Randomized Trial

Effect of Two Contrasting Interventions on Upper Limb Chronic Pain and Disability: A Randomized Controlled Trial

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Free full manuscript: www.painphysicianjournal.com **Background:** Chronic pain and disability of the arm, shoulder, and hand severely affect labor market participation. Ergonomic training and education is the default strategy to reduce physical exposure and thereby prevent aggravation of pain. An alternative strategy could be to increase physical capacity of the worker by physical conditioning.

Objectives: To investigate the effect of 2 contrasting interventions, conventional ergonomic training (usual care) versus resistance training, on pain and disability in individuals with upper limb chronic pain exposed to highly repetitive and forceful manual work.

Study Design: Examiner-blinded, parallel-group randomized controlled trial with allocation concealment.

Setting: Slaughterhouses located in Denmark, Europe.

Methods: Sixty-six adults with chronic pain in the shoulder, elbow/forearm, or hand/wrist and work disability were randomly allocated to 10 weeks of specific resistance training for the shoulder, arm, and hand muscles for 3 x 10 minutes per week, or ergonomic training and education (usual care control group). Pain intensity (average of shoulder, arm, and hand, scale 0 – 10) was the primary outcome, and disability (Work module of DASH questionnaire) as well as isometric shoulder and wrist muscle strength were secondary outcomes.

Results: Pain intensity, disability, and muscle strength improved more following resistance training than usual care (P < 0.001, P = 0.05, P < 0.0001, respectively). Pain intensity decreased by 1.5 points (95% confidence interval -2.0 to -0.9) following resistance training compared with usual care, corresponding to an effect size of 0.91 (Cohen's d).

Limitations: Blinding of participants is not possible in behavioral interventions. However, at baseline outcome expectations of the 2 interventions were similar.

Conclusion: Resistance training at the workplace results in clinical relevant improvements in pain, disability, and muscle strength in adults with upper limb chronic pain exposed to highly repetitive and forceful manual work.

Trial registration: NCT01671267.

Key words: Musculoskeletal pain, workability, shoulder pain, elbow pain, tennis elbow, wrist pain

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usculoskeletal disorders represent the most common type of occupational disease, accounting for one-third to half of all injury and illness cases registered in the EU and US (1,2). The consequences of musculoskeletal

disorders is pervasive, affecting employee health and wellbeing, and imposing a substantial socioeconomic burden due to extensive use of health care services, sickness absence, disability pension, and loss of productivity (3-7). Physical exposures such as repetitive and forceful muscle work, lack of sufficient recovery, precision demands, and awkward postures are risk factors for upper limb musculoskeletal pain (8-10). The prevalence of musculoskeletal pain in the shoulder, arm, and hand is high among slaughterhouse workers, due to the high loading intensities and cyclic repetitive muscle actions during work (8, 11-14). The rate of nonfatal occupational illnesses and injuries for workers engaged in animal slaughtering in the US is more than twice as high as the national average, and the number of cases with days away from work, job transfer, or restriction are almost 3 times the national average (15).

Lowering physical exposure through ergonomic training and education represents the default strategy to prevent the development or aggravation of musculoskeletal pain. However, ergonomic training may not be sufficient for individuals already in pain (16,17). An alternative strategy could be to increase the workers' physical capacity by physical conditioning programs performed at the workplace. Physical exercise is a cornerstone in the prevention and treatment of numerous chronic diseases (18). Thus, previous research has demonstrated promising and effective reductions of neck and shoulder pain in response to 10 - 20 weeks of resistance training at the workplace using kettlebells (19,20), elastic resistance bands (21,22), or free weight exercises (23-25) in sedentary employees. By contrast, repetitive and forceful muscle work may - in theory hinder adequate recovery between resistance training sessions and workdays. Therefore, relevant grounds exist to investigate whether resistance training is a clinically relevant intervention to reduce chronic pain and disability in workers with repetitive and forceful job tasks.

Hence, the aim of this study is to investigate the effect of 2 contrasting interventions, i.e. load reduction through ergonomic training and education (usual care) versus increased physical capacity through resistance training on pain and work disability in individuals with chronic upper limb pain exposed to highly repetitive and forceful manual work.

