached behind the participants, altering the biomechanical requirements of the exercise, which likely affected EMG activity. Additionally, both squats and stiff-legged deadlifts are versions of powerlifting exercises in which very heavy weights can be lifted (Garhammer, 1993) and it could be that CRE is better for handling such heavy loads, perhaps due to the considerable difference in external loading in the phases where the bands are slack. Still, one study reported similar improvements in isometric squat- and back extension strength after eight weeks of resistance training which included the exercises squats and stiff-legged deadlifts with ERB vs. CRE (Colado et al., 2010). However, as the programme included several other exercises it is difficult to ascribe the findings to these two exercises. The ERB training in that study was performed with TheraBand® Exercise stations – resulting in less diversity in exercise movements across the modalities. This was not done in this study, as it would have been contradictory to the overall aim of the study – to assess ERB as an easy to use and portable resistance-training modality. Nevertheless, more similar exercise set-ups between modalities might have reduced the differences in muscular activation.

Ratings of perceived exertion using the Borg CR10 scale have been found to give an adequate reflection of the muscular activation of ERB and CRE (Andersen et al., 2010; Brandt et al., 2013). Similar perceived exertion in the use of ERB and CRE was reported for lateral pulldown and unilateral rows. The finding of stiff-legged deadlifts and squats being more exhausting for CRE (only a trend for squats) is in line with higher activation of the prime movers for these exercises. Nevertheless, it could be that the lower perceived exertion with ERB could make these exercises more tolerable for patients and the general population.

Limitations

Some limitations should be acknowledged. Only young, healthy individuals were recruited. The results can therefore not necessarily be generalized

to other populations. Furthermore, it is challenging to determine the exact 10-RM with ERB, which creates some uncertainty about the matching of resistance loadings. However, this approach is used in previous studies (Aboodarda et al., 2011, 2013; Andersen et al., 2010; Calatayud et al., 2015; Jakobsen et al., 2012, 2014; Sundstrup et al., 2012, 2014), and we are unaware of a better procedure to match resistance loadings. To overcome this issue in practical settings, we recommend prescribing repetitions in wide interval ranges (e.g. 6–12, 10–15). For logistical reasons, the order of testing was not randomized (CRE performed before ERB); however, as participants only performed three repetitions with 10-RM loadings and the time between the two equivalent CRE and ERB exercises was close to an hour, we consider it unlikely that the activation levels were substantially affected. Finally, surface EMG only provides an estimate of neural activation, and there is always a possibility for cross-talk from nearby muscles despite precautions during electrode placements (Farina, 2006). Importantly, EMG data were collected in the same session for all relevant comparisons – without removing and replacing electrodes, with a standardized movement velocity.

Conclusion

In conclusion, ERB generally produced similar muscular activation levels as CRE in the end ranges where the bands were stretched, while somewhat lower activation levels were observed for ERB when the bands were relatively slack. As a training modality, ERB seems to be a viable option to CRE for the exercises' lateral pull-downs and unilateral rows, but not so much for stiff-legged deadlifts and particularly squats. Nevertheless, ERB provided largely similar activation levels of the erector spinae in stiff-legged deadlifts and for gluteus maximus and erector spinae in squats, which could make the exercises viable for patients (e.g. low back pain) who wish to strengthen their lower back and hip extensors.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

This work was supported by KLP – Kommunal Landspensjonskasse; The Norwegian Research Council through the FYSIOPRIM project – a research program on physiotherapy in primary care.

Supplemental data

Supplemental data for this article can be accessed at https://doi.org/10.1080/17461391.2017.1337229.

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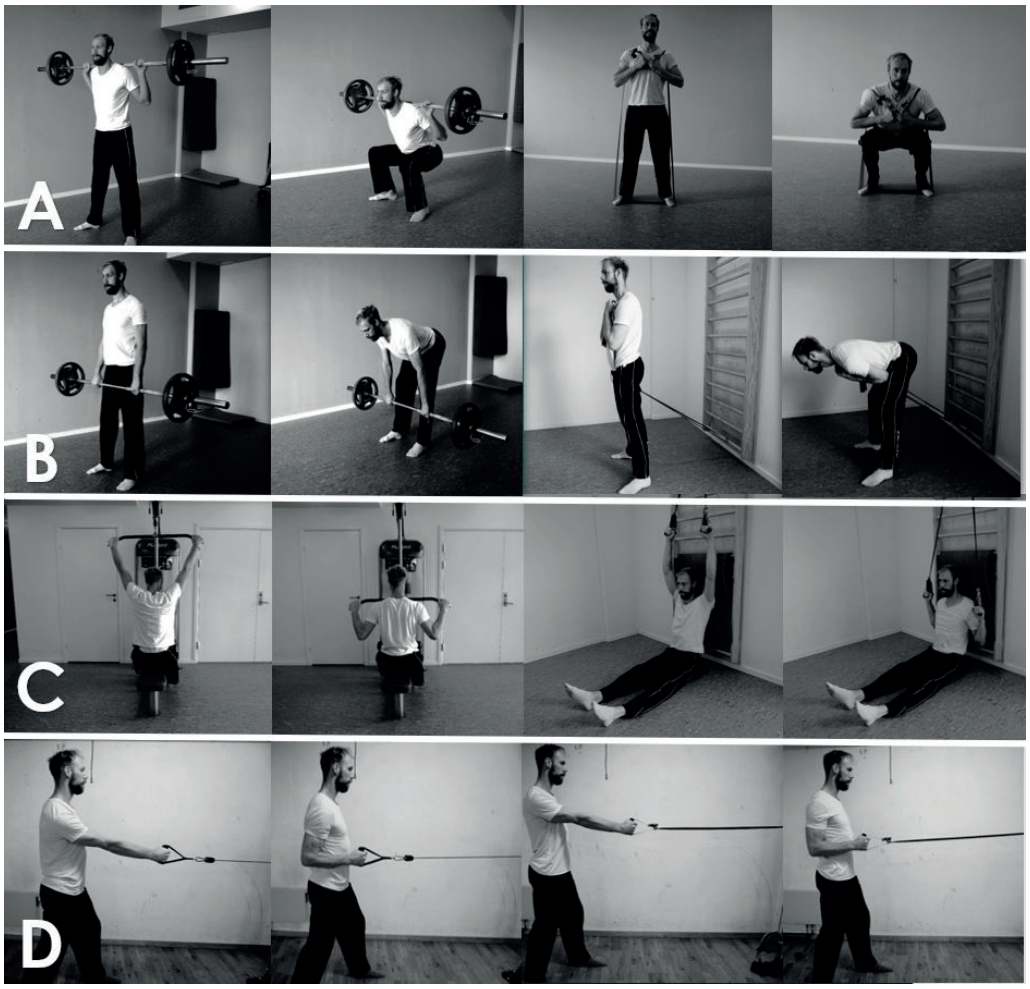
Online appendix

Online table: BORG CR10 scores immediately after 10-RM tests. Values are presented as mean (95% confidence interval).

Exercises	Elastic resistance	Conventional resistance	P-value
Squats	6.9 (6.2-7.6)	7.5 (7.0-8.1)	0.092
Stiff-legged deadlifts	6.8 (6.1-7.5)	7.7 (7.1-8.3)	0.024
Lateral pulldown	7.9 (7.3-8.4)	7.9 (7.4-8.4)	0.771
Unilateral rows	7.5 (7.0-8.1)	7.6 (7.0-8.2)	0.793

Abbreviation: RM=repetition maximum



Online Fig. Resistance exercises performed with conventional resistance equipment and elastic resistance bands: A) Squats, B) Stiff-legged deadlifts, C) Lateral pulldown, D) Unilateral rows.

Paper 3

Resistance band training or general exercise in multidisciplinary rehabilitation of low back pain? A randomized trial

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Abstract

Multidisciplinary biopsychosocial rehabilitation has been recommended for chronic low back pain (LBP), including physical exercise. However, which exercise-modality that is most advantageous in multidisciplinary biopsychosocial rehabilitation is unclear. In this study, we investigated whether multidisciplinary biopsychosocial rehabilitation could be more effective in reducing pain-related disability when general physical exercise was replaced by strength training in form of progressive resistance training using elastic resistance bands. In this single blinded (researchers), randomized controlled trial, 99 consenting adults with moderate to severe non-specific LBP were randomized to three weeks multidisciplinary biopsychosocial rehabilitation with either general physical exercise or progressive resistance band training, and were then instructed to continue with their respective home-based programs for nine additional weeks, in which three booster sessions were offered. The primary outcome was between-group difference in change on the Oswestry Disability Index (ODI) at 12-weeks. Due to early dropouts, data from 74 participants (mean age: 45 years, 57% women, mean ODI: 30.4) were obtained at baseline, 61 participants were followed-up at 3-weeks, and 46 at 12-weeks. There were no difference in the change in ODI score between groups at 12 weeks (mean difference 1.9, 95% CI: -3.6, 7.4, p=0.49). Likewise, the change in secondary outcomes did not differ between groups, except for the patient-specific functional scale (0-10), which favored general physical exercise (mean difference 1.4, 95% CI: 0.1, 2.7, p=0.033). In conclusion, this study does not support that progressive resistance band training compared to general physical exercise improve outcomes in multidisciplinary biopsychosocial rehabilitation for patients with non-specific LBP.

Introduction

Low back pain (LBP) is one of the most significant contributors to disability worldwide[1]. The current evidence indicates that a multidisciplinary biopsychosocial rehabilitation (MDR) approach is slightly more effective than a unimodal approach for treating and managing chronic LBP[2-4]. Physical exercise is usually included in MDR[2], but numerous exercise-modalities exist and we are not aware of studies investigating whether a particular form of exercise can improve outcomes from MDR more than another. In the specialist health services in Norway, the physical exercise-component of MDR for LBP typically entails an introduction to various physical activities and exercises based on the patients` interests and the therapists` recommendations (i.e. general physical exercise, GPE)

For persons with chronic LBP, exercise has been found to provide a small, but significant effect on function and pain[5-7]. However, Hayden and colleagues found strength training to be more effective for improving function in chronic LBP patients than aerobic training, mobilizing exercises and coordination exercises, and other specific exercise therapies (e.g. McKenzie exercise therapy and functional restoration)[6]. Similarly, Searle and colleagues found strength and coordination programs to be most effective, while no beneficial effects were demonstrated for aerobic and combined exercise programs[7]. It has also been suggested that strength training should be performed as progressive resistance training, starting out with low load and high number of repetitions, and progressing to high load and low number of repetitions[7-9]. This way of exercising has been recognized as a promising treatment for other musculoskeletal disorders as well[8,10-13].

Resistance training machines and free weights are commonly used for progressive resistance training, but such equipment is expensive, space-consuming and not easily available for all patients. A viable alternative that easily can be implemented in home-based programs is training with elastic resistance bands (ERB). Studies have showed that elastic

resistance bands can provide similar muscle activation to exercises performed with resistance training machines or free weights[14,15].

