Targeting shoulder complaints in employees with high mechanical shoulder exposures

PhD dissertation

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Preface

This PhD study was carried out during my employment at Elective Surgery Centre, Silkeborg Regional Hospital, Denmark, while employed as a PhD fellow at the Department of Clinical Medicine, Aarhus University, Denmark. Numerous individuals deserve a special thanks for their contributions, engagement, and support during the work.

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LIST OF SCIENTIFIC PAPERS

This PhD dissertation is based on the following papers:

Paper 1

Trøstrup J, Mikkelsen LM, Frost P, Dalbøge A, Høybye MT, Casper SD, Jørgensen LB, Klebe TM, Svendsen SW.
Reducing shoulder complaints in employees with high occupational shoulder exposures: study protocol for a cluster-randomised controlled study (The Shoulder-Café Study).
Trials. 2019;20:627.

Paper 2

Trøstrup J, Frost P, Dalbøge A, Mikkelsen LR, Høybye MT, Jørgensen LB, Casper SD, Klebe TM, Svendsen SW.
Reducing shoulder complaints in employees with high-occupational shoulder exposures: a cluster-randomised controlled study (The Shoulder-Café Study).
Journal of Occupational Rehabilitation (submitted April 2022).

Paper 3

Trøstrup J, Svendsen SW, Dalbøge A, Mikkelsen LR, Høybye MT, Jørgensen LB, Casper SD, Klebe TM, Frost P.
Increased shoulder pain across an exercise session and subsequent shoulder exercise: a prospective cohort study.
BMC Musculoskeletal Disorders (In review)

The papers are found in Appendices 1–3.

LIST OF ABBREVIATIONS

BMI	Body mass index
CI	Confidence interval
CONSORT	Consolidating standards of reporting trials
FABQ-PA	Fear-Avoidance Beliefs Questionnaire - Physical Activity
EOI	End of intervention
IQR	Interquartile range
MD	Mean difference
MCID	Minimal clinically important difference
NA	Not applicable
NR	Not relevant
NRS	Numerical rating scale
OR	Odds ratio
OSS	Oxford Shoulder Score
PGIC	Patient's Global Impression of Change
Quick-DASH	Quick-Disabilities of Arm, Shoulder and Hand questionnaire
RCT	Randomised controlled trial
SD	Standard deviation
SAP	Statistical analysis plan
SIS	Subacromial impingement syndrome
SOI	Start of intervention
SPIRIT	Standard protocol items: recommendations for interventional trials checklist
STROBE	Strengthening the reporting of observational studies in epidemiology statement
TIDieR	The template for intervention description and replication
VAS	Visual analogue scale
WAS	Work Ability Score

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1. Introduction

1. Introduction

1.1. Prevalence of shoulder complaints

Shoulder complaints are common. In the general adult population, international estimates of the monthly prevalence of self-reported shoulder complains are between 19% and 31% and the yearly prevalence is between 5% and 47% (1, 2). This large variation in prevalence may be explained by differences in case definitions (e.g., size of anatomic area) and differences in the instruments used to measure shoulder complaints (1, 2). The prevalence is highest in women (1, 2), in people aged 45 to 64 years (1), and in people with physically demanding jobs (3, 4). In primary care, shoulder complaints are the third most common musculoskeletal complaint (4). According to a Danish population-based register of primary care consultations, which included 522,000 inhabitants in August 2011 (5), the yearly prevalence of shoulder complaints was 1.4%, and about 40% of the patients were referred to secondary care (5). Although the natural history of shoulder complaints is often self-limiting, a large number of the patients seen in primary care have persistent pain and disability, and only up to 25% of the patients have recovered 6 months (6, 7) after symptom presentation and 59% after 12 months (8, 9). In this dissertation, shoulder complaint is the term used for shoulder pain and decreased shoulder function.

1.2. Clinical shoulder evaluation

The treatment of shoulder complaints is based on a clinical shoulder evaluation (10), which includes a clinical history and a physical examination with clinical tests leading to a working diagnosis (11). The working diagnosis intends to guide clinical decision-making and treatment, facilitate communication between health care providers, and ensure homogeneous patients groups in studies (12). In primary care, the most common cause of shoulder complaints is related to the rotator cuff (4). Numerous terms for non-traumatic pathology affecting the rotator cuff and related anatomical structures are used such as subacromial impingement syndrome (SIS), subacromial pain syndrome, rotator cuff disease, and rotator cuff tendinosis (12-14). The pathogenesis of non-traumatic rotator cuff-related shoulder complaints is often unclear (14, 15), and the mentioned terms are often used as umbrella terms without respect to the precise anatomical location (e.g. muscle or bursa) and mechanism (e.g. degenerative or impingement) (16). In this dissertation, SIS is used as the term for non-traumatic rotator cuff-related complaints.

SIS is defined as anterolateral shoulder pain combined with a positive result of a minimum of three of the following five clinical tests: Hawkins' test, Neer's clinical test, painful arc test, Jobe's test, and pain on resisted external rotation (17, 18). SIS accounts for 32% to 44% of the registered non-traumatic shoulder-related diagnoses in primary care (9, 19).

1.3. Risk factors

Risk factors for SIS comprise individual (e.g., demographic), psychosocial (e.g., job demands and job control), and mechanical factors (20). In relation to mechanical factors, occupational

mechanical shoulder exposures, including work with elevated arms, repetitive shoulder movements, and forceful shoulder exertions, are especially prevalent risk factors (21-25). The use of hand-arm vibration tools has also been associated with an increased risk (21, 24).

1.4. Individual and socio-economic consequences

Not all people with shoulder complaints contact their general practitioner (26) and many people work despite complaints. However, shoulder complaints have obvious individual and socio-economic consequences, with increased risk of shoulder surgery (27) and long-term sick leave (28). The combination of shoulder complaints and high occupational mechanical shoulder exposures is especially associated with increased risk of shoulder surgery (23) and long-term sick leave (28). In addition, a study has shown that among people with shoulder surgery, about 16% receive sick-leave compensation 1 year after surgery (29) and about 10% leave the labour market within 2 years after surgery due to work disability (30).

1.5. Treatment of shoulder complaints

According to Danish (15) and international guidelines (31-33), exercise therapy is recommended as first-line treatment in people with non-traumatic subacromial shoulder complaints. In Denmark, first-line treatment also includes education about self-treatment and, in the case of occupational mechanical shoulder exposures, work modifications (15).

1.5.1. Exercise therapy

The effect of exercise therapy as a treatment for shoulder complaints has been investigated in numerous randomised controlled trials (RCTs), and the effectiveness based on RCTs has been summarised in numerous systematic reviews. The systematic reviews generally find a decrease in shoulder pain and an increase in shoulder function after exercise therapy (34-42). However, the RCTs are often of varied methodological quality due to factors such as the lack of blinding, use of non-validated outcome measures, and heterogenic comparisons (different exercise programmes, without description of the control intervention, or with varied follow-up times). Thus, the results of the systematic reviews are based on a low certainty of evidence. The effect of exercise therapy has also been qualitatively summarised in two reviews of systematic reviews (43, 44). The two reviews are presented in Table 1. The review by Littlewood et al. (43) supported exercise as being superior to no treatment or placebo in terms of statistical significance, but the clinical significance was unclear. The review by Pieters et al. (44), which aimed to update the review by Littlewood et al. (43), reported increasing and strengthening evidence for the use of exercise therapy as treatment. However, most of the included studies did not comment on the clinical importance of the effectiveness, and only one of the included studies reported an effect size for the effect of exercise therapy compared with non-exercise therapy. Thus, despite an increasing number of studies showing positive effects of exercise therapy, the clinical importance is still unknown (45).

Table 1. Reviews of systematic reviews evaluating effectiveness of exercise therapy for shoulder complaints (n = 2)

Author, year, design	Systematic reviews evaluating effectiveness of exercise	Methodological study quality*	Complaint	Intervention	Comparison	Outcome and follow-up	Study conclusion
Pieters, 2020 (44), umbrella review	N = 7	High (n = 3) Moderate (n = 4)	SIS	Exercise (not specified)	Non-surgical and non-pharmacological treatments	Pain and function at short and long term	Evidence for exercise as the most important management strategy is increasing and being strengthening. A strong recommendation can be made in favour of exercise
Littlewood, 2013 (43), review of reviews	N = 13	High (n = 2) Moderate (n = 11)	SIS	Exercise (not specified)	Placebo, no treatment, or surgery	Pain and function at short and long term	Exercise might be an effective intervention although the clinical significance of the effect is unclear

*Abbreviations: SIS = shoulder impingement syndrome (SIS). * Assessed with a measurement tool for systematic reviews (the AMSTAR checklist), characterising quality in high, moderate, or low.*

The effectiveness of supervised compared with home-based exercise therapy to reduce shoulder complaints has been studied in two systematic reviews with meta-analyses (46, 47). Based on a low certainty of evidence, due to lack of blinding, few studies, heterogenic studies, and wide CIs, both reviews concluded that supervised and home-based exercise therapy are equally effective with respect to shoulder complaints (46, 47). The review by Gutierrez-Espinoza et al. (46) included four RCTs in their meta-analyses which showed a mean difference (MD) of 0.21 (95% CI, −1.36 to 1.78, p = 0.79) for pain and a standardised MD of −0.14 (95% CI −1.04 to 0.76, p = 0.76) for function. The meta-analyses, however, were based on only one RCT that aimed to compare supervised and home-based exercise therapy (Granviken et al. (48)). The review by Liaghat et al. (47), in which the meta-analyses were based on RCTs aiming to compare supervised and home-based exercise therapy, included one RCT in their analysis of pain (Granviken et al. (48) and two in their analysis of function (Granviken et al. (48) and Erdem et al. (49)). The meta-analyses showed a MD of 0.20 (95% CI, −1.07 to 1.47, p = 0.76) for pain and a MD of 1.00 (95% CI, −8.80 to 10.79, p = 0.84) for function.

Due to the low certainty of evidence for equal effectiveness of supervised and home-based exercise therapy, we wanted to explore the impact of different exercise setting (supervised and home-based), exercise programmes and follow-up times. Therefore, we conducted an overview on RCTs comparing supervised and home-based exercise therapy for shoulder complaints. This overview aimed to inform us prior to planning our new intervention including exercise, and it aimed to assess whether we could affirm the conclusions of the previous two systematic reviews. It was not a systematic review, the literature search may not be exhaustive, and no risk of bias assessment was performed. Our overview was based on the studies included in the two previous systematic reviews (46, 47), but we only included studies that compared supervised and home-based exercise therapy performed according to similar exercise programmes. To identify additional relevant or new studies, we searched in PubMed for "similar articles" of the studies included in the two previous systematic reviews. The overview was updated by the PhD candidate for this dissertation. The following data were extracted from the original studies: i) authors, year of publication, and country, ii) sample characteristics (sample size and complaint), iii) comparison groups, iv) characteristics of the exercise programme, v) length of follow-up, vi) outcome assessments and vii) study conclusion. In Table 2, the seven RCTs included in the overview are presented. Six of the RCTs showed no difference between supervised and home-based exercise therapy with respect to shoulder pain and function (48-53), whereas one showed a group difference favouring supervised exercise therapy (54). This one RCT included 19 participants with a tendon rupture, what may be an explanation for the group difference. Based on our overview of RCTs, which included RCTs with few participants and short follow-up times and without blinding, supervised and home-based exercise also seemed equally effective.

Aggravation of shoulder pain is generally recommended to be kept at a minimum during exercise therapy (32) and not to be increased after an exercise session (15). However, conflicting arguments exist for accepting or rejecting short-lasting pain aggravation during

exercise therapy. Arguments for accepting some short-lasting, localised pain [≤4/10 on the visual analogue scale (VAS)] are that pain may be beneficial for tendon healing and that it may increase exercise motivation (32). Arguments for rejecting short-lasting pain aggravation during exercise therapy are that pain may indicate suboptimal exercises, overload of stressed tissue, and that it may decrease exercise motivation (32). The reasons for the conflicting arguments are that the effects of short-lasting pain aggravation are unknown. To date, no studies have examined whether short-lasting pain aggravation during shoulder exercise affects subsequent exercise dose or exercise adherence.

Table 2. Randomised controlled trials comparing the effect of supervised and home-based exercise programmes for shoulder complaints (n = 7)

Author, year, country	N, Complaint	Comparison	Exercise programme	Follow-up	Outcome assessment	Study conclusion
Christiansen, 2021, DK (51)	208, SIS	• Supervised groups • Supervised individuals • Home-based	All groups: Same programme of aerobic and strengthening exercises, 5 exercises x 3/week for 12 weeks	3 and 6* months	Quick-DASH*, NRS, FABQ	Within-group improvements No between-group difference
Asensio-Garcia, 2018, Spain (54)	74, non-traumatic, inoperable painful shoulder (e.g., SIS).	• Supervised groups • Home-based	Same programme of stretching, strengthening, and range of movement exercises for 5 weeks (recommended weekly exercise: not reported).	5 weeks	VAS*, Constant-Murley*, Quick-DASH*	Within-group effects not reported Greater improvements on Quick-DASH in the supervised exercise group No other group differences
Erdem, 2018, Turkey (49)	41, Shoulder pain	• Supervised • Home-based	Both groups: Same programme with range of movement and strengthening exercises: 12 exercises, x 3/day for 6 weeks	6 weeks	SPADI*, DASH	Within-group improvements No between-group difference
Granviken, 2015, Norway (48)	44, SIS	• Supervised Home-based	Both groups: individualised strengthening, range of movement, and scapula stability exercises, 4–6 exercises, x 2/day for 6 weeks	6* and 26 weeks	SPADI*, NRS, FABQ, Satisfaction	Within-group improvements No between-group difference
Senbusa, 2011, Turkey (52)	77, Partial tear or SIS	• Supervised • Manual therapy plus supervised • Home-based	All groups: Similar programmes of stretching, strengthening, and range of movement exercises, x 1/day for 12 weeks	4 and 12 weeks	VAS, MASES	Within-group improvements No between-group difference
Walther, 2004, Germany (53)	60, SIS	• Supervised • Home-based	Both groups: strengthening and stretching exercises, X 2–3/week (supervised) or x 5/week (home-based) for 12 weeks.	6 and 12 months	Constant-Murley*, VAS	Within-group improvements No between-group difference

Andersen, 1999, Denmark (50)	43, SIS operated	• Supervised • Home-based	Both groups: strengthening exercises for 6 weeks	3, 6 and 12 months	Constant-Murley*, Pain (0-15 scale)	Within-group improvements No between-group difference

*Abbreviations: Constant-Murley = Constant-Murley score, DASH = Disabilities of Arm, Shoulder and Hand questionnaire, FABQ = Fear-Avoidance Beliefs Questionnaire, MASES = The Modified American Shoulder and Elbow Surgery score, NRS = numerical rating scale, Quick-DASH = Quick-Disabilities of Arm, Shoulder and Hand questionnaire, SIS = shoulder impingement syndrome, SPADI = Shoulder Pain and Disability Index, VAS = visual analogue scale. * Primary follow-up time or primary outcome.*

1.5.2. Education

According to the fear-avoidance model, concerns about pain may cause people to avoid physical activity, including exercise therapy, in order to reduce pain (55, 56), but these concerns may lead to the opposite outcome, with increased pain and disability (55-57). Education that aims to encourage participants to engage in active self-treatment and that addresses potential concerns related to pain and activity could therefore play an important treatment role (57). Reviews also support education for behavioural change and for modifying negative health beliefs in people with musculoskeletal complaints (58-61). However, evidence for the effectiveness of education in improving musculoskeletal complaints is limited (58-60, 62).

1.5.3. Work modifications

Work modifications may include workplace adaptations, adaptations of job tasks, and adaptations of working hours (63). In Denmark, work modifications are recommended in people with shoulder complaints and high occupational mechanical shoulder exposures (15). Few studies have evaluated the effect of work modifications with respect to shoulder complaints, and these studies were mainly performed in office settings without high occupational mechanical shoulder exposures (64-66). This may explain the lack of observed effect in these studies.

1.5.4. Complex interventions

A systematic review suggests that multi-component interventions, e.g., interventions that combine exercise therapy, education, and work modifications, are more effective than single-component interventions, like exercise therapy alone, with respect to pain, disability, and fear-avoidance beliefs in people with low-back pain (67). Systematic reviews also suggest that multiple-component interventions are more effective than single-component interventions with respect to return-to-work in people with musculoskeletal pain (68, 69). The reason for this may be that multi-component interventions often address an array of biopsychosocial dysfunctions, whereas single-component interventions often focus on one dysfunction (67, 69). The focus on more dysfunctions may be relevant since musculoskeletal complaints often involve both physical, psychological, social, and work-related dysfunction (67-70). The more comprehensive focus in multiple-component intervention may explain why it appears to have a better effect than single-component interventions (67-70). However, evidence for the effectiveness of multi-component interventions with respect to shoulder complaints is limited (70, 71).

A multiple-component intervention, like most rehabilitation interventions (72), is often categorised as a complex intervention (73). In this dissertation, the term complex intervention is used for a multi-component intervention. No clear distinction between a complex and a less complex intervention exists (73). The degree of complexity depends on, i.a., the number of intervention components, requirements for active patient participation

(e.g., low in surgery; high in group interventions), the number of people involved in delivering the intervention, and knowledge about the "active" intervention ingredients (74).

1.5.5. Surgery

In 2019, the British Medical Journal Rapid Recommendations contained a strong recommendation against surgery as a treatment for non-traumatic shoulder complaints diagnosed as SIS (75, 76). This recommendation was based on new evidence from two large RCTs showing no clinically important benefit of surgery compared to placebo or no treatment in relation to pain, function, and quality of life (77, 78). Recently, the Danish Health Authority published similar recommendations (15), with a strong recommendation against surgery in people with non-traumatic shoulder complaints for less than 6 months diagnosed as SIS, and with a weak recommendation against surgery in people with symptoms of SIS for more than 6 months unless exercise therapy had failed (15). However, no alternative treatment for people with persistent symptoms of SIS has been published, and therefore, non-operative treatment needs to be optimised.

1.6. The development of a group-based care

In Denmark, formalised assessment and treatment of people with shoulder complaints usually begins with their general practitioner, who may refer the patient to, e.g., a physiotherapist, massage therapist, acupuncturist, or a hospital department of rheumatology, orthopaedic surgery, or occupational medicine (79). The patient may also receive multiple referrals to different health-care providers, leading to fragmented and uncoordinated care as experienced by patients (80).

To optimise treatment of shoulder complaints, the organisation of treatment in the Central Denmark Region was rethought as a part of a cross-sectorial and interdisciplinary innovation project. The project employed a patient involvement approach including a needs assessment. The assessment showed that the patients wanted knowledge about the reasons for the shoulder complaints, and opportunities for rapid diagnosis and early treatment. To meet this and to remedy the fragmented care, a group-based intervention was pilot tested in 2014 (80). This group-based intervention encompassed clinical shoulder screening, shoulder-related education, and shoulder exercises in one café meeting plus three supervised exercise sessions and a home-based exercise programme. Participants in the pilot test were recruited from a municipal health centre (group I, n = 49 with shoulder complaints) and from three companies within the Central Denmark Region (group II, n = 53). The companies were sampled by convenience sampling on the indication that they had employees with shoulder complaints. The pilot test was performed in participants who generally had mild baseline shoulder complaints, but even so, the results indicated that the intervention could reduce self-reported shoulder complaints. The pilot test was performed without a control group. In group I, 75% of the participants had moderate and 2% had strong baseline shoulder complaints compared with 57% and 2%, respectively, at end of intervention (EOI), and 44% and 6% at 3-month follow-up. In group II, 33% of the participants had moderate and 4% had strong baseline

shoulder complaints compared with 44% and 0% at EOI, and 25% and 0% at 3-month follow-up (80). The results also indicated that the group-based intervention could motivate participants to exercise and help them navigate the healthcare system better (80). In addition, health professionals indicated that the cross-sectorial collaboration was improved through the intervention (80). These positive indications opened a further development of the intervention and served as the backdrop for the present PhD study.

Another backdrop for both the group-based intervention (80) and the present PhD study was a Danish RCT from 2003 (81). This RCT of patients having undergone lumbar spinal fusion compared three interventions: group-based back-café, group-based supervised exercises, and home-based video exercises (81). After 2 years of follow-up, leg pain and daily function were most improved in the back-café group, and sick-leave and consultations with general practitioners were least in that group. It was suggested that the beneficial effects could be ascribed to the network and interpatient relationships at the cafés because they may have facilitated patients' coping with pain and have helped them to adopt the recommended exercises. Additionally, it was suggested that the cafés provided better physiotherapist support than the supervised exercise sessions (81).

2. Aims and hypotheses

2. Aims and hypotheses

In this study, we refined the pilot-tested group-based intervention and created the Shoulder-Café intervention targeting employees with shoulder complaints and high occupational mechanical shoulder exposures. The overall aim was to develop and evaluate the Shoulder-Café with respect to shoulder complaints. The three specific aims were as follows:

Aim 1 (Paper 1)

To develop, justify, optimise, and ensure transparency of the Shoulder-Café intervention prior to a RCT.

Aim 2 (Paper 2)

To compare the Shoulder-Café (the intervention) with the Shoulder-Guidance (an active control intervention – enhanced usual care) in relation to shoulder complaints, fear-avoidance beliefs, global impression of change, and a series of supplementary outcomes (i.e., intensity of shoulder pain, symptoms and physical function in upper limb, health-related quality of life, work ability, global impression of change, overall satisfaction and feeling of being informed about how to handle shoulder complaints, perform shoulder exercises, and reduce occupational mechanical shoulder exposures).

The main **hypothesis** was that the Shoulder-Café intervention would reduce shoulder complaints more effectively than the Shoulder-Guidance intervention. In addition, it was hypothesised that reductions of fear-avoidance beliefs, improvements in global impression of change, and improvements in supplementary outcomes would be larger in the Shoulder-Café group than in the Shoulder-Guidance group.

Aim 3 (Paper 3)

To examine whether increased shoulder pain across an exercise session was associated with a lower exercise dose in the next session and whether these associations (if any) were exaggerated by high levels of fear-avoidance beliefs.

The **hypothesis** was that increased shoulder pain across an exercise session would lead to a lower exercise dose in the next exercise session, and that the increased shoulder pain would especially affect persons with high levels of fear-avoidance beliefs.

A secondary aim was to examine whether increased shoulder pain across exercise sessions together with high levels of fear-avoidance beliefs influenced overall adherence to an exercise programme.

3. Methods

3. Methods

3.1. Paper overview

An overview of the titles, designs, reporting guidelines, populations, and methods used in the three papers is presented in Table 3.

Table 3. Overview of titles and methods used in the three papers

	Paper 1 (82)	Paper 2 (83)	Paper 3 (84)
Title	Reducing shoulder complaints in employees with high occupational shoulder exposures: study protocol for a cluster-randomised controlled study (The Shoulder-Café Study)	Reducing shoulder complaints in employees with high occupational shoulder exposures: a cluster-randomised controlled study (The Shoulder-Café Study)	Increased shoulder pain across an exercise session and subsequent shoulder exercise – a cohort study
Design	Study protocol	Cluster RCT	Prospective cohort study
Reporting Guidelines	• SPIRIT (85) • TIDieR (86)	• CONSORT 2010 (87, 88)	• STROBE (89)
Analysis population	NA	N = 109	N = 109
Analysed population	NA	n = 109	n = 79
Outcomes	NA	• Primary: OSS at 6-month follow-up • Secondary: OSS, FABQ-PA and PGIC at 6-month and/or 12-month follow-up	• Exercise dose • Overall exercise adherence
Predictors	NA	• Shoulder-Café intervention	• Change in shoulder pain • High FABQ-PA
Primary statistics	NA	• Linear mixed models • Logistic regression	• Linear mixed models • Logistic regression

Abbreviations: CONSORT = the consolidating standards of reporting trials, FABQ-PA = Fear-Avoidance Belief Questionnaire-Physical Activity, NA = not applicable, OSS = Oxford Shoulder Score, PGIC = Patients Global Impression of Change, SPIRIT = the standard protocol items: recommendations for interventional trials checklist, STROBE = the strengthening the reporting of observational studies in epidemiology statement, TIDieR = the template for intervention description and replication.

3.2. Study design

Paper 1 (Appendix 1) (82) was a protocol paper describing the cluster RCT. Paper 2 (Appendix 2) (83) was a two-arm parallel cluster RCT. Paper 3 (84) (Appendix 3) was a prospective cohort study based on data collected in the cluster RCT.

3.2.1. Reporting guidelines

The three papers follow guideline from the "Enhancing the quality and transparency of health Research" (EQUATOR) network. Paper 1 follows the "Standard protocol items: recommendations for interventional trials" (SPIRIT) checklist (85) and the "Template for intervention description and replication" (TIDieR) checklist and guide (86). Paper 2 follows two guidelines from the "Consolidating standards of reporting trials" (CONSORT) statement: the updated guidelines for reporting parallel group randomised trials (88) and the extension to cluster randomised trials (87). Paper 3 follows the "Strengthening the reporting of observational studies in epidemiology" (STROBE) statement (89).

3.3. Participants

Participants included in Paper 2 and Paper 3 were the same. They were recruited among employees in occupations with high mechanical shoulder exposures (23, 90, 91) within service, manufacturing, and construction industries. Occupations with high occupational mechanical shoulder exposures (working with upper arm elevation, repetitive shoulder movements, or forceful shoulder exertion) were prioritised. At recruitment start, companies with at least 20 employees in one of five occupations (cleaning assistants, industrial bakery, carpenters, electricians, and plumbers) within the three industries (service, manufacturing, and construction) were recruited. However, due to slow recruitment, the recruitment cohort was extended to include companies with at least one employee in one of 16 occupations within the three industries: service (hairdressers, gardeners, and cleaning, kitchen, and laundry assistants), manufacturing (wood industry, industrial bakery, and dairy) or construction (carpenters, electricians, plumbers, bricklayers, house painters, blacksmiths, welders, and insulation workers). The companies were identified through the Central Business Register in the Central Denmark Region and recruited batch-wise. Companies in one municipality were recruited as one batch. Employees in the selected occupations, from companies who agreed to participate, were asked to complete a screening questionnaire (Appendix 4). Employees who were eligible according to the screening questionnaire were also interviewed by telephone to determine participation (Appendix 5). Participants were eligible regardless of previous or current treatment for shoulder complaints (apart from shoulder surgery). The inclusion and exclusion criteria are listed in Table 4. A more detailed description of the participants is found in Paper 1 (82).

Table 4. Participant eligibility

Inclusion criteria	• Self-reported shoulder pain • No previous shoulder surgery • 18 to 65 years old • Working in one of the selected occupations (within service, manufacturing, or construction industry) • Oxford Shoulder Score ≤ 40* • Provided contact information • Agreed to be contacted
Exclusion criteria	• No current shoulder pain • Prolonged sick leave expected to continue into the intervention period • Weekly working hours < 20 • Health conditions expected to affect participation • Evening or night job • Inability to communicate in Danish • Non-valid Oxford Shoulder Score • Declined further participation • Failed to consent or complete the baseline questionnaire before intervention start

** The criterion of an Oxford Shoulder Score ≤ 40 was provided to ensure that included employees had shoulder complaints. The cut-off level was based on the group-based intervention (80), where around 20% had an Oxford Shoulder Score ≤ 40. This cut-off level was supported by mean scores of 44–48 in asymptomatic populations* (92-95).

3.4. Randomisation and blinding

3.4.1. Randomisation

Participating companies, defined as clusters, were allocated to the Shoulder-Café or Shoulder-Guidance intervention by computer-generated randomisation numbers. Randomisation was performed with a 1:1 allocation ratio, stratification by industry (service, manufacturing, or construction) and with randomly permuted block sizes of 2, 4, and 6. Envelopes with randomisation numbers and corresponding intervention were prepared by a research assistant.

When all relevant employees within one batch had completed the screening questionnaire and the telephone interview, the PhD candidate (as the principal investigator) opened the envelopes for each company within that batch and invited eligible employees to the allocated intervention. To avoid long distance transportation, the employees were invited to participate in the intervention in the municipality of their company. The randomisation result was not revealed to participants before they had completed the baseline questionnaire and had signed the informed consent at their first physical meeting or appointment. In this PhD dissertation, the first meeting or appointment is defined as start of intervention (SOI).

Cluster randomisation was used to prevent contamination between participants in the Shoulder-Café and the Shoulder-Guidance groups. Companies were not informed about the number of included employees from their company or the randomisation result. However, if a workplace visit was arranged, the company was informed about it and encouraged to participate.

3.4.2. Blinding

Blinding aims to minimise performance bias (88). However, due to the character of the interventions, blinding of participants and providers was not possible. In an attempt to equalise expectations regarding the two interventions, participants were informed that the study aimed to show whether the new intervention could reduce shoulder complaints and high occupational mechanical shoulder exposures (Appendix 6–7), but they were blinded to the study hypotheses.

Statistical analyses in Paper 2 and Paper 3 were performed by the PhD candidate, who was not blinded due to unequal number of participants in the two interventions. However, to minimise the risk of bias, statistical analyses in Paper 2 were performed in line with a pre-published statistical analysis plan (SAP) (Appendix 8).

3.5. Interventions and setting

3.5.1. Interventions

The difference (Appendix 9) between the two interventions was their complexity (73, 74). The Shoulder-Café was a group intervention designed as a complex intervention with several interacting components, whereas the Shoulder-Guidance intervention was an individual intervention designed to be less complex (73, 74). Both interventions were planned as a 2- to 3-month course including:

- A home-based shoulder-exercise programme consisting of one posture correction exercise and three resistance exercises performed with an elastic band and including the possibility for individual progression. Based on previous studies showing the effect of exercise programmes (96-99), JT and three physiotherapists from the shoulder clinic at Silkeborg Regional Hospital choose the exercises. The programme was recommended to be completed three to four times per week throughout the intervention period. The programme was described in a pamphlet (Appendix 10).
- General information on occupational mechanical shoulder exposures and instructions about how to reduce the exposures. The information was provided in a pamphlet (Appendix 11).
- Two individual assessments of occupational mechanical shoulder exposures and individual written feedback about the exposure assessment (Appendix 12).

In addition, the Shoulder-Café included three 2-hour group-based café meetings with:

- Coffee, tea, and possibility for small talk and network.

- Three supervised exercise sessions performed in accordance with the home-based exercise programme (Appendix 13).
- One individual clinical shoulder evaluation (Appendix 14).
- Two education sessions: One focusing on shoulder anatomy, pain, and exercise therapy, and one focusing on work health and safety (Appendix 15).
- Possibility for questions about the first individual shoulder exposures assessment.
- Possibility for a workplace visit for those who found this to be necessary.

3.5.2. Setting

The setting under study was the Central Denmark Region with physical attendance at six geographically dispersed municipal health centres. Shoulder-Café participants had three scheduled physical café meetings, whereas Shoulder-Guidance participants had one physical appointment. The time period for recruiting companies spanned from January 2017 to December 2018 and for recruiting employees from January 2017 to May 2019. The interventions were conducted between August 2017 and August 2019.

Stakeholder group

A stakeholder group was established to facilitate the completion of the study and subsequent implementation if that was found relevant. The group had six members: three members representing trade unions [3F (manufacturing), BAR Service/Tjeneste (service), and Dansk-EL (construction)], one member representing municipal rehabilitation centres, one member representing general practice, and one member representing the Health Planning Agency in the Central Denmark Region.

3.6. Outcomes and measurement points

3.6.1. Overview of study outcomes and measurement points

Table 5 presents an overview of study outcomes, co-interventions, adverse events, baseline variables, and measurement points. Screening was mean 87 (SD = 63) days before baseline, baseline was few days before SOI, and follow-up was 6 and 12 months after SOI.

Table 5. Overview of study outcomes, co-interventions, adverse events, baseline variables, and measurement points

Measurement points	Screening	Baseline	During intervention	6 months' follow-up	12 months' follow-up
Outcomes					
Oxford Shoulder Score (100)	x	x		x*	x**
Fear-Avoidance Beliefs Questionnaire - Physical Activity (56, 101)		x##		x**	x**
Patient's Global Impression of Change (102)				x**	x***

Numerical rating scale (used at rest and during activity) (103, 104)		x		x***	x***
Quick Disabilities of Arm, Shoulder and Hand questionnaire (105)		x		x***	
EQ-5D (EQ 5D-3L and –VAS) (106, 107)		x		x***	
Work Ability Score (108, 109)		x		x***	x***
Overall satisfaction				x***	x***
Felt informed about how to • handle shoulder complaints, • perform shoulder exercises, • reduce occupational mechanical shoulder exposures				x***	
Exercise sessions			x#		
Exercise dose			x#		
Visual analogue scale (104)			x##		
Co-interventions					
Use of analgesics in last 4 weeks		x		x	
Steroid injection				x	x
Shoulder surgery				x	x
Seen by doctor because of shoulder complaints				x	
Shoulder treatment by physiotherapist outside the project				x	
Shoulder treatment by chiropractor				x	
Adverse events				x	
Baseline variables					
Age	x				
Sex	x				
Body mass index		x			
Industry	x			x	x
Smoking status		x			
Dominant-sided pain		x			
Duration of shoulder complaints		x			

** Primary outcome in Paper 2, ** secondary outcome in Paper 2, *** supplementary outcome in Paper 2, # outcome in Paper 3, ## predictor in Paper 3.*

3.6.2. Outcomes in Paper 2

The primary outcome in Paper 2 was shoulder complaints measured with the Oxford Shoulder Score (OSS) (100, 110, 111). The OSS was selected as it is one of the recommended first-choice instruments (112) and has previously been used in non-operated populations (112-114). The OSS consists of 12 items relating to shoulder pain and function in the past 4 weeks. The total score ranges from 0 (worst) to 48 (best) (111). The Danish validated version was used (115). The primary measurement point was at 6-month follow-up because this was assessed as being enough time to allow potential effects to evolve. However, since the effect of rehabilitation often depends on behaviour change and therefore is slower (116), the OSS at 12-month follow-up was added as secondary outcome.

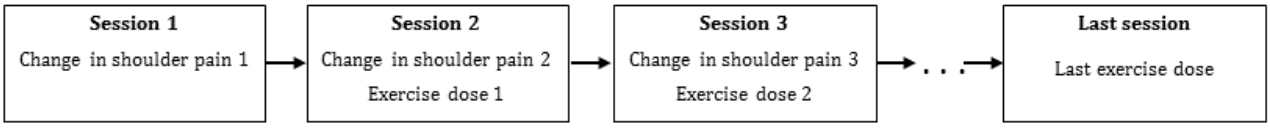
One of the secondary outcomes in Paper 2 was pain-related fear measured with the Fear-Avoidance Beliefs Questionnaire - Physical Activity (FABQ-PA) in a shoulder version (56, 101). This is considered reliable and valid in populations with shoulder complaints (117). FABQ-PA was selected because we hypothesised that reduced pain-related fear could be part of the Shoulder-Cafés mechanism of action. The FABQ-PA consists of four items, each referring to present shoulder pain in relation to physical activity. The total sum ranges from 0 (no fear) to 24 (high fear) (101). Measurement points at 6-month and 12-month follow-up were used. The other secondary outcome was participants' reflections on overall improvement regarding shoulder complaints measured with Patient's Global Impression of Change (PGIC) at 6-month follow-up. PGIC was measured on a Likert scale ranging from 1 (much better) to 7 (much worse) (102). To provide participants' long-term reflections on overall improvement, the PGIC at 12-month follow-up was added as supplementary outcome.