METHODS

Study Design

This 2-armed parallel-group, examiner-blinded, randomized controlled trial with allocation concealment was conducted among slaughterhouse workers in Denmark, from August 2012 to January 2013. The study was approved by The Danish National Ethics Committee on Biomedical Research (Ethical committee of Frederiksberg and Copenhagen; H-3-2010-062) and registered in ClinicalTrials.gov (NCT01671267) prior to enrollment of participants, which ensured that the study aim, hypothesis, and primary outcome were pre-defined. The CONSORT checklist was followed to ensure transparent and standardized reporting of the trial. All participants were informed about the purpose and content of the project and gave their written informed consent to participate in the study. All experimental conditions conformed to The Declaration of Helsinki. The study design has previously been reported (26).

Recruitment and Flow of Patients

The recruitment was 2-phased and consisted of a brief screening questionnaire followed by a personal clinical examination and questionnaire.

First, a screening questionnaire was administered to 645 Danish slaughterhouse workers (aged 18 - 67 years) employed in 2 large-scale pig slaughterhouses. Slaughterhouses in Denmark handle slaughtering, processing, packaging, and distribution of meat and employ between 500 and 2,000 workers. In total 595 individuals replied to the guestionnaire of which 410 were interested in participating in the research project. The initial inclusion criteria based on the screening questionnaire were (1) currently working at a slaughterhouse for at least 30 hours a week, (2) pain intensity in the shoulder, elbow/forearm, or hand/wrist of 3 or more on a 0 – 10 visual analog scale (VAS) during the last 3 months, (3) stating at least some work disability scoring on a 5-point scale: not at all, a little, some, much, to very much when asked the question During the last 3 months, did you have any difficulty performing your work due to pain in the shoulder, arm, or hand, (4) no participation in resistance training during the last year, (5) no ergonomic instruction during the last year. Of the 410 interested respondents, 145 met the above inclusion criteria and were invited for a clinical examination.

A total of 135 employees presented for the baseline clinical examination. Exclusion criteria were hypertension (Systolic BP > 160, diastolic BP > 100); a medical history of cardiovascular diseases; carpal tunnel syndrome; recent traumatic injury of the neck, shoulder, arm, or hand regions; or pregnancy. Furthermore, at the day of the clinical examination, participants filled in another questionnaire with the following inclusion criteria: (1) pain intensity in the shoulder, elbow/forearm, or hand/ wrist of at least 3 on a 0 - 10 VAS during the last week;

(2) pain should have lasted more than 3 months; (3) frequency of pain of at least 3 days per week during the last week.

Based on the clinical examination and associated questionnaire, 69 workers were excluded due to contraindications: 19 showed symptoms of carpal tunnel syndrome, 4 had blood pressure above 160/100 mmHg, one had a serious cardiovascular disease, and 19 did not meet the pain inclusion criteria. Furthermore, 26 were excluded because they did not speak or understand Danish sufficiently to fill in the questionnaire. The overall flow of patient enrollment is illustrated in Fig. 1.

Randomization and Blinding

On the basis of the clinical examination and associated questionnaire the 66 eligible patients with chronic pain and disability were randomly allocated to either resistance training intervention or ergonomic training and education (usual care), respectively, using a computer-generated random numbers table (SAS). Gender and worksite (2 slaughterhouses) were used as stratification variables. Subsequently, patients



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were informed by letter about group allocation. At the follow-up physical examination and questionnaire from December 2012 – January 2013, all examiners were blinded, and patients were instructed not to reveal their particular intervention. Table 1 provides baseline characteristics of the 2 intervention groups.

Due to the interventional trial design, patients and instructors (i.e. resistance training and ergonomic instructors) could not be blinded to group allocation. However, all outcome assessors and data analysts were blinded to group allocation. Further, we explained to the patients that neither of the interventions was known to be superior to the other.