This randomized clinical trial (RCT) investigated whether a three-week MDR program could be more effective in reducing LBP-related disability when GPE was replaced with progressive resistance training using ERBs. After the MDR program, the respective exercise-modalities were continued and performed as home-based training for nine weeks. We hypothesised that MDR with ERB would reduce LBP-related disability, as well as other health-related outcomes, more than MDR with GPE in patients with chronic LBP.

Material and methods

Study design, setting and participants

The study protocol has been published elsewhere[16]. In brief, the study is a single-blinded (researchers), single-center RCT. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (REK midt 2014/1157) and registered in ClinicalTrials.gov (NCT02420236). The trial is reported in accordance with the CONSORT statement[17].

The study was carried out in an outpatient hospital back and neck pain clinic (Department of Physical Medicine and Rehabilitation, St. Olavs Hospital, Trondheim University Hospital, Norway). Study participants were recruited from the clinic. A physician at the clinic assessed study eligibility during a routine screening session. Eligible patients willing to participate in the trial were randomized (1:1, block-randomization with unknown block sizes varying between 10 and 20, third-party) to the ERB-intervention group or the comparative GPE-group (see figure 1 for flow chart). Exercise was only one of the components in the more comprehensive MDR program (see below). All patients received both

written and oral information, and signed an informed consent prior to participating in the study.

Inclusion criteria for the study were as follows: 1) chronic (≥ 3 months) or recurrent (≥ 2 periods with duration ≥ 4 weeks the past year) non-specific LBP, 2) strongest LBP the last two weeks ≥ 4 on numerical pain rating scale (NRS: 0-10), and 3) age 16-70 years. Patients were excluded from the study if they: 1) had a severe somatic condition (e.g., cancer, inflammatory rheumatic disease, severe osteoporosis) or psychiatric condition that would severely impair group functioning, 2) had insufficient comprehension of Norwegian language to participate in group sessions and fill out questionnaires, 3) were awaiting surgery of the lumbar spine, 4) had alcohol or drug abuse, 5) had an ongoing compensation claim or were applying for disability pension due to LBP, 6) had been engaged in high-intensity resistance training on a regular basis during the last 6 months, or 7) had contra-indications for high-intensity resistance training (e.g., shoulder complications severely limiting the ability to conduct the training program). Additionally, physicians only referred participants to MDR if considered beneficial based on the clinical history, the motivation of the patient, and whether sufficient treatment had been attempted in primary care. The physician also compared MRI results with findings from the clinical examination. Patients with a dominating pain mechanism requiring specific treatment (e.g. surgery) or further medical examination were not included in the study.

Patients who participated in the usual MDR program, but declined to participate in the study or were excluded from study participation, were asked to participate in a reference group to assess the generalizability of the results. Participants in this group signed informed consent and completed the baseline questionnaire only.

Intervention and comparative group

More detailed information, including illustrations of the ERB-exercises, is available in the study protocol[16]. All participants were scheduled for MDR at the clinic. The MDR involved two full weeks (five days per week) of rehabilitation with a one-week break in between, and included patient education, GPE, and group discussions and individual meetings with therapists [16]. Participants in the ERB-group performed three sessions of ERB per week during the three-week MDR period (supervised in week one and three) and were instructed to perform home-based ERB three times per week in the nine weeks after completion of the MDR program (12 weeks in total). The exercises used were squats, stiff-legged deadlifts, flies, unilateral rows, reversed flies, unilateral shoulder abduction, and lateral pulldown[16]. All exercises were performed with Theraband® Elastic resistance bands (Performance Health, Akron, OH, USA). The resistance loading was progressively increased during the intervention, with the program sequenced into four periods, week 1-2: two sets of 15-20 repetitions, week 3-5: two sets of 12-15 repetitions, week 6-8: three sets of 10-12 repetitions, and week 9-12: three sets of 8-10 repetitions. All sets were to be performed to failure, thus the intensity of the first and last period corresponds to approximately 60-70% and 75-80% of one repetition maximum, respectively[18]. Participants were instructed to record all ERB-sessions in a standardized training diary[16].

Participants in the comparative group performed GPE-sessions four times in week one and five times in week three, as practiced in the ongoing MDR program at the clinic, and were recommended to stay active during the week in-between. Participants in the ERB-group also received one session of GPE in week one and two sessions in week three to have the same exercise frequency as the comparative group. The GPE-sessions included activities such as endurance training, ball games, body awareness, stretching, circle training, walks, relaxation techniques and low-intensity resistance exercises. After completing the MDR at the clinic, the

patients in the comparative group were provided with a home-based GPE-program based on their interests and the physiotherapists' recommendation.

All participants in the ERB and GPE groups were offered three booster sessions in the period between the end of the MDR program and the 12-week follow-up. These sessions focused on improving technique, making individual adjustments (including resistance loadings for the ERB-group), and ensuring adherence and compliance to the exercise programs.

Outcome measures

Questionnaires and strength tests were administered at baseline, at completion of the MDR (end of week 3), and after the home-based exercise period at week 12. The primary outcome was between-group difference in change on the Oswestry Disability Index (ODI: 0-100, higher score indicate more disability)[19] at 12-weeks follow-up. Secondary outcomes included between-group difference in change on the ODI at 3-weeks follow-up, and differences at 3- and 12-weeks follow-up for LBP-intensity (current, and worst pain last 2 and 4 weeks; Numerical Pain Rating Scale, NRS: 0-10, higher score indicate more pain[20]), number of additional pain sites indicated on a pain drawing (0-11)[21], work ability (one item from the Work Ability Index: current workability vs. lifetime best, WAI: 0-10, higher score indicate better work ability)[22], anxiety and depressive symptoms assessed with the 25-item Hopkins Symptom Checklist (HSCL-25: 1-4, higher score indicate more symptoms)[23], health-related quality of life assessed with EQ-5D-5L (0-1, higher score indicate better health)[24], fear-avoidance beliefs related to physical activity and work assessed with the Fear Avoidance Beliefs Questionnaire (FABQ physical; 0-24, and FABQ work; 0-42, higher score indicate worsening)[25], patient specific functional limitation assessed with the Patient-Specific Functional Scale (PSFS: 0-10, higher score indicate more limitation)[26], patient-rated treatment

efficacy at 3 and 12 weeks using the Global Rating of Change Scale (GRC: 1-7, very much improved to very much worse)[27], as well as isometric back extension- and grip strength[16].

Sample size

The sample size calculation was done for the mixed linear models-analysis of the primary outcome, ODI. The minimal detectable change for ODI has been proposed to be 9.5 (0-100 scale)[28], but as both groups participated in a comprehensive MDR program in the specialist care, the sample size was calculated to detect a 5-point difference between groups. With a power of 80% (α=0.05) and a marginal standard deviation of 9[29,30], a study sample of 100 participants, accounting for 20 dropouts, was required.

Statistical analysis

Primary and secondary outcomes were analyzed in accordance with the intention-to-treat principle. The between-group differences (except global rating of change) were assessed using mixed linear model[31]. All outcomes were analyzed separately using the outcome variable as the dependent variable with an interaction term of time (baseline, 3 weeks, 12 weeks) and intervention (GPE, ERB). Baseline level for the outcome variables was set by merging data from the two groups[32]. To account for baseline variation and regression to the mean we included a random intercept for participant (allowing different levels for participants in the analysis). The estimates from the mixed linear models were used to compute Cohens d effect sizes for changes from baseline to 12-weeks, within and between groups. 0.2, 0.5 and 0.8 were considered small, medium and large effects, respectively. Global rating of change was dichotomized as improved (score 1 and 2) and not improved (score 3-7)[33] and analyzed using multilevel, mixed-effect logistic regression. The EQ-5D score was converted to an

indexed value (ranging from 0 (death) to 1 (perfect health) using a crosswalk calculator, based on Danish national scoring algorithms[34].

Per-protocol analysis was performed by excluding participants in the ERB-group who trained less than 60% of the total sessions. A sensitivity analysis was performed by dichotomising all participants according to strength gain, using median percentage increase in back extension strength as cut-off. The per-protocol and sensitivity analyses were only done for the primary outcome. In these scenarios, baseline data was not merged. We also adjusted for fear avoidance related to physical activity in the sensitivity analysis.

T-tests or Fisher's exact tests, as appropriate, were used to assess differences in baseline characteristics between study participants and reference participants, and differences between participants completing the study and participants dropping out. Results with p-values <0.05 (two-tailed) was considered statistically significant. STATA/IC 13.1 (StataCorp LP, USA) and R version 2.13.1 (the R foundation, Austria) was used for analyses.

Results

Recruitment started in December 2014 and continued until September 2016. The follow-up data collection ended January 2017. Participant flow throughout the study is presented in figure 1. Out of 99 included participants, 74 participants were tested at baseline and included in the intention to treat analysis. Sixty-one and 46 participants were followed up at 3- and 12-weeks, respectively. The drop-out rates from inclusion and from baseline to 12 weeks were 53.5% and 37.8%, respectively.

FIGURE 1 ABOUT HERE

TABLE 1 ABOUT HERE

Participants` characteristics

Table 1 shows characteristics of the study sample at baseline. The mean age was 45 years (SD 12) and the majority (79%) had experienced LBP for more than one year. Seventy-nine percent were employed, 58% were sick listed, 22% had disability pension or were on work assessment allowance (a work reimbursement option in Norway after having been on sick leave for one year), and 52% had used analgesics for their LBP during the last week. The leisure time exercise index (i.e. an index from 0.78-3 based on the questions "How frequently do you exercise", "How long does each session last", and "How hard do you push yourself") indicated that the participants were moderately active in their leisure time[35].

Overall, the mean ODI score (30.4, SD: 11.4) and the NRS score for the last two weeks (6.8, SD: 2.0) indicated that the participants had moderate disability and moderate to severe pain at baseline. No significant baseline differences were observed between participants in the RCT and the reference group, except for a higher proportion of people being sick listed in the RCT. There was no significant difference between participants that completed and those who dropped out.

FIGURE 2 ABOUT HERE

Outcomes

Figure 2 shows changes in the ODI from baseline to 3- and 12-week follow-up. There was no significant difference between groups in the change from baseline to 12-weeks follow-up (mean difference: 1.6 [95% CI: -3.9, 7.0] p=0.570). From baseline (mean: 30.4 [95% CI: 27.7, 33.0]), the ODI within the GPE group decreased to 26.4 (95% CI: 22.8, 30.0) at 3-week follow-up and to 21.1 (95% CI: 17.0, 25.3) at 12-week follow-up. The corresponding ODI

values within the ERB-group was 28.1 (95% CI: 24.4, 31.9) at 3-week follow-up and 22.7 (95% CI: 18.7, 26.7) at 12-week follow-up. The improvement from baseline to 12 weeks was statistically significant for both groups, and from baseline to 3 weeks for the GPE-group.