A series of supplementary outcome measures were included: intensity of shoulder pain at rest and during activity measured on a numerical rating scale (NRS) ranging from 0 (no pain) to 10 (worst pain) (103, 104); symptoms and physical function in the upper limb measured with a Danish version of the Quick Disabilities of Arm, Shoulder and Hand questionnaire (Quick-DASH) including 11 questions calculated as a total score ranging from 0 (no disability) to 100 (most severe disability) (105); health-related quality of life measured with the Danish EQ-5D-3L comprising five questions calculated to an index score ranging from -0.624 (worst health state) to 1.0 (best health state) and the EQ-5D-VAS (106, 107); lifetime work ability measured with the single-question Work Ability Score (WAS) ranging from 0 (unable to work) to 10 (work ability at its best) (108, 109); PGIC at 12 months; overall satisfaction with the received intervention measured with a single question ranging from 1 (satisfied) to 5 (dissatisfied); the degree to which the participant felt sufficiently informed about how to handle shoulder complaints, perform shoulder exercises, and reduce occupational mechanical shoulder exposures measured with three questions each ranging from 1 (much informed) to 4 (not informed at all). Measurement points at 6-month and/or 12-month follow-up were used (Table 5).

3.6.3. Outcomes and predictors in Paper 3

The primary outcome in Paper 3 was exercise dose. Exercise dose was quantified in terms of: 1) number of repetitions, defined as the total number of repetitions per exercise session; 2) progression level, defined as the mean progression level per exercise session; 3) resistance level, defined as the mean elastic band resistance per exercise session; and 4) time until next exercise session, defined as the number of days between two exercise sessions. Exercise dose was analysed with respect to change in shoulder pain in a previous exercise session (Figure 1).

Figure 1. Change in shoulder pain and exercise dose in relation to exercise sessions



The figure shows that exercise dose is analysed in relation to change in shoulder pain in a previous session.

The other outcome in Paper 3 was overall adherence to the exercise programme, calculated according to weekly exercise sessions. Because the exercise programme was recommended to be completed three to four times per week, high overall adherence was ideally ≥ 3 weekly exercise sessions. However, as only a few participants completed ≥ 3 weekly exercise, high overall adherence was defined as ≥ 2 weekly exercise sessions. For descriptive purposes, however, complete overall adherence, a subgroup of high overall adherence, was defined as ≥ 3 weekly exercise sessions. Overall adherence was measured from SOI to EOI.

One of the predictors in Paper 3 was change in shoulder pain measured with the VAS ranging from 0 (no pain) to 10 (worst pain) (104). VAS was calculated as pain at rest shortly after an exercise session minus pain at rest shortly before an exercise session. For the analysis of exercise dose, the predictor was change in shoulder pain in a previous exercise session (Figure 1). For the analysis of overall adherence, the predictor was an individual mean change in shoulder pain during the intervention based on all exercise sessions. The other predictor was high baseline FABQ-PA classified as > 14 on the FABQ-PA (118-120).

3.7. Data collection

3.7.1. Questionnaires

Questionnaires (Appendix 4 and Appendices 16–18) were used to collect self-reported outcomes at screening, baseline, and follow-up. The questionnaires were provided electronically or on paper. Screening questionnaires were delivered to the relevant employees by the companies. If no or only a few screening questionnaires were returned, the PhD candidate or an assistant sent a reminder to the companies. Baseline and follow-up questionnaires were delivered to participants by the PhD candidate, who reminded those

participants who had not completed the questionnaires to do so. The baseline questionnaire had to be completed before SOI.

3.7.2. Exercise diaries

Exercise diaries were used to collect data on exercise dose, overall adherence to the exercise programme, and change in shoulder pain during exercise. A picture of a page in the exercise diary is presented in Figure 2. The exercise diaries had 50 pages.

Figure 2. A page in the exercise dairy

Session number:_____

Pain at rest before exercise:

No pain ☺ _____ ☹ Worst pain

Exercise		Amount of repetitions	Progression level	Resistance level
1				
2		1. set: Repetitions:_____ 2. set: Repetitions:_____ 3. set: Repetitions:_____	□ Low □ Medium □ High	□ Low □ Medium □ High
3		1. set: Repetitions:_____ 2. set: Repetitions:_____ 3. set: Repetitions:_____	□ Low □ Medium □ High	□ Low □ Medium □ High
4		1. set: Repetitions:_____ 2. set: Repetitions:_____ 3. set: Repetitions:_____	□ Low □ Medium □ High	□ Low □ Medium □ High

Pain at rest after exercise:

No pain ☺ _____ ☹ Worst pain

In the original exercise diaries, which were provided in Danish, the line for reporting pain before and after exercise was 10 cm from "No pain" to "Worst pain" ([in Danish] "Ingen smerte" til "Værst tænkelige smerte").

3.7.3. Other data sources

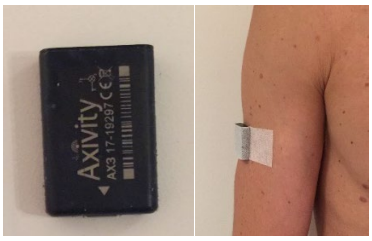
In addition to exercise diaries, BandCizer sensors (121) were used to monitor exercise activity. A BandCizer sensor is a small devise, mounted on participants' elastic-bands during exercise, used to measure exercise date, numbers of repetitions and sets, and time-under-tension (total time of muscle contraction during an exercise session (122)) for each exercise session (123). Data from the BandCizer sensors were used to compare exercise activity in Paper 2. Figure 3 shows a BandCizer sensor (3.a) and how it was mounted on an elastic band (3.b).

Figure 3. a) A BandCizer sensor; b) How the BandCizer sensor was mounted on an elastic-band (Appendix 10)

Figure 3. a Figure 3. b

Data on occupational mechanical shoulder exposures were collected twice during the intervention using Axivity accelerometers (AX3 data logger) (124) and work diaries. Participants wore an Axivity accelerometer for 1 to 5 working days and registered data in the diaries at the same time. This was performed shortly after SOI (the first exposure assessment) and shortly after EOI (the second exposure assessment). The exposure data included work with upper arm elevation (min/day), repetitive shoulder movements (º/s), and a forceful shoulder exertion (scale 0–11) (125). Figure 4 shows an Axivity accelerometer (4. a) and how participants wore it (4. b). The exposure data were analysed by a researcher, who prepared individual feedback on the shoulder exposures for each participant (Appendix 12). Shoulder-Café participants received the feedback based on the first exposure assessment at the second café meeting, where they could ask questions about the feedback. Shoulder-Guidance participants received the feedback based on the first exposure assessment by email or surface mail, while all participants received the last exposure feedback by email or surface mail.

Figure 4. a) An Axivity accelerometer; b) How the Axivity accelerometer was taped to an overarm



4. a 4. b

3.7.4. A process evaluation

To evaluate the delivery and experience of the interventions among participants and health professionals, a nested process evaluation was integrated into the study. The evaluation employed observations of the interventions and the interactions, individual interviews with four Shoulder-Café participants and three Shoulder-Guidance participants, and a focus group interview with 12 of the participating physiotherapists, including the health and safety consultant. The process evaluation was carried out by a project group which did not include the PhD candidate. Following the conclusion of analysis of the PhD papers, the process

evaluation report (126) was made available to the PhD candidate, and some of the insights from this evaluation were used in the discussion and perspective sections of this dissertation.

3.8. Sample size calculation

In Paper 2, the sample size calculation was based on an expected minimal clinically important difference (MCID) in the OSS at 6-month follow-up. With a MCID of 5 OSS points (77, 127, 128), an expected standard deviation (SD) of 8 OSS points (96), an expected intraclass correlation coefficient of 0.05 (129), an expected mean cluster-size of four, 48 participants were needed in each group to reach a power of 80% and a significance level of 0.05. To ensure that enough participants completed the study, we aimed to include 60 participants in each group. In Paper 3, all participants from the cluster RCT were included.

3.9. Statistical analyses

The analysis population in Paper 2 and Paper 3 consisted of randomised participants with a valid OSS who consented and did not withdraw their consent at any point. Descriptive statistics were presented with mean (SD), median [interquartile range (IQR)], or number and percentage depending on the distribution and type of variable. All analyses were performed using Stata 16 (StataCorp LP, College Station, TX, USA).
In Paper 2, employees who declined participation after completing the screening questionnaire were compared with the analysed population with respect to age, sex, industry, and OSS. In Paper 3, participants who were included and those who were excluded due to missing data were compared based on baseline characteristics.

3.9.1. Statistics in Paper 2

Statistical analyses in Paper 2 were based on the SAP (Appendix 8). Primary analyses were performed in accordance with the intention-to-treat principle based on the analysis population. The OSS at 6-month follow-up was analysed with linear mixed models. The analysis was performed using crude and adjusted models for baseline OSS (continuous), sex, age (continuous), and industry (service, manufacturing, construction) as fixed effects, and with company as random effect. The effect estimate was the MD (Shoulder-Café minus Shoulder-Guidance) reported with 95% confidence interval (CI) based on bootstrap with 100 repetitions allowing for non-normality of the outcome. The OSS at 12-month follow-up was analysed likewise. The other continuous outcomes (FABQ-PA, NRS, Quick-DASH, EQ-5D, and WAS) were analysed in the same way as the OSS with adjustment for the relevant baseline variable (continuous) instead of baseline OSS. Adjusted risk ratios for the categorical outcomes (PGIC (better, no better/worse), overall satisfaction (satisfied, not satisfied), and felt informed about how to handle shoulder complaints (yes, no), perform shoulder exercises (yes, no) and reduce occupational mechanical shoulder exposures (yes, no)) were analysed with logistic regression using crude and adjusted models for sex, age (continuous), and industry (service, manufacturing, construction) with robust standard errors to account for clustering at company level. The usual missing rule for the OSS (111) was used. The number

of participants with missing data was reported. Three sensitivity analyses were performed based on the OSS at 6-month follow-up: I) effects of differential loss to follow-up were analysed in accordance with four rather extreme scenarios: participants with a missing OSS at 6-month follow-up had their OSS replaced by predicted values from the regression analysis added or subtracted with 1 SD (the overall SD at six-months follow-up), II) an intention-to-treat analysis including participants with a OSS <35, and III) a per-protocol analysis including participants with full attendance at café meetings. No interim analyses were planned, and no stopping rules defined because the interventions were based on non-invasive methods not expected to cause any adverse events other than possible temporary muscle tenderness after shoulder exercise.

3.9.2. Statistics in Paper 3

Exercise dose was analysed with linear mixed models allowing for data clustering according to company and repeated measurements. Participants with a minimum of one exercise session including data for change in shoulder pain and one subsequent exercise session were kept in the models. Analyses were performed using crude and adjusted models for age (continuous), sex, body mass index (BMI) (continuous), smoking status (never, ex, current), dominant-sided pain (yes, no), baseline pain at rest (continuous), intervention arm, days since SOI (continuous), exercise session number (continuous), and with an interaction term between change in shoulder pain (continuous) and baseline FABQ-PA (high, low). Associations were presented as MDs with 95% CIs based on bootstrapping.
Overall adherence was analysed using logistic regression with robust standard errors allowing for intragroup correlation at company level. The individual mean change in shoulder pain was used as the predictor of increased shoulder pain (continuous). The analyses were performed using crude and adjusted models for age (continuous), sex, BMI (continuous), smoking status (never, ex, current), dominant-sided pain (yes, no), baseline pain at rest (continuous), intervention arm, and with an interaction term between change in shoulder pain (continuous) and baseline FABQ-PA (high, low). The risk estimates were calculated as odds ratios (ORs) with 95% CIs.

3.10. Ethics

The study was approved by the Danish Data Protection Agency on 7 September 2017 and by The Committee on Health Research Ethics in the Central Denmark Region (case number: 1–10–72-271-16) on 30 October 2017. It was registered at ClinicalTrials.gov (ID: NCT03159910) on 19 May 2017. Principles of the Declaration of Helsinki (130) was followed and informed consent was obtained from all participants.

4. Results

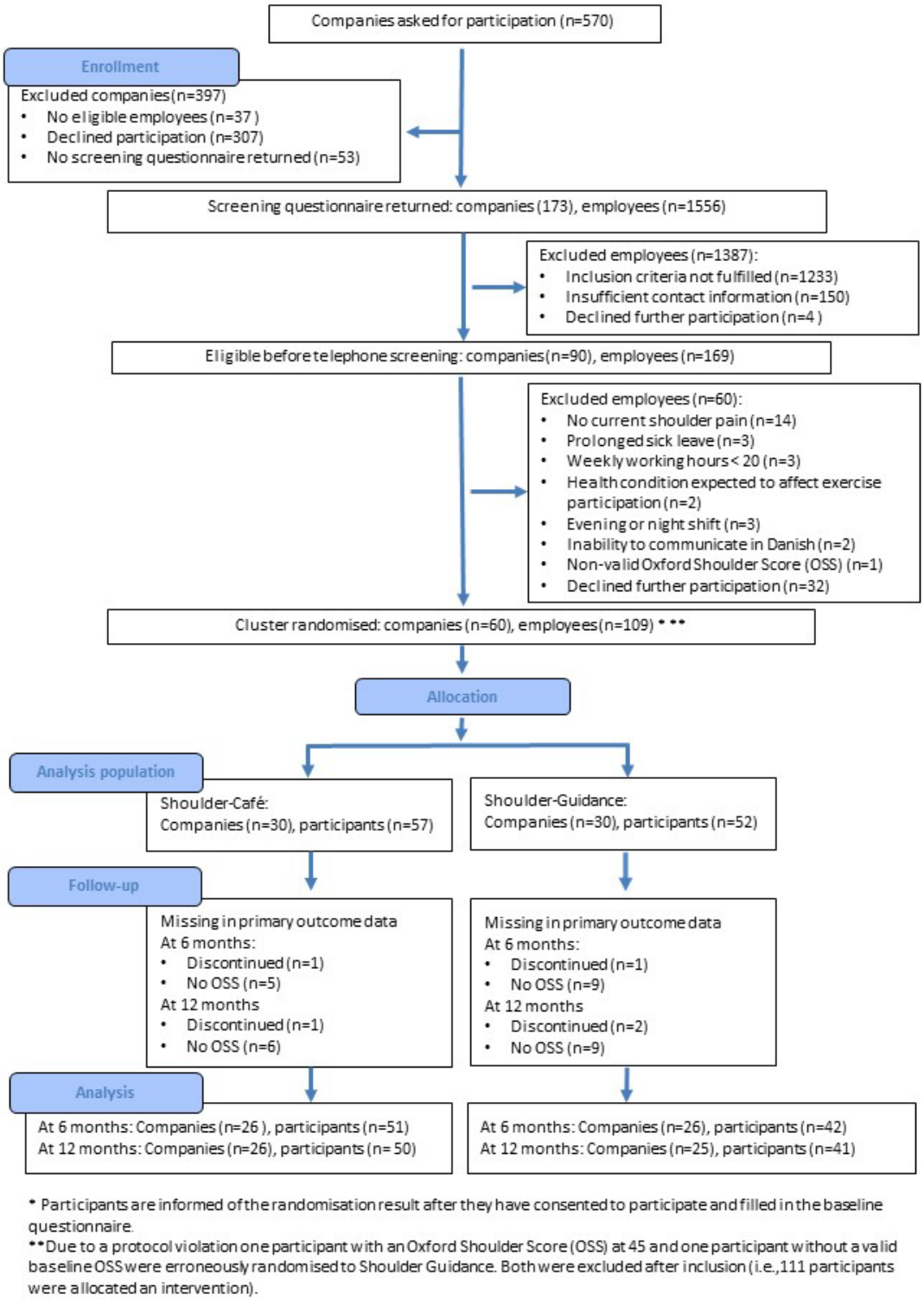
4. Results

A Shoulder-Café intervention was developed, the study was registered at Clinicaltrials.gov, and a protocol paper with the rationale, content, and delivery of the intervention was published prior to the cluster RCT (82). The Shoulder-Café was a further development of the pilot-tested group-based intervention (80), which was compared with the Shoulder-Guidance, an active control intervention. Because our target group was employees with high occupational mechanical shoulder exposures, assessments of occupational mechanical exposures, advice on work modifications, and possibility for a workplace visit were additional Shoulder-Café components compared with the pilot-tested intervention.

4.1. Participant flow

Participant flow is presented in Figure 5. A total of 1556 employees from 173 companies completed the screening questionnaire, of which 109 employees formed the analysis population. The randomisation procedure placed 57 participants in the Shoulder-Café group (30 companies) and 52 participants in the Shoulder-Guidance group (30 companies). In Paper 2, 85% of the participants were analysed at 6-month follow-up and 83% at 12-month follow-up. In Paper 3, 72% of the participants were analysed.

Figure 5. Participant flow. Combined from (83, 84).



**Due to a protocol violation, one participant with a screening Oxford Shoulder Score of 45 and one participant without a valid baseline Oxford Shoulder Score were erroneously randomised to Shoulder Guidance. Both were excluded after inclusion (i.e.,111 participants were allocated an intervention).*

4.2. Baseline characteristics

Employees who declined participation after completing the screening questionnaire (n = 32), did not differ from the analysis population (n = 109) with respect to age, sex, industry, or OSS (83) (results not shown).

The mean age of the analysis population was 47.4 (SD = 10.1) years, most were men (68%), most were construction workers (61%), and their median OSS at screening was 37 (IQR: 34 to 38). The baseline characteristics of the Shoulder-Café and Shoulder-Guidance participants appeared well-balanced, except for median duration of shoulder complaints. Participants who were excluded in Paper 3 due to missing in exercise diaries (n = 30) were comparable to those without missing data (n = 79) despite a tendency for those with missing to be younger, more often men, and more often smokers. Baseline characteristics of participants with and without missing data in Paper 2 and Paper 3 are presented in Table 6.

Table 6. Baseline characteristics for participants with and without missing variables in Paper 2 and Paper 3. Combined from (83, 84)

	Paper 2				**Paper 3**	
Intervention	Shoulder-Café	Shoulder-Guidance	Shoulder-Café	Shoulder-Guidance	Shoulder-Café and Shoulder-Guidance	
Analysis population (N)	Analysis population (109 participants)		Population with 6-months follow-up (93 participants)		Analysis population (109 participants)	
Analysed population (n)	57 participants, 30 companies	52 participants, 30 companies	51 participants, 25 companies	42 participants, 24 companies	79 participants without missing, 48 companies	30 participants with missing, 26 companies
Cluster-size	1.9 (1.3)	1.7 (1.2)	2.0 (1.4)	1.8 (1.3)	1.6 (1.1)	NR
Age in years, mean (SD)	48.8 (9.5)	45.7 (10.8)	49.6 (9.6)	46.5 (10.4)	48.0 (10.3)	45.5 (9.9)
Male, n (%)	37 (65)	37 (71)	34 (67)	30 (71)	51 (65)	23 (77)
BMI, mean (SD)	26.8 (4.8)	27.9 (6.3)*	26.7 (5.7)	28.5 (6.4)	26.9 (4.9)	27.5 (8.4)
Industry, n (%)						
Service	13 (23)	15 (29)	11 (21)	13 (31)	21 (27)	7 (23)
Manufacturing	10 (17)	3 (6)	9 (18)	1 (2)	8 (10)	5 (17)
Construction	34 (60)	34 (65)	31 (61)	28 (67)	50 (63)	18 (60)
Smoking status, n (%)						
Never	22 (37)	29 (56)	19 (37)	24 (57)	37 (47)	13 (44)
Ex	22 (39)	13 (25)	20 (39)	12 (29)	28 (35)	7 (23)
Current	14 (24)	10 (19)	12 (24)	6 (14)	14 (18)	10 (33)

Dominant-sided pain, n (%)	40 (70)	38 (73)	36 (71)	32 (76)	54 (68)	24 (80)
Duration of shoulder complaints in months, median (IQR)	60 (24 to108)*	36 (24 to 102)	60 (24 to 96)	42 (24 to 96)	39 (24 to 78)	69 (21 to 108)
FABQ-PA, mean (SD)	12.6 (5.2)	11.5 (5.4)*	12.9 (5.4)	11.3 (5.0)	11.9 (5.2)	12.9 (5.7)*
High FABQ-PA**	NR	NR	NR	NR	19 (24)	10 (34)
Diagnosis of SIS, n (%)***	22 (39)	NR	NR	NR	17 (38)	NR
OSS, median (IQR)	38 (35 to 40)	38 (36 to 42)	38 (34 to 41)	38 (36 to 41)	NR	NR
Use of analgesics in last 4 weeks, n (%)	24 (42)	26 (50)	20 (39)	21 (50)	NR	NR
NRS at rest, median (IQR)	2 (1 to 3)	2 (1 to 4)	2 (1 to 3)	2 (1 to 4)	NR	NR
High NRS at rest, n (%)#	NR	NR	NR	NR	32 (41)	16 (53)

*Abbreviations: BMI = body mass index, CI = confidence interval, FABQ-PA = Fear Avoidance Beliefs Questionnaire – Physical Activity, IQR = interquartile range, NR = not relevant, NRS = numerical rating scale, OSS = Oxford Shoulder Score, SD = standard deviation. * 1 – 4 missing, ** FABQ-PA dichotomised in high > 14 / low ≤ 14, *** evaluated in Shoulder-Café participants only, #NRS dichotomised at the median in high (3-10) / low (0-2).*

4.3. Adherence to the interventions

Eleven Shoulder-Café courses, including a mean of five participants (range: 3–9), were completed. In the Shoulder-Café group, 48 participants (84%) completed at least two café meetings, 32 (56%) completed all three café meetings, and 24 (42%) had a workplace visit. The exercise diaries were returned by 50 (88%) Shoulder-Café participants and 35 (67%) Shoulder-Guidance participants. The BandCizer sensors were returned by 51 (90%) Shoulder-Café participants and 36 (69%) Shoulder-Guidance participants. Adherence to home-based exercises was not different between the groups. According to the exercise diaries, the mean number of exercise sessions was 18.2 (SD = 10.0) in the Shoulder-Café and 15.5 (SD = 10.1) in the Shoulder-Guidance groups. According to the BandCizer sensors, the mean number of exercise sessions was 14.8 (SD = 9.5) in the Shoulder-Café and 14.1 (SD = 10.5) in the Shoulder-Guidance groups. The mean number of exercise sessions were higher when it was measures with the BandCizer than when it was based on the exercise diaries (p = 0.007).

4.4. Effectiveness of the Shoulder-Café intervention (Paper 2)

4.4.1. Shoulder complaints

Within-group differences

In the analysis population, the OSS increased from a median of 37 (IQR: 34 to 38) at screening to 38 (IQR 35 to 41) at baseline. From baseline to follow-up the OSS increased equally in the Shoulder-Café and Shoulder-Guidance groups. The median increase from baseline to 6-month and 12-month follow-up were 3 and 4 OSS points, respectively.

Between-group differences

There were no significant group differences in the OSS at 6-month or 12-month follow-up. The adjusted MD was 0.3 (95% CI: −1.6 to 2.2) and 0.2 (95% CI: −2.6 to 2.2) OSS points at 6-month and 12-month follow-up, respectively (Table 7).

4.4.2. Fear-avoidance beliefs

Within-group differences

From baseline to 6-month follow-up, the FABQ-PA decreased from a mean of 12.6 (SD = 5.2) to 10.3 (SD = 5.3) in the Shoulder-Café group, and from a mean of 11.5 (SD = 5.4) to 9.7 (SD = 9.7) in the Shoulder-Guidance group. The FABQ-PA decreased from baseline to 12-month follow-up in both groups. At 12-month follow-up, the mean value of the FABQ-PA was 10.3 (SD = 6.2) in the Shoulder-Café group and 9.5 (SD = 6.4) in the Shoulder-Guidance group.

Between-group differences

No significant group difference was found in the FABQ-PA at 6-month or 12-month follow-up (Table 7).

4.4.3. Participants' reflections of overall improvement

Within-group differences

At 6-month follow-up, 32 (64%) Shoulder-Café participants and 26 (63%) Shoulder-Guidance participants had improved with respect to the PGIC. At 12-month follow-up, these numbers were 36 (73%) Shoulder-Café participants and 21 (51%) Shoulder-Guidance participants.

Between-group differences

At 6-month follow-up, there were no group differences with respect to the PGIC, but at 12-month follow-up, the PGIC favoured the Shoulder-Café intervention (Table 7).

4.4.4. Supplementary outcomes

Between-group differences

At 6-month follow-up, Shoulder-Café participants were significantly better informed about how to handle shoulder complaints and reduce occupational mechanical shoulder exposures, and at 12-month follow-up, overall satisfaction favoured the Shoulder-Café intervention (Table 7). With respect to the remaining supplementary outcomes, no significant group differences were found (Table 7).

Table 7. Effectiveness of the Shoulder-Café compared with Shoulder-Guidance intervention with respect to primary, secondary, and supplementary outcomes. The linear mixed model and logistic regression analyses were performed according to the intention-to-treat principle based on the analysis population (n = 109) (83)

	Shoulder-Café		Shoulder-Guidance		Group difference			
					Crude		Adjusted *	
Primary outcome, n, mean (SD)					**Mean differences, 95% CI**			
OSS, at 6 months	51	40.4 (5.5)	42	40.1 (5.7)	0.3	−1.5 to 2.2	0.3	−1.6 to 2.2
Secondary outcomes								
Continuous variables, n, mean (SD)					**Mean differences, 95% CI**			
OSS, at 12 months	50	40.3 (7.3)	41	40.4 (5.0)	−0.1	−2.2 to 1.9	−0.2	−2.6 to 2.2
FABQ – PA, at 6 months	51	10.3 (5.3)	42	9.7 (5.9)	0.6	−1.4 to 2.7	−0.1	−2.4 to 2.2
FABQ – PA, at 12 months	49	10.3 (6.2)	41	9.5 (6.4)	0.9	−1.3 to 3.0	0.3	−1.9 to 2.5
Categorical outcome, n (%)					**Risk Ratio, 95% CI**			
PGIC improved, at 6 months		32 (64)		26 (62)	1.0	0.8 to 1.4	1.0	0.7 to 1.4
Supplementary outcomes								
Continuous variables, n, mean (SD)					**Mean differences, 95% CI**			
NRS at rest, at 6 months	50	1.9 (1.9)	42	2.0 (1.8)	−0.0	−0.8 to 0.7	0.1	−0.6 to 0.8
NRS at rest, at 12 months	50	1.7 (2.0)	41	2.4 (2.1)	−0.8	−1.6 to 0.0	−0.8	−1.7 to 0.0
NRS during activity, at 6 months	51	3.0 (2.7)	42	3.1 (2.5)	−0.1	−0.9 to 0.7	−0.1	−1.0 to 0.7
NRS during activity, at 12 months	50	3.2 (2.5)	41	3.4 (2.4)	−0.3	−1.1 to 0.6	−0.5	−1.4 to 0.5
Quick-DASH symptom scale, at 6 months	50	18.7 (14.4)	42	21.0 (16.6)	−2.3	−8.6 to 4.0	−1.7	−6.8 to 3.3
Quick-DASH work module, at 6 months	51	16.1 (15.8)	41	20.3 (20.3)	−4.2	−10.6 to 2.1	−1.7	−7.5 to 4.1
EQ-5D-3L, at 6 months	50	0.83 (0.1)	42	0.79 (0.1)	0.03	−0.00 to 0.07	0.03	−0.01 to 0.06
EQ 5D-VAS, at 6 months	50	78.7 (13.6)	41	74.0 (18.7)	4.8	−1.3 to 10.9	5.3	−1.2 to 11.9
WAS, at 6 months	51	7.5 (1.7)	41	7.4 (1.8)	0.0	−0.6 to 0.6	0.0	−0.6 to 0.5
WAS, at 12 months	50	7.6 (2.1)	41	7.5 (2.2)	0.1	−0.7 to 0.8	0.1	−0.6 to 0.8

Categorical outcome, n (%)					**Risk Ratio, 95% CI**			
PGIC improved, at 12 months		36 (73)		21 (51)	1.4	1.1 to 1.9**	1.5	1.1 to 2.0**
Overall satisfaction, at 6 months		44/51 (86)		28/42 (67)	1.3	1.0 to 1.6**	1.3	1.0 to 1.6
Overall satisfaction, at 12 months		43/49 (88)		27/42 (62)	1.4	1.1 to 1.8**	1.4	1.1 to 1.8**
Felt informed about how to								
• handle shoulder complaints		48/51 (94)		25/42 (60)	1.6	1.2 to 2.0**	1.5	1.2 to 1.9**
• perform shoulder exercises		47/50 (94)		35/42 (83)	1.1	0.9 to 1.3	1.1	0.9 to 1.4
• reduce occupational mechanical exposures, at 6 months		42/51 (82)		15/42 (36)	2.3	1.5 to 3.6**	2.3	1.4 to 3.8**

*Abbreviations: CI = confidence interval, FABQ-PA = Fear Avoidance Beliefs Questionnaire – Physical Activity, NRS = numerical rating scale, OSS = Oxford Shoulder Score, PGIC = Patients' Global Impression of Change, Quick-DASH = Quick Disabilities of Arm, Shoulder and Hand questionnaire, SD = standard deviation, WAS = Work Ability Score. * Continuous outcomes were adjusted for the baseline value of the relevant outcome, sex, age and industry as fixed effects, and company as a random effect. Dichotomised outcomes were adjusted for sex, age, and industry using robust standard errors. ** Significant difference.*

4.4.5. Sensitivity analyses

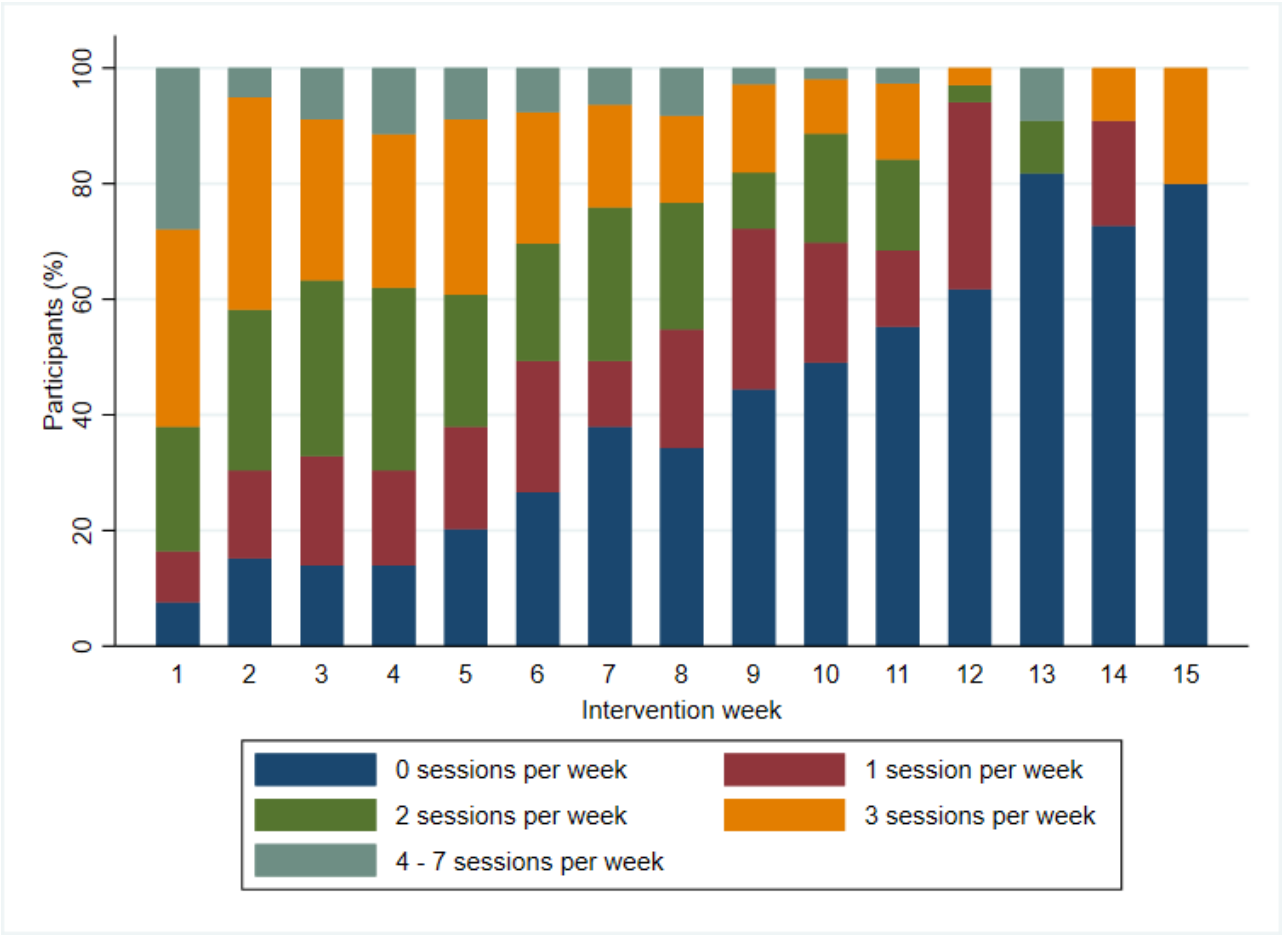
Between-group differences

No group differences were found in the three sensitivity analyses of the OSS at 6-month follow-up: I) differential loss to follow-up analysed by the four scenarios for replacing missing values of OSS, II) intention-to-treat analysis restricted to participants with OSS <35 (n = 13 Shoulder-Café and n = 7 Shoulder-Guidance participants) showed a MD of 1.3 (95% CI −10.4 to 13.1), and III) per-protocol analysis restricted to participants with full attendance (n = 32 Shoulder-Café and n = 42 Shoulder-Guidance participants) showed a MD of 0.6 (95% CI −1.5 to 2.7).

4.5. Shoulder pain and subsequent shoulder exercise (Paper 3)

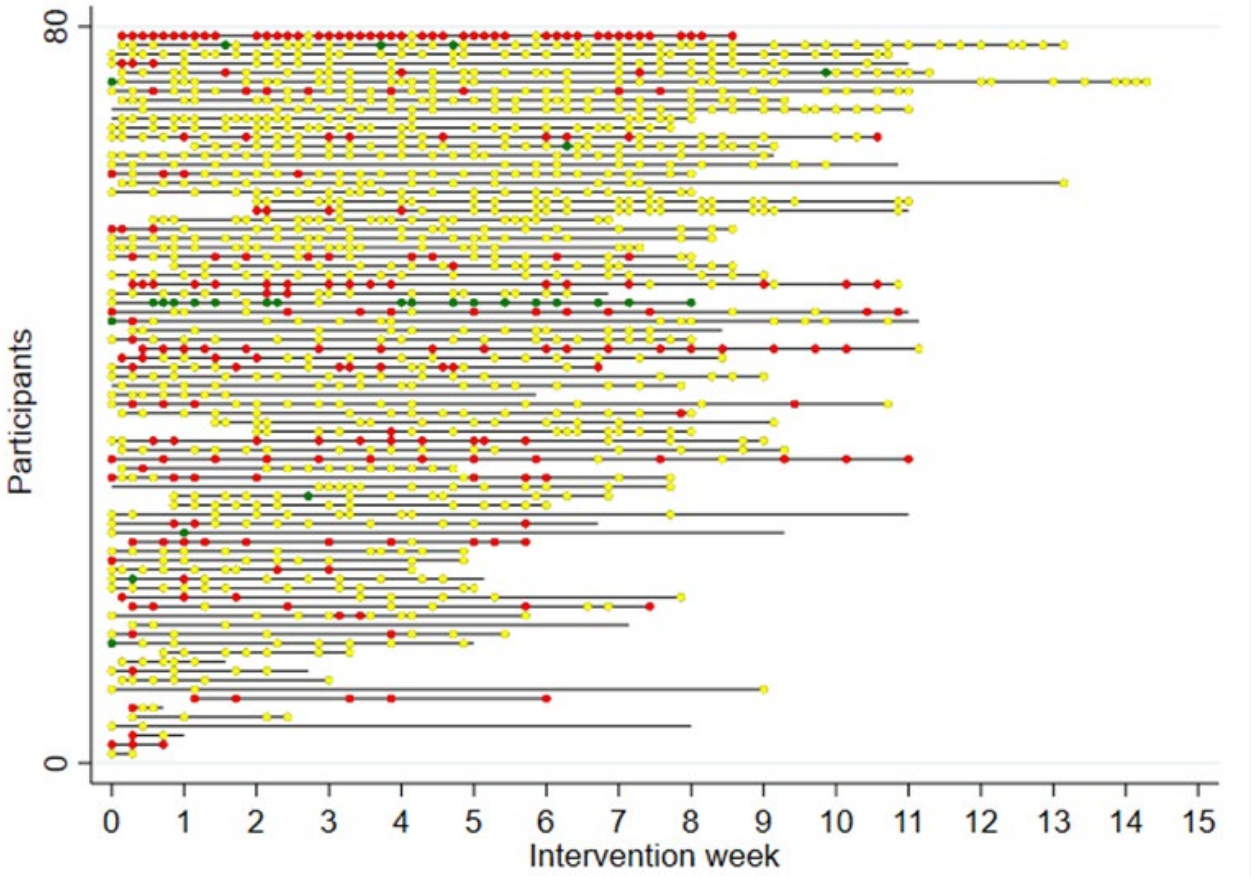
The 79 (72%) participants in Paper 3 performed 1401 exercise sessions during 850 intervention weeks. This corresponds to a mean of 17.7 (range: 2–50) exercise sessions per participant, and a mean number of 1.6 (range: 0–7) weekly exercise sessions during the intervention period. Figure 6 presents the distribution of weekly exercise sessions according to intervention week and shows that the frequency of zero exercise sessions increased during the intervention.