Interventions

Resistance training: Patients were allocated to a 10 week intervention period and parallel assigned to receive either resistance training or ergonomic training (usual care, control group) at their worksite. The specific intervention activities have been described in detail previously (26). In brief, subjects randomized to the resistance training group (n = 33) performed supervised high-intensity resistance training for the shoulder, arm, and hand muscles for 10 minutes 3 times a week. The training program consisted of 8 resistance exercises: 1 - 2: shoulder rotation in 2 planes with elastic tubing (Thera-Band), 3 - 4: ulnar and radial deviation of the wrist using sledgehammers, 5: eccentric training of the wrist extensors using a FlexBar (Thera-Band), 6: wrist flexion and extension by the use of a wrist roller

(IronMind), 7: flexion of the hand using a hand gripper (IronMind), 8: extension of the hand and fingers using expand-your-hand bands (IronMind). Training intensity (loads) was progressively increased from 20 repetition maximum (RM) at the beginning of the training period to 8 RM during the latter phase according to the principle of periodization and progressive overload (27). All training sessions took place in designated training rooms located at the worksites and were supervised by a skilled instructor, who instructed the participants in correct exercise techniques, and performing individual exercise adjustments when needed. At the first training session each participant received exercise equipment for home training (red and green Thera-Band elastic tubing and a green Thera-Band Hand Xtrainer) in case of absence from work (e.g. vacation).

Ergonomic training: Health and safety managers and safety representatives with existing knowledge about ergonomic risk-factors on the specific slaughterhouses provided information necessary to identify ergonomic hazards in the workplace. Based on this information, a specially trained ergonomic group in each slaughterhouse conducted a job hazard analysis and in correspondence with health and safety managers and safety representatives, developed a system for hazard prevention and control. The participants in the ergonomic group (n = 33) received ergonomic training and education based on the practical outcomes of the worksite analysis and the hazard prevention system. The intervention was implemented by health

Table 1. Baseline characteristics of the two intervention groups. Values are means (SD).

	Resistance training	Ergonomic training (~usual care)
n	33	33
Number of men/women	25/8	26/7
Age (years)	48 (9)	43* (9)
Height (cm)	174 (10)	177 (9)
Weight (kg)	83 (20)	86 (17)
BMI (kg·m-2)	28 (6)	28 (5)
Average pain intensity of the shoulder, elbow/forearm and hand/wrist during the last week (scale 0–10)	4.5 (1.2)	4.5 (1.2)
Shoulder pain intensity during the last week (scale 0–10)	5.6 (2.2)	5.7 (2.0)
Elbow/Forearm pain intensity during the last week (scale 0-10)	4.1 (2.9)	4.2 (2.4)
Hand/Wrist pain intensity during the last week (scale 0–10) Work disability (DASH work module; scale 0–100) Wrist extensor strength (Newton) Shoulder rotation strength (Newton)	3.9 (2.8) 28.3 (13.8) 111 (25) 76 (17)	3.7 (2.6) 27.8 (13.8) 110 (25) 77 (17)

* difference between groups at baseline, P < 0.05.

and safety managers and safety representatives at the 2 slaughterhouses and took place during the initial weeks, which corresponds to the standard worksite ergonomic prescription. The majority of the ergonomic training addressed job specific hands-on training where participants received appropriate guidance and training in how to correctly handle the individual work stations. Supervisors affiliated with each department of the slaughterhouse monitored and helped participants to continue using proper work practice during the rest of the intervention period.

Primary Outcome Measures

The primary outcome was the change from baseline to 10-week follow-up in pain intensity (average of 3 regions; shoulder, elbow/forearm, and hand/wrist, respectively) experienced during the last 7 days. Pain intensity was rated subjectively using the 0 – 10 modified VAS, where 0 indicates "no pain at all" and 10 indicate "worst pain imaginable" (21,28). The shoulder, elbow/ forearm, and hand/wrist regions were defined by drawings from the Nordic questionnaire (29).

Secondary Outcome Measures

Participants rated work disability at baseline and follow-up by the work module of the Disability of the Arm Shoulder and Hand (DASH) questionnaire:

Select which best describes your physical ability in the past week. Did you have any difficulty...

- 1) Using your usual technique for your work?
- 2) Doing your usual work because of arm, shoulder or hand pain?
- 3) Doing your work as well as you would like?
- 4) Spending you usual amount of time doing your work?

Participants replied on a 5-point Likert scale from "no difficulty" to "'unable." For comparability with VAS pain scores, the work disability score was normalized on a scale of 0 – 100, where 100 represents the highest level of disability (30).