Table 2 shows changes in secondary outcomes from baseline to 12-week follow-up. The change for the PSFS was significantly larger for the GPE-group compared to the ERB-group (mean [95% CI): 1.4 (0.1, 2.7), p=0.033). There were no other significant differences between groups in changes from baseline to 3- (Online table 1) or 12-week follow-up (table 2).

TABLE 2 ABOUT HERE

For between-group changes from baseline to 12 weeks, effect sizes were small or very small, with the exception of PSFS which was of medium magnitude in favor of GPE. Between and within group effects sizes are presented in online table 2.

Per protocol and sensitivity analysis

Fourteen of the 24 participants in the ERB-group with follow-up at 12 weeks completed at least 60% of the prescribed training sessions, and were included in the per protocol analysis. There was no significant difference on ODI at 12 weeks between the GPE-group and those with more than 60% completed training sessions (mean -2.5 [95% CI: -9.9, 4.8], p=0.50; favoring ERB). Twelve participants from the ERB-group and eight from the GPE-group increased their back extension strength above the median and were included in the sensitivity analysis. There was no difference in change for the ODI between participants who increased strength above the median compared to those who did not (mean 0.6 [95% CI: -5.8, 7.0], p=0.85; favoring increased strength)

Discussion

This study found no additional effect of replacing GPE with ERB for patients with chronic LBP enrolled in a MDR-program in the specialist health services. The ERB and the GPE group improved their ODI score from baseline to 12-weeks follow up with 7.7 and 9.3 points respectively, with no significant difference between groups. Furthermore, there were no significant differences between groups for any of the secondary outcomes, except that PSFS improved more from baseline to 12-week follow-up in the GPE compared to the ERB-group. Both groups had improved in most of the health-related outcomes at 12-weeks.

Although the ERB-intervention used in this study followed the current recommendations for resistance training for novices[36], we observed little difference in back-extension strength between the groups after the intervention. This made us question the adherence to the home-based ERB-program, and if adherence was related to improvement in ODI. Only 14 of the 24 patients, who participated at 12-weeks follow-up, performed at least 60% of the scheduled home-based training sessions. However, the per-protocol analysis demonstrated that even for those completing more than 60% of the training sessions, ERB was not more effective than GPE in improving ODI. A possible reason for the lack of difference in strength gain could be that some participants trained with lower intensity than prescribed during the home-based training period, as suggested by inspection of the training diaries. Patients, with a history of pain and fear-avoidance behavior, might benefit from closer follow-up during a home-based training period. Further, we cannot exclude the possibility that some of the participants in the GPE-group performed some sort of resistance training during the home-based training period. Therefore, we performed a sensitivity analysis to assess whether patients who increased back-extension strength, regardless of group allocation, had greater improvements on the ODI compared to patients who did not increase their strength.

However, we found no difference between these two subgroups which strengthens our main findings.

There are several possible explanations for the lack of a differential effect of the two exercise modalities. ERB or GPE was provided in combination with MDR, limiting the room for additional improvements induced by a particular exercise method. We are unaware of studies comparing different exercise modalities within MDR, therefore it is difficult to directly compare our results with previous studies investigating resistance-exercise interventions for patients with LBP[9,37]. Furthermore, physical exercise can be perceived less important for patients enrolled in MDR in a specialist care unit, as they might be more affected by psychological and social factors compared to patients in primary health care[2]. This assumption is supported by the average HSCL-baseline score in our study sample, which was around the cut-off level for anxiety and depression (i.e., HSCL-25 > 1.75)[38] (table 1). Further, back examination with reassurance, as provided in the initial screening session, resembles brief intervention which previously have been found effective in reducing sick leave for workers with LBP[39]. The screening session was performed prior to baseline testing and this may to some extent explain the low baseline scores on FABQ. Higher FABQ scores has been reported for a similar population when FABQ was answered before to the screening session[40]. Finally, although some studies have shown promising results for ERB[9,37], our findings are in line with a systematic review[41], showing that improvements in physical capacity (including muscular strength) are weakly correlated with improvements in pain and disability in patients with chronic LBP.

Our finding of improvement on the PSFS for the GPE-group compared to the ERB-group indicates that there might be some beneficial effects of exposure to various exercises, which also may involve a larger degree of tailoring. Considering that PSFS relates to activities rated important by the participant, it might be that the GPE was more suitable for improving

this outcome than a general ERB-program, as the participants in collaboration with therapists chose which exercises to include in the home-based GPE-program. The participants' influence on the GPE-program might have resulted in better adherence than in the ERB-program; however, this remains speculative since the GPE-group did not record activity in a diary. It should also be noted that the difference between groups was relatively small (mean difference 1.4, 95% CI: 0.1, 2.7, p=0.033) and, considering the number of tests performed, we cannot exclude the possibility of a type I error. Thus, this finding should be interpreted with caution.

This study had some limitations. Participants were enrolled in MDR in a specialist back and neck pain clinic. Caution should be shown in generalization of the results to other settings. Although we followed recommended measures to increase compliance and adherence[16], we experienced a considerable number of dropouts limiting statistical power. However, as dropouts were evenly distributed between the groups, we consider the risk of selective attrition bias to be low. Therefore, we contend it is unlikely that the conclusion would be altered with additional participants or a lower drop-out rate. Moreover, there were no differences in baseline characteristics for patients who completed the intervention and those who dropped out. Further, patients who took part in the study were similar to those in the reference group, i.e., patients enrolled for MDR at the clinic but who refused to participate or who were excluded from the study. This indicates that the patients who completed the intervention are a representative sample of the population. While both the ERB and GPE group improved on most outcomes from baseline to 12 weeks, we cannot distinguish the effects from the programs and the effects of time. Despite forming clear procedures for management of the groups, we cannot exclude the occurrence of a potential carry-over effect as the same team of physiotherapists provided both the ERB- and GPE-interventions. Finally, it was not possible to blind participants or therapists managing the interventions, but test-

leaders and researchers conducting the analyses were blinded, and participants were blinded to the researchers` hypotheses.

In summary, our findings provide no support that replacing GPE with ERB in MDR will improve LBP-related disability in patients with chronic non-specific LBP.

Perspectives

LBP is a leading cause of disability in most countries across the world[1]. While numerous treatment options exists, none have been found to provide more than small to moderate effects[3,42]. MDR including exercise is considered more effective than unimodal treatments for chronic LBP, but it is unclear which exercise-modality that should be incorporated in MDR. Recent evidence suggests that resistance training could be a promising treatment option for persons with chronic LBP. This study investigated whether patients participating in MDR could have greater benefits when replacing the usual general physical exercise with progressive resistance training using elastic resistance bands. However, we observed similar changes for both groups and encourage clinicians to advice patients' to choose between these exercise options based on their interests and motivation.

Acknowledgements

We express our gratitude to all patients participating in the project. We would also like to thank Ida Reitan Berthelsen, Janne-Birgitte Bloch Børke and Bitten Kihl Olsen and the rest of the employees at St. Olavs Hospital – Department of Physical Medicine and Rehabilitation, Trondheim, Norway, for their enthusiasm and contributions to the project. We also acknowledge the effort by Lars Vikan Rise for managing booster sessions, and Synnøve Fossheim Karlsen and Atle Melleby Kongsvold for assistance with testing. The studies are funded by KLP – Kommunal Landspensjonskasse, and the Norwegian Research Council

through the FYSIOPRIM project– a research program on physiotherapy in primary health care. Performance Health (Akron, OH, USA) provided Theraband® Elastic bands for this study. None of the funders had/have any saying in developing the study design, data collection and analysis, decision to publish or preparation of this manuscript or future manuscripts. The authors declare no conflict of interest.

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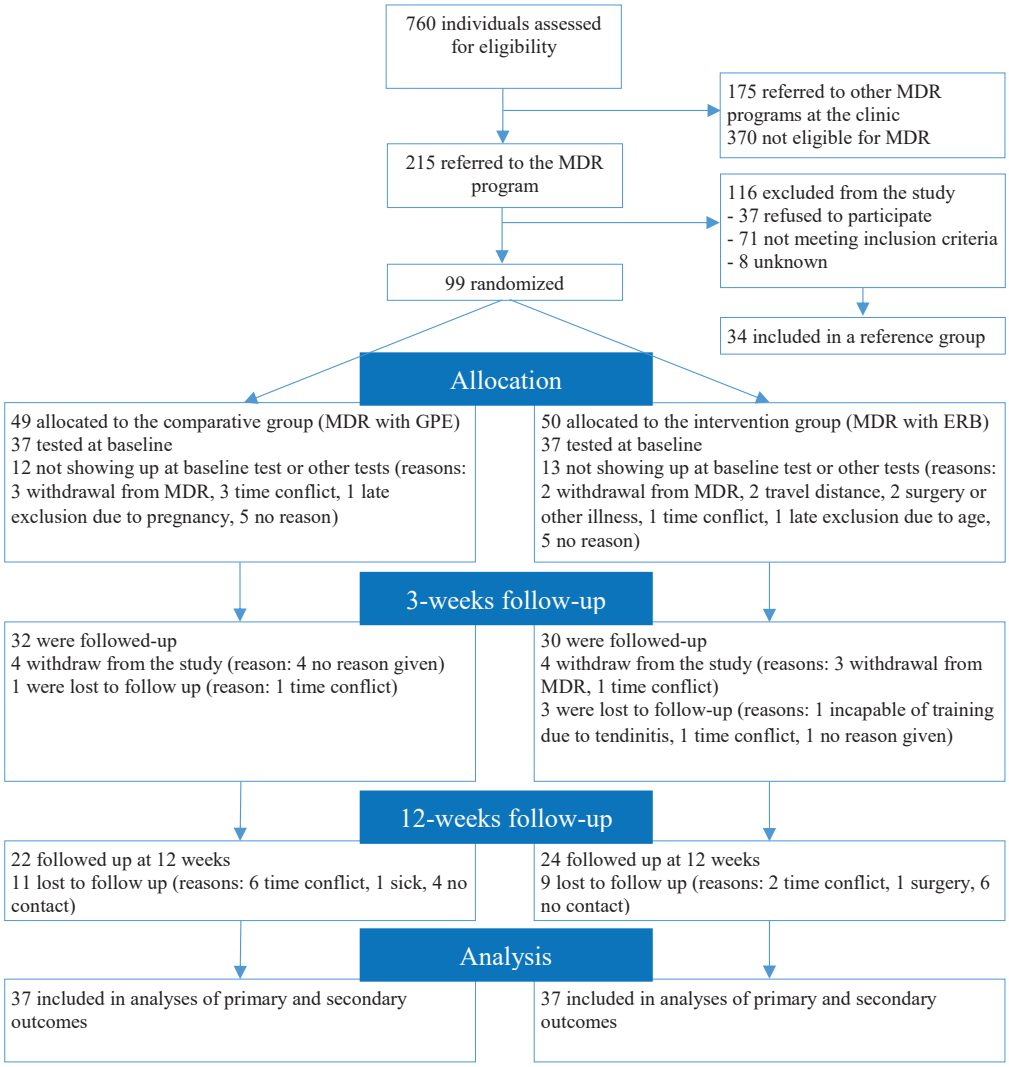