Figure 6. Distribution of weekly exercise sessions according to intervention week (84)



A total of 141 of the 1401 exercise sessions had missing information on pain before or after the exercise session. Change in shoulder pain was therefore calculated for 1260 (90%) exercise sessions. The mean level of shoulder pain shortly before and after an exercise session was 1.6 (SD = 1.5) and 1.9 (SD = 1.8) VAS points, respectively, and the mean change in shoulder pain was 0.4 (SD = 1.0) VAS points. Figure 7 shows change in shoulder pain for each exercise session with coloured dots representing pain increase (red), unchanged pain (yellow), or decreased pain (green). The figure shows that unchanged pain was most common.

Figure 7. Distribution of exercise sessions according to intervention week (n = 1260). The coloured dots represent the direction of change in shoulder pain. Green dots (n = 28) represent reduced pain, yellow dots (n = 1003) represent unchanged pain, and red dots (n = 229) represent increased pain. The 79 participants were sorted according to the total number of performed exercise sessions (84)



A total of 59 of the 1260 exercise sessions with data for change in shoulder pain were not followed by a subsequent session. Thus, 1201 (95%) exercise sessions were used in the analyses of associations between increased shoulder pain and exercise dose. Table 8 shows the adjusted results of these analyses. No associations were found irrespective of baseline FABQ-PA. With respect to crude associations, increase in shoulder pain was associated with a small decrease in progression level and resistance level (84) (results not shown).

Table 8. Adjusted associations between increase in shoulder pain, including fear-avoidance beliefs, across an exercise session and the subsequent exercise dose. The linear mixed model analyses were based on 1201 exercise sessions performed by 79 participants. Estimates are reported as mean differences (MDs) with 95% confidence intervals (CIs) (84)

Predictors	**Number of repetitions**		**Progression level**		**Resistance level**		**Time until next exercise session (days)**	
	Adjusted*		Adjusted*		Adjusted*		Adjusted*	
	MD	95% CI	MD	95% CI	MD	95% CI	MD	95% CI
Change in shoulder pain**	−1.3	−3.4 to 0.9	−0.0	−0.1 to 0.0	−0.0	−0.1 to 0.0	−0.6	−2.4 to 1.3
High FABQ-PA***	−5.7	−28.8 to 17.3	0.1	−0.2 to 0.4	0.1	−0.3 to 0.5	0.0	−0.1 to 0.1
Interaction between change in shoulder pain and FABQ-PA***	0.2	−6.8 to 7.1	−0.0	−0.2 to 0.1	−0.1	−0.2 to 0.1	0.5	−1.7 to 2.7

Abbreviation: FABQ-PA = Fear-Avoidance Beliefs Questionnaire – Physical Activity.
** Adjusted for age, sex, body mass index, smoking status, dominant-sided pain, baseline pain at rest, intervention group, days since start of intervention, session number and included an interaction term between change in shoulder pain and fear-avoidance beliefs. ** A 1-cm increase on the visual analogue scale (0 = no pain, 10 = worst pain). *** FABQ-PA dichotomised in high > 14 / low ≤ 14.*

A total of 31 (39%) participants had high overall adherence, 11 (36%) of whom had complete overall adherence. The 31 participants with high overall adherence performed 828 (60%) of the 1401 exercise sessions. Table 9 shows that increased shoulder pain and baseline FABQ-PA did not influence overall adherence to the exercise programme. The results were similar for crude analyses.

Table 9. Analysis of high overall adherence to the exercise programme in relation to individual mean change in shoulder pain, fear-avoidance beliefs, and the potential interaction between change in shoulder pain and fear-avoidance beliefs. The logistic regression analyses were based on 1401 exercise sessions performed by 79 participants. Estimates are reported as odds ratios (ORs) with 95% CIs (84)

	High adherence*			
	Crude		Adjusted**	
	OR	95% CI	OR	95% CI
Change in shoulder pain***	0.6	0.3 to 1.0	0.6	0.2 to 1.4
High FABQ-PA#	0.9	0.3 to 2.4	1.2	0.4 to 4.3
Interaction between change in shoulder pain and high FABQ-PA#			0.3	0.0 to 1.9

*Abbreviation: FABQ-PA = Fear-Avoidance Beliefs Questionnaire – Physical Activity. * Defined as an average of ≥ 2 weekly exercise sessions, ** Adjusted for age, sex, body mass index, smoking status, dominant-sided pain, baseline pain at rest, intervention arm, and with interaction between change in shoulder pain and FABQ-PA. *** A 1-cm increase on the visual analogue scale (0 = no pain, 10 = worst pain), # FABQ-PA dichotomised in high > 14 / low ≤ 14.*

5. Discussion

5. Discussion

5.1. Key results

The overall aim of this PhD study was to develop and evaluate the Shoulder-Café intervention targeting employees with shoulder complaints and high mechanical shoulder exposures. A protocol paper was published to ensure the transparency of the study, prevent study duplication, and increase the possibility of publishing the study (131). The overall results showed that the Shoulder-Café intervention had been developed and evaluated. The main hypothesis was that the Shoulder-Café intervention would be more effective than the Shoulder-Guidance intervention with respect to shoulder complaints, fear-avoidance beliefs, and global impression of change, but the main results showed that the Shoulder-Café intervention was not more effective than the Shoulder-Guidance intervention. Supplementary outcomes of feeling informed about how to handle shoulder complaints and reduce occupational mechanical shoulder exposures, global impression of change (at 12-month follow-up), and overall satisfaction, showed a favour of the Shoulder-Café intervention. Shoulder complaints were reduced at follow-up in both groups.

The study also showed that increased shoulder pain across an exercise session was not associated with a lower exercise dose in the next exercise session, regardless of the level of fear-avoidance beliefs, and that increased shoulder pain across exercise sessions and high fear-avoidance beliefs did not influence overall adherence to the exercise programme.

5.2. Bias and confounding

Selection bias occurs if comparisons are made between groups of people that differ in characteristics other than the variables assessed in a study and if the characteristics are related to the outcome (132). In Paper 2, the OSS at 6-month follow-up was missing for 16 participants. If these participants had responded differently with regard to the outcomes than those who responded, selection bias would have occurred. However, as participants with and without missing data were comparable with regard to baseline characteristics, we assessed this risk to be low. Attrition bias is a type of selection bias. Attrition means a reduction in the number of participant's due to loss of follow-up. Attrition bias occurs when loss to follow-up is systematically different between study groups because differentiated loss induces a risk of difference in characteristics between the study groups (134). In Paper 2, attrition was different in the two groups (11% versus 19% were lost to follow-up based on the OSS at 6 months), inducing risk of attrition bias (134). However, baseline characteristic remained comparable in the two groups, and thus the risk of attrition bias seems low. Participants without a valid OSS were purposefully omitted in the primary analysis. Instead of using imputation, we performed sensitivity analyses to evaluate any effects of differential loss to follow-up. Results of these sensitivity analyses were comparable with the main results, which supports the assumption of a low risk of selection bias and indicates that loss to follow-up was less likely to explain the lack of effectiveness. In Paper 3, 30 participants were excluded due to missing exercise diaries. These participants may have adhered less to our exercise

programme. However, since excluded and included participants were comparable with regard to baseline characteristics and missing pain reports for the exercise sessions were limited (10%), we have no reason to suppose that the lack of associations in Paper 3 was caused by selection bias due to missing data.

Results of Paper 2 and Paper 3 were based on self-reported data, inducing a potential risk of information bias. In Paper 2, differentiated reporting due, e.g., to a desire to give socially acceptable answers could affect the outcomes differently in the Shoulder-Café and Shoulder-Guidance interventions, leading to information bias. Blinding of participants minimises this risk of information bias regarding differentiated reporting, but due to the character of the interventions, blinding was not possible. Instead, we sought to equalise participants' expectations by allocating all participants to an active intervention, and by blinding them to the study hypotheses.
Self-reported exercise dose has previously been overestimated, e.g., in people with patellofemoral pain (133). In Paper 2, the number of performed exercise sessions was based on self-reported exercise diaries and BandCizer sensors. We found that the number of exercise sessions was overestimated in the diaries, but we found no group differences with regard to either the diaries or the sensors. In Paper 3, exercise dose was based on the diaries, but we have no reasons to believe that the overestimation was systematically related to shoulder pain. Therefore, we assume that the self-reported exercise performance did not affected the lack of effectiveness in Paper 2 or the lack of associations in Paper 3.

Confounding is a bias which may increase or decrease a real study effect. In Paper 2, confounding would have occurred if a variable, e.g., participants' ages (the possible confounder) was associated with the variable under study (e.g., the OSS) and related to the outcome (effectiveness). The randomised design minimised the risk of confounding, and the well-balanced baseline characteristics indicate a successful randomisation process. The median duration of shoulder complaints, however, tended to be longer in the Shoulder-Café group, but as the group difference (24 months) represents less than 10% based on the range, we assess this difference to be minimal. In addition, the main analyses in Paper 2 were adjusted for the most possible confounders (sex, age, and industry), which further minimised the risk of confounding. Paper 3 was an observational study, making it more prone to risk of confounding. Therefore, to minimise the risk of bias due to confounding, we decided a priori to include a range of possible confounders in the analyses.

5.3. Comparison with existing literature

In Denmark, the recommended first-line treatment in people with non-traumatic subacromial shoulder complaints is exercise therapy and education about self-treatment, and it also includes work modifications in people with occupational mechanical shoulder exposures (15). Despite the increasing number of studies showing effect of using exercise therapy as a treatment for shoulder complaints (44), the clinical effect is still unknown (43-45). In

addition, the evidence for the effects of education (60) and work modifications (65) is limited. Few studies have evaluated the effect of interventions aiming to reduce shoulder complaints in people with occupational mechanical shoulder exposures, and most of the results are disappointing (64-66). Only one study included participants with high occupational mechanical shoulder exposures and found that resistance exercise was more effective than ergonomic guidance (134). For Danish patients experiencing shoulder complaints, usual treatment is experienced fragmented. Our early needs assessment in the innovation project documented this (80). Therefore, to avoid such fragmentation should arise, the Shoulder-Café intervention served to unify the usual fragmented components, pre-empting the experience in a cohort of participants. Participants in our study were not patients, but they were at risk of becoming future patients, given their shoulder complaints and high occupational shoulder exposures. Our assumption was that an intervention, even preceding severe shoulder complaints, would pre-empt an experience of fragmentation, in case the participants ended up as patients. This assumption was based on the fact that the participants were better informed about their shoulder complaint and about self-management through the education in the intervention. Therefore, to unify the usual fragmented components used to treat shoulder complaints and high occupational mechanical shoulder exposures, we developed the Shoulder-Café intervention. The Shoulder-Café intervention was based on positive experiences from a pilot-tested group-based shoulder intervention (80) and positive results from a back-café intervention (81). But the foundation for the intervention was weak because there was a lack of evidence for the included components. The results showed, contrary to our hypothesis, that the Shoulder-Café intervention was not more effective than the Shoulder-Guidance. This warrants further reflection.

For back pain, complex interventions are suggested to be more effective in reducing pain than are less complex interventions (67). This aligns with the positive results of the previous back-café intervention that focused on psychological and social factors in addition to exercise therapy (81). However, for shoulder complaints, evidence for the effect of complex interventions is limited (70). Our study plus two other studies (71, 135) of participants with shoulder complaints showed no difference between a complex and a less complex intervention. These studies, however, were quite heterogeneous. One of them (71) was, like our study, a RCT but the difference between the complex and the less complex intervention was the assignment of a case manager to help with return to work. The other was not an RCT (135), and for this reason the comparability between the complex and the less complex intervention was low. In the light of evidence for back pain but the limited evidence for shoulder complaints, studies are needed that evaluate the effectiveness of complex intervention in persons with shoulder complaints.
Instead, an explanation for the lack of effectiveness may be that the Shoulder-Café and the Shoulder-Guidance intervention were too similar. This may especially be true since we compared two active interventions of non-evidence-based components with uncertain mechanisms of action. Another explanation may be that effectiveness was based on a 5-point

OSS group difference. The 5-point OSS difference was based on previous studies (77, 127, 128), but since shoulder complaints were less severe in our participants compared to participants in previous studies, detecting such a group difference may have been difficult to achieve. Our sensitivity analysis restricted to participants with more severe complaints (an OSS score < 35) also showed no group difference, but the power of analysis was low because only 20 participants were included and the 95% CI of the MD was wide. Therefore, the analysis may be flawed due to a type 2 error. The OSS was developed for patients undergoing shoulder surgery (100), which is a population with higher complaints than the group of participants included in this study. An explanation for the lack of effectiveness may therefore also be a ceiling effect (136) because we used the OSS in a group with modest shoulder complaints. However, no participants achieved the best OSS score (an OSS of 48 point) and only 12 (11%) participants had an OSS score > 42 points (0- to 48-point scale). Therefore the ceiling effect does not seem to be the explanation (136).
Another explanation for the lack of effectiveness may be an insufficient dose of the added Shoulder-Café components. This may especially be the case when taking the level of adherence to the café meetings into account. However, since the per-protocol analysis of participants with full adherence also showed no group difference, insufficient dose does not seem to explain the lack of effectiveness. The per-protocol analysis included 74 participants, and thus the power of the analysis was low. The 95% CI of the MD was narrow and without any indication of a clinically relevant group difference. Thus, we assess the risk of a type 2 error to be minimal in this case. Another possible explanation for the lack of effectiveness is the follow-up time. Participants completed the OSS 6 and 12 months after the SOI, but not at the EOI. We are aware that potential effects at the EOI were not identified, but we aimed to show long-term effectiveness. In addition, we expected that 12 months would allow potential effects to evolve. However, since effects of rehabilitation often depend on behaviour change (116), 12-month follow-up may be insufficient. Other RCTs among employees with physically demanding jobs and musculoskeletal complaints have also failed to show improvements in musculoskeletal pain and health status at 12-month follow-up (137-139). These RCTs compared interventions including physical exercise or active group work with cognitive training or control interventions. These RCTs pointed out that an insufficient intervention dose or too short a follow-up time could be possible explanations for the lack of effectiveness. In addition, results of the back-café intervention at 2-year follow-up support the need for a follow-up that is longer than 12 months (81). Another possible explanation for the lack of effectiveness is that the interventions were not delivered as intended. However, based on the nested process evaluation, the intervention material was experienced as sufficient and well described, and the only difference between the Shoulder-Café and the Shoulder-Guidance interventions was that there were fewer physiotherapist at the café meetings, which was due to fewer participants per café meeting (126).

With respect to some of the supplementary outcomes, the Shoulder-Café was more effective. Shoulder-Café participants felt better informed about how to handle shoulder complaints and

reduce occupational mechanical shoulder exposures and were more satisfied with the received intervention. These results may indicate a greater awareness about self-treatment in the Shoulder-Café group due to the network and social support at the café meetings. This is supported by the pilot-tested group-based shoulder intervention (80), the back-café intervention (81), and the process evaluation in which social gatherings and the opportunity for small talk were valued by participants (126). However, these results have a tenuous foundation because they were based on only supplementary outcomes.

Shoulder complaints were improved within both groups at follow-up, which may be explained by an effect of exercise therapy (43, 44), equal effects of supervised and home-based exercise therapy (46, 47), or the natural history of shoulder complaints (140). The improvements, however, were not clinically relevant (113, 127, 128). This was contrary to previous RCTs (48, 99, 141) that used the Shoulder Pain and Disability Index (SPADI) to measure the effect of exercise therapy, but was in line with another RCT (51) that used the Quick-DASH. The OSS was used to measure the effect of conservative treatment, including exercise therapy, in at least three previous RCTs (96, 142, 143), in which clinically important improvements being reached in two of them (96, 143). Based on this, the instrument used to measure the effect does not seem to be the reason for the absence of a clinically relevant effect. Instead, the low degree of baseline pain intensities may be an explanation. This theory aligns with two of the RCTs in which the participants had more severe baseline pain intensities (approximately 6 on a 0–10 scale), and in which clinically important improvements were reached (141, 143). It also aligns with a recent meta-analysis in which clinically important improvements of exercise interventions were reached in workers with more severe pain intensities (≥3 on a 0–10 points scale) but not in those with less severe pain intensities (<3 on the 0–10 points scale) (144). However, despite the low degree of pain intensities, our participants had more shoulder complaints than people without a history of shoulder complaints (93-95).

5.3.1. Shoulder pain and subsequent exercise

Paper 3 showed that increased shoulder pain across an exercise session was not associated with a lower exercise dose in the next exercise session, which was contrary to our hypothesis. An explanation for this may be that the low increase in pain across an exercise session was too low to affect the subsequent exercise dose. Thus, we cannot rule out whether a higher level of the increase in pain across an exercise session would lead to an association between increased shoulder pain and lower subsequent exercise dose. This should be investigated in a future study. Also, increased pain did not influence overall adherence to the exercise programme. This may also be explained by the low pain increase across exercise sessions. Pain may increase adherence in persons who are motivated for getting rid of their pain (145). Pain may also decrease adherence if pain is low and not a real concern, and if the "only" exercise aim is to prevent the pain from getting worse (146). Thus, the low baseline pain in our study may have decreased adherence to the exercise programme.

5.3.2. Fear-avoidance beliefs

Paper 2 showed that fear-avoidance beliefs were reduced in the Shoulder-Café and the Shoulder-Guidance interventions at follow-up, but no group difference was found. Two previous RCTs have also shown reduced fear-avoidance beliefs after treatment for shoulder complaints (51, 96). One of these RCTs showed a group difference favouring supervised exercise over usual care (96), whereas the other, which compared three different exercise settings, showed no group difference (51).

Our exercise programme included information about expected pain aggravation during exercise, and a recommendation about reduced exercise dose in the subsequent session if the pain aggravation did not decrease within 1 hour after exercise. This information could have affected some of the participants, especially those with high FABQ-PA because they may be more likely to avoid exercise due to pain (55, 57). However, we did not observe such a pattern. Instead, in Paper 3, we found that FABQ-PA did not affect the association between increased pain and exercise dose or overall adherence**.** To our knowledge, this was the first study to investigate the effects of fear-avoidance beliefs with respect to doses of shoulder exercise. However, a systematic review (147) concluded that fear-avoidance beliefs were not a predictor for a worse shoulder outcome after physiotherapy. We assess that this supports our results. Contrary to Paper 3, an association between higher fear-avoidance beliefs and lower adherence to shoulder exercise has been reported (148). A reason for an association in the previous study and not in our study may be the focus on more chronic complaints in the previous study (148).

5.4. External validity

External validity, or generalisability, is the degree to which study findings hold true in other settings (132). People who agree to participate in research interventions may be different from people who decline participation. If that is the case, study findings have low external validity. However, a necessary condition for external validity is also that the internal validity is strong, meaning that study findings are correct for the studied population (132).

About half of the companies who were asked to participate declined. This is a relatively high number, indicating that results may be less generalisable to employees in other companies with high occupational mechanical shoulder exposures. This is unknown, but it implies that an effort to identify barriers for company participation may be an aim in future studies of employees with shoulder complaints. In the present study, participation was without cost for the companies. This is a strength since economic consequences could affect the participation rate further. However, economic consequences may still be a part of the explanation because some of the declining companies told us that they were afraid of increased sick leave if there was a focus on shoulder complaints.

Our screening questionnaire was completed by 1556 employees of which only four declined participations. A total of 169 employees were telephone interviewed but 32 employees declined participation subsequently, which is a relatively high number. However, in view of the assessed variables (age, sex, industry, and OSS) employees declining participation were comparable with those who were included. In addition, the pragmatic multi-centre design with a high number of included companies and occupations supports the generalisability of results in Paper 2 to people with shoulder complaints and high occupational mechanical shoulder exposures in Denmark and in other countries with similar working conditions.

One of the inclusion criteria in the study was an OSS ≤ 40 at screening. In asymptomatic populations, the mean OSS score is 42–48 (92-95), supporting that our participants had shoulder complaints despite their generally low baseline pain intensities. In addition, we find it unlikely that participants would agree to participate if they did not experience significant shoulder complaints. However, results in Paper 3 may have a low generalisability to persons with more severe shoulder complaints.

6. Conclusion

6. Conclusion

In the Shoulder-Café intervention, shoulder complaints, fear-avoidance beliefs, and global impression of change were not reduced more effectively than they were in the Shoulder-Guidance intervention. This was the case even though the supplementary results indicated that the Shoulder-Café participants felt better informed about how to handle shoulder complaints and reduce occupational shoulder exposures, had a better impression of change (at 12-month follow-up), and were more satisfied with the intervention (Paper 1 and Paper 2).

Increased shoulder pain across an exercise session was not a barrier for subsequent exercise dose regardless of fear-avoidance beliefs, and increased shoulder pain and high levels of fear-avoidance beliefs did not influence overall adherence to the exercise programme (Paper 3).

7. Perspectives and future studies

7. Perspectives and future studies

This dissertation contributed insights about the effectiveness of a new group-based intervention, the Shoulder-Café, for employees with shoulder complaints and high mechanical shoulder exposures. Despite not finding the Shoulder-Café intervention to effectively reduce shoulder complaints in comparison to the Shoulder-Guidance intervention, this is still a relevant finding in terms of future design and delivery of interventions in this field. The results, however, call for reflection on the assumptions that formed this PhD study, which have been provided in this dissertation.

We measured the participants occupational mechanical shoulder exposures, but it remains to be explored if the Shoulder-Café is more effective to reduce these exposures than the Shoulder-Guidance intervention. This will be reported in a future study. Based on supplementary outcomes, the study indicated that awareness about self-treatment and intervention satisfaction was higher with the Shoulder-Café intervention. The supplementary outcomes about the feeling of being informed were included to elucidate suggested mechanisms of action for an effect of the Shoulder-Café interventions but, despite the positive indications, the Shoulder-Café intervention was not effective. We prepared for a cost evaluation by including the EQ-5D as an outcome measure but, due to lack of time, the evaluation has not yet been conducted. It is possible that increased awareness leads to better self-management of complaints that may reduce need for and use of healthcare services, but this is still to be explored in a future study. This also means that we are currently not able to know if our initial assumption that an intervention in a population of non-patient individuals with high occupational shoulder exposure would find the healthcare services less fragmented if, in need of treatment, they had previously been informed and educated about self-management.

Paper 3 showed that increased shoulder pain was not a barrier for subsequent exercise dose or for exercise adherence regardless of fear-avoidance beliefs. However, it remains to be explored whether these results are generalisable to patient populations with higher intensities of shoulder pain.

The combination of shoulder complaints and high occupational mechanical shoulder exposures is a well-known risk for shoulder surgery (27) and long-term sick leave (28). Treatment to reduce shoulder complaints among employees with high occupational mechanical shoulder exposures is therefore highly relevant. The Shoulder-Café intervention was an attempt to pre-empt such potential future interventions by educating the participants on their shoulder complaints,-by motivating self-management in the form of exercise, and by providing a better sense of the shoulder complaint. However, based on the findings documented in this dissertation, the Shoulder-Café intervention may not be the way to move forward. It is however certain that we need to do more to prevent and intervene with the large burden of shoulder complaints.

8. References

8. References

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9. English Summary

9. English summary

Background

Shoulder complaints are common in the general population, and they are especially common in employees with high mechanical shoulder exposures. In Denmark, the treatment of shoulder complaints often requires repeated visits to different healthcare providers, which leads to fragmented and uncoordinated usual care. To unify the fragmented usual care treatment of shoulder complaints, a group-based intervention was pilot-tested in 2014, and the results were positive.

The overall aim of this PhD study was to develop and evaluate the Shoulder-Café intervention targeting employees with shoulder complaints and high mechanical shoulder exposures. The three specific aims were: 1) to develop the Shoulder-Café intervention, 2) to evaluate the effectiveness of the Shoulder-Café intervention compared with the Shoulder-Guidance intervention (an active control intervention – enhanced usual care), 3) to examine whether increased shoulder pain was associated with a lower subsequent exercise dose and whether these associations (if any) were exaggerated by high levels of fear-avoidance beliefs, and to examine whether increased shoulder pain across exercise sessions together with high levels of fear-avoidance beliefs influenced overall adherence to an exercise programme.

Methods

Paper 1 was a protocol paper describing the cluster randomised controlled trial (RCT), Paper 2 was a two-arm parallel cluster RCT, and Paper 3 was a prospective cohort study based on the cluster RCT. Participants were employees with shoulder complaints and high occupational mechanical shoulder exposures. They were recruited from selected companies (clusters) in the Central Denmark Region. The companies were randomised, and the participants were allocated to Shoulder-Café or Shoulder-Guidance intervention.

In Paper 2, the primary outcome was shoulder complaints measured with the Oxford Shoulder Score (OSS) at 6-month follow-up. Secondary outcomes were fear-avoidance beliefs measured with the Fear-Avoidance Belief Questionnaire - Physical Activity (FABQ-PA) at 6-month and 12-month follow-up, and impression of change measured with Patients Global Impression of Change (PGIC) at 6-month follow-up. A series of supplementary outcome measures were also included. Primary analyses were performed according to the intention-to-treat principle. Continuous outcomes were analysed with linear mixed models, categorical outcomes with logistic regression analyses.

In Paper 3, the outcomes were exercise dose (i.e., number of repetitions, progression level, resistance level, and time until next exercise session) and overall adherence. The outcomes were analysed with linear mixed models and logistic regression.

Results

In Paper 1, the Shoulder-Café intervention was described. In Paper 2, 60 companies were randomised, and 109 participants were allocated to intervention (57 to Shoulder-Café and 52

to Shoulder-Guidance). Shoulder complaints were improved within both intervention groups at follow-up, but no statistically significant group differences were found at 6-month or 12-month follow-up with respect to the OSS [adjusted MD 95% confidence interval (95 % CI): 0.3 (−1.6 to 2.2) and −0.2 (−2.6 to 2.2)]. Also, no group differences were found in the FABQ-PA at 6- or 12-month follow-up [adjusted MD (95% CI): −0.1 (−2.4 to 2.2) and 0.3 (−1.9 to 2.5)] or in PGIC at 6-month follow-up [(adjusted risk ratio (RR) (95% CI): 1.0 (0.7 to 1.4)]. Some of the supplementary outcomes favoured the Shoulder-Café intervention: information about how to handle shoulder complaints and reduce occupational mechanical shoulder exposures at 6-month follow-up [Adjusted RR (95% CI): 1.5 (1.2 to 1.9) and 2.3 (1.4 to 3.8)], and PGIC and overall intervention satisfaction at 12-month follow-up [adjusted RR (95% CI): 1.5 (1.1 to 2.0) and 1.4 (1.1 to 1.8)]. In Paper 3, 79 participants (48 companies) were included. There was no association between increase in pain and the subsequently exercise dose [for a 1-cm increase in pain on a visual analogue scale (0–10) during an exercise session, the adjusted number of repetitions, progression level, and resistance level in the next exercise session were −1.1 (95% CI −3.6 to 1.4), 0.0 (95% CI −0.1 to 0.0), and 0.0 (95% CI −0.1 to 0.0), respectively. The number of days until the next exercise session was −0.4 (95% CI −1.8 to 0.9)]. There were no interactions with FABQ-PA. Increased shoulder pain and high FABQ-PA did not influence overall adherence [adjusted odds ratio (95% CI): 0.6 (0.2 to 1.4) and 1.2 (0.4 to 4.3)].

Conclusion

The Shoulder-Café intervention was developed (Paper 1). Shoulder complaints, fear-avoidance beliefs, and global impression of change (at 6-month follow-up) were not reduced more effectively in the Shoulder-Café intervention than in the Shoulder-Guidance intervention. Supplementary outcomes regarding information about how to handle shoulder complaints and reduce occupational shoulder exposures, global impression of change (at 12-month follow-up), and overall satisfaction favoured the Shoulder-Café intervention (Paper 2). Increased shoulder pain across an exercise session was not a barrier for subsequent exercise dose or overall adherence to the exercise programme, regardless of fear-avoidance beliefs (Paper 3).

10. Dansk resumé

10. Dansk resumé

Baggrund
Skulderproblemer er hyppige i den generelle befolkning og er især hyppige hos medarbejdere i erhverv med høje mekaniske skuldereksponeringer. I Danmark kræver behandlingen af skulderproblemer ofte gentagne besøg hos forskellige sundhedspersoner, hvilket fører til fragmenterede og ukoordinerede udrednings- og behandlingsforløb. For at samle de fragmenterede udrednings- og behandlingsforløb blev en gruppebaseret intervention pilottestet i 2014, og resultaterne var positive.

Det overordnede formål med dette ph.d.-studie var at udvikle og evaluere Skulder-Café interventionen rettet mod medarbejdere med skulderproblemer og høje mekaniske skuldereksponeringer. De tre specifikke mål var: 1) at udvikle Skulder-Café interventionen, 2) at evaluere effekten af Skulder-Café interventionen sammenlignet med Skulder-Vejlednings interventionen (en aktiv kontrol-intervention – øget normal behandling), 3) at undersøge om øgning i skuldersmerter var forbundet med en efterfølgende lavere træningsdosis, og om disse sammenhænge (hvis nogen) var forøget ved høje fear-aviodance belief (tanker om og frygt for at opleve smerte), og at undersøge om øgning i skuldersmerter i forbindelse med træning sammen med høje fear-aviodance belief påvirkede den overordnede træningsadherence.

Metode
Artikel 1 var en protokolartikel, der beskrev det cluster randomiserede kontrollerede studie (RCT), Artikel 2 var et to-arm parallel cluster RCT, og Artikel 3 var en prospektiv kohorteundersøgelse baseret på det cluster RCT. Deltagerne var medarbejdere med skulderproblemer og høje mekaniske erhvervsmæssige skulderekspo neringer. Medarbejderne var rekrutteret fra udvalgte virksomheder (clusters) i Region Midtjylland. Virksomhederne blev randomiseret, og deltagerne blev allokeret til Skulder-Café eller Skulder-Vejlednings intervention.
I Artikel 2 var det primære outcome skulder problemer målt med Oxford Shoulder Score (OSS) ved 6-måneders opfølgning. Sekundære outcomes var fear-aviodance belief målt med Fear-Avoidance Belief Questionnaire - Physical Activity (FABQ-PA) ved 6- og 12-måneders opfølgning og overordnet oplevelse af ændring målt med Patients' Global Impression of Change (PGIC) ved 6-måneders opfølgning. Der var desuden inkluderet en række supplerende outcome mål. De primære analyser blev udført efter intention-to-treat princippet. Kontinuerte outcomes blev analyseret med linear mixed models og kategoriske outcomes med logistisk regression.
I Artikel 3 var outcomes henholdsvis træningsdosis (dvs. antal repetitioner, progressionsniveau, modstandsniveau og antal dage indtil næste træningssession) og overordnet træningsadherence. Analyserne blev udført med linear mixed modeller og logistisk regression.

Resultater

I Artikel 1 blev Skulder-Café interventionen beskrevet. I Artikel 2 blev 60 virksomheder randomiseret, og 109 deltagere blev allokeret til intervention (57 til Skulder-Café og 52 til Skulder-Vejledning). Ved 6 og 12 måneders opfølgningen var skulderproblemer reduceret i begge grupper, men der var ingen statistisk signifikante gruppeforskelle efter hverken 6 eller 12 måneder [justeret gennemsnitlig forskel (MD) 95 % konfidensinterval (95 % CI): 0,3 (−1,6 til 2,2) og −0,2 (−2,6 til 2,2)]. Der var heller ikke gruppeforskelle i FABQ-PA ved 6 eller 12 måneders opfølgning [justeret MD (95 % CI): −0,1 (−2,4 til 2,2) og 0,3 (−1,9 til 2,5)] eller i PGIC ved 6 måneders opfølgning [(justeret risk ratio (RR) (95 % CI): 1,0 (0,7 til 1,4)]. Nogle af de supplerende outcomes favoriserede imidlertid Skulder-Café interventionen: Information om hvordan man håndterer skulderproblemer og reducerer arbejdsmæssige mekaniske skuldereksponeringer (ved 6 måneders opfølgning) [Justeret RR (95 % CI): 1,5 (1,2 til 1,9) og 2,3 (1,4 til 3,8)] samt PGIC og tilfredshed med interventionen (ved 12 måneders opfølgning) [justeret RR (95 % CI): 1,5 (1,1 til 2,0) og 1,4 (1,1 til 1,8)].

I Artikel 3 var 79 deltagere (48 virksomheder) inkluderet. Øgning i skuldersmerter var ikke forbundet med en efterfølgende lavere træningsdosis (ved en 1 cm's smertestigning på en visuel analog skala (0-10 points skala)) under en træningssession var det justerede antal repetitioner, progressionsniveau og modstandsniveau i den næste træningssession henholdsvis −1,1 (95 % CI −3,6 til 1,4), 0,0 (95 % CI −0,1 til 0,0) og 0,0 (95 % CI −0,1 til 0,0). Antal dage indtil næste træningssession var −0,4 (95 % CI −1,8 til 0,9)]. Der var ingen interaktioner med FABQ-PA. Øgede skuldersmerter og høj FABQ-PA påvirkede ikke træningsadherence [justeret odds ratio (95 % CI): 0,6 (0,2 til 1,4) og 1,2 (0,4 til 4,3)].

Konklusion

Skulder-Café interventionen blev udviklet (Artikel 1). Skulderproblemer, fear-avoidance beliefs, og overordnet oplevelse af ændring (ved 6-måneders follow-up) blev ikke reduceret mere effektivt i Skulder-Café interventionen end i Skulder-vejlednings interventionen. Supplerende outcomes indikerede at Skulder-Café interventionen var foretrukket i forhold til information om hvordan man håndterer skulderproblemer og reducerer erhvervsmæssige skuldereksponeringer, overordnet oplevelse af ændring (ved 12-måneders opfølgning) og tilfredshed med interventionen (Artikel 2). Øgede skuldersmerter på tværs af en træningssession var ikke en barriere for efterfølgende træningsdosis eller overordnet træningsadherence uanset fear-aviodance belief (Artikel 3).