Maximal voluntary isometric contraction strength (MVC) was obtained for the shoulder and wrist muscles using a custom-built dynamometer with 2 strain gauge load cells (KIS-2, 1 KN, Vishay Transducers Systems). Patients were seated upright in a chair with the elbow flexed at 90° while applying outward-directed force to a vertical orientated handlebar (dynamometer setting) in front of them. The anterior part of the forearm was supported by the dynamometer setting and allowed the participants to push against during the isometric MVC. Maximal shoulder

muscle strength (MVC) was assessed during concurrent isometric external rotation of the gleno-humeral joint while wrist strength was measured by isometric extension of the radio-carpal joint. The patients performed 2 attempts of each MVC, separated by a 30 second rest period, and were instructed to apply force to the handlebar (i.e. dynamometer) as fast and forcefully as possible. The MVC trial with the highest peak force was selected in each individual for further statistical evaluation.

Sample Size

Power calculations performed prior to the study showed that 27 participants in each group were necessary for testing the null hypothesis of equality of treatment at an alpha level of 5%, a statistical power of 95%, a minimally relevant difference in pain intensity of 1.5 and SD of 1.5 on a scale of 0 - 10. At an estimated dropout or loss to follow-up of 10%, the minimal number of patients in each group at baseline was 30.

Statistical Analysis

All statistical analyses were performed using the SAS statistical software for Windows (SAS Institute, Cary, NC). The outcomes were analyzed according to the intention-to-treat principle using a repeated measures 2×2 mixed-factorial design (Proc Mixed), with time, group, and time by group as independent categorical variables (fixed factors). Each patient was entered as a random effect. Analyses were adjusted for gender, workplace, and pain intensity at baseline.

The proportion of patients showing improvement or a worsening in chronic pain symptoms are reported in accordance with Andersen et al (21). Much improvement was defined as \geq 50% decrease, some improvement as between \geq 25% and < 50% decrease in VAS scores, and no change as between < 25% decrease and < 25% increase, some worsening as between \geq 25% and < 50% increase, and much worsening as \geq 50% increase from baseline to follow-up (21).

Finally we calculated effect sizes as Cohen's d (31) based on average pain intensity (between-group differences divided by the pooled standard deviation).

An alpha level of 0.05 was used for statistical significance. Outcome variables are reported as betweengroup least square mean differences and 95% confidence intervals from baseline to follow-up.

RESULTS

Table 1 shows baseline characteristics of the patients. At baseline, age was slightly higher in the

resistance training group compared with the ergonomic training group (P = 0.05). However, we found no significant influence of age (P = 0.74) on the primary outcome. There were no significant differences among the groups for the remainder of the variables.

Five participants did not complete the intervention; 3 in the resistance training group and 2 in the ergonomic training group (Fig. 1). These participants did not present for the follow-up examination, but we included their baseline data in the statistical analyses. In the training group, one patient dropped out due to job transfer, one patient dropped out due to illness unrelated to the resistance training program, and one patient dropped out due to training having no subjective effect on upper-limb pain levels. In the ergonomic training group, one patient dropped out due to job transfer while one patient dropped out due to illness unrelated to the ergonomic training program.

Adherence to the ergonomic training program was 97%, as one individual refused to receive any ergonomic training and education. The resistance training group performed on average 2.4 of the 3 intended training sessions per week, corresponding to a training adherence of 81%.

Participants' Outcome Expectations

According to a 7-point scale at baseline, the individuals involved in the study had similar outcome expectations to the 2 interventions concerning the effectiveness on chronic pain. The 7-point scale ranged from -3 to 3; where -3 represented "much worsening" of pain symptoms, 0 represented "no change" in pain symptoms, and 3 represented "much improvement" in pain symptoms. The mean expectations of the outcome of the resistance training intervention and the ergonomic training (usual care) were 1.5 ± 1 and 1.4 ± 1.2 , respectively.