Fig. 1 Participant flow: MDR= Multidisciplinary rehabilitation, GPE= General physical exercise, ERB= Elastic resistance band-training

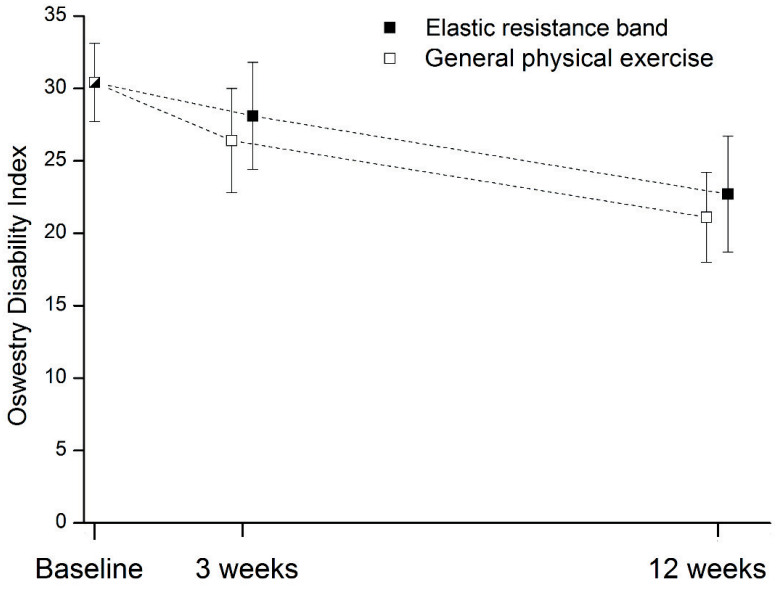

Fig. 2 Between-group difference in change in the oswestry disability index (0-100) from baseline to 12-weeks. Values are means and 95% confidence intervals

Table 1: Baseline characteristics of participants by treatment group.

	GPE-group (n=37)	ERB-group (n=37)	Reference group (n=34)
Sociodemographic characteristics			
Age, mean (SD)	43 (13)	47 (11)	45 (15)
Women, %	54	59	45
BMI, kg/m^2, mean (SD)	30.6 (6.4)	28.4 (4.2)	N/A
Married or live-in partner, %	74	81	82
Higher education (high school and above), %	40	45	47
Employed (full-time or part time), %	80	78	62
Sick listed (fully/partially), %	67	50	34
Work assessment allowance[1] or disability pension, %	18	26	37
Work description/Physical work demands			
- Mostly sitting, %	25	32	35
- Much walking, %	44	24	15
- Much lifting and walking/heavy physical labor, %	31	44	50
Self-reported health right now			
- Poor, %	13	6	18
- Not so good, %	68	77	52
- Good/very good, %	18	17	30
Leisure time exercise index (0.78-3.00), mean (SD)	1.99 (0.57)	1.91 (0.48)	2.05 (0.52)
Have used analgesics for LBP the last week, %	57	49	45
≥ 1 year duration of current LBP, %	76	81	85
LBP recurring more than three times/year, %	50	58	66
Baseline score for primary outcome			
Oswestry Disability Index (0-100), mean (SD)	32.5 (13.4)	28.1 (8.5)	30.1 (12.3)
Baseline scores for secondary outcomes			
Numerical Pain Rating Scale (0-10)			
- LBP right now, mean (SD)	4.9 (2.0)	4.4 (1.6)	5.4 (2.1)
- Worst LBP last two weeks, mean (SD)	7.2 (1.9)	6.5 (2.0)	7.4 (1.9)
- Worst LBP last four weeks, mean (SD)	7.5 (2.1)	6.4 (1.6)	7.6 (1.8)
Additional pain sites (0-11), mean (SD)	2.1 (2.4)	1.7 (2.0)	2.5 (2.4)
EQ-5D, mean (SD)	0.690 (0.368)	0.727 (0.212)	0.699 (0.129)
Work ability index (WAI: 0-10), mean (SD)	4.3 (2.2)	4.4 (2.4)	4.5 (2.6)
Fear avoidance beliefs questionnaire			
- Part A – Activity beliefs (0-24), mean (SD)	8.0 (5.4)	7.5 (5.2)	7.5 (6.1)
- Part B – Work beliefs (0-42), mean (SD)	20.1 (8.3)	17.9 (10.4)	20.9 (11.8)
Patient Specific Functional Scale (0-10), mean (SD)	6.9 (1.6)	6.6 (2.3)	N/A
Hopkins symptoms checklist 25 (1-4), mean (SD)	1.82 (0.55)	1.66 (0.49)	1.67 (0.53)
Back extension strength (N), mean (SD)	738 (269)	622 (231)	N/A
Grip strength (kg), mean (SD)	39.1 (13.4)	36.8 (12.9)	N/A

GPE= General physical exercise, ERB= Elastic resistance band-training

[1]Work assessment allowance can be applied for in Norway after being on sick leave for one year

[2]The leisure time index is calculated based on the questions "How frequently do you exercise", "How long does each session last", and "How hard do you push yourself". A score of 1.18 indicates very inactive and 3 indicates very active[1].

Table 2: Secondary outcomes, estimated means and 95% confidence intervals from baseline to 12 weeks

	Baseline	12 weeks		Between-group comparison	
Outcome		GPE	ERB	Difference	
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	p-value
LBP (NRS; 0-10)					
Current	4.6 (4.2, 5.1)	3.4 (2.7, 4.2) **	4.0 (3.3, 4.8)	0.6 (-0.4, 1.6)	0.266
Worst last 2wks	6.8 (6.4, 7.4)	4.9 (4.0, 5.7) **	5.7 (4.8, 6.5) **	0.8 (-0.3, 2.0)	0.168
Worst last 4wks	7.0 (6.5, 7.5)	5.5 (4.7, 6.3) **	6.2 (5.4, 7.0) **	0.7 (-0.4, 1.8)	0.184
Additional pain sites (0-10)	1.9 (1.4, 2.4)	1.6 (0.7, 2.5)	2.5 (1.7, 3.4)	0.9 (-0.2, 2.1)	0.113
WAI (0-10)	4.3 (3.7, 4.9)	5.6 (4.7, 6.5) **	5.5 (4.7, 6.4) **	-0.1 (-1.3, 1.1)	0.925
HSCL-25 (1-4)	1.74 (1.64, 1.85)	1.46 (1.31, 1.62) **	1.56 (1.41, 1.71) **	0.10 (-0.08, 0.30)	0.291
EQ-5D	0.709 (0.685, 0.733)	0.717 (0.676, 0.758)	0.730 (0.680, 0.753)	0.013 (-0.043, 0.068)	0.649
FABQ A (0-24)	7.7 (6.6, 8.7)	5.2 (3.7, 6.8) **	5.4 (3.7, 7.1) **	0.5 (-1.6, 2.6)	0.637
FABQ B (0-42)	18.6 (15.8, 21.4)	16.4 (12.8, 20.0)	16.0 (12.4, 19.7)	-0.4 (-4.8, 4.1)	0.880
GRC (improved)	N/A	52 % (32%, 79%)	40 % (23%, 59%)	OR: 0.62 (0.2, 1.97)	0.408
PSFS (0-10)	6.8 (6.2, 7.4)	4.0 (3.0, 5.0) **	5.4 (4.4, 6.3) **	1.4 (0.1, 2.7)	0.033
Back extension strength (N)	685 (627, 742)	762 (680, 844) *	838 (759, 919) **	77 (-21, 175)	0.125
Grip strength (kg)	37.8 (35.0, 40.9)	39.5 (36.1, 43.0)	40.5 (37.1, 43.9) *	0.9 (-1.7, 3.6)	0.489

GPE, General physical exercise group; ERB, Elastic resistance band group; NRS, Numerical pain rating scale; LBP, Low back pain; WAI, Work ability index; HSCL-25, Hopkins symptom checklist 25; FABQ A, Fear avoidance beliefs questionnaire in relation to physical activity; FABQ B, Fear avoidance beliefs questionnaire in relation to work; GRC, Global rating of change scale; PSFS, Patient specific functioning scale; OR, Odds ratio. Significant change from baseline within group, *p<0.05; **p<0.01.

Online table 1: Secondary outcomes, estimated means and 95% confidence intervals from baseline to 3 weeks

	Baseline	3 weeks		Between-group comparison	
Outcome		GPE-group	ERB-group	Difference	
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	p-value
NRS (0-10)					
LBP right now	4.6 (4.2, 5.1)	4.4 (3.8, 5,1)	4.1 (3.4, 4.8)	-3.1 (-1.2, 0.6)	0.499
Worst LBP last two weeks	6.8 (6.4, 7.4)	6.4 (5.7, 7.1)	6.3 (5.6, 7.0)	-0.6 (-1.1, 0.9)	0.907
Worst LBP last four weeks	7.0 (6.5, 7.5)	7.0 (6.3, 7.7)	6.8 (6.1, 7.5)	-0.2 (-1.2, 0.8)	0.685
Additional pain sites (0-10)	1.9 (1.4, 2.4)	2.2 (1.5, 2.9)	2.3 (1.5, 3.0)	0.1 (-0.9, 1.0)	0.876
WAI (0-10)	4.3 (3.7, 4.9)	4.8 (3.4, 5.6)	5.0 (4.2, 5.8)	0.2 (-0.9, 1.3)	0.706
HSCL-25 (1-4)	1.74 (1.64, 1.85)	1.56 (1.42, 1.70)	1.51 (1.37, 1.65)	-0.06 (-0.22, 0.11)	0.504
EQ-5D	0.709 (0.685, 0.733)	0.696 (0.661, 0.731)	0.717 (0.680, 0.753)	0.021 (-0.028, 0.069)	0.399
FABQ A (0-24)	7.7 (6.6, 8.7)	5.7 (4.2, 7.3)	5.2 (3.7, 6.8)	-0.5 (-2.4, 1.4)	0.508
FABQ B (0-42)	18.6 (15.8, 21.4)	16.5 (13.2, 19.8)	15.4 (11.9, 19.0)	-1.1 (-5.2, 3.0)	0.610
GRC (improved)	N/A	25% (13%, 42%)	42% (26%, 59%)	OR: 2.13 (0.75, 6.16)	0.153
PSFS (0-10)	6.8 (6.2, 7.4)	6.2 (5.4, 7.1)	6.5 (5.6, 7.3)	0.2 (-0.9, 1.4)	0.701
Back extension strength (N)	685 (627, 742)	737 (663, 810)	744 (665, 822)	7 (-84, 98)	0.880
Grip strength (kg)	37.8 (35.0, 40.9)	39.7 (36.4, 43.0)	37.1 (33.7, 40.5)	-2.6 (-5.1, 0.1)	0.042

GPE, General physical exercise; ERB, Elastic resistance band; NRS, Numerical pain rating scale; LBP, Low back pain; WAI, Work ability index; HSCL-25, Hopkins symptom checklist 25; FABQ A, Fear avoidance beliefs questionnaire in relation to physical activity; FABQ B, Fear avoidance beliefs questionnaire in relation to work; GRC, Global rating of change scale; PSFS, Patient specific functioning scale; OR, Odds ratio

Online table 2: Within- and between-group Cohen`s d effect sizes and 95% confidence intervals of improvement from baseline to 12 weeks.