11. Appendices

11. Appendices

Appendix 1: **Paper 1**

Appendix 2: **Paper 2**

Appendix 3: **Paper 3**

Appendix 4: **Screening questionnaire**
[In Danish "Spørgeskema om arbejde og skulderproblemer"]

Appendix 5: **Telephone interview registration form** [In Danish]

Appendix 6: **Pamphlet about the study**
[In Danish "Folder om forskningsprojektet"]

Appendix 7: **Participant information**
[In Danish "Deltagerinformation"]

Appendix 8: **Statistical analysis plan (SAP)**

Appendix 9: **Content, time schedule and differences of the Shoulder-Café and the Shoulder-Guidance.**

Appendix 10: **Home-based exercise programme**
[In Danish "Hjemmetræning"]

Appendix 11: **How to reduce occupational shoulder exposures**
[In Danish "Arbejdsbelastninger"]

Appendix 12: **Example of feedback on shoulder exposures**
[In Danish "Eksempel på feedback brev"]

Appendix 13: **Guideline for supervised exercises**
[In Danish "Manual til superviseret træning"]

Appendix 14: **Clinical shoulder evaluation form**
[In Danish " Klinisk skulderundersøgelse]

Appendix 15: **Educational slides about shoulder and workplace counselling**
[In Danish "undervisningsslides"]

Appendix 16: **Baseline questionnaire**
[In Danish "Spørgeskema A"]

Appendix 17: **6-months follow-up questionnaire**
[In Danish "Spørgeskema B"]

Appendix 18: **12-months follow-up questionnaire**
[In Danish "Spørgeskema C"]

Paper 1

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Trials

STUDY PROTOCOL Open Access

Reducing shoulder complaints in employees with high occupational shoulder exposures: study protocol for a cluster-randomised controlled study (The Shoulder-Café Study)

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Abstract

Background: In Denmark, exercise therapy in combination with work modification is the first-choice treatment for persons with shoulder complaints and high occupational shoulder exposures. To obtain this treatment they must visit several healthcare providers, which makes usual care fragmented and uncoordinated. Therefore, we developed a new intervention which unifies the expertise that is needed. The main hypotheses are that a group-based Shoulder-Café intervention will more effectively reduce (1) shoulder complaints and (2) occupational shoulder exposures than an individual-based Shoulder-Guidance intervention (active control – enhanced usual care).

Methods: A cluster-randomised trial is conducted including 120 employees with high occupational shoulder exposures. Companies (clusters) are randomised to either Shoulder-Café or Shoulder-Guidance with a 1:1 allocation ratio. Participants are 18–65 years old and have an Oxford Shoulder Score (OSS) ≤ 40. Both interventions include a home-based shoulder-exercise programme, assessment of shoulder exposures by technical measurements and self-report, and general information on how to reduce shoulder exposures. The Shoulder-Café course also includes three café meetings with physiotherapist-supervised exercises, clinical shoulder evaluation, education on shoulder anatomy, workplace-orientated counselling, and an opportunity for a workplace visit by a health and safety consultant. The primary outcomes are the OSS at 6-month follow-up (hypothesis I), and the mean number of min/day with the arm elevated > 60° shortly after the end of the intervention (hypothesis II). We will use a mixed-model analysis that allows for company clustering, and data will be analysed according to the intention-to-treat principle.

Discussion: Persons with shoulder complaints and high occupational shoulder exposures are an obvious target group for secondary prevention efforts. We developed the Shoulder-Café to reduce shoulder complaints and shoulder exposures while unifying the expertise that is needed to evaluate and treat shoulder complaints. If the intervention is effective, it would warrant widespread implementation.

(Continued on next page)

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(Continued from previous page)
Trial registration: Clinicaltrials.gov, ID: NCT03159910. Registered on 18 May 2017

Keywords: Exercise, Intervention, Mechanical exposure, Occupation, Randomised controlled trial, Shoulder, Training programme

Background

Shoulder complaints prevail in the working-age population and constitute a common reason to consult a general practitioner [1]. In the general population, the prevalence of self-reported shoulder complaints is estimated to be 16–26% [1, 2] and in the general working population, the prevalence of subacromial impingement syndrome (SIS) has been reported to be 2–8% [3, 4]. In occupations with high mechanical shoulder exposures (work with elevated arms, repetitive shoulder movements, and forceful shoulder exertions), the risk of shoulder complaints and SIS is approximately doubled [5–10]. High occupational shoulder exposures are even associated with an approximately doubled risk of surgery for SIS [11–13], and when combined with shoulder complaints, a more than five-fold increase in risk of later surgery has been reported [14]. Based on these findings, persons with shoulder complaints and high occupational shoulder exposures seem an obvious target group for secondary prevention efforts.

The Danish Health Authority recommends exercise therapy as the first-choice treatment for shoulder complaints related to SIS [15, 16]. In case of shoulder complaints in combination with high occupational shoulder exposures, the Danish Health Authority also recommends work modifications [16]. Relevant modifications include reduction of exposures in specific job tasks (e.g. changes to work equipment and work practices, adjustments of workplace layout) and changes of the employee's task distribution so that the duration of tasks with high exposures is reduced. To meet the recommendations of the Danish Health Authority, usual care today often entails repeated visits to several different healthcare providers (general practitioners, physiotherapists in private practice and municipalities, departments of orthopaedic surgery, departments of occupational medicine) and municipal job centres [17]. This makes usual care fragmented and uncoordinated as experienced by the patients [18]. To unify the necessary expertise to evaluate and treat shoulder complaints, a café intervention was recently developed and pilot-tested in Central Denmark Region [18]. The café concept was based on an intervention study of patients after lumbar spinal fusion, where participants in a Back-Café (three café meetings plus one exercise instruction by a physiotherapist, and featuring the opportunity to exchange experiences) scored better in daily function than participants in group-based physiotherapist-supervised exercises and individual-based video training [19]. This indicated the positive effects of a café concept per se. We further developed the pilot-tested café intervention [18] to target employees with shoulder complaints and high occupational shoulder exposures. Our café intervention, the Shoulder-Café, unifies clinical examination of the shoulders, patient education, supervised and home-based shoulder exercises, advice from a health and safety consultant on work modifications, and assessment of shoulder exposures at work.

Pain-related fear may be a reason why people avoid physical activities, including shoulder exercises, and reduction of an exaggerated reaction pattern of this kind might be part of the café intervention's mechanism of action [20–22]. A Danish randomised controlled trial of the effectiveness of physical therapy exercises versus usual care after surgery for SIS showed that fear-avoidance beliefs (as measured by the Fear-Avoidance Beliefs Questionnaire – Physical Activity (FABQ-PA) scale in a version modified for the shoulder [23, 24] were reduced in the intervention group at 12-month follow-up (a reduction of 3 points was observed on a score ranging from 0 to 24 points with higher scores reflecting a higher tendency for fear-avoidance beliefs [25]). The same trial assessed Patients' Global Impression of Change (PGIC) [26] and found that 65% of the patients in the exercise group experienced improvement in their shoulder condition compared to 49% in the usual care group [25]).

This trial compares a group-based Shoulder-Café intervention with an individual-based Shoulder-Guidance intervention (active control – enhanced usual care). The main hypotheses are that the Shoulder-Café will more effectively reduce (I) shoulder complaints and (II) occupational shoulder exposures than the Shoulder-Guidance. In relation to hypothesis I, we also expect a larger reduction of fear-avoidance beliefs, a larger improvement in PGIC, and larger improvements in a series of supplementary outcomes in the Shoulder-Café group than in the Shoulder-Guidance group.

Methods

Design and setting

The design is a cluster-randomised controlled trial with two parallel groups: Shoulder-Café and Shoulder-Guidance. We chose cluster-randomisation at the company level to prevent contamination between groups. T_0 is the start of the intervention. With regard to hypothesis I, baseline data is collected shortly before T_0 and follow-up data is collected by questionnaire 6 and 12 months after T_0. With regard to hypothesis II, baseline data is collected

shortly after T_0 and follow-up data is collected shortly after end of intervention (EOI, around 3 months after T_0). The setting is Central Denmark Region. A stakeholder group with members from trade unions, municipal rehabilitation centres, general practice, and the Health Planning Agency in Central Denmark Region has been established to facilitate the completion of the project and subsequent implementation of the Shoulder-Café if the results favour this intervention. This study protocol is written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist [27] (Additional file 1 a and b) in conjunction with the Template for Intervention Description and Replication (TIDieR) Checklist [28].

Trial population

The trial population consists of employees from occupations with high mechanical shoulder exposures who experience shoulder complaints. Relevant occupations are identified by means of a Danish Job Exposure Matrix (The Shoulder JEM), which is based on five experts' ratings and covers all occupations in Denmark [29]. We selected occupations which fulfilled at least one of the following criteria: upper-arm elevation $> 90° \geq 1$ h/day, highly repetitive work ≥ 0.5 h/day, moderately repetitive work ≥ 4 h/day, and a forceful shoulder exertion score ≥ 3 range (1 (light) to 5 (near maximal)) [11, 14]. Kitchen assistants with moderate exposures are also included to ensure sufficient representation of women. Companies are recruited in batches according to their geographical location. To achieve adequate patient enrolment, we will gradually widen the geographical distribution of companies within Central Denmark Region and include more occupational groups. The selected occupations are grouped according to industry: service (cleaning, kitchen and laundry assistants, hairdressers, and gardeners/paviours), manufacturing (dairy, bread, and wood-industry workers) and construction (electricians, carpenters, plumbers, bricklayers, house painters, welders, blacksmiths, and insulation workers). In a batch mode, we contact relevant companies in Central Denmark Region with at least 10 employees identified in The Central Business Register (https://datacvr.virk.dk/data/index.php?q=forside&language=en-gb). If a company accepts participation, employees from the relevant occupations are asked to fill in an electronic or postal screening questionnaire which – together with telephone screening – determines eligibility. The companies will distribute the questionnaires because, according to the Danish Data Protection Act, they are not allowed to give us a list with all possible participants. Thus, we cannot calculate the exact percentage that participated. We aim to include 120 participants in the trial (see the 'Sample size' section below).

Based on the screening questionnaire, employees are invited to participate in the telephone screening if they meet the following inclusion criteria: aged 18–65 years, employed in one of the selected occupations, and with an Oxford Shoulder Score (OSS) ≤ 40 [30, 31]. The OSS, which exists in a Danish version [32], consists of 12 items, each referring to the past 4 weeks, with a total score ranging from 0 (worst) to 48 (best). We set the screening criterion at an OSS ≤ 40 to ensure that the included employees have shoulder complaints. The cut-off level was based on the pilot café intervention [18], where around 20% had an OSS ≤ 40, and is supported by mean scores of 42–47 in asymptomatic populations [33, 34]. Employees are excluded if they do not provide sufficient contact information or decline further participation. Based on the telephone screening, the following additional exclusion criteria are applied: no current shoulder complaints, sickness absence expected to continue into the intervention period, weekly working hours < 20, previous shoulder surgery, previous breast cancer operation, other health conditions expected to affect participation (e.g. rheumatoid arthritis, pregnancy), and inability to communicate in Danish. Employees may also decline further participation at this step. An additional exclusion criterion is failure to complete the baseline questionnaire (electronic or postal) before T_0. The time between completion of the screening questionnaire and the telephone screening is expected to be around 5 weeks, and the subsequent time before enrolment is expected to be around 4 weeks. Companies are included if they are represented by at least one participant. Figure 1 presents the expected flow of participants through the study.

Randomisation

Companies (clusters) are randomly allocated to Shoulder-Café or Shoulder-Guidance with a 1:1 allocation ratio using computer-generated random-number assignment. Randomisation is stratified by industry (service, manufacturing, construction) using blocking within strata with randomly permuted block sizes of 2, 4, and 6. A research assistant prepares closed envelopes with printed randomisation numbers and the corresponding intervention inside. Companies are contacted batch-wise. When all relevant employees from a company have completed screening, the principal investigator (JT) opens the envelope and invites eligible employees from the company to their first Shoulder-Café or Shoulder-Guidance attendance. The randomisation result is not revealed to the participants until they have signed the informed consent (obtained by JT) and completed the baseline questionnaire. The baseline questionnaire includes self-reported typical occupational shoulder exposures (see 'Other assessments' below), while baseline assessment of occupational shoulder exposures

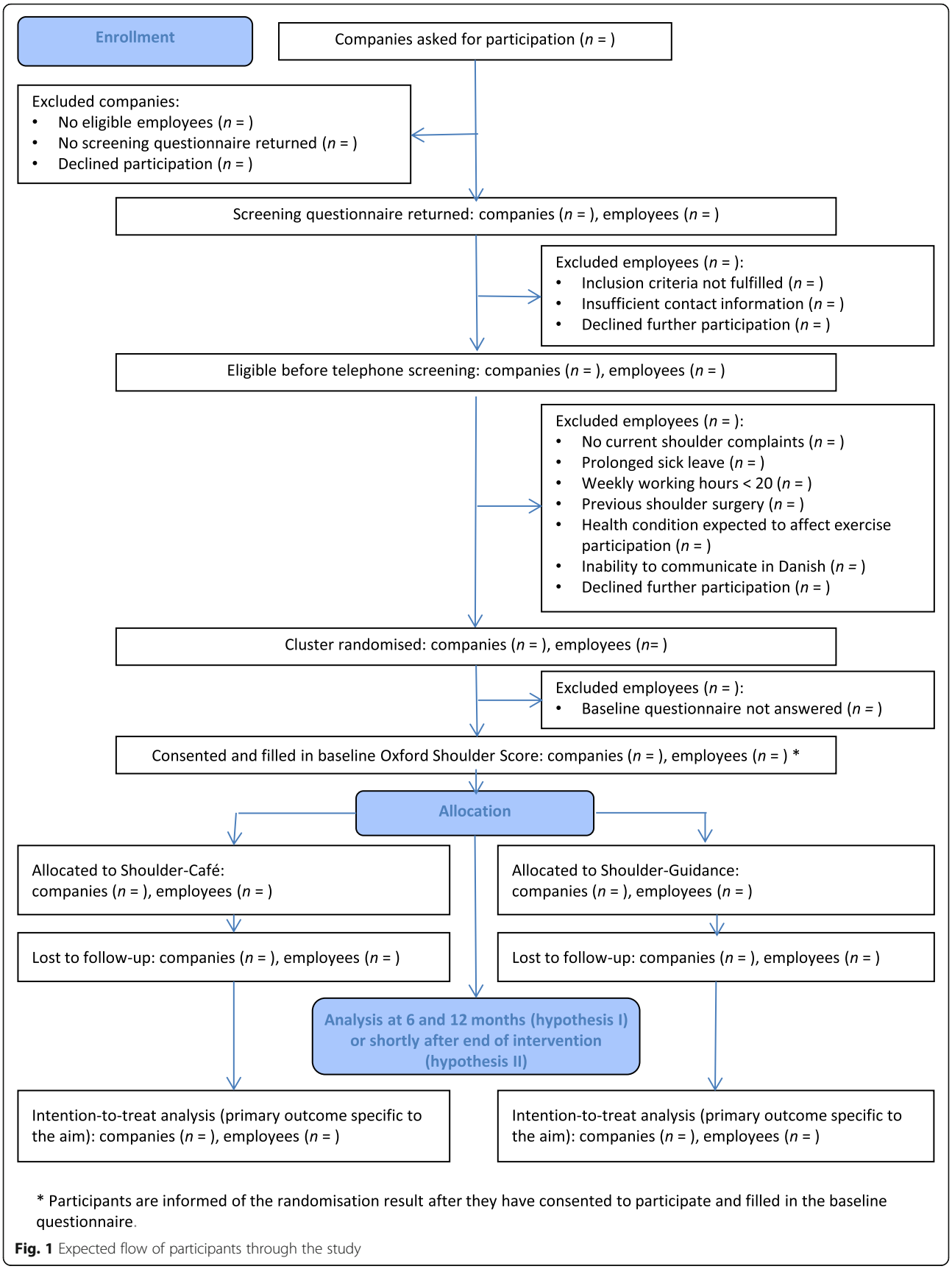

Fig. 1 Expected flow of participants through the study

with respect to hypothesis II takes place after the randomisation result has been revealed.

Interventions

The Shoulder-Café is designed as a complex intervention [35] with interacting components unified into a group intervention, whereas the Shoulder-Guidance is a simpler individual intervention. Consecutively, around 60 employees are scheduled to attend one of around 12 Shoulder-Café courses. Concurrently, around 60 employees are scheduled to attend a Shoulder-Guidance course. Each course lasts around 3 months with variations depending on practical issues; e.g. care givers' time schedules. Physical attendance will take place at six geographically dispersed municipal health centres. A description of the Shoulder-Café and Shoulder-Guidance is presented in Table 1.

The following elements are identical in the Shoulder-Café and the Shoulder-Guidance:

- A home-based shoulder-exercise programme with instructions for individual tailoring, described in a pamphlet (Additional file 2). Exercises for treating shoulder complaints have shown promising results [25, 36–38], but the optimal type, intensity, frequency, and duration of these exercises are not clear [39–43]. Our exercise programme was constructed by JT in cooperation with three physiotherapists from the Orthopaedic Shoulder Department at Silkeborg Regional Hospital (SRH). Based on studies showing

Table 1 Content and time schedule of the Shoulder-Café and the Shoulder-Guidance

Shoulder-Café	Shoulder-Guidance (active control – enhanced usual care)
1st café meeting (T_0): • Distribution of home-based exercise pamphlet, BandCizer©, Axivity accelerometers[a], diaries, andelastic bands • Presentation of participants and networking with the group • Supervised exercises with individual tailoring according to the exercise pamphlet • Clinical evaluation of the participants' shoulders • Education about shoulder anatomy	1st intervention contact – individual appointment (T_0): • Distribution of home-based exercise pamphlet, BandCizer©, Axivity accelerometers[a], diaries, and elastic bands
At home: • Home-based exercises and exercise diary At work: • Shoulder exposure assessment and work diary	At home: • Home-based exercises and exercise diary At work: • Shoulder exposure assessment and work diary
2nd café meeting (~ 1.5 month after T_0): • Written feedback on the 1st exposure assessment • Written general advice on reduction of occupational shoulder exposures • Supervised exercises with individual tailoring according to the pamphlet • Education about shoulder exposures • Advice on work modifications and possibility to ask questions about the 1st exposure assessment • Offer of a workplace visit to find ways to reduce the exposures • Networking with the group	2nd intervention contact – postal letter or email (~ 1.5 months after T_0): • Written feedback on the 1st exposure assessment • Written general advice on reduction of occupational shoulder exposures
At home: • Home-based exercises and exercise diary	At home: • Home-based exercises and exercise diary
3rd café meeting (end of intervention ~ 3 months after T_0): • Distribution[a] of Axivity accelerometers and work diaries • Supervised exercises with individual tailoring according to the pamphlet • Networking with the group	3rd intervention contact – postal letter (end of intervention ~ 3 months after T_0): • Distribution of Axivity accelerometers and work diaries
At work: • Shoulder exposure assessment and work diary	At work: • Shoulder exposure assessment and work diary
Postal letter or email: • Written feedback on the exposure assessment shortly after end of intervention	Postal letter or email: • Written feedback on the exposure assessment shortly after end of intervention
6-month follow-up (~ 6 months after T_0): • Electronic or postal questionnaire	6-month follow-up (~ 6 months after T_0): • Electronic or postal questionnaire
12-month follow-up (~ 12 months after T_0): • Electronic or postal questionnaire	12-month follow-up (~ 12 months after T_0): • Electronic or postal questionnaire

[a]The Axivity accelerometer is mounted, unless the participant is going on holiday or expects atypical work, e.g. due to course participation. A pamphlet "How to use Axivity" is handed out to all participants together with the accelerometer

the effect of exercise programmes [25, 36–38, 44], easily learned exercises were selected taking into account elements known to motivate exercise adherence (e.g. a limited number of exercises) [45]. The programme consists of four exercises: one posture-corrective exercise and three resistance exercises, performed bilaterally with an elastic band (Thera-band©). The three resistance exercises, each with three levels, consist of two exercises for the scapula-stabilising muscles (wall slide and low row/high row) and one for the rotator cuff muscles (external rotation). Participants are recommended to start with the exercises at level 1, and to perform three sets of up to 15 repetitions three to four times per week during the intervention period and preferably also thereafter. When a participant is able to perform three sets of 15 repetitions of an exercise without aggravating pain (lasting > 1 h after exercise), they are encouraged to progress to the next level of that particular exercise

- General information on occupational shoulder exposures and how to reduce them, described in a pamphlet (Additional file 3). The pamphlet, developed by AD, in collaboration with PF, SWS, and SDC, focusses on work with elevated arms, repetitive shoulder movements, and forceful shoulder exertions. It is based on previous assessments of occupational shoulder exposures [29], exposure-response relationships with shoulder disorders [11–14], and years of experience from work as occupational health physicians (PF and SWS) and as a health and safety consultant (SDC)
- Assessment of occupational shoulder exposures based on:
  - Technical measurements of postures and movements performed using an Axivity (AX3) accelerometer [46] processed to yield min/day with the arms elevated > 30°, > 60°, and > 90°, and median angular velocity (°/s) (as a measure of repetition) during work. Axivity measurements are performed on the more affected shoulder (right shoulder in case of similar symptoms). The accelerometer is fixed with double-sided adhesive tape to the lateral part of the upper arm with its proximal part just distal to the deltoid muscle. Data is recorded with a sampling rate of 50 Hz. The participants are instructed to wear the accelerometer for at least one and preferably five working days and to register working hours (start and stop times), main tasks, and whether it was a typical working day in a work diary. Data from one measurement day of ≥ 4 h per person is considered enough for characterisation at the group level
  - Self-reported estimates of the average level of forceful shoulder exertions for each working day using the Borg CR-10 scale [47]

Exposure assessment is performed shortly after the first café meeting/intervention contact and shortly after EOI (see Table 1). All participants receive individual written feedback on their shoulder exposures after these two exposure assessment periods (Additional file 4).

Shoulder-Café

A Shoulder-Café course includes three café meetings spaced around 6 weeks apart. The principal investigator (JT) will attend all first and third café meetings. Each café meeting lasts for about 2 h and includes 15–30 min of 'small talk' and exchange of experiences over a cup of coffee/tea to secure social networking and interpersonal relationships. In addition, a Shoulder-Café course contains:

- Individually tailored shoulder exercises (in accordance with the exercise pamphlet, Additional file 2), supervised by physiotherapists from the six municipality health centres. At each café meeting, the attending physiotherapist spends 1 h demonstrating the exercises, correcting participants performing the exercises, and answering questions in relation to the exercises. To secure fidelity, the physiotherapists have attended a training session led by JT prior to the first café meeting and follow a pre-defined guideline (Additional file 5)
- A clinical shoulder evaluation of each participant performed at the first café meeting by a physiotherapist according to a pre-specified form (Additional file 6) and manual. The manual is based on the Danish guideline for diagnosing patients with shoulder complaints [15] and was developed by JT in cooperation with three physiotherapists from the Orthopaedic Shoulder Department at SRH, an orthopaedic surgeon (TK), and two occupational health physicians (PF and SWS). The aim of the examination is to characterise the participants clinically. If, as an exception, a participant is identified with a 'red flag' (e.g. progressive non-mechanical pain or weight loss) [48], they are advised to contact their general practitioner and a statement regarding advice against exercise is recorded; the participant will still be included in the intention-to-treat analyses. The three physiotherapists, who take turns performing the examinations, had been physiotherapists for 12–18 years, had special training in clinical evaluation of shoulder complaints, and had worked for 3–7 years in the Orthopaedic Shoulder Department at SRH at the start of the interventions

- Education about shoulder anatomy (Additional file 7) for 45 min at the first café meeting is provided by the above-mentioned experienced physiotherapists. The goal is to educate participants in the taking of appropriate action to reduce their shoulder complaints
- Workplace-orientated counselling focussing on reducing shoulder exposures. The counselling is given by a health and safety consultant (SDC), who had been a physiotherapist for 18 years and had been working as a health and safety consultant for 14 years at the start of the interventions. He has 45 min at his disposal at the second café meeting (Additional file 8), where he also answers questions about the individual feedback on shoulder exposures (Additional file 4). The counselling is based on theories from 'The motivational conversation' [49], 'Stages of change' [50], and 'The health belief model' [50] in order to increase the participants' motivation for self-generated changes. There is also time to discuss organisational and other factors which might be barriers for work modifications. Previous experience indicates that health and safety advice is less likely to be implemented if the advice is too general or will take a long time to implement [51]. Therefore, our focus is on feasible and specific work modifications that can be implemented within a short time frame, i.e. modifications that are cheap, uncomplicated, and fit workplace conditions. Advice on more far-reaching modifications may also be given. A workplace visit by the health and safety consultant is an option when necessary to find ways to reduce the shoulder exposures. Plans of action that are based on a workplace visit are often focussed and clearly outlined, which increases their chances of being implemented [51]. The workplace visits are attended by the health and safety consultant, the participant, a working environment representative, and, if possible, the employer/supervisor. Initially, one to three tasks are prioritised. These entail high shoulder exposures and are difficult to perform while having shoulder complaints. Again, the focus is on specific work modifications that are feasible within a short time frame. The advice is documented in a workplace visit registration form by the health and safety consultant and categorised as ways to reduce high-task exposures (technical solutions) and ways to reduce the duration of tasks with high exposures (organisational solutions) for the individual participant. After the workplace visit, the health and safety consultant sends a summary of the advice to the employee, the working environment representative, and the employer/supervisor. We have resources for a maximum of 50 1-h workplace visits

The physiotherapists, who supervise the exercises and perform the clinical examinations, and the health and safety consultant are financially compensated by the project.

Shoulder-Guidance

The Shoulder-Guidance includes an initial 20–30-min individual appointment, staffed by a physiotherapist student or a project physiotherapist; the remaining parts of the guidance are delivered as postal letters or emails.

Outcome measures

Additional file 11: Table S2 provides the time schedule of the trial and the timing of assessments of primary, secondary, and supplementary outcomes as well as assessments of baseline characteristics and measures of adherence and adverse events.

Primary outcomes

In relation to hypothesis I The primary outcome is the OSS at 6-month follow-up. We chose a patient-reported outcome [52] which directly measures the participants' shoulder complaints. The OSS has been translated and cross-culturally adapted to Danish [32] and is a valid, reliable, and responsive shoulder-specific measure [30, 53–56]. It is one of the recommended first-choice instruments in patients with shoulder disorders [57]. The OSS was developed for patients undergoing shoulder surgery [30], but has also been used in patients who have not been operated on [55, 56] and asymptomatic persons [33, 34]. Follow-up after 6 months was chosen to allow the potential effects on shoulder pain and disability to evolve.

In relation to hypothesis II The primary outcome is work with the arm elevated > 60° (min/day) according to Axivity measurements shortly after EOI. This outcome was chosen based on the available evidence that work with elevated arms (assessed in various ways) is associated with an increased risk of shoulder complaints and SIS [5, 7, 8, 10] and because we think that this measure will be more responsive to change than min/day with the arm elevated > 90°, which has been quite well studied [10–14], but occurs to a limited extent in some of the included occupations. The timing was chosen because we expect that most work modifications will occur within the intervention period and because we want to use the second measurement feedback to motivate the participants for further work modifications.

Secondary outcomes

In relation to hypothesis I Listed in order of priority, the secondary outcomes are:

- The OSS at 12-month follow-up. We added this time point because increasing effects of a training intervention 12 months after T_0 has been reported previously [25]
- The FABQ-PA scale [23] at 6-month follow-up in a version modified for the shoulder [24]. The FABQ-PA scale contains four items about shoulder pain in relation to physical activity [20, 23, 24]. As mentioned in the 'Background' section, reduction of exaggerated fear-avoidance beliefs may be part of the café intervention's mechanism of action [20–22]
- The PGIC [26] at 6-month follow-up, which reflects the participants' general impression of change with regard to their shoulder condition rated on a 7-point Likert scale ranging from 1 (much better) to 7 (much worse) (https://www.sciencedirect.com/science/article/pii/S2287888215300684). Our a priori definition of improvement is the range 1 'Much better', 2 'Better', and 3 'A little better'
- The FABQ-PA scale [23] at 12-month follow-up

In relation to hypothesis II Listed in order of priority, the secondary outcomes are:

- Min/day working with the arm elevated > 90° according to Axivity measurements shortly after EOI
- Mean median angular velocity (°/s) according to Axivity measurements shortly after EOI
- Average forceful shoulder exertions assessed by the Borg CR-10 scale [47] shortly after EOI
- Min/day working with the arm elevated > 30° according to Axivity measurements shortly after EOI

Supplementary outcomes

In relation to hypothesis I Intensity of shoulder pain at rest and during activity measured on a numerical rating scale (NRS, ranging from 0 (no pain) to 10 (worst imaginable pain)), quick version of the Disabilities of the Arm, Shoulder and Hand (quick DASH) and work module [58], health-related quality of life using the EuroQol five-dimension, three-level health survey (EQ 5D-3 L) [59], work ability using the Work Ability Score [60, 61], PGIC at 12 months' follow-up, overall satisfaction with the intervention at 6 and 12 months, and the degree to which the participant felt sufficiently informed about (1) how to handle shoulder complaints, (2) how to perform shoulder exercises, and (3) how to reduce occupational shoulder exposures at 6-month follow-up (5-point scales).

In relation to hypothesis II Work modifications according to questionnaire information at 6-month follow-up.

Supplementary outcome measures will be selected from these variables.

Other assessments

Other baseline assessments are smoking status, body mass index, duration of shoulder complaints, psychosocial work exposures (job demands, job control, and social support based on the Karasek-Theorell model) [62], occupational mechanical shoulder exposures (self-reported upper-arm elevation, repetitive shoulder movements, forceful shoulder exertions, and use of vibrating tools). In addition, job title, weekly working hours, and system of wage payment are assessed at baseline and at 12-month follow-up and work status is assessed at 12-month follow-up. At 6- and 12-month follow-up, all participants are also asked how often exercise was performed.

Adherence

Adherence to the home-based exercise programme is monitored using an exercise diary and a BandCizer© sensor mounted on the elastic band (Thera-band©). The BandCizer© records the exercise-dose quantified as time under tension [63–65]. Adherence to the exposure assessment will be described as the percentage of the participants who have one work day or more with ≥ 4 h of Axivity data and/or a Borg CR-10 rating in the first and in the second exposure assessment period. For the Shoulder-Café group, adherence to café meetings will also be described (Additional file 11: Table S2).

Co-interventions and adverse events

The questionnaires at 6- and 12-month follow-up will ask about co-interventions and adverse events (Additional file 11: Table S2).

Data collection and data management

All questionnaires will be collected by the principal investigator (JT). Companies will be reminded by email and telephone if few or no screening questionnaires have been returned after 1–2 months. Participants who do not return the follow-up questionnaires will be reminded to do so by email and finally by postal letter. Data from the paper screening questionnaires will be scanned by PostNord [66]. Data from electronic screening, baseline, and follow-up questionnaires will be directly captured in REDCap (version 7.4.17, Vanderbilt University), while data from the paper versions of the baseline and follow-up questionnaires and from exercise diaries will be manually

entered into REDCap. Data from the BandCizer© will be processed to yield date, number of training sessions, number of exercise sets, number of repetitions, time under tension for each repetition, and total time under tension for each training session. Variables based on data from the BandCizer© will be entered into REDCap. Axivity data (Axivity Ltd., Newcastle upon Tyne, United Kingdom) will be downloaded using OmGui open-source software (OmGui Version 1.0.0.28; Open Movement, Newcastle University, Newcastle upon Tyne, United Kingdom) and saved in raw format files. MatLab (Build 8.6.0.267246 (R2015b) 64 bit) and STATA 15 (StataCorp LP, College Station, TX, USA) will be used for data processing and statistical analyses. Data cleaning will be documented in Stata do files. Questionnaires and other documents, which are not provided as supplementary materials (Additional files 1, 2, 3, 4, 5, 6, 7, 8, and 9), are available in Danish and can be requested from JT (Additional file 10).

Blinding

Blinding of participants and care providers is not possible due to the character of the interventions. To prevent this from influencing the answers on the OSS and other patient-reported outcomes, all participants receive an active intervention. With respect to shoulder exposures, the outcome assessor (AD) will be blinded to intervention arm. We have developed a statistical analysis plan (SAP) to minimise the risk of analysis bias (Additional file 9).

Sample size

We aim to be able to show a minimum clinically important difference between the groups of at least 5 points in the OSS [67, 68] at 6-month follow-up. With an expected SD of 8 points [25], an intraclass correlation coefficient of 0.05 [69, 70], and a mean cluster-size of four, the study size needs to be ≥ 96 (2 × 48) with a two-sided significance level of 0.05 and a power of 0.80. We aim to include 60 employees in each group to ensure that 50 employees in each group complete the study. Power calculations were carried out with Stata 15 (StataCorp LP, College Station, TX, USA; power twomeans with cluster option).

Statistical methods

All analyses will be performed according to intention-to-treat principle. Regarding hypothesis I, a mixed-model analysis of the OSS will be performed including 'intervention' (Shoulder-Café and Shoulder-Guidance), 'time' (6- and 12-month follow-up), 'intervention × time', baseline OSS, sex, age, and industry (service, manufacturing, construction) as fixed effects, adjusting for random effects of participant and company (cluster). The FABQ-PA will be analysed likewise, but will be adjusted for baseline FABQ-PA instead of baseline OSS. In the analysis of PGIC at 6 months the outcome will be dichotomised as described above. We will use a risk-difference model if around 50% of the participants improve. If a considerably smaller percentage (< 20%) improves, we will employ a relative-risk model using improved as the outcome, while, if a considerably larger percentage (> 80%) improves, we will employ a relative-risk model using 'not improved' as the outcome. The analysis of PGIC will be adjusted for sex, age, and industry and use robust standard errors to take clustering at company level into account.

Regarding hypothesis II, a mixed-model analysis of the primary outcome (min/day working with the arm elevated > 60°) will be performed including 'intervention' (Shoulder-Café and Shoulder-Guidance), baseline min/day working with the arm elevated > 60°, sex, age, and industry (service, manufacturing, construction) as fixed effects, adjusting for random effects of company (cluster). The analyses for the secondary outcomes will be performed likewise, but will be adjusted for the respective baseline values instead of the baseline number of min/day working with the arm elevated > 60°.

If no more than two questions in the OSS are left unanswered, single mean imputation will be used [31], otherwise the total score will be left missing. Axivity measures are considered missing in case of < 4 h of measurement data during one working day. Loss to follow-up will be addressed by sensitivity analyses comparing realistic scenarios; subgroup analyses are not intended. Additional information is available in the SAP (Additional file 9).

Harms and data monitoring

The intervention is based on non-invasive methods and is not expected to cause any adverse events other than possible temporary muscle tenderness after shoulder exercises. Therefore, no data monitoring committee has been established and no stopping rules defined. Any unexpected serious adverse event will be reported to the Committee on Health Research Ethics in Central Denmark Region within 7 days after the principal investigator (JT) has become aware of the event.

Publication policy

Hypotheses 1 and 2 will be addressed in separate publications. The main publication regarding hypothesis I will be prepared first and the main publication regarding hypothesis II shortly thereafter. We intend to publish positive, negative, and inconclusive results. Authorship will be determined in accordance with the recommendations of the International Committee of Medical Journal Editors. Furthermore, we plan to disseminate the results to key stakeholders through the projects' stakeholder group. The authors do not have any publication restrictions.