Pain, Disability, and Muscle Strength

Fig. 2 illustrates the change in pain intensity from baseline to 10 week follow-up. A priori hypothesis testing showed a strong group by time interaction for pain intensity (P < 0.001). Compared with the ergonomic training group, average pain intensity decreased -1.5 (-2.0 to -0.9) in the resistance training group (Table 2). The same pattern was observed for regional shoulder (P < 0.01), elbow/forearm (P < 0.05), and hand/wrist (P < 0.01) pain intensity (Fig. 2.). In the resistance training group, 73% experienced some or much improvement of pain (Table 3), while this was only the case for 32% in the ergonomic group. In the resistance training group, only 3% experienced worsening of pain (Table 3), while this was the case for 26% in the ergonomic group. The effect size (Cohen's d) of the change in pain was 0.91 and categorized as large (\geq 0.80) with resistance training.

Analysis of variance showed a group by time interaction for work disability (work module of the DASH questionnaire) (P = 0.05). Compared to ergonomic training, work disability improved to a greater extent with resistance training (-8.8 [-15.6 to -2.0] scale 0 – 100, Table 2).

A group by time interaction was also observed for wrist and shoulder muscle strength (P < 0.0001). Compared with the ergonomic training group, both strength parameters increased to a greater extent in the resistance training group (Table 2).

DISCUSSION

Our study showed clinically relevant improvements in pain, work disability, and muscle strength in industrial workers with upper limb chronic pain in response to 10 weeks of customized resistance training at the work place.

Patients allocated to resistance training experienced a clinically relevant reduction in average pain intensity score of 1.8 points from baseline to follow-up with half of the participants responding with much improvement. Previous studies have shown effective reductions in neck and shoulder pain in response to 10 – 20 weeks of strength training using kettlebells (19,20), elastic rubber bands (21,22), or free weight exercises (23-25) in office workers and laboratory technicians. However, while office workers and laboratory technicians mostly perform repetitive low-force working tasks, slaughterhouse workers are exposed to a setting of highly repetitive high-force work tasks for which the effect of resistance training intervention has not previously been examined.

Few studies have investigated the effect of occupational rehabilitation programs on upper limb pain in individuals involved in moderate-to-heavy manual work. Ludewig and Borstad (32) reported positive treatment effects of an 8-week home exercise program in construction workers with shoulder pain and impingement syndrome. The individuals performing home-training (everyday stretching and shoulder strengthening exercises 3 days a week) reported a greater relief in symptoms, function, and disability than symptomatic inactive controls. However, the inclusion of an inactive control



Table 2. Changes in average pain intensity (average of pain in shoulder, elbow/forearm, and hand/wrist), work disability (DASH; work module) and maximal muscle strength from baseline to 10-week follow-up. Differences of each group are shown on the left, and contrasts between the groups on the right. Values are means (95% confidence interval).

	Difference from baseline to follow-up		Between group difference	
	Reistance training	Ergonomic training (usual care)	Resistance vs Ergonomic	P Value
Average pain intensity (0–10)	-1.8 (-2.3 to -1.2)	-0.3 (-0.8 to 0.3)	-1.5 (-2.0 to -0.9)	< 0.0001
DASH-W score (0–100)	-6.5 (-13.2 to 0.1)	2.8 (-3.7 to 9.4)	-8.8 (-15.6 to -2.0)	< 0.05
Shoulder rotation strength (N)	28 (19 to 36)	-10 (-18 to -2)	37 (28 to 45)	< 0.0001
Wrist extensor strength (N)	30 (18 to 42)	-11 (-23 to 2)	42 (29 to 54)	< 0.0001

P < 0.05).

Table 3. Percentage of participants showing improvement, no change or worsening of perceived pain intensity in the shoulder, elbow/forearm and hand/wrist regions from baseline to 10-week follow-up (P < 0.01). Cut-points were: < 25% = no change; $\geq 25\%$ to < 50% = some change; $\geq 50\% =$ much change.

	Average pain intensity for shoulder, elbow/forearm and hand/wrist (%)		
	Resistance training	Ergonomic training (usual care)	
Much improvement	50	16	
Some improvement	23.3	16	
No change	23.3	42	
Some worsening	0	13	
Much worsening	3.3	13	

group and the fact that no objective measures were obtained to support muscular adaptations to training weakens the validity of their results. Thus, these results may have been influenced by placebo effects due to higher subjective outcome expectations in the trained individuals compared with their inactive controls (33). By contrast, the present study compared 2 likely effective interventions that had similar outcome expectations of the patients at baseline, thereby minimizing the effect of placebo on changes in pain in one group over the other.