Outcome	General physical exercise	Elastic resistance band	Elastic resistance bands compared to general physical exercise
Oswestry disability index	0.82 (0.45, 1.18,)	0.68 (0.33, 1.03)	-0.14 (-0.62, 0.34)
NRS, current LBP	0.59 (0.21, 0.97)	0.31, (-0.06, 0.68)	-0.28 (-0.78, 0.22)
NRS, worst LBP last 2 weeks	0.91 (0.51, 1.31)	0.54 (0.16, 0.92)	-0.37 (-0.89, 0.15)
NRS, worst LBP last 4 weeks	0.73 (0.32, 1.13)	0.37 (-0.19, 0.76)	-0.36, (-0.88, 0.17)
Additional pain sites	0.14 (-0.28, 0.56)	-0.30 (-0.69, 0.09)	-0.44 (-0.99, 0.10)
Work ability index	0.52 (0.15, 0.9)	0.50 (0.15, 0.85)	-0.02 (-0.51, 0.47)
HSCL-25	0.60 (0.31, 0.89)	0.39 (0.12, 0.67)	-0.21 (-0.60, 0.18,)
EQ-5D	0.08 (-0.32, 0.47)	0.20 (-0.19, 0.59)	0.12 (-0.40, 0.65)
FABQ A	0.58 (0.26, 0.91)	0.48 (0.16, 0.79)	-0.11 (-0.54, 0.33)
FABQ B	0.21 (-0.11, 0.52)	0.24 (-0.07, 0.55)	0.03 (-0.39, 0.46)
PSFS	1.23 (0.80, 1.66)	0.62 (0.20, 1.03)	-0.61 (-1,18, -0.05)
Back extension strength	0.31 (0.02, 0.59)	0.61 (0.33, 0.89)	0.31 (-0.09, 0.70)
Grip strength	0.13 (-0.01, 0.27)	0.20 (0.63, 0.33)	0.07 (-0.13, 0.27)

NRS, Numerical pain rating scale; LBP, Low back pain; HSCL-25, Hopkins symptom checklist 25; FABQ A, Fear avoidance beliefs questionnaire in relation to physical activity; FABQ B, Fear avoidance beliefs questionnaire in relation to work; PSFS, Patient specific functioning scale;

Paper 4

Resistance training versus general physical exercise in multidisciplinary rehabilitation of chronic neck pain: A randomized controlled trial

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Abstract

Objective: To investigate if progressive resistance training using elastic resistance bands improves neck-related disability more than general physical exercise in multidisciplinary rehabilitation of chronic neck pain.

Design: Researcher-blinded, randomized controlled trial.

Methods: Fifty-nine patients with non-specific, chronic neck pain (mean age: 46 years, disability (neck disability index, 0-100): 35.4, worst neck pain last two weeks (numerical pain rating scale, 0-10): 6.3) were randomized to 3-week multidisciplinary rehabilitation including either general physical exercise or progressive resistance training with elastic bands. Participants were instructed to continue their respective home-based training programs for nine additional weeks. Outcomes were assessed at baseline, after 3-weeks and after 12-weeks. The primary outcome was the between-group difference in change in the neck disability index from baseline to 12-weeks.

Results: Thirty-four and 31 participants were followed up at 3- and 12-weeks, respectively. We observed no between-group differences apart from a greater increase in shoulder abduction strength for the progressive resistance-training group at 12-weeks.

Conclusion: This study provides no evidence in favour of replacing general physical exercise with progressive resistance training using elastic resistance bands in multidisciplinary rehabilitation of chronic neck pain. We recommend clinicians to advise either of these exercise-types based on the patient`s interests and motivation.

Keywords: Musculoskeletal disorders, Disability evaluation, Chronic pain, Function, Muscle strength, Biopsychosocial

Introduction

Chronic neck pain is a main contributor to disability across the globe and more research is needed to identify better ways of managing the condition (1). Some studies suggest that progressive resistance training (PRT) of the neck and shoulder muscles is beneficial for chronic neck and shoulder pain (2-7). For low back pain it has been suggested that PRT, targeting whole-body muscle strength, could be more beneficial than specific back exercises, possibly due to an overall improved physical functioning (8, 9). This could also be the case for persons with chronic neck pain, as this condition frequently coexists with pain in other body regions (10), and patients with chronic pain often are deconditioned (11).

Multidisciplinary rehabilitation (MDR) is often recommend for patients with chronic and disabling neck pain to address both physical and psychosocial aspects of the condition (12, 13). MDR usually includes general physical exercise (GPE), patient education, group discussions and individual meetings with therapists (13-16). In Norway, the exercise part of MDR typically entails an introduction to activities and exercises that fit with the patients` interests. However, high-intensity strength training such as PRT is usually not included. Considering the promising results of high-intensity strength training (2-5), it is possible that the effects of MDR could be improved by replacing GPE with PRT.

While conventional resistance-training equipment is relatively spacious and expensive, elastic resistance bands can be used as a viable alternative when performing PRT in small clinics or at home (17, 18). In this study, we investigated the effects of replacing GPE with PRT in a 3-week MDR-program for patients with chronic neck pain, followed by 9-weeks home-based training (GPE or PRT). All PRT-sessions were performed with elastic resistance bands. We hypothesized greater improvement in neck pain-related disability, and other health related outcomes, with PRT than GPE.

Methods

Study design, setting and participants

This was a single-blinded (test leaders and researchers) randomized controlled trial (RCT). The trial was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway and is registered in ClinicalTrials.gov (NCT02420197). The results are reported in accordance with the CONSORT-statement(19).

The RCT was carried out at an outpatient hospital back- and neck pain clinic (hereafter "the clinic") at the Department of Physical Medicine and Rehabilitation, St. Olavs Hospital, Trondheim, Norway. This trial has a similar design and recruitment procedure as a previous RCT in patients with low back pain, and the methods are partly overlapping (20). Patient characteristics were registered at baseline, while primary and secondary effect measures were obtained at baseline, week 3 and week 12.

A physician at the clinic screened patients for eligibility to the MDR-program and to the RCT. Inclusion criteria were: 1) chronic (≥3 months) or recurrent (≥2 episodes with duration ≥4 weeks the past year) non-specific neck pain, 2) worst neck pain during the last two weeks ≥4 on numerical rating scale (NRS, 0-10), and 3) 16-70 years of age. Exclusion criteria were: 1) awaiting neck surgery, 2) a severe somatic condition (e.g., cancer, inflammatory rheumatic disease, severe osteoporosis), 3) insufficient comprehension of Norwegian language to participate in group sessions and fill out questionnaires, 4) psychiatric condition expected to severely impair group functioning, 5) alcohol or drug abuse, 6) ongoing compensation claim or applying for disability pension due to neck pain, 7) engaged in high-intensity strength training on a regular basis for the last six months, and 9) contra-indications for high-intensity strength training (e.g., shoulder complications severely limiting the ability to conduct the training program). In addition, as usual at the clinic, patients were only enrolled to MDR if the physician considered it beneficial for the patients based on their clinical history, whether sufficient treatment had been attempted in primary care, and whether patients were motivated to participate in the program.

Eligible patients were informed (written and orally) about the study. Those who were willing to participate signed a written consent form before baseline testing. Patients were consecutively

randomized to either the PRT-group (intervention) or the GPE-group (comparison). Randomization (1:1) was performed with blocks of unknown sizes, using a web-based program provided by the Unit for Applied Clinical Research, Norwegian University of Science and Technology.

Patients, who were enrolled in the MDR-program but were excluded from the RCT or declined participation, were asked to participate in a reference group to assess the generalizability of the results. Those who accepted to participate in this group signed a consent form and completed the baseline questionnaire.

Intervention and comparison program

All participants received a 3-week MDR-program for chronic neck pain at the clinic. The MDR was managed by professionals working at the clinic (physiotherapists, physicians, social workers, and psychologists) and consisted of individual consultations, exercise, group discussions along with patient education targeting stress management, goal-setting, physical activity, work participation and enhanced understanding of neck symptoms and neck anatomy. The only difference between the groups was the exercise component, which consisted of PRT in the intervention group and GPE (i.e., usual practice) in the comparison group. Participants in both groups were instructed to continue with their respective exercise programs for the following 9 weeks after completion of the MDR, i.e., 12 weeks of PRT or GPE in total. Participants in both groups were offered three group-based booster sessions in week five, seven and nine. The booster sessions were administered by physiotherapists from the clinic, and were used to assist participants with motivation, technique and progression related to their respective programs.

Participants in the intervention group performed PRT with Theraband® Elastic bands (colours: yellow-gold) three times per week (supervised during week one and three). They were also given door anchors and handles, to use with the elastic bands, and were instructed to record all training sessions in a diary. The PRT-program consisted of the exercises stiff-legged deadlifts, flies, unilateral rows, reversed flies, lateral pulldown, unilateral shoulder abduction(20), and specific neck flexion and extension (Fig. 1). Each exercise should be performed until muscular failure, i.e. unable to complete one more repetition with good form, for two sets of 15-20 repetitions in week 1-2, two sets of 12-15

repetitions in week 3-5, three sets of 10-12 repetitions in week 6-8, and three sets of 8-10 repetitions in week 9-12. Participants` should progress to heavier resistance bands when they performed more repetitions than prescribed, or if they rated a set lighter than seven on the Borg CR10 scale (21).

[FIG. 1 ABOUT HERE]

The GPE-program was provided as usual at the clinic: four sessions in week 1, and three sessions in week 3. To reduce attention bias, the intervention group also had one session of GPE in week one to match the number of supervised sessions. During the GPE-sessions, participants were introduced to various activities including circle-training, low-intensity resistance exercises, endurance training, ball games, body awareness, stretching, and relaxation techniques. Participants were provided a home-based activity program upon completion of the rehabilitation at the clinic, reflecting their interests and the physiotherapists` recommendations.