Satellite studies

Two prospective cohort studies are planned based on the cluster-randomised trial. One study, with the OSS as the primary outcome, will investigate the relative influence of shoulder exercises and reduced occupational shoulder exposures on shoulder complaints. Another study will investigate the intensity of shoulder pain at rest and during activity (NRS) monitored week by week using short message service as a predictor of subsequent weekly exercise dose, and the potential influence of fear-avoidance beliefs on this relationship. Further, a process evaluation [71, 72] is nested in the trial to assist later contextualisation of the outcomes. The findings from this may point to areas that warrant further consideration or development prior to a potential wider implementation of the Shoulder-Café intervention. The process evaluation employs semi-structured interviews [73] with eight participants from the Shoulder-Café ($n = 4$) and Shoulder-Guidance ($n = 4$) conducted 1 month after EOI and 12 observations [74] of Shoulder-Café ($n = 9$) and Shoulder-Guidance ($n = 3$) sessions. All interviews and observations are supervised by a senior project participant (MTH). Further, a focus group interview is conducted with self-selected professionals (physiotherapists from hospital and municipalities and the health and safety consultant) ($n = 12$).

Discussion

Several studies have found that exercise is effective in reducing shoulder complaints [25, 36–41, 43, 75, 76], but optimal ways to exercise remain to be established. Few studies have evaluated interventions that have addressed occupational shoulder exposures in order to prevent or reduce shoulder complaints [77–79]. The disappointing results of these studies may be related to the fact that for the most part they were completed in office environments and healthcare settings, where shoulder exposures are at most moderate to begin with [77–79]. Only one study that we are aware of included participants with high shoulder exposures, but did not document whether the intervention reduced the exposures [80]. The combination of shoulder exercises and workplace-orientated advice using a café concept is a novel approach, which minimises the fragmentation that is characteristic of usual care today and adds potential benefits of delivering the intervention in a group setting rather than individually [81] (e.g. social support in combination with professional guidance and exchange of ideas for improving work practices between group members).

The strengths of this study are the randomised controlled design, cluster-randomisation at company level to prevent contamination between groups, use of validated patient-reported outcomes to assess shoulder complaints, and technical measurements of shoulder postures and movements.

Stigmatisation of employees with shoulder complaints is avoided as the intervention takes place outside the company and after working hours. This enables participants to decide whether they want to inform their workplace about their participation.

A limitation of the study is the inability to blind participants to the intervention, but both groups receive an active intervention in order to reduce the risk of biased outcome reporting. Baseline assessment of occupational shoulder exposures takes place after the randomisation result has been revealed. However, Axivity accelerometers are mounted on all participants at their first intervention appointment and we use technical measurements performed on several working days. This should guard against differential participation and differential misclassification of occupational shoulder exposures. Additionally, participants and non-participants will be compared with respect to self-reported occupational shoulder exposures according to the baseline questionnaire. To minimise the risk of analysis bias, we have developed a SAP prior to any analysis.

A further limitation is that it is not possible to differentiate between the separate effects of exercise, work modification, diagnostic clarification, education, workplace-orientated counselling, and group processes on the participants' shoulder complaints, but the analyses in relation to hypothesis II and one of the planned satellite studies will reveal to which extent reduced occupational shoulder exposures may have played a part. To give a further indication of the relative influence of the intervention elements, we will ask the participants at 6-month follow-up to which degree they feel that the intervention provided them with sufficient knowledge about (1) how to handle shoulder complaints, (2) how to exercise, and (3) how to reduce their shoulder exposures. The process evaluation may aid in this evaluation. If shoulder exposures are reduced by handing over high-load tasks to colleagues, the problem may only be relocated. On the other hand, the possibility of exposure modification in periods with increased pain may be in all employees' favour.

If the results turn out to be positive, we believe that the Shoulder-Café intervention has the potential to be implemented on a larger scale. The pilot-tested café intervention is already implemented in three municipalities in Central Denmark Region, and the project has a stakeholder group to back up the process. Further, it should be possible to develop the intervention to involve other musculoskeletal regions, which has already been requested by one of the participating municipalities.

Trial status

Protocol version 1.0: Issue date: 22 January 2019. Recruitment of participants started in May 2017 and is ongoing. Recruitment of participants is expected to end no later than June 2019.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-019-3703-y.

Additional file 1. a: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist. b: World Health Organisation (WHO) Trial Registration Data Set.

Additional file 2. Pamphlet – Home-based shoulder exercise programme. (Images on page 1 were bought from Colorbox. Other photos are our own).

Additional file 3. Pamphlet – How to reduce occupational shoulder exposures. (Images are our own).

Additional file 4. Individual feedback on occupational shoulder exposures.

Additional file 5. Guideline for supervised exercises.

Additional file 6. Clinical shoulder examination form.

Additional file 7. Educational slides – shoulder anatomy. (Images on page 3 were bought from Colorbox. Other photos are our own).

Additional file 8. Educational slides – workplace counselling. (Images are our own).

Additional file 9. Statistical analysis plan (SAP).

Additional file 10. List of questionnaires and other documents used in the project.

Additional file 11: Table S2. Schedule for study procedures. For each batch of companies, the two interventions (Shoulder-Café and Shoulder-Guidance) start and end simultaneously.

Abbreviations

CI: Confidence interval; EOI: End of intervention; FABQ-PA: Fear Avoidance Beliefs Questionnaire – Physical Activity; OSS: Oxford Shoulder Score; PGIC: Patients' Global Impression of Change; SAP: Statistical analysis plan; SRH: Silkeborg Regional Hospital; T_0: Start of intervention

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Authors' contributions

The trial was planned by all authors. JT is responsible for participant recruitment and data collection and has drafted this manuscript in close collaboration with SWS. All authors have revised the manuscript for important intellectual content and have read and approved the final manuscript. All authors will have access to the final trial data set.

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Availability of data and materials

Not applicable since this manuscript is a study protocol.

Ethics approval and consent to participate

The Danish Data Protection Agency approved the study on 7 September 2016 (case number: 1–16–02-498-16). The trial protocol, the informed consent forms, and other requested documents have been reviewed by The Committee on Health Research Ethics in Central Denmark Region, which approved the trial on 20 March 2017 (case number: 1–10–72-271-16). Written consent is obtained from all participants. The trial was registered at ClinicalTrials.gov on 18 May 2017 (ID: NCT03159910). Important protocol modifications will be communicated to these agencies.

Consent for publication

Written informed consent was obtained from the person appearing in the exercise pamphlet (Additional file 2). A copy of this consent is available for review by the Editor-in-Chief of this journal.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Paper 2

TITLE PAGE

Reducing shoulder complaints in employees with high occupational shoulder exposures: a cluster-randomised controlled study (The Shoulder-Café Study)

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Abstract

Purpose. To evaluate if a group-based Shoulder-Café intervention could reduce shoulder complaints more effectively than an individual-based control intervention in employees with shoulder complaints and high occupational shoulder exposures.

Methods. A cluster-randomised trial of 109 participants from 60 companies in Central Denmark Region. Companies were randomised and allocated to either Shoulder-Café or control intervention. Participants in both interventions received a pamphlet on home-based shoulder exercises and a pamphlet with general information on reducing occupational shoulder exposures, and had their occupational shoulder exposures assessed. Shoulder-Café participants also received three café-meetings with casual discussion, clinical shoulder evaluation, education about shoulder anatomy and occupational shoulder exposures, workplace-oriented counselling, supervised exercises, and an optional workplace visit. The primary outcome measure was the Oxford Shoulder Score (OSS) at 6-month follow-up. Secondary outcome measures were the OSS at 12 months, Fear-Avoidance Beliefs Questionnaire - Physical Activity at 6 and 12 months, and Patients' Global Impression of Change at 6 months. The study also included seven supplementary outcome measures.

Results. Both groups improved from baseline to 6 months with respect to the primary outcome ($P<0.01$). No group differences were found for the primary outcome (mean difference (MD) [95% confidence interval]: 0.3 [-1.6;2.2]) or secondary outcomes. Supplementary outcomes of "informed about handling shoulder complaints" and "informed about reducing occupational exposures" at 6 months, and "Patients' Global Impression of Change" and "overall satisfaction" at 12 months favoured the Shoulder-Café intervention.

Conclusion. The Shoulder-Café intervention did not reduce shoulder complaints more effectively than the control intervention.

Keywords:

Exercise, occupational groups, physical therapists, rehabilitation, shoulder pain.

Trial registration: The trial was registered at Clinicaltrials.gov on 19 May 2017 (ID: NCT03159910).

Introduction

Shoulder complaints are common in the general population. One-month prevalence estimates range from 19 to 31% [1]. In occupations with high shoulder exposures (i.e., work requiring elevated arms, repetitive shoulder movements, and forceful shoulder exertions), the risk is nearly doubled [2-4]. For individuals, shoulder complaints are a health burden. For society, they are an economic burden [5]. Combined, these facts make people with shoulder complaints and high occupational shoulder exposures a clear target group for secondary prevention efforts.

In Denmark, the evaluation and treatment of shoulder complaints generally require repeated visits to several healthcare providers (e.g., general practitioners, physiotherapists, rheumatologists, orthopaedic surgeons, and occupational physicians) [6]. Thus, people with shoulder complaints may experience fragmented and uncoordinated care [7]. According to Danish guidelines, first-line treatment for non-traumatic shoulder complaints includes exercise [8, 9], education about shoulder anatomy [8], and in case of high occupational shoulder exposures also work modifications [8]. There is evidence for positive effects of shoulder exercise, but it is uncertain if the effects are clinically relevant [10]. The evidence for effects of the two last-mentioned treatment components is insufficient [10-13]. Complex interventions [14] that focus on biopsychosocial components seem more effective for reducing back pain than less complex interventions [15], but evidence with respect to shoulder complaints is lacking [16, 17].

In 2014, a group-based intervention for people with shoulder complaints was developed and pilot-tested in Central Denmark Region [7]. The goal was to support self-management and create a more cohesive treatment process [7]. The pilot test indicated that an intervention including a clinical shoulder screening, education about shoulder anatomy, and supervised exercises could reduce

shoulder complaints and enhance participants' motivation for home-based exercises [7]. To target employees with shoulder complaints and high occupational shoulder exposures, we then created the group-based Shoulder-Café intervention, which also includes workplace-oriented counselling.

Among people with shoulder pain, avoidance of activities due to fear of pain exacerbation can contribute to persistent pain and disability [18]. Higher fear can also influence the effectiveness of treatment [19, 20]. A part of the Shoulder-Café intervention's mechanism of action may be to reduce exaggerated fear-avoidance beliefs and thus create more positive outcomes.

Aim

We aimed to compare a group-based Shoulder-Café intervention with an individual-based control intervention (also called Shoulder-Guidance). Specifically, we wanted to test the hypothesis that the Shoulder-Café intervention could reduce shoulder complaints more effectively than the control intervention. We also aimed to compare the effects of the two interventions on fear-avoidance beliefs and global impression of change (at 6 months), and on a series of supplementary outcomes (i.e., intensity of shoulder pain, disability of the upper limbs, health-related quality of life, work ability, global impression of change (at 12 months), overall satisfaction with the intervention received, and feeling sufficiently informed).

Methods

Study design

We conducted a cluster-randomised controlled study with two parallel groups in Denmark between January 2017 and August 2020. The study was pre-registered in Clinical Trials (Clinicaltrials.gov, ID: NCT03159910). It was approved by the Danish Data Protection Agency (case number: 1-16-02-

498-16) and the Committee on Health Research Ethics in Central Denmark Region (case number: 1–10–72-271-16). All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and participation was based on written informed consent. The study protocol was published while the participant inclusion was ongoing [21]. There were no deviations from the protocol except for post-hoc sensitivity analyses (see below). Supplementary outcomes were pre-planned and described in the protocol [21], but in the Clinical Trial registration, only primary and secondary outcomes were listed. The supplementary outcomes were selected to evaluate other potential positive effects of the Shoulder-Café intervention with "feeling informed" as a possible mechanism of action of the Shoulder-Café. As pre-planned, results based on the occupational shoulder exposure assessments will be reported later [21].

Participants

Participants were employees in occupations with high shoulder exposures. Relevant occupations were identified in the Danish Shoulder Job Exposure Matrix [21, 22] and chosen if they fulfilled one or more of the following criteria: highly repetitive work ≥0.5 hours/day, moderately repetitive work ≥4 hours/day, upper arm elevation >90° ≥1 hour/day, and a force score ≥3 (1 to 5 (max)) [21]. Kitchen assistants with moderate exposures were also included to secure female representation. Companies located in Central Denmark Region were identified through the Central Business Register. Employees in service (hairdressers, gardeners, and cleaning/kitchen/laundry assistants), manufacture (wood industry, industrial bakeries, and dairies), or construction (carpenters, electricians, plumbers, bricklayers, house painters, blacksmiths, welders, and insulation workers) were invited to fill in a screening questionnaire. The questionnaires were distributed to employees by their employers as, companies were not allowed to share a list of employee contact information

according to the Danish Data Protection Act. Based on the screening questionnaire, eligibility was determined. Inclusion criteria were:

- Self-reported shoulder pain
- No previous shoulder surgery
- Age 18–65 years
- Relevant occupation
- Oxford Shoulder Score (OSS) ≤40 [23, 24] (see below)
- Sufficient contact information
- Contact permission

The OSS is a 12-item questionnaire on shoulder complaints. Results are summarised as a total score of 0 (worst) to 48 (best) [24]. This study's OSS cut-off score of ≤40 was based on the pilot test [7] where approximately 20% had an OSS ≤40. The mean OSS in asymptomatic populations is around 47 [25]. The screening questionnaires were completed between January 2017 and December 2018. Eligible employees were invited to a telephone screening to further determine eligibility. They were eligible regardless of previous or current treatment for shoulder complaints (apart from shoulder surgery). Exclusion criteria were:

- No current shoulder pain
- Prolonged sick leave expected to continue into the intervention period
- <20 weekly working hours
- Health conditions expected to affect exercise participation (e.g., rheumatoid arthritis)
- Evening or night shifts
- Inability to communicate in Danish
- Non-valid OSS

- Participation declined after the telephone screening

Randomisation

Randomisation was performed at cluster level, where each company constituted a cluster. Companies represented by at least one participant were randomised to the Shoulder-Café or the control intervention [21]. Computer-generated randomisation with a 1:1 allocation ratio was used with stratification by industry. Randomisation was performed in blocks with randomly permuted block sizes of 2, 4, and 6 companies.

To achieve random allocation, a research assistant prepared closed envelopes with printed randomisation numbers. Once all eligible employees from a company were identified, the principal investigator (JT) allocated companies and invited the employees. The randomisation result was not revealed to the participants until they had completed the baseline questionnaire and signed informed consent forms.

Interventions and setting

The Shoulder-Café intervention was designed as a complex intervention [14]. The control intervention had a less complex design. Intervention periods were approximately three months, with in-person meetings at six municipal health centres in Central Denmark Region.

Table 1 presents the intervention components and the time schedule. More details about the intervention components were previously published [21]. Both interventions included two individual assessments of occupational shoulder exposures. Measurements of work with elevated arms and repetitive shoulder movements were performed with an accelerometer (Axivity AX3) for

1 to 5 working days, while forceful shoulder exertions were assessed by self-report. All participants received written feedback on the measurements and assessments, a pamphlet with written information about how to reduce occupational shoulder exposures, and a pamphlet with home-based shoulder exercises with possibility for individual tailoring. The exercises were based on previous studies showing effect of exercises and were recommended to be performed 3-4 times per week.

The Shoulder-Café additionally included three in-person, group-based café-meetings lasting two hours each. The meetings were scheduled approximately six weeks apart. The first café-meeting included group-based education about shoulder anatomy and individual clinical shoulder evaluations by physiotherapists from an orthopaedic shoulder department. The second meeting included group-based education about occupational shoulder exposures and advice on work modifications by a health and safety consultant (SDC). Participants could also ask questions about their first individual exposure assessment and, if relevant, a workplace visit by the health and safety consultant was arranged. The third café-meeting included group-based discussion with feedback on all study components, focusing on self-treatment including maintaining exercise routines and reducing occupational shoulder exposures after the intervention period. All three café-meetings included a 60-minute supervised exercise session (according to the pamphlet) managed by municipal physiotherapists experienced in shoulder rehabilitation. There were also 15–30 minutes of casual discussion/networking with the group (managed by JT).

Table 1 Components and time schedule of the Shoulder-Café and Control interventions

Shoulder-Café intervention	**Control intervention (Shoulder-Guidance)**

1st group-based café-meeting: • Distribution of home-based exercise pamphlets, accelerometers and question about forceful shoulder exertions • *Casual group discussion* • *Education about shoulder anatomy* • *Clinical shoulder evaluation* • *Supervised exercises*	1st contact - individual appointment: • Distribution of home-based exercise pamphlets, accelerometers and question about forceful shoulder exertions
Before next meeting: home-based exercises and assessment of occupational shoulder exposures	Before next contact: home-based exercises and assessment of occupational shoulder exposures
2nd group-based café-meeting (~6 weeks after 1st meeting): • Distribution of pamphlets with information on how to reduce occupational shoulder exposures • Written feedback on the 1st exposure assessment *and possibility for questions regarding the assessment* • *Casual group discussion* • *Education about occupational shoulder exposures* • *Workplace-oriented counselling* • *Offer of an individual workplace visit*	2nd contact – mail (~6 weeks after 1st contact): • Distribution of pamphlets with information on how to reduce occupational shoulder exposures • Written feedback on the 1st exposure assessment

• *Supervised exercises*	
Before next meeting: home-based exercises	Before next contact: home-based exercises
3rd group-based café-meeting (~6 weeks after 2nd meeting): • Distribution of accelerometers and question about forceful shoulder exertions • *Casual group discussion* • *Discussion with focus on subsequent self-treatment* • *Supervised exercises*	3rd contact – mail (~6 weeks after 2nd contact): • Distribution of accelerometers and question about forceful shoulder exertions
After end of intervention: • Assessment of occupational shoulder exposures and mail with written feedback on the exposure assessment (~3 weeks after 3rd contact) • Maintain home-based exercises	After end of intervention: • Assessment of occupational shoulder exposures and mail with written feedback on the exposure assessment (~3 weeks after 3rd contact) • Maintain home-based exercises

Informed consent was completed by all participants at the first group-based café-meeting or contact. Components written in italics were only included in the Shoulder-Café intervention.

A manual was followed for clinical shoulder evaluations and, to ensure coherence with the exercise pamphlet, supervising physiotherapists attended a training session before their first Shoulder-Café meeting [21].

Data collection and outcome measures

Baseline and follow-up data were collected via questionnaires. Baseline questionnaires were distributed 1–7 days before intervention start, and follow-up questionnaires approximately 6 and 12 months after intervention start (corresponding to 3 and 9 months after end of intervention).

The primary outcome measure was shoulder complaints measured by the Danish validated OSS [26] at 6 months. Secondary outcomes were the OSS at 12 months, fear-avoidance beliefs measured with the Fear-Avoidance Beliefs Questionnaire - Physical Activity (FABQ-PA) [27] at 6 and 12 months, and global impression of change measured with Patients' Global Impression of Change (PGIC) at 6 months. The FABQ-PA was used in a shoulder version with a sum score ranging from 0 (low fear) to 24 (high fear) [27]. PGIC was measured on a 7-point Likert Scale ranging from 1 (much better) to 7 (much worse).

A series of supplementary outcome measures were included: Intensity of shoulder pain at rest and during activity measured at 6 and 12 months on a numerical rating scale (NRS) ranging from 0 (no pain) to 10 (worst pain) [28]. Disability of the upper limbs measured at 6 months with the Quick Disabilities of Arm, Shoulder and Hand questionnaire (Quick-DASH) [29]. The Quick-DASH-symptoms scale includes 11 questions and the Quick-DASH-work scale includes 4 questions. The total score for each Quick-DASH scale ranges from 0 (no disability) to 100 (most severe disability). The Quick-DASH was used in a Danish validated version [30]. Health-related quality of life was measured at 6 months using the Danish EuroQol 5-dimensional 3-level questionnaire (EQ-5D-3L) and the Visual Analogue Scale (EQ-5D-VAS) [31, 32]. EQ-5D-3L comprises 5 items which are converted into an index score ranging from -0.624 (worst health state) to 1.0 (best health state). The EQ-5D-VAS ranges from 0 (no pain) to 10 (worst pain). Current work ability compared to

lifetime's best was measured using the single-item Work Ability Score (WAS) at 6 and 12 months ranging from 0 (unable to work) to 10 (work ability at its best) [33]. PGIC at 12 months. Participants' overall satisfaction with the intervention received measured on a 5-point scale ranging from 1 (satisfied) to 5 (dissatisfied) at 6 and 12 months. The degree to which the participants felt sufficiently informed about how to handle shoulder complaints, perform shoulder exercises, and reduce occupational shoulder exposures at 6 months measured on a scale ranging from 1 (much informed) to 4 (not informed at all).

Information about co-interventions (i.e., analgesics use within the last 4 weeks and health care consultations within the last 3 months measured at 6 months and steroid injection and shoulder surgery within the last 3 months measured at 6 and 12 months) was also collected. A process evaluation, performed in 2020, was nested in the study aiming to contextualise the interpretation of the results. The evaluation was based on data from 7 individual participant interviews (n=4 from the Shoulder-Café intervention, n=3 from the control intervention) and one focus group interview with participating physiotherapists (n=12), plus observations during Shoulder-Café meetings [34].

Blinding

The character of the interventions made it impossible to blind participants and providers of the interventions but all participants received an active intervention and were blinded to the study hypothesis.

Sample size

Sample size calculation used the expected decrease in the OSS based on a previous study [35]. Forty-eight participants per group were required to show a minimal clinically important difference

of at least 5 points in the OSS at 6-month follow-up [36] with an expected SD of 8 points [35], an intraclass correlation coefficient of 0.05 [37], a mean cluster size of 4, a 2-sided significance level of 0.05, and a power of 0.80 [38]. To ensure that at least 50 employees in each group completed the study, we aimed to include 60 employees in each group.

Adherence

Adherence to café-meetings was defined as attending at least two of the three café-meetings. For both groups, adherence to home-based exercises was assessed as the mean number of exercise days per person, based on data from self-reported exercise diaries [21] and BandCizer sensors (BandCizer ApS, Denmark). The BandCizer sensor is a small devise mounted on an elastic-band used to measure exercise date and numbers of sets and repetitions for each exercise session [39].

Statistical analyses

Analyses were performed according to a pre-published statistical analysis plan [21]. Continuous variables are presented as means and standard deviations (SD) or as medians and interquartile ranges (IQR) depending on their distributions, and categorical variables as numbers and percentages. Eligible employees who declined participation after completing the telephone screening were compared to randomised participants based on screening data (age, sex, industry, and the OSS). The analysis population consisted of those who agreed to participate, completed the baseline questionnaire, signed the informed consent form, and did not withdraw study consent.

The primary outcome measure was analysed using mixed models. Analyses were performed with adjustments for baseline OSS (continuous), sex, age (continuous), and industry (service, manufacture, construction) as fixed effects, and company as a random effect. The effect estimate

was the mean difference (MD) (Shoulder-Café minus control intervention) reported with a 95% confidence interval (CI) based on bootstrap (with 100 replications) to allow for non-normality of the outcome. The OSS was also analysed at 12 months. Other continuous variables (FABQ-PA, NRS, Quick-DASH-symptoms, Quick-DASH-work, EQ-5D-3L, EQ-5D-VAS, and WAS) were analysed likewise and adjusted for the corresponding baseline variable.

PGIC was dichotomised into improved ("much better", "better", and "a little better") and unimproved ("unchanged", "a little worse", "worse", "much worse"), and then the adjusted risk ratio [40] was calculated. PGIC was analysed adjusted for sex, age (continuous), and industry (service, manufacture, construction) using robust standard errors to allow for clustering at the company level. Other dichotomised variables: overall satisfaction ("satisfied", "not satisfied") and informed ("yes", "no")) were analysed like PGIC. The usual missing rule [24] for the OSS was used, and the number of participants with missing data was reported. The analyses were made according to the intention-to-treat principle and were based on the analysis population.

To evaluate any effect of differential loss to follow-up, a sensitivity analysis of the primary outcome was performed because more than 5% of the primary outcome measures were missing [21]. We used four scenarios where we replaced the missing OSS-values with predicted values from the regression analysis by alternately adding or subtracting 1 SD (the overall SD at 6 months) to the intervention groups.

The interventions were based on non-invasive methods and were not expected to cause any adverse events apart from potential shoulder pain aggravation related to exercising. Therefore, no interim analyses were planned and no stopping rules defined. Two post-hoc sensitivity analyses were performed: an intention-to-treat analysis restricted to participants with baseline OSS <35, and a per-

protocol analysis restricted to participants with full attendance to the three café-meetings or the first contact of the control intervention). All analyses were performed using Stata 16 (StataCorp LP, College Station, TX, USA).

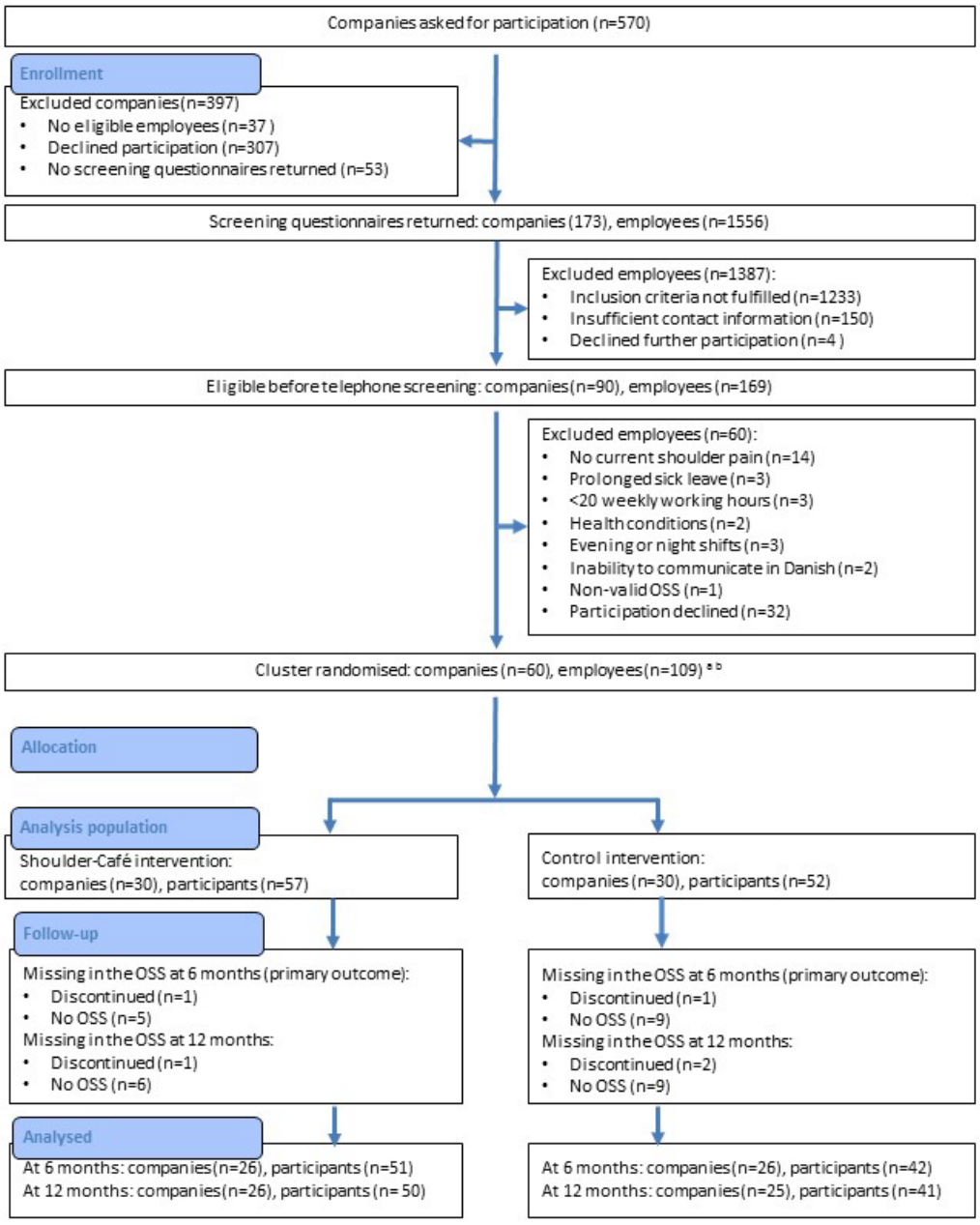
Role of the funding sources

The funders played no role in design, conduct, or reporting of this study.

Results

Participants

Fig. 1 Flow of companies and participants through the study



Abbreviations: OSS=Oxford Shoulder Score.
[a]Participants were informed of the randomisation result after they had consented to participate and filled in the baseline questionnaire.
[b]Due to a protocol violation one participant with an OSS of 45 and one participant without a valid baseline OSS were erroneously randomised to control intervention. Both were excluded after inclusion (i.e., 111 participants were initially allocated an intervention).

Fig. 1 shows the flow of companies and participants through the study: 1556 employees from 173 companies completed the screening questionnaire and 109 participants from 60 companies were included in the study (the mean cluster size was 1.8 (SD 1.3)). The questionnaires were complete

for 85% (n=93) and 83% (n=91) of the participants at 6 and 12 months. Employees, who declined participation after the telephone screening (n=32), were comparable to those randomised (n=109) with respect to age, sex, industry, and the OSS (results not shown).

The analysis population consisted of 57 Shoulder-Café participants (mean cluster size 1.9 (SD 1.3)) and 52 control participants (mean cluster size 1.7 (SD 1.2)). The two groups appeared well balanced at baseline and at 6 and 12 months, except maybe for duration of shoulder complaints (Table 2). Shoulder-Café participants were included in one of 11 Shoulder-Café courses, with 3 to 9 participants (mean 5) per course.

Table 2 Baseline characteristics of the analysis population

Population	**Analysis population (n=109)**		**Population with follow-up at 6 months (n=93)**		**Population with follow-up at 12 months (n=91)**	
	Shoulder-Café n=57	**Control intervention n=52**	**Shoulder-Café n=51**	**Control intervention n=42**	**Shoulder-Café n=50**	**Control intervention n=41**
Demographic variables						
Age (years), mean (SD)	48.8 (9.5)	45.7 (10.8)	49.6 (9.6)	46.5 (10.4)	50.1 (8.8)	45.2 (10.9)
Sex, n (%)						
Male	37 (65)	37 (71)	34 (67)	30 (71)	34 (68)	27 (66)
Female	20 (35)	15 (29)	17 (33)	12 (29)	16 (32)	14 (34)
Occupation, n (%)						

Service	13 (23)	15 (29)	11 (21)	13 (31)	10 (20)	14 (34)
Manufacture	10 (17)	3 (6)	9 (18)	1 (2)	9 (18)	2 (5)
Construction	34 (60)	34 (65)	31 (61)	28 (67)	31 (62)	25 (61)
Smoking status, n (%)						
Never	22 (37)	29 (56)	19 (37)	24 (57)	19 (38)	23 (56)
Ex	22 (39)	13 (25)	20 (39)	12 (29)	20 (40)	11 (27)
Current	14 (24)	10 (19)	12 (24)	6 (14)	11 (22)	7 (17)
BMI, mean (SD)	26.8 (4.8)	27.9 (6.3)[a]	26.7 (5.7)	28.5 (6.4)	26.9 (4.9)	28.4 (6.6)[a]
Dominant-sided pain, n (%)	40 (70)	38 (73)	36 (71)	32 (76)	35 (70)	31 (75)
Duration of shoulder complaints (months), median (IQR)	60 (24;108)[a]	36 (24;102)	60 (24;96)[a]	42 (24;96)	60 (24;108)[a]	36 (18;96)
Analgesics use within last 4 weeks, n (%)	24 (42)	26 (50)	20 (39)	21 (50)	19 (38)	21 (51)
Outcome variables						
OSS, median (IQR)	38 (35;40)	38 (36;42)	38 (34;41)	38 (36;41)	39 (35;41)	38 (36;41)
FABQ-PA, mean (SD)	12.6 (5.2)	11.5 (5.4)[a]	12.9 (5.4)	11.3 (5.0)	12.9 (5.4)	11.9 (4.5)

NRS at rest, median (IQR)	2 (1;3)	2 (1;4)	2 (1;3)	2 (1;4)	2 (1;3)	2 (1;4)
NRS during activity, median (IQR)	4 (2;7)	4 (2;6)	4 (2;7)	4 (3;6)	4 (2;7)	4 (2;6)
Quick-DASH-symptoms, mean (SD)	23.1 (12.8)	24.0 (12.9)	22.8 (12.7)	23.8 (12.6)	22.7 (12.8)	23.5 (13.1)
Quick-DASH-work, mean (SD)	25.7 (19.2)[a]	27.4 (18.7)[a]	24.2 (17.6)[a]	25.8 (17.6)[a]	24.2 (17.8)[a]	25.5 (17.4)[a]
EQ-5D-3L, median (IQR)	0.78 (0.8;0.8)	0.78 (0.7;0.8)	0.82 (0.7;0.8)	0.78 (0.7;0.8)	0.82 (0.7;0.8)	0.78 (0.7;0.8)
EQ-5D-VAS, median (IQR)	75 (61;81)[a]	75 (64;81)	76 (65;80)[a]	75 (64;82)	76 (69;80)[a]	75 (65;82)
WAS, median (IQR)	7 (6;8)	7 (6;8)	7 (6;8)	8 (6;8)	7 (6;8)	8 (6;8)

Abbreviations: BMI=body mass index, CI=confidence interval, EQ-5D-3L= EuroQol health-related quality of life 5-dimensional 3-level questionnaire. EQ-5D-VAS= EuroQol health-related quality of life Visual Analogue Scale, FABQ-PA=Fear Avoidance Beliefs Questionnaire – Physical Activity, mo=monthsRS=numerical rating scale, OSS=Oxford Shoulder Score, PGIC=Patients' Global Impression of Change, Quick-DASH=Quick Disabilities of Arm, Shoulder and Hand questionnaire, WAS=work ability score.

[a]1–4 missing.

Adherence

In the Shoulder-Café group, 84% participated in at least 2 café-meetings and 56% in all 3 of them. A workplace visit was performed for 24 participants (42%). The exercise diary and the BandCizer were returned by 88% and 90% of the Shoulder-Café participants, and by 67% and 69% of the control participants. Adherence to home-based exercises was not different between the groups. The mean total number of self-reported and BandCizer measured exercise days was 18.2 (SD 10.0) and 14.8 (SD 9.5) in the Shoulder-Café group and 15.5 (SD 10.1) and 14.1 (10.5) in the control group.

Effectiveness of intervention

Primary outcome

There was no difference between groups in the OSS at 6 months (Table 3). Shoulder complaints increased from screening (median 37.0 (IQR: 34;38) OSS points) to baseline (median 38.0 (IQR 35;41) OSS points). The OSS also increased by a median of 3 points from baseline to 6 months in the Shoulder-Café group, and by a median of 3.5 points in the control group).

Secondary outcomes

There were no differences between the groups in the FABQ-PA or PGIC at 6 months, or in the OSS or the FABQ-PA at 12 months (Table 3).

Supplementary outcomes

Shoulder-Café participants felt better informed about handling shoulder complaints and how to reduce occupational exposures at 6 months compared with control participants, and at 12 months PGIC and overall satisfaction favoured the Shoulder-Café intervention. No other differences were found (Table 3).