The magnitude of change in pain to be clinically meaningful has been widely debated in the literature. In patients with chronic pain, a change in pain intensity of 2 on a 0 - 10 scale is considered to be moderately clinically meaningful whereas a change of one is considered a minimal important change (34). Using an identical scale, Farrar et al (35) found that an absolute change of -1.74 and relative change of -27.9% were best associated with their definition of clinically important improvements at the individual level in clinical trials of chronic pain therapy. However, individual criteria for clinically relevant changes in pain intensity cannot be transferred to similar group changes, and an additional multi-factorial evaluation of the pros and cons of interventions is recommended (34). A large heterogeneity exists between studies in the definition of clinically important changes in pain, which led Ruyssen-Witrand et al (36) to suggest that both absolute differences and proportions of responders should be presented (Table 3) along with a comparison of the primary outcome and the clinically relevant difference in pain used in the sample size calculation.



In the present study, half of the participants performing resistance training demonstrated much improvement in pain symptoms (i.e. at least 50% pain reduction) and a quarter experienced some improvement (i.e. between 25 – 50% pain reduction), which was a significantly higher proportion compared with the ergonomic group (Table 3). Involving all resistance training participants, average chronic pain decreased 39% from baseline to follow-up. The absolute change in average chronic pain between resistance training and usual care ergonomic training was 1.5, and the effect size, calculated as Cohen's d, could thus be categorized as large (≥ 0.80). Thus, the resistance training intervention induced clinically relevant improvements in pain compared with ergonomic training.

The resistance training intervention was also more effective than ergonomic training in improving work disability as assessed by the work module of the DASH questionnaire. Thus, the pain reduction was paralleled by functional improvements of the arm, shoulder, and hand during daily work tasks. This is in line with a randomized controlled trial by Andersen et al (25) in laboratory technicians showing reductions of work disability of the shoulder, arm, and hand in response to 20 weeks of resistance training compared with waiting list controls. However, the inclusion of a waiting list control group rather than comparison with usual care increases the risk of greater outcome expectations in their treated group (25).

The resistance training intervention was also more ef-

fective than ergonomic training in increasing strength of the shoulder and wrist muscles. This was expected as the resistance training program was designed to effectively strengthen the painful muscles in the shoulder, arm, and hand. An increase in physical capacity would likely lower relative exposure during work which could indirectly have contributed to the observed improvements in pain and disability (37). A key ingredient in the program was the use of eccentric training – i.e. controlled lowering of the weight –which has shown promising effects in the treatment of several specific upper extremity disorders such as shoulder tendinopathies (38,39) and lateral epicondylitis (40).

Our study has both strengths and limitations. The randomized controlled design with concealed allocation and blinded clinical examiners protects against systematic bias. Further, the low loss of patients at followup, the high adherence to the intervention regimes, and inclusion of drop-outs in the statistical analysis allowed us to test the actual effect of the interventions. A general weakness of behavioral interventions is that blinding of participants and those administrating the intervention is not possible. Accordingly, perceived and reported pain may be influenced by outcome expecta-

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tions. However, to minimize this type of bias we included 2 active interventions groups rather than comparing treatment with a waiting list group. A strength of our study is that patient outcome expectations at baseline were similar to the resistance training and ergonomic training interventions, suggesting that placebo effects are unlikely to differentially affect the 2 groups. The gains in shoulder and wrist extensor strength observed among individuals allocated to resistance training but not ergonomic training further supports that the occurrence of beneficial physiological adaptations was a result of the intervention activity (resistance exercise) per se. Finally, the exclusion and inclusion criteria used in the present study confines the generalizability of our results to workers with chronic pain in the arm, shoulder, and hand regions, and who are exposed to highly repetitive and forceful work.

CONCLUSION

Resistance training at the workplace results in clinically relevant improvements in pain, disability, and muscle strength in adults with upper limb chronic pain exposed to highly repetitive and forceful manual work.

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