Questionnaires

The primary outcome was the between-group difference in neck pain-related disability from baseline to 12 weeks, assessed by the Neck Disability Index (NDI, 0-100). NDI is a questionnaire with 10 items covering pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation (22).

Secondary outcomes included the between-group difference in NDI from baseline to three weeks, and the between-group changes from baseline to three and 12 weeks for: 1) current neck pain and worst neck pain in the last two and four weeks assessed by the Numerical Pain Rating Scale (NPR, 0-10), higher score indicate more pain (22), 2) number of additional pain sites indicated on a pain drawing (0-11) (23), 3) anxiety and depressive symptoms assessed by Hopkins Symptom Checklist (1-4), higher score indicate stronger symptoms (24), 4) health-related quality of life assessed by EQ-5D-5L (<0-1), higher score indicate better health (25), 5) limitation in function assessed by the patient specific functional scale (0-10), higher score indicates more limitation (26), 6) fear-avoidance beliefs regarding physical activity (0-24) and work-related activities (0-42) assessed by the Fear-

avoidance beliefs questionnaire, higher scores indicate higher fear avoidance (27), 7) workability assessed by a single item from the Workability Index "current workability compared with lifetime best" (0-10), higher score indicates better workability (28).

Physical measurements

Secondary outcomes also included between-group changes in maximum voluntary isometric contraction (MVC) in shoulder abduction, neck flexion and neck extension (performed as described in Vannebo et. al (29)), and pressure pain threshold.

During shoulder abductor MVC (online Fig. 1) participants sat on a stool with their back against a wall, arms held straight out from the side of the body just below shoulder height, and elbows held in approximately 90° angle in the transverse plane with the palm facing downwards. The elbow to floor distance was registered, to ensure reliable testing conditions from time to time. Force was only recorded for the dominant arm, where a strap attached around the elbow joint formed a straight line down to the force transducer, bolted to a platform. For balance, the setup was identical for the non-dominant arm, but without the force transducer. Participants then performed three shoulder abductor MVCs with 1 min rest between attempts. Force (newton) was recorded and analyzed using MuscleLab software (version 10.3.26.0, Ergotest Technology AS, Langesund, Norway). The highest value was used in the analysis.

Pressure pain threshold (online Fig. 2) was assessed by an algometer (Type II Somedic Production, Sweden), using a contact area of 10 mm. The algometer was applied at a speed of pressure equal to 40 kPa/s, and held in a perpendicular angle to the pressure point during testing. Pressure pain threshold for musculus tibialis anterior was measured midway between the lateral condyle of the tibia and the lateral malleolus of the fibula. The test was performed three times, with one-minute rest between tests. The average value was used in the analysis. A similar method has been used to assess pain sensitivity in non-painful regions of the body for neck patients in a previous study (30).

Statistical analysis

From pilot data of the present population, sample size was calculated for the mixed linear model analysis of the primary outcome, NDI. The minimal detectable change for NDI has been proposed to be 3.5 on a 0-50 scale (corresponding to 7 on a 0-100 scale) (22). However, we expected a decrease in NDI for both groups, as they participated in MDR in the specialist care. Hence, the sample size was calculated to detect an additional difference of 5 points between groups (0-100 scale). With 80% power (p=0.05) and assuming a 0.5 within-participant correlation between baseline and the 12 weeks, an estimated 40 participants in each arm (80 in total) was necessary to detect a difference between groups of 5 points on the NDI. To take dropouts into account (31), we aimed to include 50 participants in each group (100 in total).

Effect-differences between groups for each of the primary and secondary outcomes were assessed separately using mixed linear analysis with multilevel modeling. This model of analysis do not require imputation of missing data (32). As this was an RCT with patients from the same population, we assumed no systematic differences between groups at baseline. Thus, the group means at baseline were combined to optimize statistical power (32). The following levels were used in the analysis: baseline, GPE after three weeks, PRT after three weeks, GPE after 12 weeks and PRT after 12 weeks. The outcome variable was included as the dependent variable, group x time interaction effects were included as the fixed effect, and participant ID was included as random effect (to allow for different levels for participants in the analysis). The EQ-5D index was calculated using a crosswalk index calculator based on the Danish tariff (33). Cohens d effect sizes were calculated for all changes from baseline to 12-weeks, with effect sizes of 0.2, 0.5 and 0.8 representing small, medium and large effects, respectively.

Results are presented as means with 95% confidence intervals (CI). A p-value <0.05 was considered to indicate statistical significance. All statistical analysis were done in STATA 14 for Windows (StataCorp LP, USA).

[FIG. 2 ABOUT HERE]

Results

Recruitment started on December 4, 2014 and continued until November 2, 2016. The inclusion was stopped without reaching the desired number of participants, due to slow recruitment rate and upcoming changes at the clinic. In total, 74 patients consented to participate but 15 of these dropped out prior to baseline testing (i.e., no data acquired). Thus, baseline data was obtained from 30 and 29 participants in the PRT and GPE groups, respectively, and these were included in the main analysis. In total, 34 participants participated at the 3-weeks follow-up, while 31 participants participated at the 12-weeks follow-up (see Fig. 2 for flow-chart).

Participants` characteristics

Baseline characteristics for the GPE- and PRT-group were similar at baseline (Table 1). Participants mean age was 46 (SD 10) years, 68% were women and 78% were employed. A leisure-time exercise index score of 2 (range: 0.78-3) indicated that participants were moderately active at baseline (34). Additionally, participants generally reported moderate disability (NDI: 35.4, SD: 10.3) and moderate to strong pain in the last two weeks (NRS: 6.3, SD: 2.1).

[TABLE 1 ABOUT HERE]

Outcomes

We found no statistically significant difference between groups on the primary outcome, between-group change in NDI from baseline to 12-weeks follow-up (Table 2). At 12 weeks, the PRT-group had increased their shoulder abductor MVC strength more than the GPE-group (mean difference 17, 95% CI: 2, 31, p=0.022). The GPE-group displayed a greater improvement in fear-avoidance beliefs regarding physical activity at 3 weeks than the PRT group (mean difference 2.7, 95% CI: 0.3, 5.0, p=0.027). No statistical differences were observed for any of the other secondary outcomes at 3- or 12-weeks. Effect sizes in change from baseline to 12-weeks are presented in the Online table.

Twelve participants in the PRT-group submitted their training diaries at the end of the intervention. On average, they had completed 3 PRT-sessions per week during the first 3 weeks, and 2.7 sessions per week during the 9 weeks of home-based training.

We observed no significant differences in baseline characteristics between participants in the RCT and the reference group (n=39, data not shown).

[TABLE 2 ABOUT HERE]

Discussion

This RCT provides no evidence in support of replacing GPE with PRT in MDR for patients with non-specific chronic neck pain. We observed no difference in the change of the NDI score (primary outcome) from baseline to 12 weeks between the PRT-group and the GPE-group. The PRT-group reported lower 'worst' neck pain in the last 2 and 4 weeks at 12-week follow-up (moderate effect sizes); however, the difference did not reach statistical significance. We were unable to recruit the desired number of participants and the current trial is therefore underpowered. Nevertheless, the change in the NDI score from baseline to 12 weeks was nearly identical between the groups and it is unlikely that we would have observed a significant group difference if the desired number of patients had participated.

Previous studies, reporting effect of PRT on neck pain have been conducted in occupational settings (2-6), while we recruited patients referred to MDR in the specialized care. Specialized care is mainly reserved for patients with substantial psychosocial impact (35), and the specialist care unit requires that sufficient medical examinations and treatment options available in the primary care setting has proven unsuccessful before referral (i.e. active physiotherapy or other relevant treatments). Supporting that our participants had a complex symptom-picture, the mean baseline scores were above the cut-off level for anxiety and depression (HSCL > 1.75) (36). Further, the work ability index score was quite low at baseline, indicating that patients were in a state of health where they felt unable to cope with their responsibilities at work. Moreover, participants in this study reported multiple pain sites in addition to their neck pain. Widespread pain is associated with a more complex symptom

picture (10), and has also been reported to be inversely associated with recovery for patients with chronic low back pain (37). Finally, most participants reported more than 1-year duration of their current neck pain and had responded poorly to previous treatment in primary care. Thus, the chronicity and complexity of the participants' symptoms, in combination with the fact that all patients participated in MDR which included some form of exercise, might have left limited room for additional improvements by PRT.

We are not aware of other studies that have evaluated the effect of PRT in combination with a comprehensive MDR-program for patients referred to specialized care. The effect of PRT on neck pain is mainly evaluated in occupational settings and/or in supervised groups (2-6), while most of the training in the current study was home-based. Jakobsen and colleagues found that training at the workplace together with colleagues had higher compliance and was more effective for reducing neck pain than home-based training (38). We found that compliance was quite high in the 12 of 29 patients who delivered the training diary after the home training period (average of 2.7 sessions per week). It is possible that the actual training intensity and progression in resistance loading, suggested to be important for reduced neck pain and disability (39), was too low in our subjects as we were unable to detect improvement in neck flexor and extensor MVC strength. It can also be assumed that those who returned the training diary were more compliant than those who did not.

General hyperalgesia can accompany chronic neck pain (40). A study by Andersen and colleagues found PRT to improve the sensitivity to pain in both the trapezius and the tibialis anterior muscles (30). In our study, the pressure pain threshold of the tibialis anterior remained essentially unchanged. However, the threshold at baseline was almost double for the patients in our study than for the office workers in the study by Andersen and colleagues, reinforcing that these study populations are quite different.

This study had some limitations. Despite taking measures to maintain compliance and adherence as recommended (31), we were unable to reach the desired number of participants, and we also experienced some dropouts which increases the probability for a type II error. However, the results of this study probably reflect how replacing GPE with PRT would appear in clinical practice where home-based training is used and compliance will vary. The study included patients referred to a

specialized back and neck pain unit and the results cannot be generalized to other populations. Due to the nature of the intervention, neither patients nor clinicians were blinded to group allocation, but assessors and researchers were blinded during testing and analyses. Furthermore, the same group of clinicians provided PRT and GPE, and carry-over effects could potentially have occurred. In addition, it is possible that clinicians were more comfortable providing the usual GPE than the new PRT-intervention, which may have favored the former. Importantly, the clinicians at the clinic were involved with the planning of the interventions, and we had regular meetings to ensure appropriate implementation of the intervention. Finally, we cannot exclude the possibility that some participants in the GPE-group performed resistance training in the home-based training period. The study sample was similar to the patients included in the reference group, indicating that our participants were representative of the study population they were recruited from.

In conclusion, the current RCT provide no evidence in favor of replacing GPE with PRT using elastic resistance bands in MDR, to enhance the improvement in neck pain-related disability. We recommend clinicians to advise either of these exercise-types, for patients with moderate to severe non-specific neck pain, based on the patient`s interests and motivation.