Table 3 Effectiveness of the Shoulder-Café compared with the control intervention with respect to primary, secondary, and supplementary outcomes. The mixed model and relative risk analyses were performed according to the intention-to-treat principle based on the analysis population

	Shoulder-Café		**Control**		**Effectiveness[a]**	
Primary outcome, *n, mean (SD)*					*Mean difference, 95% CI*	
OSS at 6 months	51	40.4 (5.5)	42	40.1 (5.7)	0.3	-1.6;2.2
Secondary outcomes						
Continuous variables, n, mean (SD)					*Mean difference, 95% CI*	
OSS at 12 months	50	40.3 (7.3)	41	40.4 (5.0)	-0.2	-2.6;2.2
FABQ – PA at 6 months	51	10.3 (5.3)	42	9.7 (5.9)	-0.1	-2.4;2.2
FABQ – PA at 12 months	49	10.3 (6.2)	41	9.5 (6.4)	0.3	-1.9;2.5
Dichotomised variable, n/total n with valid information (%)					*Risk ratio, 95% CI*	
PGIC improved at 6 months		32/50 (64)		26/42 (62)	1.0	0.7;1.4
Supplementary outcomes						
Continuous variables, n, mean (SD)					*Mean difference, 95% CI*	
NRS at rest at 6 months	50	1.9 (1.9)	42	2.0 (1.8)	0.1	-0.6;0.8
NRS at rest at 12 months	50	1.7 (2.0)	41	2.4 (2.1)	-0.8	-1.7;0.0
NRS during activity at 6 months	51	3.0 (2.7)	42	3.1 (2.5)	-0.1	-1.0;0.7
NRS during activity at 12 months	50	3.2 (2.5)	41	3.4 (2.4)	-0.5	-1.4;0.5
Quick-DASH-	50	18.7 (14.4)	42	21.0 (16.6)	-1.7	-6.8;3.3

symptoms at 6 months						
Quick-DASH-work at 6 months	51	16.1 (15.8)	41	20.3 (20.3)	-1.7	-7.5;4.1
EQ-5D-3L at 6 months	50	0.83 (0.1)	42	0.79 (0.1)	0.03	-0.01;0.06
EQ 5D-VAS at 6 months	50	78.7 (13.6)	41	74.0 (18.7)	5.3	-1.2;11.9
WAS at 6 months	51	7.5 (1.7)	41	7.4 (1.8)	0.0	-0.6;0.5
WAS at 12 months	50	7.6 (2.1)	41	7.5 (2.2)	0.1	-0.6;0.8
Dichotomised variables, n/total n with valid information (%)					*Relative risk, 95% CI*	
PGIC improved at 12 months		36/49 (73)		21/41 (51)	1.5	1.1;2.0*
Satisfied at 6 months		44/51 (86)		28/42 (67)	1.3	1.0;1.6
Satisfied at 12 months		43/49 (88)		27/42 (62)	1.4	1.1;1.8*
Informed about how to handle complaints at 6 months		48/51 (94)		25/42 (60)	1.5	1.2;1.9*
Informed about exercising at 6 months		47/50 (94)		35/42 (83)	1.1	0.9;1.4
Informed about reducing exposures at 6 months		42/51 (82)		15/42 (36)	2.3	1.4;3.8*

Abbreviations: CI=confidence interval, EQ-5D-3L= EuroQol health-related quality of life 5-dimensional 3-level questionnaire. EQ-5D-VAS= EuroQol health-related quality of life visual analogue scale, FABQ-PA=Fear Avoidance Beliefs Questionnaire – Physical Activity, NRS=numerical rating scale, OSS=Oxford Shoulder Score, PGIC=Patients' Global Impression of

Change, Quick-DASH=Quick Disabilities of Arm, Shoulder and Hand questionnaire, WAS=work ability score.

[a]Continuous outcomes were adjusted for the baseline value of the outcome measure, sex, age, and industry as fixed effects, and company as a random effect. Dichotomised outcomes were adjusted for sex, age, and industry using robust standard errors.

[*]Statistically significant.

Co-interventions

No differences were observed between groups for analgesics use or the number of health care consultations at 6 months, or for steroid injection or shoulder operation at 6 and 12 months (results not shown).

Sensitivity analyses

The four scenarios for replacing missing OSS values did not indicate differential loss to follow-up. Analyses restricted to participants with OSS <35 (13 Shoulder-Café and 7 control participants) showed a mean difference of 1.3 (95% CI -10.4;13.1). The per-protocol analysis restricted to participants with full attendance (32 Shoulder-Café and 42 control participants) showed a mean difference of 0.6 (95% CI -1.5;2.7).

Adverse events

Shoulder pain aggravation was not different between the groups (shoulder pain aggravation was reported by 29% in the Shoulder-Café and 24% in the control group). No other adverse events were noted.

Discussion

The Shoulder-Café intervention was not more effective to reduce shoulder complaints or fear-avoidance beliefs than the control intervention. Supplementary outcomes indicated that more Shoulder-Café participants felt informed about handling shoulder complaints, felt informed about reducing occupational shoulder exposures, reported improvements in their shoulder condition, and were satisfied with the received intervention.

Primary strengths of the study were use of a cluster-randomised design, limited loss to follow-up, and analyses performed in line with a pre-published statistical analysis plan [21]. The study setting being close to "real life" was also an a priori strength in case of a subsequent implementation process. The primary outcome measure was the OSS. Although it was developed for patients undergoing shoulder surgery [23], the OSS has been previously used in patients without shoulder surgery [41], and it is one of the recommended first-choice instruments for patients with shoulder complaints [42]. The median OSS increased from screening to baseline, which could narrow the scope for further improvement at follow-up. However, the increase was slight and the mean OSS improved further from baseline to follow-up. Effectiveness in our study required a group-difference of 5 OSS points, which was based on a previous study of patients with more severe shoulder complaints [36], but since our participants had only modest shoulder complaints, a group-difference of 5 OSS points may have been difficult to achieve. The post-hoc analysis restricted to participants with more severe complaints (OSS <35) also did not show any group-difference but the power was low and the 95% CI of the MD wide. The OSS was not completed at end of intervention, thus potential effects at that time point were not identified, but we were interested in longer-term effects. In our main analysis, we chose to omit participants without a valid OSS at 6 months rather than perform analyses with imputations of missing OSS values. With the rather extreme replacement of

missing values of the OSS, our sensitivity analyses indicated that differential loss to follow-up was unlikely to explain the lack of effect. Blinding of participants was not possible due to the nature of the interventions, but as both interventions were active, the risk of bias due to lack of blinding was minimised.

Based on positive experiences from the group-based pilot-test for patients with shoulder complaints [7], we hypothesised that the Shoulder-Café intervention was more effective than the control intervention. This turned out not to be the case. A possible explanation for the lack of effectiveness is that the Shoulder-Café and the control intervention were too similar since both were active interventions. With moderate to low level evidence, complex interventions have been found effective to reduce pain and fear-avoidance beliefs in patients with low-back pain [15] and, with strong level evidence, to increase return to work in people with musculoskeletal complaints [43]. The results regarding shoulder complaints are conflicting, however [16, 17]. Another explanation may be that the effectiveness was evaluated based on intention-to-treat analyses since only 56% of the Shoulder-Café participants adhered fully to the café-meetings. The per-protocol analysis of participants with full adherence was, however, similar to the intention-to-treat analysis and the 95% CI of the MD was narrow (-1.5;2.7). Therefore, we assess the risk of erroneously rejecting our hypothesis to be low in this case.

We thought that adding Shoulder-Café components including a social opportunity to share experiences would make participants more able and willing to take appropriate action, and that this could reduce shoulder complaints more effectively than the control intervention. That was not the case but some results regarding supplementary outcomes were in favour of the Shoulder-Café intervention. In addition, findings from the nested process evaluation supported the supplementary

results, including preference for a group setting [34]. The occupational shoulder exposures have not yet been analysed, but a reason for the lack of differences between groups might be that the exposures were not reduced more effectively in the Shoulder-Café than in the control intervention.

Reasons for the OSS improvements within both groups could be the natural history of shoulder complaints [44]. Another reason could be effects of exercises [10, 12]. Equal effects of home-based and supervised exercise have been reported [45] and exercise adherence was not different in the two groups. The within-group improvements were smaller than the minimal clinically important difference [36], which is most likely explained by the low intensity of shoulder complaints in our population [46]. We also hypothesised that the Shoulder Café would reduce fear-avoidance beliefs more effectively than the control intervention, which was not found. Together with previous conflicting results [35, 47], this may indicate that fear-avoidance beliefs play a minor role as a mechanism of action in case of shoulder complaints.

Generalisability

The high number of included companies and screened employees and the "real life setting" of the study promises well for the generalisability of the results to other people with shoulder complaints and high occupational shoulder exposures.

Conclusions

This study demonstrated that the Shoulder-Café intervention did not reduce shoulder complaints more effectively than the control intervention. Changes in fear-avoidance beliefs and patients' impressions of change were also alike.

Perspectives

Shoulder complaints are especially common in employees with high occupational shoulder exposures [2-4], and are related to individual and societal burdens [5]. Prevention and treatment of shoulder complaints among these employees are therefore highly relevant. The Shoulder-Café intervention was our suggestion to solve this problem, but we found that the Shoulder-Café intervention was not more effective than the control intervention for this population. Thus, the intervention may not be the way to move forward in case of only modest shoulder complaints.

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Statements and Declarations

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Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Author Contributions

All authors contributed to the study conception and design. J. Trøstrup made the analyses and wrote the first draft in close collaboration with P. Frost and S.W. Svendsen. All authors significantly contributed to the interpretation of data and revision of the manuscript. All authors read and approved the final manuscript.

Data Availability

An anonymised dataset for research purposes will be available from the corresponding author if necessary approvals have been acquired.

Ethics approval

The study was approved by the Danish Data Protection Agency (case number: 1-16-02-498-16). All study procedures were in accordance with the ethical standards. Approval was granted by the Committee on Health Research Ethics in Central Denmark Region (case number: 1–10–72-271-16).

Consent to participate

Participation was based on written informed consent.

Consent to publish

All participants signed informed consent in relation to their participation in the study and to the use of their data.

Paper 3

TITLE PAGE

Title: Increased shoulder pain across an exercise session and subsequent shoulder exercise: a prospective cohort study

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ABSTRACT

Background: Shoulder complaints are common and the recommended first-line treatment is exercise therapy. However, it remains unknown if increased shoulder pain after an exercise session is a barrier for subsequent exercise dose or adherence, particularly in people with high fear-avoidance beliefs. Such knowledge could indicate ways to optimise shoulder rehabilitation.
The primary aim was to examine whether increased shoulder pain across an exercise session was associated with a lower exercise dose, and if the associations (if any) were exaggerated by high levels of fear-avoidance beliefs.

Methods: The study is a prospective cohort study based on a randomised controlled trial anchored in a public orthopaedic department in Central Denmark Region 2017–2019. Participants were employees (n = 79) with shoulder complaints and high occupational shoulder exposures. The intervention was a home-based or partly supervised exercise programme lasting 2–3 months. Linear mixed models were used to examine the associations between change in shoulder pain and exercise dose (i.e., number of repetitions, progression level, resistance level and time until next exercise session).

Results: For 1-cm increase in pain on a visual analogue scale (0–10) during an exercise session, the number of repetitions, progression level and resistance level in the next session were −1.1 (95% CI −3.6 to 1.4), 0.0 (95% CI −0.1 to 0.0) and 0.0 (95% CI −0.1 to 0.0), respectively. The time until the

next exercise session was −0.4 (95% CI −1.8 to 0.9) days. There were no interactions with fear-avoidance beliefs.

Conclusions: Increased pain across an exercise session was not a barrier for subsequent exercise dose regardless of fear-avoidance beliefs.

Clinical Trial Registration: The trial was registered at Clinicaltrials.gov 19/05/2017 (ID: NCT03159910)

Keywords: Adherence; Fear-avoidance beliefs; Prospective; Rehabilitation.

BACKGROUND

Shoulder complaints are common in the adult population, with a prevalence of 19–31% episodes monthly depending primarily on case definitions [1]. Exercise therapy is recommended as first-line treatment [2-5], and supervised and home-based exercise are equally effective [5-8]. During exercise therapy, aggravation of shoulder pain should be kept to a minimum [3] and the exercise dose in the subsequent session should be reduced if pain aggravation does not subside shortly after exercising [3, 9, 10]. Two views exist regarding the accepted degree of shoulder pain aggravation during exercise therapy [3, 8]. One group argues that pain aggravation may indicate overload of stressed tissues because of too difficult exercises or too high exercise load and decrease exercise motivation [3]; whereas another group argues that pain aggravation may guide exercise progression and increase exercise motivation [3]. Persons who exercise to reduce shoulder complaints report lower motivation if the exercise feels harmful, but higher motivation if the exercise feels beneficial [11, 12].

According to the fear-avoidance model, negative appraisals of pain may cause people to avoid physical activities, including exercise therapy, in order to reduce pain, but this may instead lead to increased pain and disability [13-15]. Two studies of patients with shoulder complaints receiving exercise therapy [16, 17] showed an advantage of low fear-avoidance beliefs for a better outcome, whereas another study [18] showed no prediction role of fear-avoidance beliefs. The effect of fear-avoidance beliefs on exercise dose has not been investigated, but higher levels of fear-avoidance beliefs were associated with a higher probability of quitting an exercise intervention in people with non-specific chronic neck and shoulder pain [16].

We are not aware of studies that have examined whether increased shoulder pain after an exercise session is a barrier for subsequent exercise dose or adherence, particularly in people with high fear-avoidance beliefs. Such knowledge could indicate ways to optimise shoulder rehabilitation.

The primary aim of this study was to examine whether increased shoulder pain across an exercise session was associated with a lower exercise dose in the next session, and if the associations (if any) were exaggerated by high levels of fear-avoidance beliefs. A secondary aim was to examine whether increased shoulder pain across exercise sessions together with high levels of fear-avoidance beliefs influenced overall adherence to an exercise programme.

METHODS

Design and setting

We conducted a prospective cohort study based on a cluster randomised controlled trial which compared two interventions to reduce shoulder complaints among employees with high occupational shoulder exposures (ID: NCT03159910 at Clinicaltrials.gov on 19/05/2017) [19]. The Committee on Health Research Ethics in Central Denmark Region approved the study (case number: 1-10-72-271-16). All participants provided written informed consent. We report the study using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

According to the randomisation, which was performed at company level, participants were enrolled in a Shoulder-Café or Shoulder-Guidance intervention between August 2017 and August 2019. In-person meetings took place at six municipal health centres in Central Denmark Region. All participants completed a baseline questionnaire before the randomisation result was revealed to

them. An intervention period of 12 weeks was intended, but due to work schedules of the physiotherapists and holidays, the periods varied.

Study population

The study population has previously been described including detailed in- and exclusion criteria [19]. In brief, the participants were 18–65 years of age, employed in occupations with high mechanical shoulder exposures (i.e., service, manufacturing and construction), experienced shoulder pain, were without previous shoulder surgery and had an Oxford Shoulder Score (OSS) ≤ 40. The OSS is a 12-item patient-reported tool to measure shoulder pain and function ranging from 0 (worst) to 48 (best) [20-22].

Interventions

All participants were advised to follow a home-based shoulder exercise programme described in a pamphlet [19]. The programme was based on effect of published exercise programmes [9, 23-26], and included elements known to motivate exercise adherence (few exercises [3, 27], progression with individual adjustments [3] and elastic bands making exercise possible everywhere [12, 28]). The 15-minute programme was recommended to be followed three to four times per week throughout the intervention. In addition to one posture correction exercise, the programme comprised three resistance exercises performed bilaterally with an elastic band: two exercises for the scapula stabilising muscles and one for the rotator cuff muscles. Each resistance exercise had three progression levels and three resistance levels (elastic band) (low = 1, medium = 2 and high = 3) (Additional file 1). Participants were recommended to start with the lowest progression and resistance levels, and to perform as many repetitions as possible until they were able to perform more than three sets of 15 repetitions. At this point, they were advised to progress the exercises.

Progression included using an elastic band with higher resistance, and to go on to the next progression level when the highest resistance level was reached. Participants were informed that pain aggravation (without further specification) during exercise could be expected, but if the aggravation did not cease within 1 hour after the exercise session, they were recommended to decrease one progression or resistance level, or to decrease the number of repetitions in the next exercise session [19].

Additionally, the participants in the Shoulder-Café group were offered three supervised exercise sessions performed in accordance with the exercise pamphlet, and a clinical shoulder examination performed by a physiotherapist [19]. Based on the clinical shoulder evaluation, subacromial impingement syndrome was considered to be present if anterolateral shoulder pain was accompanied by a positive result of at least three of the following five clinical tests: Hawkins' test, Neer's clinical test, painful arc test, Jobe's test and pain on resisted external rotation [29, 30].

Outcomes

Exercise dose was quantified in terms of: number of repetitions, defined as the total number of repetitions per exercise session; progression level, defined as the mean progression level per exercise session (mean across exercise sets per session); resistance level, defined as the mean elastic band resistance per exercise session (mean across exercise sets per session); time until next exercise session, defined as the number of days between two exercise sessions.

Overall adherence to the exercise programme was classified as high or low, with high overall adherence defined as an average of ≥ 2 weekly exercise sessions. Exercise dose and overall adherence were based on information reported in an exercise dairy (Additional file 1).

Predictors

Change in shoulder pain was calculated as shoulder pain at rest shortly after an exercise session minus shoulder pain at rest shortly before the exercise session using a visual analogue scale (range 0 cm [no pain] to 10 cm [worst pain]) [31]. A positive change in shoulder pain score indicated an increase in pain. For descriptive purposes, we defined decreased shoulder pain as a change of < -1 cm, unchanged shoulder pain as a change of -1 to 1 cm, and increased shoulder pain as a change of > 1 cm. The choice of these definitions was based on the observed distribution of changes in shoulder pain across exercise sessions. Information about pain was obtained from the exercise dairy (Additional file 1).

Fear-avoidance beliefs were assessed using the score (range 0 [no fear] to 24 [high fear]) of a shoulder version of the Fear-Avoidance Beliefs Questionnaire - Physical Activity (FABQ-PA) [32-34]. The baseline FABQ-PA was used as a dichotomised score (low ≤ 14, high > 14) [35, 36].

Covariates

Potential confounders comprised age, sex, body mass index (BMI), smoking status, dominant-sided pain, baseline pain at rest (measured with a numerical rating scale [NRS] ranging from 0 (no pain) to 10 [worst pain]), intervention group, days since start of intervention and session number. For descriptive purposes, pain at rest was dichotomised at the median (low, high). Apart from intervention group, days since start of intervention and session number, information on the covariates was collected through the baseline questionnaire.

Statistical methods

Continuous variables were presented as means with standard deviations (SD) or medians with interquartile ranges (IQR) depending on their distributions, and categorical variables as numbers

and percentages. In descriptive analyses, missing values for number of repetitions, progression level and resistance level were replaced by values from the most recent exercise session with non-missing values, except for the first session, where missing values were replaced by values from the subsequent session. Remaining missing values were not replaced.

The associations between change in shoulder pain and exercise dose were analysed using linear mixed models allowing for clustering of data according to company and repeated measurements. Participants with a minimum of one exercise session including data for change in shoulder pain and one subsequent exercise session were kept in the models. Analyses were performed using crude and adjusted models including age (continuous), sex, BMI (continuous), smoking status (never, ex, current), dominant-sided pain (yes, no), baseline NRS at rest (continuous), intervention group, days since start of intervention (continuous), session number (continuous) and an interaction term between change in shoulder pain (continuous) and baseline FABQ-PA (high, low). Associations were presented as mean differences with 95% CI based on bootstrapping (with 100 replications) to allow for non-normality of the outcome.

The influence of increased shoulder pain and baseline FABQ-PA score on overall adherence (high, low) was analysed using logistic regression with robust standard errors allowing for intragroup correlation at company level. The analyses were performed using crude and adjusted models for age (continuous), sex, BMI (continuous), smoking status (never, ex, current), dominant-sided pain (yes, no), baseline NRS at rest (continuous), intervention group and interaction between change in shoulder pain (continuous) and FABQ-PA score (high, low). Overall adherence was presented as odds ratio (OR) with 95% CI. All analyses were performed using Stata 16 (StataCorp LP, College Station, TX, USA).

RESULTS

A total of 79 participants from 48 companies were included in this study (Figure 1). Baseline characteristics of participants in the cluster randomised controlled trial (n = 109) are presented in Table 1 showing that the included participants and those with missing data (n = 30) were comparable. In the Shoulder-Café group, subacromial impingement syndrome was revealed in 38% (17/45) of the included participants and in 42% (5/12) of the participants with missing data.

Figure 1: Flowchart

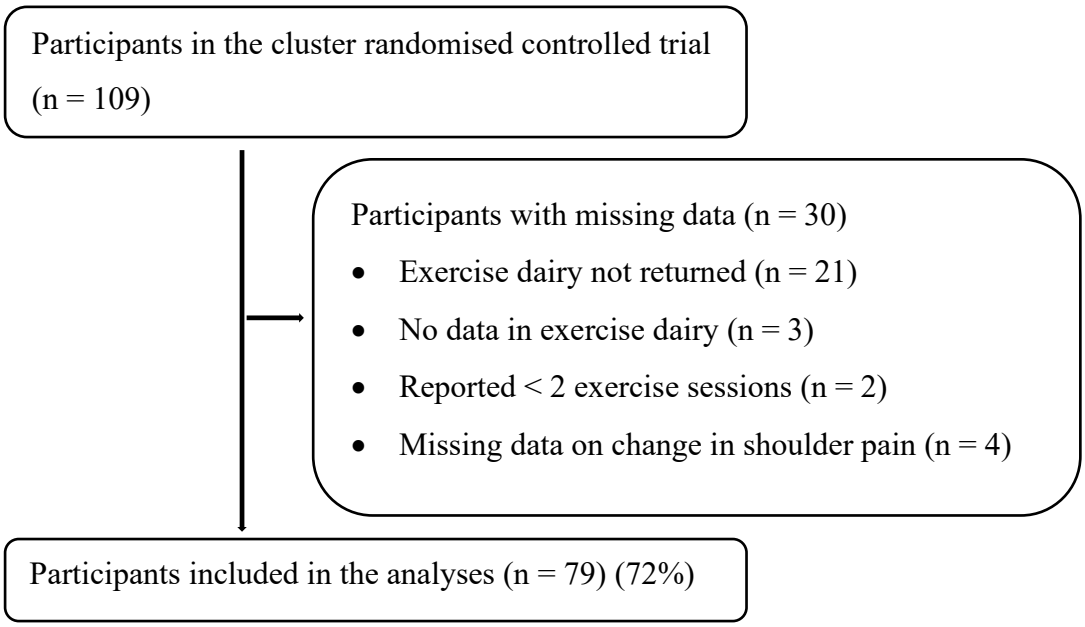


Table 1: Participant baseline characteristics according to analysis status (n = 109)

Characteristics	Participants included in the analyses (n = 79)	Participants with missing data (n = 30)
Age (years), mean (SD)	48.0 (10.3)	45.5 (9.9)

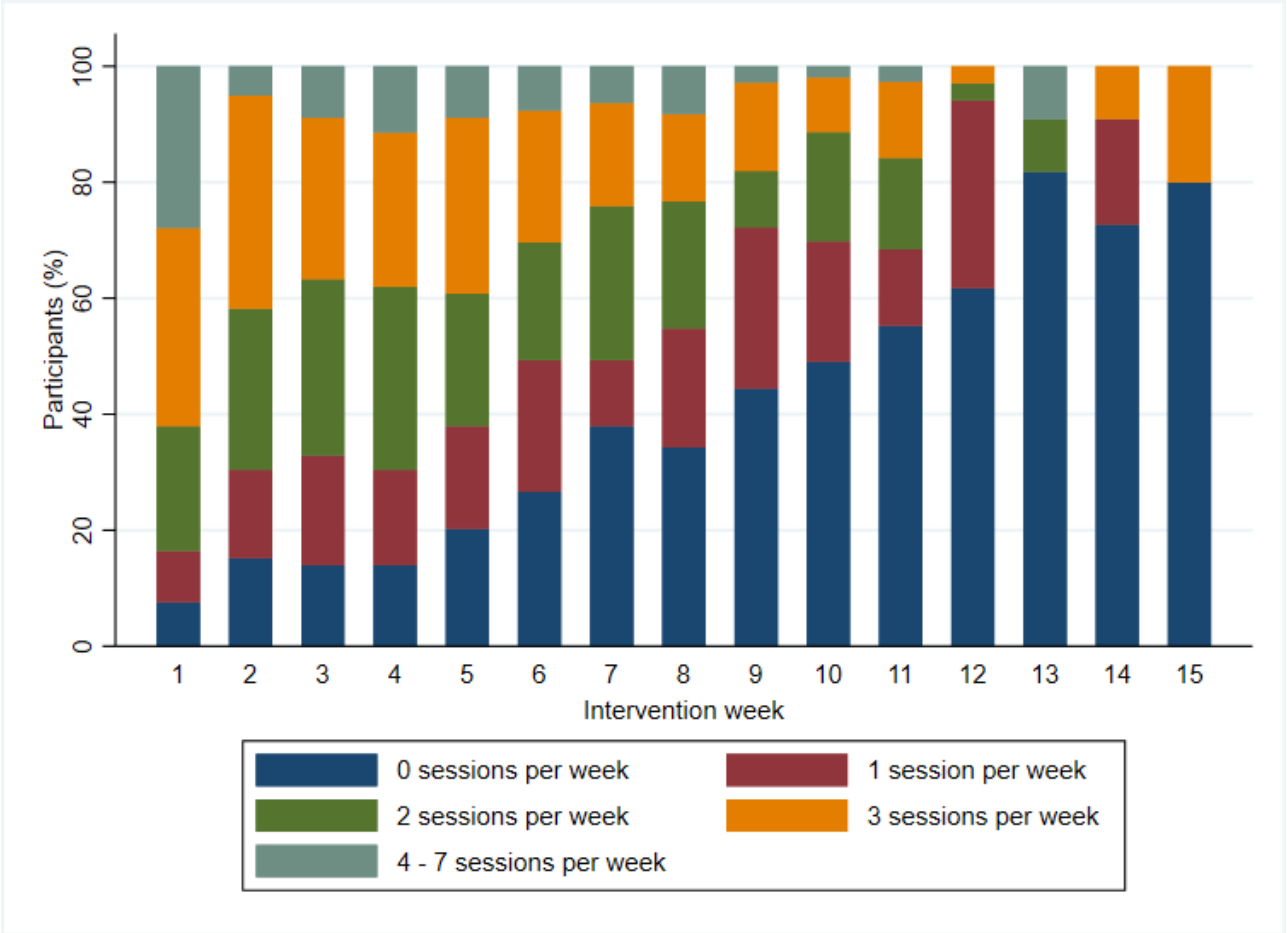
Men, n (%)	51 (65)	23 (77)
BMI, mean (SD)	26.9 (4.9)	27.5 (8.4)
Occupation		
Service	21 (27)	7 (23)
Manufacturing	8 (10)	5 (17)
Construction	50 (63)	18 (60)
Smoking status, n (%)		
Never	37 (47)	13 (44)
Ex	28 (35)	7 (23)
Current	14 (18)	10 (33)
Dominant-sided pain, n (%)	54 (68)	24 (80)
High FABQ-PA score, n (%)	19 (24)	10 (34)*
NRS at rest, median (IQR)	2 (1 to 3)	3 (1 to 4)
High NRS at rest (NRS)**, n (%)	32 (41)	16 (53)
NRS during activity, median (IQR)	4 (2 to 6)	5 (2 to 7)
Symptom duration (months), median (IQR)	39 (24 to 78)	69 (21 to 108)

Abbreviations: BMI = body mass index; FABQ-PA = Fear-Avoidance Beliefs Questionnaire – Physical Activity (0 [no fear-avoidance] – 24 [high fear-avoidance]); IQR = interquartile range; NRS = Numerical Rating Scale (0 (no pain) – 10 (worst imaginable pain)); SD = standard deviation. * FABQ-PA score missing in 1 participant in this group. ** Baseline pain at rest dichotomised at the median (2, IQR 1–3) for all participants in the Shoulder Café Study (n = 109) (0–2 vs 3–10).

The intervention period was between 7 and 15 weeks in which the home-based exercises should be followed. Additionally, in the Shoulder Café group, 96% (43/45) participated in two and 67% (30/45) participated in three supervised exercise sessions.

The total number of intervention weeks among all participants was 850, during which a total of 1401 exercise sessions was performed. This corresponds to a mean of 17.7 (range: 2–50) exercise sessions per participant and a mean of 1.6 (range: 0–7) weekly exercise sessions. Figure 2 shows the distribution of weekly exercise sessions according to intervention week. The frequency of zero weekly exercise sessions increased during the intervention.

Figure 2: Weekly exercise sessions according to intervention week (n = 79)



The participants performed a total of 1401 exercise sessions during 850 intervention weeks. The number of participants under intervention decreased gradually from 79 in week 7 to 5 in week 15.

Table 2: Characteristics of 1401 exercise sessions performed during intervention (n = 79).

Number of exercise sessions in relation to the two intervention periods *	Number of repetitions, mean (SD)	Progression level (range 1 - 3) mean (SD)	Resistance level (range 1 - 3) mean (SD)	Time until next exercise session (days), median (IQR)
Intervention weeks 1–7 (n = 1102)	124.4 (31.7)	2.1 (0.5)	2.0 (0.6)	2.7 (2.3 to 3.4)
Intervention weeks 8–15 (n = 299) **	118.7 (35.0)	2.2 (0.4)	2.0 (0.7)	2.6 (2.3 to 3.4)

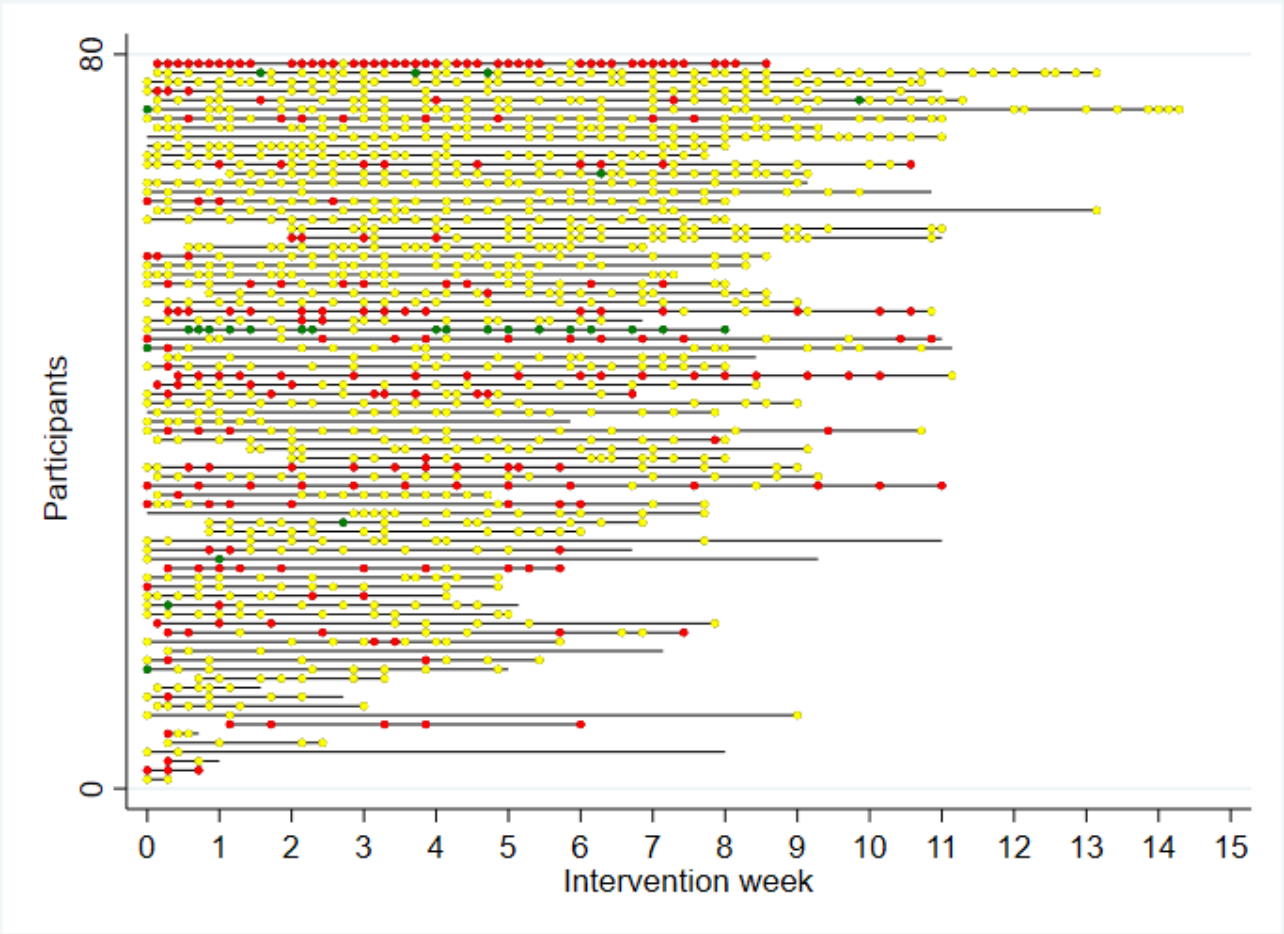
Abbreviations: IQR = interquartile range; SD = standard deviation. * Between three and 23 missing values for number of repetitions, progression level and resistance level were replaced by values from the prior or subsequent exercise sessions. ** The intervention period ended after 8–15 weeks.

Table 2 presents characteristics of the 1401 exercise sessions according to the first (1–7 weeks) and last (8–15 weeks) period of intervention, showing no indications of exercise progression between the two periods.

Change in shoulder pain was missing for 141 sessions, leaving 1260 exercise sessions for further analyses. The mean shoulder pain shortly before and shortly after an exercise session was 1.6 (SD 1.5) and 1.9 (SD 1.8), respectively. Figure 3 illustrates the distribution of the 1260 exercise sessions with data for change in shoulder pain showing that unchanged pain was most common. Reduced

pain was found after 2% of the exercise sessions and increased pain was found after 18% of the exercise sessions.

Figure 3: Distribution of exercise sessions (n = 1260) according to intervention week.



The 79 participants were sorted according to the number of sessions they had performed. They performed a total of 1260 exercise sessions. Green dots (n = 28) represent reduced pain after an exercise session, yellow dots (n = 1003) represent unchanged pain, and red dots (n = 229) represent increased pain.

Out of the 1260 exercise sessions, 59 sessions were not followed by further sessions, leaving 1201 sessions for the analyses of associations between change in shoulder pain and subsequent exercise

dose. As seen in Table 3, increased shoulder pain across an exercise session did not influence the adjusted exercise dose, and no interaction between change in shoulder pain and high FABQ-PA score was found.

(**Table 3**: Linear mixed models for shoulder pain and subsequent exercise dose, taking fear-avoidance beliefs into account)

Thirty-one participants had high overall adherence. Table 4 shows that change in shoulder pain and high FABQ-PA score did not influence overall adherence to the exercise programmes (adjusted odds ratio [95% CI]: 0.6 [0.2 to 1.4] and 1.2 [0.4 to 4.3]). The likelihood ratio test had a p-value of 0.12 for no interaction between change in shoulder pain and high FABQ-PA score.

Table 4: Logistic regression analysis of high overall adherence to the exercise programme.