Acknowledgement

The study was funded by KLP – Kommunal Landspensjonskasse, and the Norwegian Research Council through the FYSIOPRIM project– a research program on physiotherapy in primary health care. Theraband® Elastic bands used in the study was provided by Performance Health (Akron, OH, USA).

The authors would like to thank all patients that participated in the study, and the employees at St. Olavs Hospital – Department of Physical Medicine and Rehabilitation, Trondheim, Norway. We also acknowledge the effort by Ida Reitan Berthelsen and Lars Vikan Rise for managing booster sessions, and Synnøve Fossheim Karlsen and Atle Melleby Kongsvold for their assistance with testing.

The authors have no conflict of interest to declare.

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Table 1: Baseline characteristics

	General physical exercise (n=30)	Progressive resistance training (n=29)	Reference group (n=39)
Age, mean (SD)	48.2 (10.6)	44.6 (8.1)	49 (12)
Women, %	63	72	58
BMI, kg/m^2, mean (SD)	27 (5)	25 (4)	N/A
Married or live-in partner, %	67	79	67
Higher education (high school), %	30	41	37%
Employed (full-time or part time), %	73	83	76
Sick listed (fully/partially), %	33	48	62
Work assessment allowance[1] or disability pension, %	33	32	15
Work description/Physical work demands			
- Much sitting, %	57	59	42
- Much walking, %	21	18	26
- Much lifting and walking/heavy physical labor, %	22	23	32
Self-reported health right now			
- Poor/Not so good, %	67	72	75
- Good/very good, %	33	28	25
Leisure time exercise index (1.18-3.00), mean (SD)	1.98 (0.61)	2.01 (0.48)	2.01 (0.66)
Have used analgesics for neck pain the last week, %	60	55	57
≥ 1 year duration of current neck pain, %	87	80	82
Neck Disability Index (0-100), mean (SD)	35.4 (9.8)	35.3 (10.8)	35.9 (2.3)
Current neck pain (0-10), mean (SD)	4.4 (1.9)	4.2 (2.1)	4.8 (2.0)
Worst neck pain last 2wks (0-10), mean (SD)	5.9 (1.9)	6.7 (2.2)	6.1 (1.9)
Worst neck pain last 4wks (0-10), mean (SD)	6.8 (2.1)	7.4 (1.7)	7.0 (2.0)
Additional pain sites (0-10), mean (SD)	3.5 (3.0)	3.4 (3.0)	2.9 (2.4)
EQ-5D (<0-1), mean (SD)	0.656 (0.130)	0.702 (0.088)	0.680 (0.11)
Work ability index (0-10), mean (SD)	4.7 (2.2)	4.4 (2.8)	3.7 (2.5)
FABQ – Physical activity (0-24), mean (SD)	6.4 (5.5)	5.9 (3.9)	7.4 (5.0)
FABQ – Work (0-42), mean (SD)	17.2 (9.1)	17.9 (7.7)	18.8 (10.5)
Patient Specific Functional Scale (0-10), mean (SD)	6.7 (2.3)	7.3 (2.0)	N/A
Hopkins symptoms checklist 25 (1-4), mean (SD)	1.9 (0.5)	1.7 (0.5)	1.8 (0.4)
Shoulder abductor MVC strength (N), mean (SD)	180 (80)	175 (76)	N/A
Neck extensor MVC strength (N), mean (SD)	163 (71)	133 (53)	N/A
Neck flexor MVC strength (N), mean (SD)	119 (52)	109 (52)	N/A
Pressure pain threshold (N), mean (SD)	654 (336)	621 (287)	N/A

FABQ = Fear avoidance belief questionnaire, MVC = Maximal voluntary isometric contraction
[1]Work assessment allowance can be applied for in Norway after being on sick leave for one year

Table 2: Primary and secondary outcomes, estimated means and 95% confidence intervals

	Baseline	3 weeks		Between-group comparison		12 weeks		Between-group comparison	
Outcome		GPE	PRT	Difference		GPE	PRT	Difference	
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	p	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	p
NDI (0-100)	35.4 (32.6, 38.2)	28.6 (24.0, 33.2)	33.6 (28.4, 38.7)	5.0 (-1.8, 11.7)	0.148	26.8 (21.8, 31.8)	27.0 (21.9, 32.1)	0.2 (-6.7, 7.1)	0.956
Current neck pain (0-10)	4.3 (3.8, 4.8)	3.5 (2.6, 4.3)	4.5 (3.5, 5.4)	1.0 (-0.2, 2.2)	0.095	4.1 (3.2, 5.1)	3.7 (2.8, 4.6)	-0.5 (-1.7, 0.8)	0.454
Worst neck pain last 2wks (0-10)	6.3 (5.8, 6.9)	6.7 (5.8, 7.6)	6.2 (5.3, 7.2)	-0.5 (-1.7, 0.8)	0.460	6.5 (5.5, 7.4)	5.3 (4.3, 6.2)	-1.2 (-2.5, 0.1)	0.068
Worst neck pain last 4wks (0-10)	7.1 (6.6, 7.6)	7.3 (6.5, 8.1)	7.5 (6.7, 8.4)	0.2 (-0.9, 1.3)	0.709	6.9 (6.0, 7.7)	5.8 (5.0, 6.7)	-1.0 (-2.1, 0.8)	0.068
Additional pain sites (0-11)	3.3 (2.6, 4.1)	3.1 (2.1,4.1)	2.7 (1.7, 3.8)	-0.4 (-1.6, 0.8)	0.541	3.1 (2.0, 4.3)	2.4 (1.4, 3.5)	-0.7 (-2.1, 0.7)	0.313
WAI (0-10)	4.5 (3.9, 5.2)	5.0 (4.1, 5.9)	5.6 (4.6, 6.6)	0.6 (-0.6, 1.8)	0.327	5.5 (4.6, 6.4)	6.1 (5.1, 7.1)	0.6 (-0.6, 1.8)	0.360
HSCL-25 (1-4)	1.8 (1.7, 1.9)	1.7 (1.5, 1.8)	1.6 (1.4, 1.8)	-0.1 (-0.3, 0.1)	0.377	1.7 (1.5, 1.9)	1.6 (1.4, 1.8)	-0.1 (-0.3, 0.1)	0.298
EQ-5D (<0-1)	0.67 (0.64, 0.70)	0.72 (0.67, 0.77)	0.73 (0.67, 0.78)	0.01 (-0.06, 0.07)	0.883	0.70 (0.65, 0.75)	0.72 (0.67, 0.77)	0.02 (-0.05, 0.09)	0.594
FABQ Physical activity (0-24)	6.2 (5.0, 7.4)	4.6 (2.8, 6.4)	7.3 (5.4, 9.2)	2.7 (0.3, 5.0)	0.027	4.9 (3.0, 6.9)	5.4 (3.5, 7.4)	0.5 (-2.0, 2.9)	0.713
FABQ Work (0-42)	17.4 (15.3, 19.6)	18.0 (14.9, 21.1)	15.9 (12.8, 18.9)	-2.1 (-5.8, 1.5)	0.251	19.0 (15.8, 22.2)	16.0 (13.0, 19.0)	-3.0 (-6.7, 0.8)	0.123
PSFS (0-10)	7.0 (6.3, 7.7)	6.1 (5.1, 7.2)	6.9 (5.7, 8.0)	0.7 (-0.8, 2.2)	0.350	5.7 (4.5, 6.8)	5.2 (3.9, 6.5)	-0.5 (-2.1, 1.2)	0.568
Shoulder abductor MVC (N)	177 (159, 196)	191 (171, 211)	186 (165, 206)	-5 (-18, 9)	0.479	183 (163, 204)	200 (180, 221)	17 (2, 31)	0.022
Neck flexor MVC (N)	114 (101, 127)	130 (115, 144)	132 (117, 148)	-5 (-18, 9)	0.479	134 (119, 150)	137 (122, 151)	3 (-10, 16)	0.684
Neck extensor MVC (N)	147 (131, 163)	173 (155, 191)	170 (151, 188)	-3 (-20, 13)	0.674	162 (143, 181)	173 (155, 192)	12 (-6, 29)	0.192
Pressure pain threshold	636 (559, 713)	655 (562, 749)	581 (485, 675)	-75 (-170, 21)	0.126	666 (562, 769)	599 (504, 694)	-67 (-172, 39)	0.215

NDI = Neck disability index, GPE = General physical exercise, PRT = Progressive resistance training, WAI = Work ability index, HSCL-25 = Hopkins symptom checklist 25, FABQ = Fear avoidance beliefs questionnaire, PSFS = Patient specific functioning scale, MVC = maximal isometric voluntary contraction

Online table 2: Within- and between-group Cohen`s d effect sizes and 95% confidence intervals of improvement from baseline to 12 weeks.

Outcome	General physical exercise	Elastic resistance band	Elastic resistance bands compared to general physical exercise
Neck disability index	0.78 (0.31, 1.25)	0.76 (0.29, 1.24)	-0.02 (-0.65, 0.62)
NRS, current NP	0.08 (-0.45, 0.51)	0.30 (-0.13, 0.72)	0.22 (-0.36, 0.80)
NRS, worst NP last 2 weeks	-0.07 (-0.49, 0.35)	0.46 (0.05, 0.90)	0.53 (-0.04, 1.10)
NRS, worst NP last 4 weeks	0.10 (-0.30, 0.51)	0.62 (0.21, 1.02)	0.51 (-0.03, 1.07)
Additional pain sites	0.07 (-0.30, 0.43)	0.32 (-0.01, 0.64)	0.25 (-0.23, 0.73)
Work ability index	0.40 (0.06, 0.75)	0.64 (0.26, 1.02)	0.23 (-0.27, 0.73)
HSCL-25	0.14 (-0.16, 0.43)	0.36 (0.06, 0.65)	0.22 (-0.19, 0.63)
EQ-5D	0.24 (-0.19, 0.66)	0.39 (-0.03, 0.82)	0.16 (-0.42, 0.74)
FABQ A	0.26 (-0.11, 0.63)	0.16 (-0.22, 0.54)	-0.10 (-0.62, 0.42)
FABQ B	-0.19 (-0.53, 0.16)	0.17 (-0.14, 0.49)	0.36 (-0.10, 0.82)
PSFS	0.53 (0.07, 0.98)	0.72 (0.20, 1.24)	0.19 (-0.47, 0.86)
Shoulder abductor MVC	0.08 (-0.06, 0.22)	0.31 (0.17, 0.44)	0.23 (0.03, 0.42)
Neck flexor MVC	0.39 (0.20, 0.57)	0.44 (0.27, 0.61)	0.05 (-0.20, 0.30)
Neck extensor MVC	0.24 (0.03, 0.44)	0.42 (0.24, 0.61)	0.18 (-0.09, 0.46)
Pressure pain threshold	0.10 (-0.17, 0.37)	-0.12 (-0.35, 0.11)	-0.22 (-0.57, 0.13)

NRS, Numerical pain rating scale; NP, Neck pain; HSCL-25, Hopkins symptom checklist 25; FABQ A, Fear avoidance beliefs questionnaire in relation to physical activity; FABQ B, Fear avoidance beliefs questionnaire in relation to work; PSFS, Patient specific functioning scale; MVC, Maximal isometric voluntary contraction

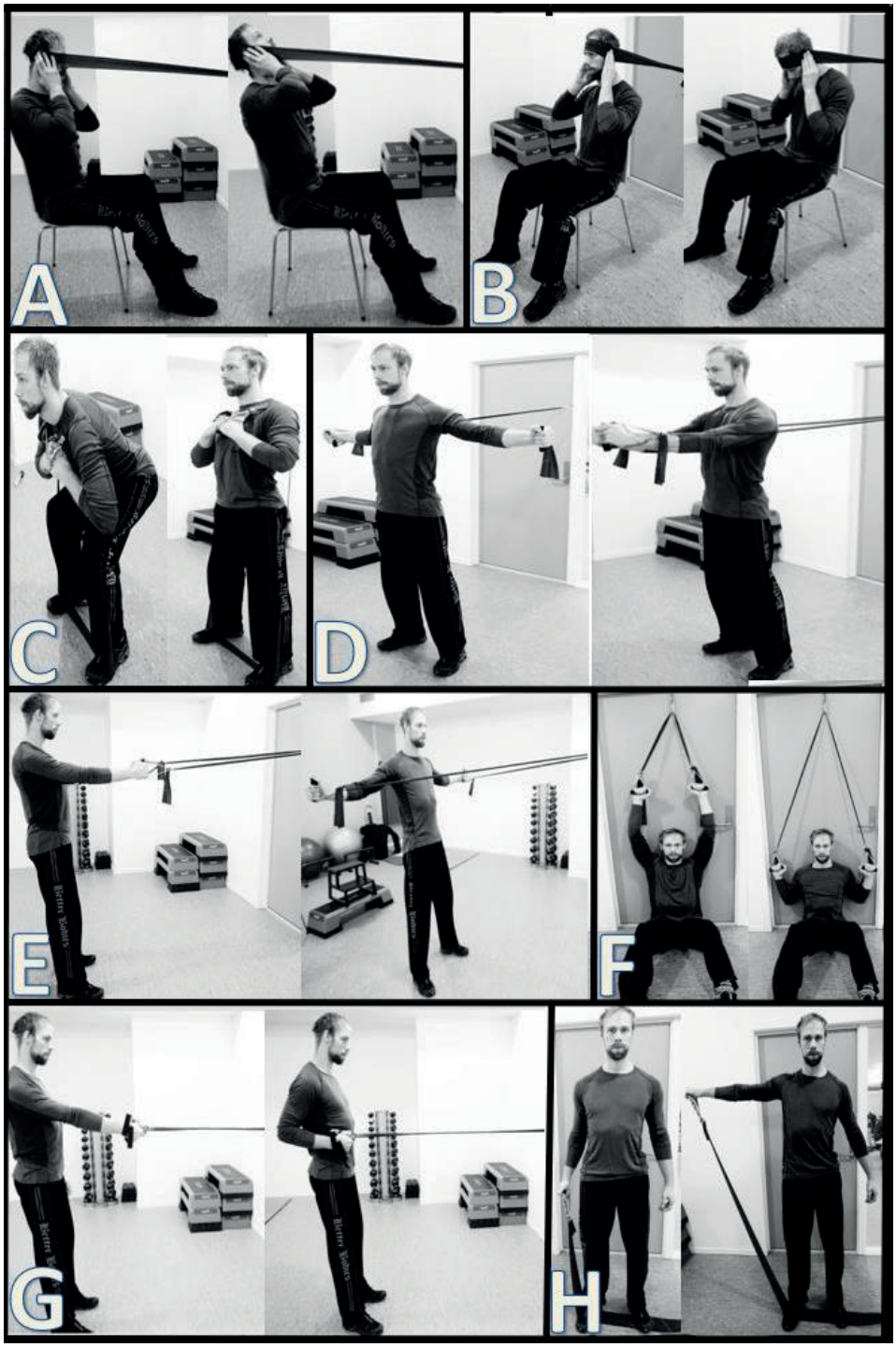


Fig.1 Illustration of the elastic resistance bands exercises; A) neck extension, B) neck flexion, C) squats, D) flies, E) reversed flies, F) lateral pulldown, G) unilateral row, H) shoulder abduction.

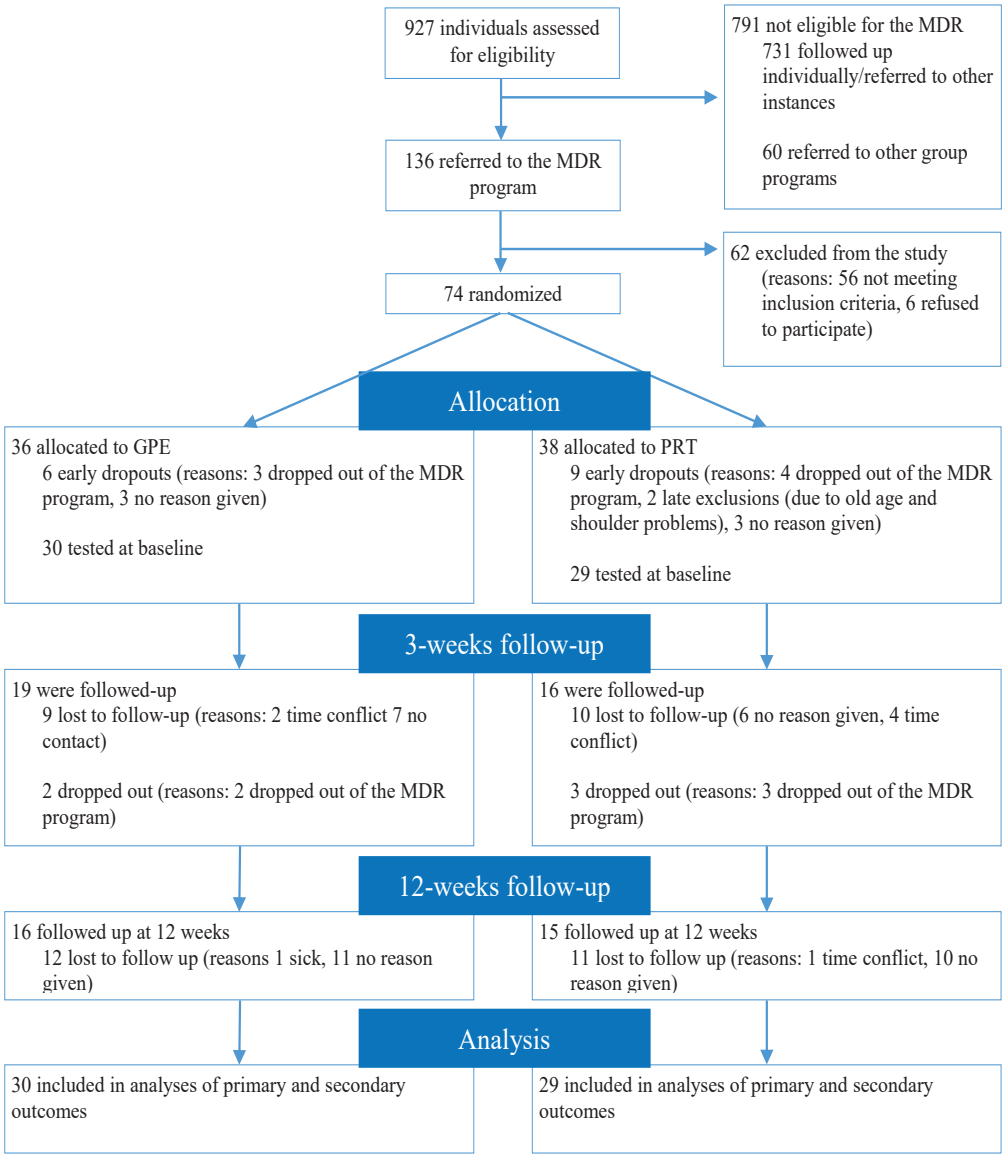
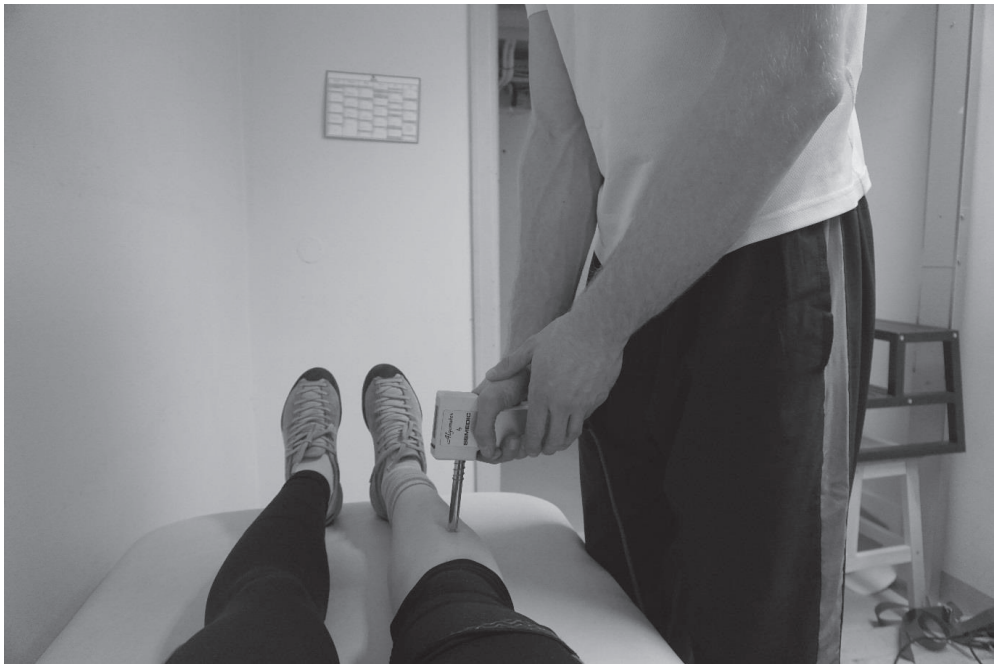


Fig. 2 Participant flow: MDR = Multidisciplinary rehabilitation, GPE = General physical exercise, PRT = Progressive resistance training.

Online Fig.1 Setup for test of shoulder abduction strength.



Online Fig.2 Setup for test of pressure pain threshold for tibialis anterior.