Predictor	High overall adherence			
	Crude		Adjusted*	
	OR	95% CI	OR	95% CI
Change in shoulder pain (for a VAS increase of 1 cm)	0.6	0.3 to 1.0	0.6	0.2 to 1.4
High FABQ-PA score	0.9	0.3 to 2.4	1.2	0.4 to 4.3
Interaction between change in shoulder pain and high FABQ-PA score			0.3	0.0 to 1.9

The analyses were performed in relation to individual mean change in shoulder pain across all exercise sessions in the intervention period, fear-avoidance beliefs and their potential interaction.

The analyses were based on 1401 exercise sessions performed by 79 participants. Estimates are reported as odds ratios (OR) with 95% confidence intervals (CI).

Abbreviations: CI = confidence interval; FABQ-PA = Fear-Avoidance Beliefs Questionnaire – Physical Activity (dichotomised: low ≤ 14; high > 14); OR = odds ratios; VAS = Visual Analogue Scale (0 [no pain] – 10 [worst imaginable pain]).

* Adjusted for age, sex, body mass index, smoking status, dominant-sided pain, baseline pain at rest, intervention arm and with interaction between change in shoulder pain and high FABQ-PA score.

DISCUSSION

This study demonstrated no associations between increased shoulder pain across an exercise session and lower subsequent exercise dose, regardless of the level of fear-avoidance beliefs. In addition, increased shoulder pain across exercise sessions and high fear-avoidance beliefs did not influence overall adherence to the exercise programme.

Strengths of the study include the prospective design, the high participation (72%), the high data completeness and the repeated data collection. The main limitation was the low increase in pain across exercise sessions, i.e., low exposure contrast. Although it is reassuring that the exercise programme generally did not markedly aggravate shoulder pain, we cannot rule out that higher increases in pain across an exercise session, depending on the severity of the shoulder disorders or the exercise programme, may lead to a subsequently reduced exercise dose. The participants were informed that pain aggravation during exercise could be expected, and if the pain did not decrease within 1 hour after exercise, they were advised to reduce the exercise dose in the subsequent exercise session. This information could have especially affected participants with a high FABQ-

PA score because they may be more likely to avoid exercise due to pain [13, 14], but we did not observe such a pattern. None of the main results were statistically significant, which might suggest that the study was underpowered. However, the mean differences were minimal for increase in shoulder pain, FABQ-PA and their interactions, so these factors did not seem to play any considerable role for subsequent exercise dose. Exercise dose and overall adherence was assessed by self-report, but we find it unlikely that under- or over-reporting of exercise would be systematically related to increase in pain across an exercise session. Therefore, we do not think that the self-reported information biased our results.

Our study showed no indications of exercise progression despite all participants having a detailed description of the progression method in the exercise pamphlet, and even though 43 Shoulder-Café participants took part in two or three supervised exercise sessions where progression was explained. Another study of 12 weeks' supervised shoulder exercises found that the resistance level increased by 74% [23], but we are not aware of studies that have described progression in home-based settings. The low increase in pain across an exercise session in our study indicates that pain is not a barrier to exercise progression. Therefore, we think that limited supervision is the most likely explanation for the lack of progression.

Baseline FABQ-PA score in the present study was comparable to previous studies of participants with shoulder complaints [32, 34]. In a study of participants with more than 6 months of neck or shoulder pain [15], persons with high fear-avoidance beliefs were more likely to drop out of the home-based exercise intervention [16]. In contrast, our study found no association between FABQ-PA score and overall adherence to exercise. Participants in the previous study had comparable baseline fear-avoidance beliefs and pain intensities (4 on the NRS) with our participants. Therefore,

we think that the inclusion of patients with chronic pain in the previous study may explain why fear-avoidance beliefs played a part in that study but not in ours.

Our exercise programme was designed to support adherence. Adherence in our study was comparable with previous studies of home-based shoulder exercise [37, 38], but higher adherence has also been reported [39, 40]. A study [39] reported 88% completion of planned daily sessions, and another [40] reported 96% completion of at least one daily session, compared with 39% completion of at least two weekly sessions in our study. A reason for our rather low adherence may be that baseline pain in our participants was too low to motive frequent exercise performance [12]. Our participants had not sought treatment for their complaints, whereas previous participants were in contact with the health authorities [39, 40]. Another explanation could be lack of time because about 40% of the participants in one of the previous studies were on sick leave [39] compared with none of our participants. The other previous study did not inform about sick leave, but baseline pain was high (7–8 on the NRS) [40], indicating a probability of sick leave. Lack of time can decrease exercise motivation [12], thus sick leave may enhance motivation for exercise.

In the present study, participants with missing data tended to be younger, more often men, more often smokers and have a longer pain duration, but were broadly comparable with those included. Due to the missing data, we are not able to tell whether these participants forgot to report their completed exercise sessions or whether they did not exercise, but we tend to assume the latter. However, participants with these characteristics may need extra attention and guidance in relation to exercise therapy.

In the present study [19], employees could be included if they had at least slight shoulder complaints (OSS scores ≤ 40), but pain intensities at baseline and during exercise were generally low. Thus, our results do reveal whether an association exits between increases in higher pain intensities across an exercise session and subsequent exercise dose. Future studies of patients, e.g., in hospital departments of orthopaedic surgery, may examine whether this is the case.

CONCLUSION

Increased shoulder pain across an exercise session was not a barrier for subsequent exercise efforts nor overall exercise adherence, regardless of fear-avoidance beliefs among persons with slight shoulder complaints.

ABBREVIATIONS

BMI = body mass index; FABQ-PA = Fear-Avoidance Beliefs Questionnaire - Physical Activity; IQR = interquartile ranges; NRS = numerical rating scale; OR = odds ratio; OSS = Oxford Shoulder Score; SD = standard deviations.

DECLARATIONS

Ethical approval and consent to participate: The study was approved by the Committee on Health Research Ethics in Central Denmark Region on 20 March 2017 (case number: 1-10-72-271-16) and by the Danish Data Protection Agency on 7 September 2016 (case number: 1-16-02-498-16). Written informed consent was obtained from all participants. The study was performed in accordance with the ethical principles described in the Declaration of Helsinki.

Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available due [to some of the data being a part of a RCT study and a Ph.D. dissertation, which has not yet been published. The data is stored in our hospital] but are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: All authors contributed to the plan and the design of the study. JT managed the project, collected the data and drafted the manuscript. JT and PF performed the data analysis and interpreted the results supported by SWS, AD and LRM. MTH, LBJ and TMK supported throughout the process. All authors contributed to the manuscript, and read and approved the final manuscript.

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Table 3: Linear mixed models for shoulder pain and subsequent exercise dose, taking fear-avoidance beliefs into account.

Predictors	Number of repetitions			Progression level			Resistance level			Time until next session (days)		
	Crude	Adjusted*		Crude	Adjusted*		Crude	Adjusted*		Crude	Adjusted*	
	MD	MD	95% CI	MD	MD	95% CI	MD	MD	95% CI	MD	MD	95% CI
Change in shoulder pain (for 1 cm VAS increase)	−0.7	−1.3	−3.4 to 0.9	−0.1**	-0.0	−0.1 to 0.0	−0.1**	-0.0	−0.1 to 0.0	−0.4	-0.6	−2.4 to 1.3
High FABQ-PA score	−2.3	−5.7	−28.5 to 17.1	0.1	0.1	−0.2 to 0.4	0.1	0.1	−0.3 to 0.5	0.3	0.0	−0.8 to 0.8
Interaction between change in shoulder pain and high FABQ-PA		0.2	−6.8 to 7.1		−0.0	−0.2 to 0.1		−0.1	−0.2 to 0.1		0.5	−1.7 to 2.7

The analyses were based on 1201 exercise sessions performed by 79 participants.

Abbreviations: CI = confidence interval; FABQ-PA = Fear-Avoidance Beliefs Questionnaire – Physical Activity (dichotomized; low ≤ 14; high > 14).); MD = mean differences; VAS = Visual Analogue Scale (0 [no pain] – 10 [worst imaginable pain]).

*Adjusted for age, sex, body mass index, smoking status, dominant-sided pain, baseline pain at rest, intervention group, days since start of intervention and session number with an interaction term between change in shoulder pain and fear-avoidance beliefs. **Significant association ($p < 0.05$).

Additional file 1: An extract from a page in the exercise dairy

Session number:_____

Pain at rest before exercise:

No pain ☺ _____ ☹ Worst pain

Exercise		Amount of repetitions	Progression level	Resistance level
1				
2		1. set: Repetitions:_____ 2. set: Repetitions:_____ 3. set: Repetitions:_____	□ Low □ Medium □ High	□ Low □ Medium □ High
3		1. set: Repetitions:_____ 2. set: Repetitions:_____ 3. set: Repetitions:_____	□ Low □ Medium □ High	□ Low □ Medium □ High
4		1. set: Repetitions:_____ 2. set: Repetitions:_____ 3. set: Repetitions:_____	□ Low □ Medium □ High	□ Low □ Medium □ High

Pain at rest after exercise:

No pain ☺ _____ ☹ Worst pain

In the original exercise diaries, which were provided in Danish, the line for reporting pain before and after exercise was 10 cm from "No pain" to "Worst pain".

Spørgeskema nr. 1

Spørgeskema om arbejde og skulderproblemer

– til ansatte på virksomheder i Region Midtjylland

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

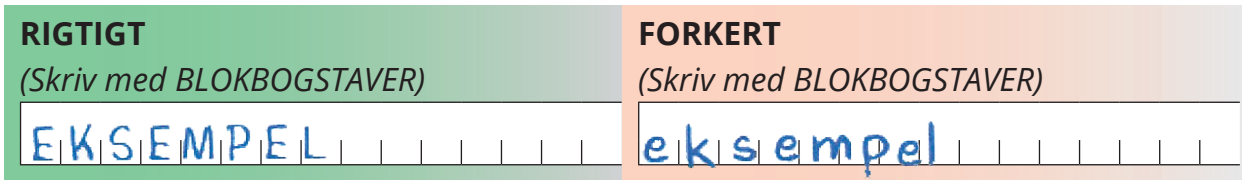
Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

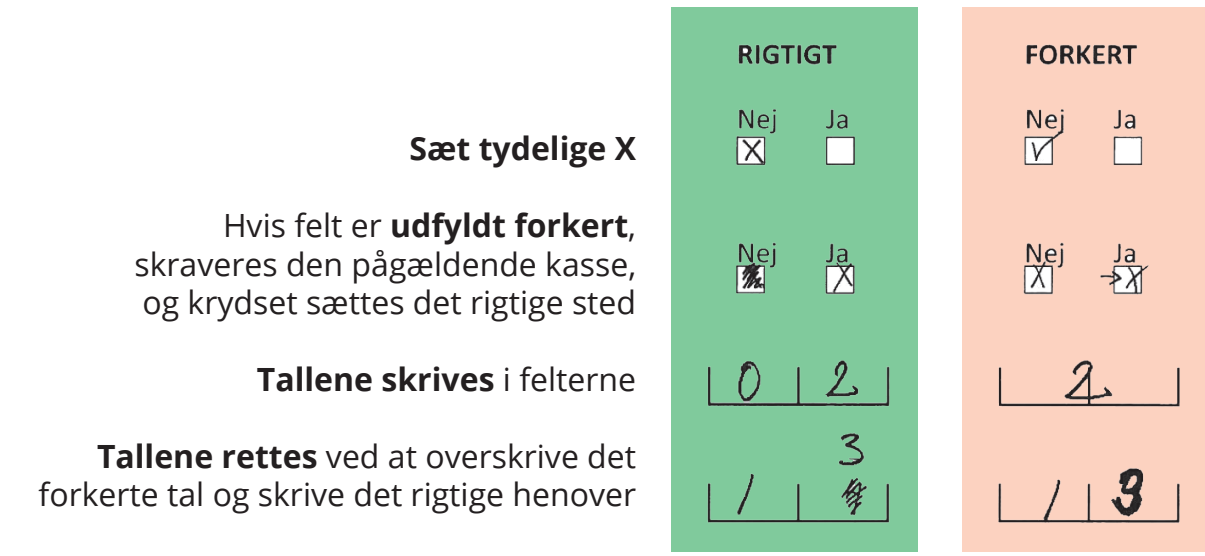
VEJLEDNING

Dette spørgeskema henvender sig til ansatte på virksomheder i Region Midtjylland med arbejde inden for industri, håndværk eller service.

Sådan udfylder du spørgsmålet

Vi beder dig om at svare på spørgsmålene efter de anvisninger, der er angivet i spørgeskemaet. Brug venligst en **sort** eller **blå kuglepen**. Sæt kryds og skriv tal så de er nemme at tolke, som vist i nedenstående eksempler:





Du kan læse mere om undersøgelsen på skemaets bagside.

Hvis du har spørgsmål om spørgeskemaet
Du er velkommen til at stille spørgsmål om spørgeskemaet til:

Jeanette Trøstrup, Regionshospitalet Silkeborg på tlf. 24 75 91 53 (hverdage 9-14) eller på e-mail jeatro@rm.dk.

Dato

1. Dato for udfyldelse af spørgeskemaet

Skriv dato:

|__|__| / |__|__| / |__|__|__|__|
dag måned år

Arbejde

2. Hvad er din nuværende stillingsbetegnelse?

Vær så præcis som muligt. Skriv fx "montør for køkkenfirma" i stedet for "montør" eller "fabriksarbejder på møbelfabrik" i stedet for "fabriksarbejder".

Skriv med BLOKBOGSTAVER.

Stillingsbetegnelse <u>på dansk</u>: _____

3. Hvad er din ugentlige arbejdstid?

Her tænkes på den aftalte arbejdstid ifølge overenskomst eller anden aftale – fx 37 timer per uge. Hvis du har flere job, tænkes der på det samlede antal timer. Rund op til nærmeste hele timetal.

Skriv antal: |__|__| timer per uge.

4. Hvornår blev du ansat i din nuværende stilling?

Skriv årstal: |__|__|__|__|

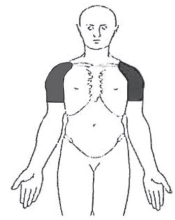
Skulder

5. Er du nogensinde blevet <u>opereret</u> i én eller begge skuldre?

Sæt ét X.

Nej	☐
Ja, højre skulder	☐
Ja, venstre skulder	☐
Ja, begge skuldre	☐

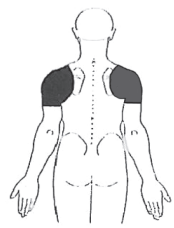
6. I løbet af de sidste 4 uger …
Har du haft smerter på <u>forsiden</u> af højre eller venstre skulder (det skraverede område på tegningen)?



Sæt ét X.

Nej	☐
Ja	☐

7. I løbet af de sidste 4 uger …
Har du haft smerter på <u>bagsiden</u> af højre eller venstre skulder (det skraverede område på tegningen)?



Sæt ét X.

Nej	☐
Ja	☐

De følgende spørgsmål (8-21) handler om den skulder, du især har problemer med. Hvis du har lige store problemer med højre og venstre skulder, bedes du tænke på højre skulder, når du svarer.

8. I løbet af de sidste 4 uger …
Hvordan vil du beskrive den <u>værste</u> smerte du har haft i *din skulder?*

Sæt ét X.

Ingen	Mild	Moderat	Svær	Uudholdelig
☐	☐	☐	☐	☐

9. I løbet af de sidste 4 uger …
Har du haft svært ved at tage tøj på, på grund af din skulder?

Sæt ét X.

Intet besvær	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

10. I løbet af de sidste 4 uger …
Har du haft svært ved at komme ind og ud af en bil eller ved at bruge offentlig transport på grund af din skulder?

Sæt ét X.

Intet besvær	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

11. I løbet af de sidste 4 uger …
Har du været i stand til at bruge kniv og gaffel – *på samme tid?*

Sæt ét X.

Ja, let	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

12. I løbet af de sidste 4 uger …
Kunne du *selv* klare de daglige indkøb?

Sæt ét X.

Ja, let	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

13. I løbet af de sidste 4 uger …
Kunne du bære en bakke med en tallerken med mad gennem et lokale?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

14. I løbet af de sidste 4 uger ...
Kunne du børste/rede dit hår med den dårlige arm?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

15. I løbet af de sidste 4 uger ...
Hvordan vil du beskrive den smerte, du normalt har haft i din skulder?

Sæt ét X.

Ingen	Mild	Moderat	Svær	Uudholdelig
☐	☐	☐	☐	☐

16. I løbet af de sidste 4 uger ...
Kunne du hænge dit tøj op i en garderobe, *med din dårlige arm?*

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

17. I løbet af de sidste 4 uger ...
Har du været i stand til at vaske og tørre dig selv under begge arme?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

18. I løbet af de sidste 4 uger ...
Hvor meget har smerten fra din skulder forstyrret dit normale arbejde (inkl. husligt arbejde)?

Sæt ét X.

Slet ikke	En lille smule	Moderat	Meget	Totalt
☐	☐	☐	☐	☐

19. I løbet af de sidste 4 uger …
Har du været besværet af smerter i din skulder i din seng om natten?

Sæt ét X.

Ingen nætter	1 til 2 nætter	Nogle nætter	De fleste nætter	Hver nat
☐	☐	☐	☐	☐

20. Hvilken grad af smerter har du i din skulder i dag, når du sidder *med armen helt i ro?*

Sæt ét X.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Værst tænkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

21. Inden for de sidste 24 timer…
Hvad var den værste grad af smerter i din skulder *ved brug af armen?*

Sæt ét X.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Værst tænkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Baggrund

22. Er du mand eller kvinde?

Mand	☐
Kvinde	☐

23. Hvor gammel er du?

Skriv din alder.

År: ☐☐

Hvis du har haft problemer med skulderen inden for de sidste 4 uger, kan du mulig-vis deltage i del 2 af dette forskningsprojekt: Reduktion af skulderbelastende arbejde og skulderproblemer.

24. Må vi kontakte dig med yderligere information om del 2 af forskningsprojektet?

Hvis du er en af dem, vi vil bede om at deltage, vil vi i løbet af nogle få uger sende dig et brev om projektet. Derefter vil vi kontakte dig telefonisk.

Nej	☐
Ja	☐ – og mine kontaktoplysninger er:

Skriv med BLOKBOGSTAVER.

Fornavn(e): _____

Efternavn: _____

Vejnavn: _____

Husnummer: _____

Postnummer: _____

By: _____

Telefonnummer: _____ eller _____

E-mail: _____

Tak for din besvarelse

Læg skemaet i kuverten og send den til os

Hvem får dette spørgeskema

Dette spørgeskema indgår i forskningsprojektet Reduktion af skulderbelastende arbejde og skulderproblemer. Skemaet uddeles til ansatte inden for industri, håndværk og service.

Formålet med undersøgelsen
Formålet med dette spørgeskema er at finde frem til personer, som har problemer med skulderen og kan have glæde af en ny indsats. Den nye indsats skal nedsætte belastninger af skulderen på arbejdet og forebygge længerevarende skulderproblemer.

Det er frivilligt at deltage
Ved at udfylde og indsende skemaet giver du dit samtykke til at deltage i spørgeskemaundersøgelsen.

Hvis du har haft problemer med skulderen inden for de sidste 4 uger, kan du muligvis blive bedt om at deltage i en senere del af dette forskningsprojekt. Du vil i så fald modtage yderligere information.

Dine svar behandles fortroligt
Undersøgelsen er anmeldt til Datatilsynet efter persondataloven, og Datatilsynet har fastsat nærmere vilkår for undersøgelsen for at beskytte deltagernes privatliv. Region Midtjylland er dataansvarlig.

Personer, der arbejder med undersøgelsen, har tavshedspligt. Resultaterne offentliggøres kun i en form, hvor enkeltpersoner ikke kan genkendes.

Hvem står bag projektet
Bag undersøgelsen står undertegnede forskere ved Center for Planlagt Kirurgi, Regionshospitalet Silkeborg, Arbejdsmedicinsk Klinik, Århus Universitetshospital og Arbejdsmedicinsk Klinik, Regionshospitalet Herning.

Venlig hilsen

Jeanette Trøstrup, projektansvarlig, fysioterapeut, ph.d.-studerende
Lone Ramer Mikkelsen, fysioterapeut, ph.d.
Mette Terp Høybye, antropolog, ph.d.
Thomas Martin Klebe, overlæge
Poul Frost, overlæge, ph.d.
Annett Dalbøge, Humanfysiolog, ph.d.
Lene Bastrup Jørgensen, sygeplejerske, forskningschef, ph.d.
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Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

Registreringsark til telefoninterview

Spørgeskemanr (ID_JT):_____

Fornavn: _____ Efternavn:_____

Adresse:_____

Dato for tlf opkald ____ ____ _____ Deltagerinformation sendt / mailet: dato:_____

Screenings-OSS score:_____ (Skal være ≤ 40)

Køn: _____ Alder:_____

Email:_____

RedCap ID_____ BY for mulig indsats:_____

Personerne informeres om opringningen vedrører projektet, hvori de har udfyldt "**Spørgeskemaet om arbejde og helbred**", og at **formålet med opringningen** er at høre, om de er interesseret i at deltage og afklare, om de kan deltage i den nye indsats.

1. Jeg/vi har sendt/mailet deltagerinformation til dig, har du modtaget det? (tjek for korrekt email)

□ Nej □ Ja

2. Har du en anden mail? (særligt hvis der bruges arbejdsmail)

□ Nej □ Ja:_____

3. Har du stadig skulderproblemer?

□ Nej □ Ja

Evt. kommentar til spm 3: _____

_____

_____

4. Har du problemer med helbredet, som kan have betydning for deltagelse i træning?

□ Nej

□ Ja – hvilke? (der spørges eksplicit til graviditet og tidligere behandling for brystkræft)_____

_____

_____

5. Er du sygemeldt lige nu?

□ Nej

□ Ja - Hvis ja, forventer du at være i arbejde igen inden for de næste 4 uger?

□Nej □ Ja □ Ved ikke

6. Er du stadig ansat som _____ (stillingsbetegnelse)

ved _____ _____ (virksomhedens navn og BY)

□ Nej □ Ja

7. Har du mobiletelefon?

□ Nej □ Ja – nummer: _____

Personerne informeres om, om de kan deltage eller ej.

Personer, der kan deltage, informeres nærmere om projektet med udgangspunkt i den skriftlige deltagerinformation**. Se dokumentet "Informationsprocedure"**

8. Er du interesseret i at deltage i projektet?

□ Nej □ Ja □ Måske

Personer, der kan deltage, får oplyst:

9. Første mødedato og sted:_____ Kan du evt.denne dato? □ Nej - □ Ja - □ Måske

Brev med disse oplysninger og det præcise mødetidspunkt vil blive sendt, evt. per e-mail.

10. Personen in- eller ekskluderes:

□ Inkluderes

□ Ekskluderes

11. Evt. kommentar:_____

_____

_____

Appendix 6

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Om forskningsprojektet

Reduktion af skulderbelastende arbejde og skulderproblemer

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

Invitation

Virksomheden inviteres hermed til at deltage i en videnskabelig undersøgelse. Formålet er at udvikle en ny indsats, som effektivt kan forebygge længerevarende skulderproblemer og nedsætte belastninger af skulderen på arbejdet.

Målgruppen er medarbejdere inden for industri, håndværk og service, der oplever skulderproblemer.

Hvad omfatter deltagelse?
Undersøgelsen består af to dele:

Del 1 – alle medarbejdere inden for de relevante faggrupper
Denne del omfatter besvarelse af et spørgeskema.

Det tager ca. 5 minutter at udfylde spørgeskemaet, som returneres til os i vedlagt svarkuvert.

Del 2 – nogle få medarbejdere
Ud fra besvarelserne kan nogle medarbejdere blive inviteret til at deltage i afprøvning af indsatsen.

Indsatsen indeholder skuldertræning samt målinger af belastninger af skulderen på arbejdet.

- Nogle deltagere vil desuden få skulderen undersøgt af en specialuddannet fysioterapeut.

- Enkelte deltagere vil få tilbud om, at en arbejdsmiljørådgiver fra projektet kan besøge virksomheden for at finde muligheder for at nedsætte belastninger af skulderen. Dette vil ske efter aftale med virksomheden.

Indsatsen omfatter 1 til 3 mødegange, der vil foregå uden for arbejdstiden i et lokalt sundhedshus.

Praktiske oplysninger
Deltagelse i undersøgelsen er frivillig, og medarbejderne kan til enhver tid træde ud af undersøgelsen. Projektet er godkendt af Videnskabsetisk Komité for Region Midtjylland (sagsnr. 1-10-72-271-16) og under Region Midtjyllands generelle anmeldelse til Datatilsynet (sagsnr. 1-16-02-498-16).

Alle deltagere i projektets del 2 får tilbagemelding om egne målinger af belastninger af skulderen.

Hvem foretager undersøgelsen?
Undersøgelsen fortages af Center for Planlagt Kirurgi, Regionshospitalet Silkeborg og de arbejdsmedicinske klinikker i Herning og Århus.

Undersøgelsen er finansieret af Folkesundhed I Midten (Region Midtjylland), Task Force for Nære Sundhedstilbud og Sundhedsinnovation (Region Midtjylland), Forsknings- og udviklingspuljen (Danske Regioner), Aarhus Universitet, Danske Fysioterapeuter, Helga og Peter Kornings Fond og Gigtforeningen.

Kontaktoplysninger
For yderligere oplysninger kontakt:

Jeanette Trøstrup
Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Falkevej 1-3, bygning 9
8600 Silkeborg
Tlf: 24 75 91 53
E-mail: jeatro@rm.dk

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Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

Appendix 7

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Deltagerinformation

Reduktion af skulderbelastende arbejde og skulderproblemer

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

Invitation

Vi vil spørge, om du vil deltage i forskningsprojektet *Reduktion af skulderbelastende arbejde og skulderproblemer*. Målgruppen er ansatte inden for industri, håndværk og service, som har problemer med skulderen.

Projektets formål

Forskningsprojektet skal vise, om belastninger af skulderen på arbejdet og længerevarende skulderproblemer kan nedsættes gennem en ny indsats.

Plan for projektet

Vi tilrettelægger alle mødetidspunkter uden for arbejdstiden. Undersøgelsen starter i et lokalt sundhedshus nær din arbejdsplads. Når du har afleveret samtykkeerklæringen og udfyldt et spørgeskema, vil du og de øvrige deltagere blive fordelt tilfældigt mellem følgende to indsatser:

1) Skulder-Café

Du skal møde op til tre café-møder af cirka 2 timers varighed fordelt over 2-3 måneder.
Café-møderne har 10-12 deltagere og indeholder:

- Undersøgelse af dine skuldre ved en specialuddannet fysioterapeut
- Undervisning i skulderens anatomi samt arbejdsrelateret forebyggelse givet af en specialuddannet fysioterapeut og en arbejdsmiljørådgiver
- Skuldertræning vejledt af en fysioterapeut
- Hjemmetræning af skulderen cirka 15 minutter 3-4 gange pr. uge i 2-3 måneder
- Råd om hvordan man kan nedsætte belastninger af skulderen i arbejdet. Eventuelt kan en arbejdsmiljørådgiver besøge din arbejdsplads.
- Måling af belastninger af skulderen på arbejdet ved start og slut på indsatsen.
  Du får udleveret måleudstyr (2 x 3 cm) og får tilbagemelding om dine måleresultater
- SMS besvarelse om graden af aktuelle skuldersmerter to gange om ugen i 2-3 måneder
- Besvarelse af et spørgeskema cirka 5 og 12 måneder efter første café-møde

2) Skulder-Vejledning

Du skal møde op til én vejledning, som varer cirka 30 minutter.
Skulder-Vejledningen sker til én deltager ad gangen og indeholder:

- Hjemmetræning af skulderen cirka 15 minutter 3-4 gange pr. uge i 2-3 måneder
- Råd om hvordan man kan nedsætte belastninger af skulderen i arbejdet
- Måling af belastninger af skulderen på arbejdet ved start og slut på indsatsen. Du får udleveret måleudstyr (2 x 3 cm) og får tilbagemelding om dine måleresultater
- SMS besvarelse om graden af aktuelle skuldersmerter to gange om ugen i 2-3 måneder
- Besvarelse af et spørgeskema cirka 5 og 12 måneder efter vejledningsmødet.

Nytten ved projektet
Projektets resultater vil danne udgangspunkt for en forbedret indsats for personer med skulderbelastende arbejde og skulderproblemer. Hvorvidt du selv vil få gavn af din deltagelse, vil afhænge af indsatsernes effekt.

Der forventes ingen bivirkninger, risici, komplikationer eller ulemper
Forbigående muskelømhed kan forekomme efter klinisk skulderundersøgelse og skuldertræning.

Dine rettigheder
Det er frivilligt at deltage. Vi opfordrer dig til at læse tillægget 'Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt'. Du har mulighed for betænkningstid, før du beslutter, om du vil deltage. Hvis du beslutter dig for at deltage, bedes du underskrive vedlagte samtykkeerklæring senest ved første fremmøde. Hvis du vælger ikke at deltage, vil du ikke blive kontaktet yderligere af os.

Du kan når som helst og uden grund trække dit samtykke tilbage.

Økonomiske forhold ved deltagelse
Du vil ikke modtage betaling eller anden godtgørelse i forbindelse med projektet.

Afbrydelse af din deltagelse i forskningsprojektet
Hvis der sker ændringer af din helbredstilstand, som kan påvirke din deltagelse, vil vi vurdere, om din deltagelse må afbrydes.

Øvrige informationer om projektet
Projektet er godkendt af Videnskabsetisk Komité for Region Midtjylland (sagsnr. 1-10-72-271-16) og under Region Midtjyllands generelle anmeldelse til Datatilsynet (sagsnr. 1-16-02-498-16). Region Midtjylland er dataansvarlig.

Projektet udføres af undertegnede forskere i et samarbejde mellem Center for Planlagt Kirurgi, Regionshospitalet Silkeborg, Arbejdsmedicinsk Klinik, Aarhus Universitetshospital og Arbejdsmedicinsk Klinik, Regionshospitalet Herning.

Projektet er økonomisk støttet af:

- Folkesundhed I Midten, Region Midtjylland: 1.043.305 kr.
- Task Force for Nære Sundhedstilbud og Sundhedsinnovation, Region Midtjylland: 600.000 kr.
- Udviklings- og forskningspuljen, Danske Regioner: 500.000 kr.
- Aarhus Universitet: 450.000 kr.
- Danske Fysioterapeuters Fond for Forskning: 400.000 kr.
- Savværksejer Jeppe Juhl og Hustru Ovita Juhls Mindelegat: 100.000 kr.
- Gigtforeningen: 276.124 kr.
- Helga og Peter Kornings Fond: 10.000 kr.

Projektgruppen har ingen økonomisk tilknytning til de fonde, som har tildelt bevilling.

Adgang til forskningsresultater
Resultaterne af projektet offentliggøres kun i en form, hvor enkeltpersoner ikke kan genkendes. Der bliver udarbejdet videnskabelige artikler til internationale tidsskrifter.

Hvis du vil vide mere
Hvis du vil vide mere om projektet, inden du beslutter dig for at deltage, eller hvis du i løbet af projektet ønsker yderlige oplysninger, er du velkommen til at kontakte Jeanette Trøstrup på telefon: 24 75 91 53 (hverdage kl. 9-15) eller e-mail: jeatro@rm.dk.

Venlig hilsen

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Poul Frost, overlæge, ph.d.
Annett Dalbøge, Humanfysiolog, ph.d.
Lene Bastrup Jørgensen, sygeplejerske, forskningschef, ph.d.
Susanne Wulff Svendsen, professor, overlæge, ph.d.

Grafisk Service 4205

Statistical analysis plan (SAP)

Reducing shoulder complaints in employees with high occupational shoulder exposures: a cluster-randomised controlled study (The Shoulder-Café Study)

ClinicalTrials.gov ID: NCT03159910

Protocol version 1.0, SAP version 1.0, 10 January 2019

Names, affiliations and roles of SAP contributors

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INTRODUCTION

Please refer to the study protocol regarding background and rationale. This trial compares a group-based Shoulder-Café intervention with an individual-based Shoulder-Guidance intervention (active control – enhanced usual care). The main hypotheses are that the Shoulder-Café will reduce I) shoulder complaints and II) occupational shoulder exposures more effectively than the Shoulder-Guidance. The trial results for hypotheses I and II will be reported in two separate papers.

METHODS

Design

The trial uses a cluster-randomised controlled design with two parallel interventions: Shoulder-Café and Shoulder-Guidance. The intervention duration is around 3 months.

Population and randomisation

Details on screening, eligibility, and recruitment including a template flow diagram are provided in the study protocol. According to the sample size calculation in the study protocol, the study size needs to be ≥96 (2 x 48). We aim to include 60 employees in each group to ensure that 50 employees in each group complete.

Randomisation is performed at company (cluster) level with a 1:1 allocation ratio and stratified by industry using blocking within strata with randomly permuted block sizes of 2-4-6. Blocking within strata is used to ensure an equal distribution of the interventions between industries, while randomly permuted block sizes ensure allocation concealment. The randomisation result is not revealed to the participants, until they have signed the informed consent and completed the baseline questionnaire.

Baseline assessment of occupational shoulder exposures is performed after the randomisation result has been revealed.

The analysis population for hypotheses I and II consists of all participants with baseline questionnaire information (including a valid Oxford Shoulder Score (OSS)) and randomised allocations, who have not withdrawn their consent to contribute to the study at any time between inclusion and the first submission of a manuscript to a scientific journal. All analyses will be based on the analysis population according to the intention-to-treat principle.

Study outcomes

Details on primary, secondary, and supplementary outcomes are provided in the study protocol. Regarding hypothesis I, the primary outcome is the OSS at 6 months. Listed in order of priority, the secondary outcomes are: the OSS at 12 months, the Fear Avoidance Beliefs Questionnaire – Physical Activity (FABQ-PA) at 6 months, the Patients' global impression of change (PGIC) at 6 months, and the FABQ-PA at 12 months.

Regarding hypothesis II, the primary outcome is the mean number of minutes/day working with the arm elevated > 60˚ shortly after end of intervention (EOI). Measurement days, which fulfill the quality requirement of $\geq$ 4 hours/day, are normalised to the participant's scheduled working hours that day according to the work diary, and the outcome is calculated as the total number of minutes working with the arm elevated > 60˚ across the measurement days for each participant divided by the number of measurement days for the participant (1–5 days). the number of measurement days for the participant (1–5 days). Listed in order of priority, the secondary outcomes are: the mean number of minutes/day working with the arm elevated > 90˚ shortly after EOI, calculated as

described above, the mean median angular velocity (˚/s) shortly after EOI, calculated as the mean of the medians for each measured working day for each participant, the Borg CR-10 shortly after EOI, calculated as the mean of the rated working days for each participant, and the mean number of minutes/day working with the arm elevated > 30˚ shortly after EOI, calculated as described for the primary outcome.

Schedule for study procedures

The schedule for study procedures including assessment of primary, secondary, and supplementary outcomes is presented in the study protocol. Regarding hypothesis I, follow-up takes place 6 and 12 months after T_0 = start of intervention; regarding hypothesis II, follow-up takes place shortly after end of intervention (EOI). The interventions are based on non-invasive methods and are not expected to cause any adverse events other than possible temporary muscle tenderness after shoulder exercises. Therefore, no interim analyses are planned and no stopping rules defined.

Characteristics of non-participants

Employees may decline to participate any further at two steps of the recruitment process; step 1) the screening questionnaire and step 2) the telephone interview (see the template flow diagram in the study protocol). At each of these two steps, we will compare those who agreed to participate with those who declined based on data from the screening questionnaire (age, sex, industry, and the OSS). Regarding hypothesis II, participants and non-participants will also be compared with respect to self-reported occupational shoulder exposures at baseline.

Baseline characteristics of the analysis population

Continuous variables will be summarised by mean and standard deviation (or median and inter quartile range if data is skewed); categorical variables will be summarised by number and percentage. Baseline characteristics of the analysis population will be summarised and presented as illustrated in Tables 1A (hypothesis I) and 1B (hypothesis II).

Adherence

For the analysis population and the population completing follow up, adherence to the home-based exercise programme will be described according to intervention arm as the mean (SD) number of days/person where exercises were performed during the intervention period according to the exercise diary and BandCizer© recordings. Adherence to the exposure assessment will be described according to intervention arm as the percentage of the analysis population that has ≥ 1 work day with ≥ 4 hours of Axivity data and/or a Borg-CR10 rating 1) shortly after T_0 and 2) shortly after EOI. For the Shoulder-Café group, adherence to café-meetings will be described as the percentages of the participants who completed three, two, or only one café meeting. For the Shoulder-Guidance group, adherence to intervention contacts will not be further described because all participants have to attend the 1st individual appointment to be included and are not scheduled to further contacts.

Table 1A Baseline characteristics of the analysis population regarding hypothesis I.

Population	**Analysis population**		**Population with follow-up at 6 months**		**Population with follow-up at 12 months**	
	Shoulder-Café n	**Shoulder-Guidance n**	**Shoulder-Café n**	**Shoulder-Guidance n**	**Shoulder-Café n**	**Shoulder-Guidance n**
Age, mean (SD)						
Sex, n (%)						
Female						
Male						
Industry, n (%)						
Service						
Manufacture						
Construction						
OSS, mean (SD)						
FABQ-PA, mean (SD)						

Abbreviations: OSS = Oxford Shoulder Score, FABQ-PA = Fear Avoidance Beliefs Questionnaire – Physical Activity.

Table 1B Baseline characteristics of the participants regarding hypothesis II.

Population	**Participants with exposure assessment shortly after T_0**		**Participants with exposure assessment shortly after T_0 and shortly after EOI**	
	Shoulder-Café n	**Shoulder-Guidance n**	**Shoulder-Café n**	**Shoulder-Guidance n**
Age, mean (SD)				
Sex, n (%)				
Female				
Male				
Industry, n (%)				
Service				
Manufacture				
Construction				
OSS, mean (SD)				
Arm elevation (minutes/day), mean (SD)				
> 60°				
> 90°				
Repetitive shoulder movements (median angular velocity, °/s), mean (SD)				
Forceful shoulder exertions (Borg CR-10), mean (SD)				
Arm elevation (minutes/day), mean (SD) > 30°				

Abbreviation: EOI = end of intervention, OSS = Oxford Shoulder Score.

Statistical principles and analyses

Regarding hypothesis I, a mixed model analysis of the OSS will be performed including "intervention" (Shoulder-Café and Shoulder-Guidance), "time" (6 and 12 month follow-up), "intervention x time", baseline OSS (linear), sex, age (linear), and industry (service, manufacture, construction) as fixed effects, adjusting for random effects of participant and company (cluster); the effect estimate will be the mean difference (Shoulder-Café minus Shoulder-Guidance) at each time point, reported with a 95% confidence interval (CI). FABQ-PA will be analysed likewise, but will be adjusted for baseline FABQ-PA instead of baseline OSS. In the analysis of PGIC, we will dichotomise the outcome as improved (no/yes) and use a risk difference model if around 50% of the participants improve. If a considerably smaller percentage (< 20%) improves, we will employ a relative risk model (log-binomial model) using improved as the outcome, while if a considerably larger percentage (> 80%) improves, we will employ a relative risk model using not improved as the outcome. The analysis of PGIC will be adjusted for sex, age, and industry and use robust standard errors to take into account clustering at company level.

Regarding hypothesis II, a mixed model analysis of the primary outcome (minutes/day working with the arm elevated > 60˚ shortly after EOI) will be performed including "intervention" (Shoulder-Café and Shoulder-Guidance), baseline minutes/day working with the arm elevated > 60˚ (linear), sex, age (linear), and industry (service, manufacture, construction) as fixed effects, adjusting for random effects of company (cluster); the primary effect estimate will be the mean difference (Shoulder-Café minus Shoulder-Guidance), reported with a 95% CI. The analyses for the secondary outcomes will be performed likewise, but will be adjusted for the respective baseline values instead of the baseline number of minutes/day working with the arm elevated > 60˚.

Results for continuous outcomes will be presented as adjusted values, but unadjusted mean values will also be shown, see tables 2A and 2B; results for PGIC will be presented in text. All CIs will be bootstrapped so that they will be robust to deviations from distributional assumptions; this will also minimise effects of outlying outcome measures, which is already minimised because we include baseline measures in the analyses. No adjustment for multiplicity is planned. We do not intend to perform per-protocol and subgroup analyses. Regarding hypothesis II, we will perform sensitivity analysis, where we exclude working days with unusual shoulder exposures according to the work diary (e.g., if a person reports unusual shoulder exposures a given working day, the mean exposure will be based on the remaining working days with usual shoulder exposures).

Usual missing rules for the OSS will be used. Numbers of participants with missing data will be reported. Imputation will not be performed as we have no extra information that is not already included in the mixed model, which will account for missing values that are missing completely at random given the variables included in the model.

If more than 5% of the primary outcome measures in any of the intervention groups are missing, we will undertake sensitivity analyses of the primary outcomes to evaluate any effects of differential loss to follow-up. Regarding hypotheses I and II, missing values of the OSS at 6 and 12 months and missing minutes/day > 60˚ shortly after EOI will be checked using the model based predicted values going through more scenarios: Shoulder-Café + 0 SD and Shoulder-Guidance + 1 SD; Shoulder-Café + 0 SD and Shoulder-Guidance - 1 SD; Shoulder-Café + 1 SD and Shoulder-Guidance + 0 SD, and Shoulder-Café - 1 SD and Shoulder-Guidance + 0 SD.

Axivity data (Axivity Ltd, Newcastle, United Kingdom) will be downloaded using OmGui open-source software (OmGui Version 1.0.0.28; Open Movement, Newcastle University, Newcastle upon Tyne, United Kingdom) and saved in raw format files. MatLab (Build 8.6.0.267246 (R2015b) 64 bit) and STATA 15 (StataCorp LP, College Station, TX, US) will be used for data processing and statistical analyses. Data cleaning will be documented in Stata do files.

The final analyses are planned to take place when 12 month follow-up has been reached for all participants and when the data has been cleaned. The paper regarding hypothesis I is expected to be prepared around August 2020 and the paper regarding hypothesis II shortly thereafter.

We have published our study protocol including this SAP to minimise the risk of analysis bias.

Table 2A Effectiveness Shoulder-Café compared with Shoulder-Guidance with respect to primary and secondary outcomes (hypothesis I).

	Shoulder-Café	Shoulder-Guidance	Effectiveness	
	n	n	Mean difference *	95% CI
Primary outcome				
OSS at 6 months, mean (SD)				
Secondary outcomes				
OSS at 12 months, mean (SD)				
FABQ-PA at 6 months, mean (SD)				
FABQ-PA at 12 months, mean (SD)				

* Adjusted for the baseline value of the relevant outcome, sex, age, and industry using mixed models including company and participant as random effects.

Abbreviations: CI = confidence interval, FABQ-PA = Fear Avoidance Beliefs Questionnaire – Physical Activity, OSS = Oxford Shoulder Score, PGIC = Patients' Global Impression of Change.

Table 2B Effectiveness of Shoulder-Café compared with Shoulder-Guidance with respect to primary and secondary outcomes (hypothesis II).

	Shoulder-Café			Shoulder-Guidance			Effectiveness	
	n	Mean	SD	n	Mean	SD	Mean difference*	95% CI
Primary outcome								
Arm elevation (minutes/day) > 60°								
Secondary outcomes								
Arm elevation (minutes/day) > 90°								
Repetitive shoulder movements (median angular velocity, °/s)								
Forceful shoulder exertions (Borg CR-10)								
Arm elevation (minutes/day) > 30°								

* Adjusted for the baseline value of the relevant outcome, sex, age (linear), and industry (service, manufacture, construction) as fixed effects, and random effect of company (cluster).

Abbreviation: CI = confidence interval.

Appendix 9: Content, time schedule and differences of the Shoulder-Café and the Shoulder-Guidance (Trøstrup J. et al, Trials. 2019; 20 (1):627.).

Shoulder-Café	**Shoulder-Guidance (active control – enhanced usual care)**
1st café meeting (T_0): • Distribution of home-based exercise pamphlet, BandCizer©, Axivity accelerometers*, diaries, and elastic bands • Presentation of participants and networking with the group • Supervised exercises with individual tailoring according to the exercise pamphlet • Clinical evaluation of the participants' shoulders • Education about shoulder anatomy	1st intervention contact - individual appointment (T_0): • Distribution of home-based exercise pamphlet, BandCizer©, Axivity accelerometers*, diaries, and elastic bands
At home: • Home-based exercises and exercise diary At work: • Shoulder exposure assessment and work diary	At home: • Home-based exercises and exercise diary At work: • Shoulder exposure assessment and work diary
2nd café meeting (~1.5 month after T_0): • Written feedback on the 1st exposure assessment • Written general advice on reduction of occupational shoulder exposures • Supervised exercises with individual tailoring according to the pamphlet • Education about shoulder exposures • Advice on work modifications and possibility to ask questions about the 1st exposure assessment • Offer of a workplace visit to find ways to reduce the exposures • Networking with the group	2nd intervention contact – postal letter or email (~1.5 month after T_0): • Written feedback on the 1st exposure assessment • Written general advice on reduction of occupational shoulder exposures
At home: • Home-based exercises and exercise diary	At home: • Home-based exercises and exercise diary
3rd café meeting (end of intervention ~3 months after T_0): • Distribution* of Axivity accelerometers and work diaries • Supervised exercises with individual tailoring according to the pamphlet • Networking with the group	3rd intervention contact – postal letter (end of intervention ~3 months after T_0): • Distribution of Axivity accelerometers and work diaries
At work: • Shoulder exposure assessment and work diary	At work: • Shoulder exposure assessment and work diary
Postal letter or email: • Written feedback on the exposure assessment shortly after end of intervention	Postal letter or email: • Written feedback on the exposure assessment shortly after end of intervention
6-month follow-up (~6 months after T_0): • Electronic or postal questionnaire	6-month follow-up (~6 months after T_0): • Electronic or postal questionnaire
12-month follow-up (~12 months after T_0): • Electronic or postal questionnaire	12-month follow-up (~12 months after T_0): • Electronic or postal questionnaire

* The Axivity accelerometer is mounted, unless the participant is going on holiday or expects atypical work, e.g. due to course participation.

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Hjemmetræning

Reduktion af skulderbelastende arbejde og skulderproblemer

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

VEJLEDNING til hjemmetræningen

Træningen

- Du skal træne 3-4 gange om ugen, mens du deltager i forskningsprojektet. Træningen må gerne deles op i flere perioder om dagen, så du fx træner øvelse 1 om morgenen, øvelse 2 til middag og øvelse 3 + 4 om aftenen.
  Det vigtigste er, at du 3-4 gange per uge kommer igennem alle øvelserne.

- Kropsholdningen, som du træner i øvelse 1, skal du opretholde, mens du laver øvelse 2, 3 og 4.

- Bevægelighed og styrke skal opbygges gradvist. Du skal derfor starte med sværhedsgrad let, medmindre du har fået besked på andet.

- Øvelse 2, 3 og 4 er inddelt i 3 sværhedsgrader: let, middel og høj.

- Du skal udføre så mange gentagelser, du kan. Når du kan udføre mere end 3 sæt á 15 gentagelser af én øvelse med en god kontrol og uden forværring af dine skuldersmerter, skal du øge elastikkens styrke. Elastik farverne **gul**, **rød** og **grøn** indikerer elastikkens styrke. Gul er den letteste og grøn den sværeste.

- Start med øvelserne af "let sværhedsgrad" og gå først videre til "mellem sværhedsgrad", hvis du kan tage 3 sæt á 15 gentagelser.
  Hvis du kan tage 3 sæt á 15 gentagelser af "mellem sværhedsgrad", skal du gå videre til "høj sværhedsgrad".
  Det er ikke sikkert, at du er på samme niveau ved hver øvelse.

- Alle øvelserne skal udføres i roligt og kontrolleret tempo. For at sikre god muskulær symmetri skal alle øvelser udføres for begge skuldre.

Smerter og ømhed under og efter træning

- Når du træner, kan du undervejs forvente ømhed i dine skuldermuskler. Dette er helt normalt.

- Hvis dine kendte skuldersmerter forværres og hvis smerterne ikke falder tilbage til det niveau, de var før du startede træningen (indenfor 1 time), er det måske et udtryk for, at du træner ved for højt niveau. Du skal derfor gå ét niveau tilbage.

Registrering af hjemmetræning

- For at følge din træning så tæt som muligt, vil vi bede dig udfylde den udleverede træningsdagbog.

- Din træning skal desuden registreres med en Bandcizer-sensor, som skal være placeret på din træningselastik under alle dine træningssessioner (læs om Bandcizeren bagerst i denne pjece).

Øvelse 1: Holdningskorrektion

Øvelsen skal øge din bevidsthed om kropsholdning og give dine skuldre større bevægelsesfrihed.

Start position → Slut position

Start position: Stå med hoftebreddes afstand mellem fødderne.
Prøv at "falde sammen i ryggen".

Slut position: Ret dig nu op og skyd brystbenet let frem. Forestil dig at du har en snor fastgjort til toppen af dit hoved, og at den trækker sig op mod loftet.

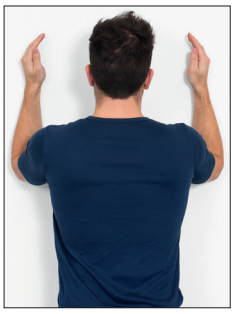
Forstil dig, at du herved bliver lang og lige i ryg og nakke, og at dine skuldre kommer en smule tilbage og op. Gentag øvelsen 3 gange. **Denne kropsholdning skal du opretholde, mens du laver de følgende skulderøvelser.** Slap herefter af igen.

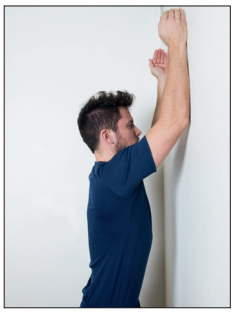
Øv dig desuden i dette dagen igennem, så du gradvist tilvænner dig denne kropsholdning.

Øvelse 2: Øvelse for musklerne omkring skulderbladet

Let sværhedsgrad

Start position → Slut position

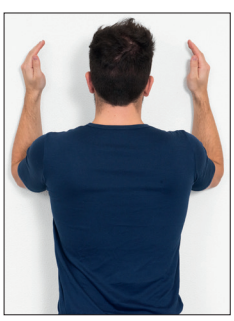


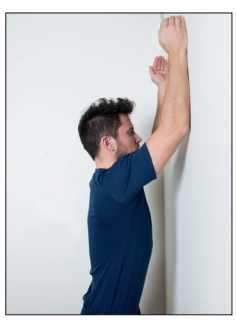


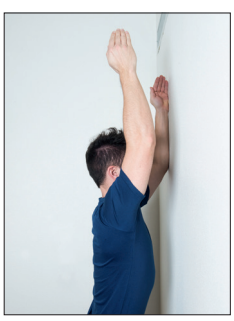
Placér lillefingersiden af din hånd og underarm ind mod væggen (lige under 90°), glid armene langsomt op ad væggen til albuerne er strakte, og glid herefter ned igen til startposition. Skuldrene må gerne løfte sig lidt med op mod ørerne undervejs i øvelsen. (Øvelsen udføres uden elastik).

Mellem sværhedsgrad

Start position → Slut position



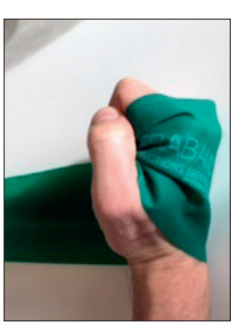


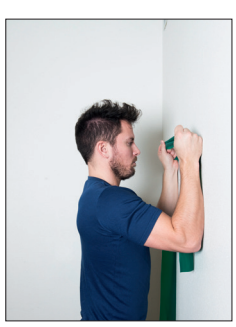


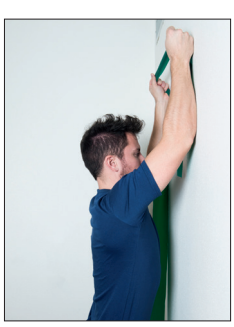
Udføres som beskrevet under "Let sværhedgrad". Desuden, når armene er strakte, løfter du skiftevis højre og venstre arm lidt bagud og tilbage på væggen igen. Herefter lader du armen glide ned ad væggen igen til startposition. (Øvelsen udføres uden elastik).

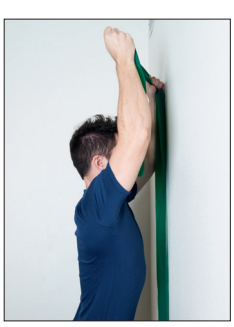
Høj sværhedsgrad

Start position → Slut position









Elastikfarve

Gul ☐

Rød ☐

Grøn ☐

Øvelsen udføres som beskrevet under "Mellem sværhedsgrad", men med brug af træningselastik.
Hold elastikken i begge hænder og sørg for, at den er viklet en gang rundt om hånden (se billedet af hånd med elastik viklet omkring).

Husk at lillefingersiden skal holdes ind mod væggen og at tomlen peger bagud under hele øvelsen.

Øvelse 3: Træning af musklerne omkring skulderbladet

Let sværhedsgrad

Start position → Slut position

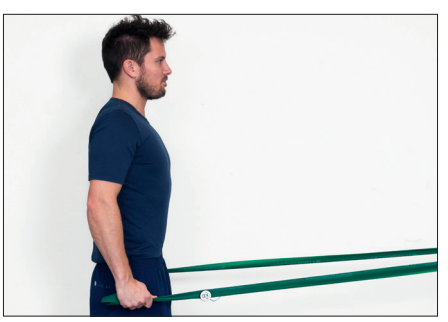
Elastikfarve

Gul ☐

Placér en elastik omkring et dørhåndtag og luk døren. Tag fat om elastikken med begge hænder. Gå så langt fra døren, at elastikken strammes op, og armene er strakte foran dig (skuldrene er i en 45° vinkel). Albuerne holdes strakte gennem hele øvelsen. Træk nu elastikken langsomt tilbage således at armene flugter med kroppen. Hold stillingen et par sekunder. Vend herefter tilbage til startpositionen. Ved denne øvelse skal du spænde i maven. Husk desuden en god kropsholdning.

Mellem sværhedsgrad

Start position → Slut position



Elastikfarve

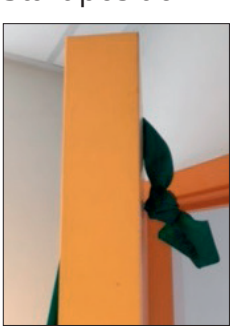
Rød ☐

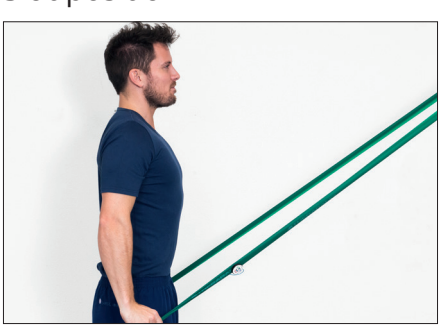
Grøn ☐

Udføres som "Let sværhedsgrad" men med sværere elastik.

Høj sværhedsgrad

Start position → Slut position





Elastikfarve

Gul ☐

Rød ☐

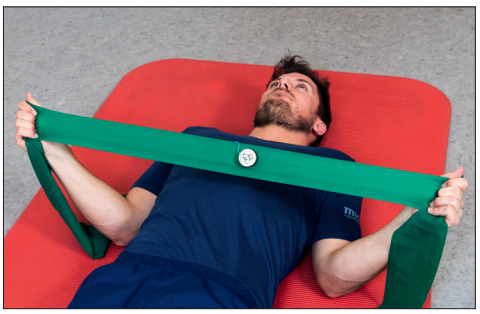
Grøn ☐

Bind en knude midt på elastikken og sæt den fast på en dør (se billede af dør med elastik). Luk døren. Tag fat om elastikken med begge hænder. Gå så langt fra døren, at elastikken strammes op, og armene er løftede i cirka 90°. Albuerne holdes strakte gennem hele øvelsen. Træk nu elastikken tilbage således at armene flugter med kroppen. Hold stillingen et par sekunder. Vend herefter tilbage til startpositionen.

Øvelse 4: Træning af de små stabiliserende muskler omkring skulderleddet

Let sværhedsgrad

Start position → Slut position



Elastikfarve

Gul ☐

Lig på ryggen og hold fast om elastikken (se billede). Hold albuerne bøjet i 90° og hold albuerne ind til kroppen under hele øvelsen. Drej underarmen lidt udad så der kommer spænding på elastikken. Hold spændingen et par sekunder, og drej herefter tilbage til udgangsstillingen igen, så spændingen på elastikken aftager.

Mellem sværhedsgrad

Start position → Slut position

Elastikfarve

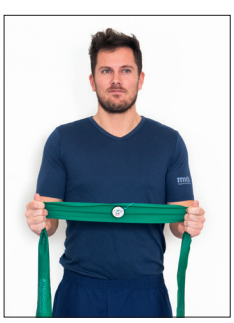
Gul ☐

Rød ☐

Stående. Placér en elastik omkring hænderne og drej underarmen udad, så der kommer spænding på elastikken. Hold spændingen et par sekunder, og drej herefter underarmen tilbage til udgangsstillingen igen, så spændingen på elastikken aftager.

Høj sværhedsgrad

Start position → Slut position



Elastikfarve

Gul ☐

Rød ☐

Grøn ☐

Stående. Placér en elastik omkring hænderne og drej underarmen udad, så der kommer spænding på elastikken. Hold spændingen på elastikken og før armene op over hovedet og ned igen. Drej herefter underarmen indad igen, så spændingen på elastikken aftager. Skuldrene må gerne løfte sig lidt med op mod ørerne undervejs i øvelsen.

Vejledning til brug af BandCizer-sensoren

Generelt
- BandCizeren skal sættes på din træningselastik, hver gang du træner.

Påsætning
- BandCizeren clipses fast på elastikken ved hjælp af dens to magneter. Under træningen skal den være placeret midt på træningselastikken (som vist på billedet).

Lys og blink
- Rødt og violet blink betyder, at BandCizeren registrerer bevægelse og træning.
- Ved opladning lyser BandCizer rødt, men skifter til grøn, når batteriet er ladet mere end 80% op.
- Hurtigt blinkende rødt eller violet lys angiver lavt batteriniveau.

Hvis du skal **transportere** BandCizeren, bedes du hænge BandCizeren rundt om træningselastikken.

BandCizer skal **oplades** jævnligt - gerne efter hver træning.

Hvis du har spørgsmål eller problemer med Bandcizeren, kan du kontakte projektleder, **Jeanette Trøstrup på tlf.: 24 75 91 53 (hverdage 9-15) eller på e-mail: jeatro@rm.dk**

Grafisk Service 3385

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

Skulderbelastende arbejde

Arbejde der kan belaste skuldrene omfatter:

- Arbejde med højt løftede arme
- Arbejde med repetitive skulderbevægelser også kaldet ensidig gentaget arbejde (EGA)
- Kraftbetonet arbejde

I denne pjece kan du læse om de forskellige former for skulderbelastende arbejde og hvordan man kan nedsætte belastningerne.

Telefonnummer:
24 75 91 53

Det siger loven

Alle arbejdsopgaver skal planlægges, tilrettelægges og udføres sikkerheds- og sundhedsmæssigt fuldt forsvarligt.

Deltagelse er frivillig

Deltagelse i forskningsprojektet er frivillig, og du kan på ethvert tidspunkt træde ud af undersøgelsen. Projektet er godkendt af Videnskabsetisk Komité for Region Midtjylland og under Region Midtjyllands generelle anmeldelse til Datatilsynet.

Kontaktoplysninger

Jeanette Trøstrup
Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Vest
Tlf.nr.: 24 75 91 53

regionmidtjylland

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Arbejdsbelastninger

Reduktion af skulderbelastende arbejde og skulderproblemer

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Arbejde med højt løftede arme

Arbejde med højt løftede arme er arbejde, hvor en eller begge albuer er løftet til omkring eller over skulderhøjde (90 grader).

Arbejde med højt løftede arme forekommer ofte hos:

- Malere
- Elektrikere
- Isolatører
- Stilladsarbejdere
- VVS-installatører
- Tømrer

Repetitive skulderbevægelser

Repetitive skulderbevægelser er arbejde med hurtigt gentagne skulderbevægelser, hvilket udføres en stor del af arbejdsdagen.

Arbejde med repetitive skulderbevægelser forekommer ofte hos:

- Slagteriarbejdere
- Pakkeriarbejdere
- Vaskeriarbejdere
- Rengøringsassistenter
- Køkkenassistenter
- Bagere

Kraftbetonet arbejde

Kraftbetonet arbejde er arbejde, der er fysisk anstrengende for skulderen herunder løfte-, trække- og skubbe-arbejde.

Kraftbetonede arbejde forekommer ofte hos:

- Stilladsarbejdere
- Slagteriarbejdere
- Træarbejdere
- Murerarbejdsmænd
- Fjerkræslagtere
- Tømrer

Hvordan mindskes belastningen?

- Reducer antallet af højt placerede emner eller arbejdstiden med højt løftede arme
- Benyt tekniske hjælpemidler hvor det er muligt
- Indret arbejdspladsen hensigtsmæssigt og sørg for tilstrækkelig arbejdsplads

Hvordan mindskes belastningen?

- Benyt tekniske løsninger fx ved brug af maskiner eller robotter til at udføre de repetitive arbejdsopgaver
- Reducer tiden med repetitivt arbejde fx ved rotation, så det repetitive arbejde fordeles blandt medarbejderne

Hvordan mindskes belastningen?

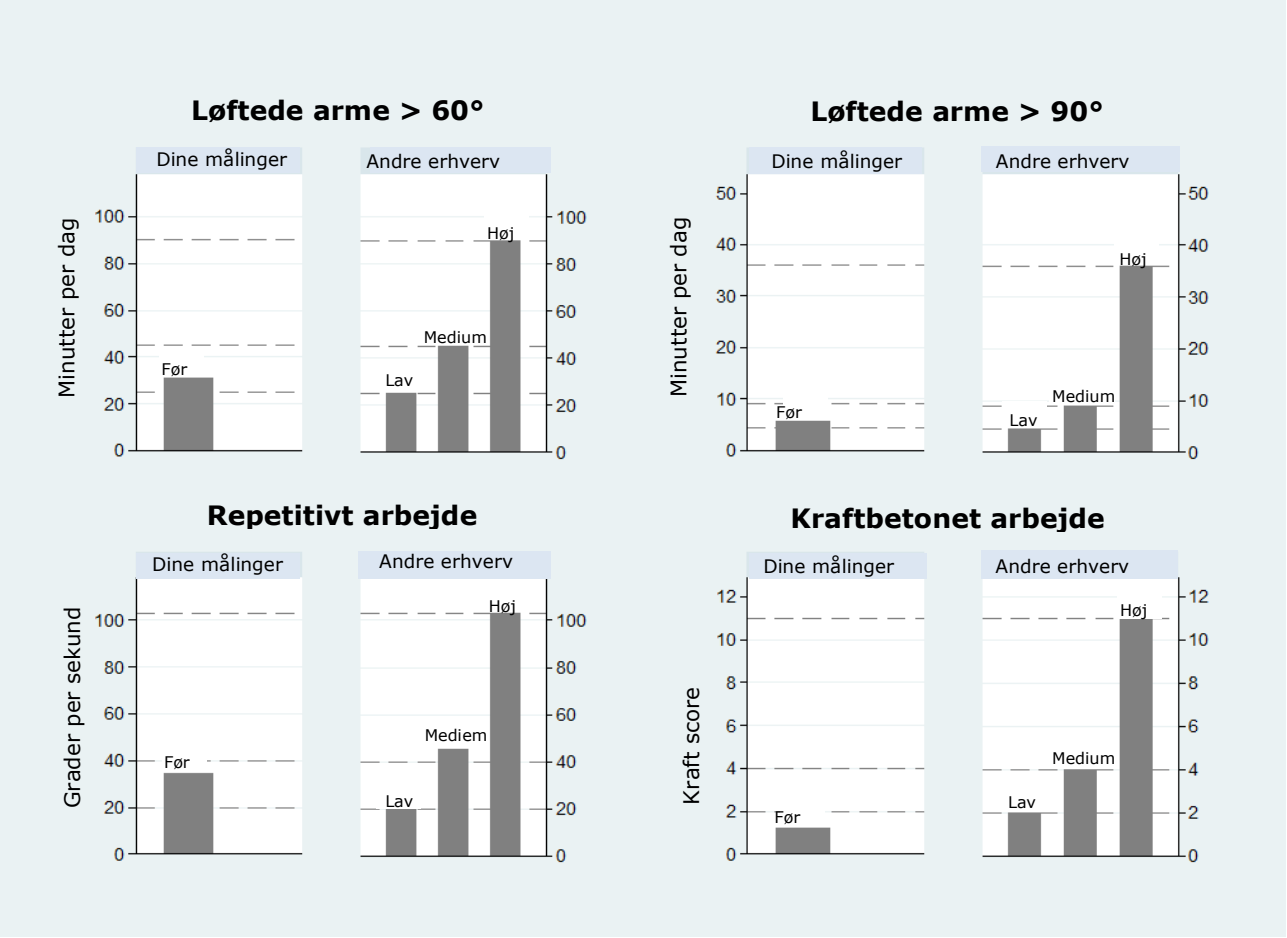
- Planlæg og tilrettelæg arbejdet fx bestil og benyt emner som vejer mindre
- Tekniske løsninger fx lift, kran, hejsespil og lignende udstyr til at håndtere tunge genstande
- Vær flere om de tungeste løft

Første feedback brev

Kære xxxx,

Efter dit første møde har du i 1 til 5 arbejdsdage fået din arbejdsmæssige skulderbelastninger målt med en Axivity og du har udfyldt en dagbog.

Baseret på dine målinger og dagbogen, kan vi se at du medium eksponeret I forhold til arbejde med løftede arme (> 60° and > 90°) og repetitivt arbejde, samt lavt eksponeret i forhold til kraftbetonet arbejde. Hvis du har spørgsmål hertil, er du meget velkommen til at kontakte os.



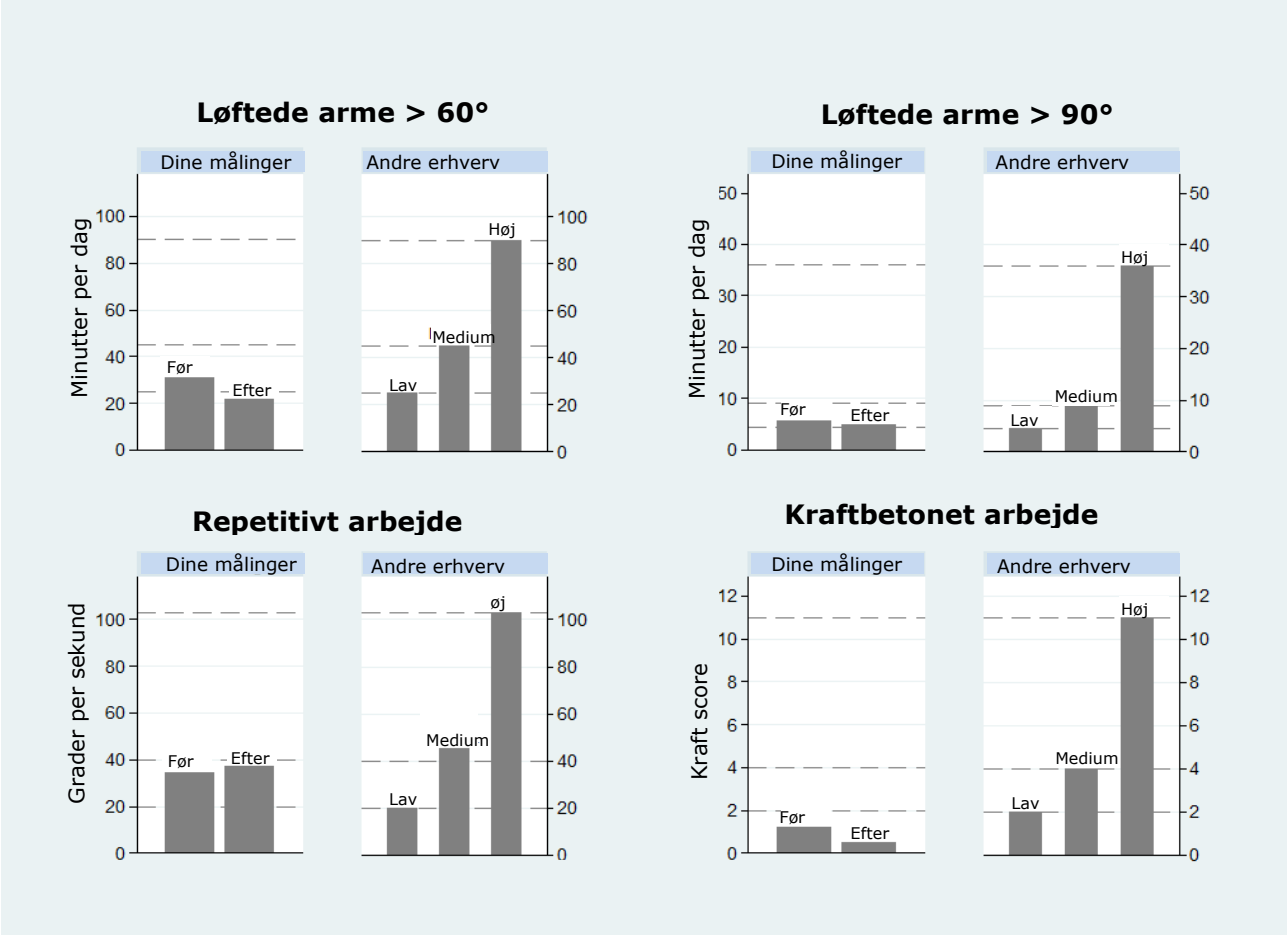
Andet feedback brev

Kære xxxx,

Tak for din deltagelse i projektet "Reduktion af skulderbelastende arbejde og skulderbelastninger"

Vi har nu analyseret data fra din anden Avivity måling og dagbog. Figuren nedenfor viser dine resultater. Du kan sammenligne din anden måling med din første måling (før og efter)

Du er velkommen til at kontakte Jeanette Trøstrup, hvis du har spørgsmål hertil.
(telefon 2475 9153; eller e-mail: jeatro@rm.dk).



Manual til superviseret træning

Den superviserede træning varetages af de kommunale fysioterapeuter. Til hvert cafe-møde er der afsat cirka én time til træningsvejledning og supervision.

Registrering af træning
I samarbejde med deltageren registrer den kommunale fysioterapeut første træningssession i træningsdagbog. Det er vigtigt at fysioterapeuten viser, hvordan træningsdagbogen udfyldes korrekt.

Sådan foregår den superviserede træning:
1. Den kommunale fysioterapeut (eller Jeanette Trøstrup) udlever træningselastikker samt BandCizer-sensor til alle deltagere ved første cafemøde. Hver deltager modtager 2 meter Thera-Band latex fri i hhv. gul, rød og grøn (Ved behov kan der desuden udleveres en blå og/eller en sort elastik).
2. Den kommunale fysioterapeuten demonstrerer hver øvelse, og deltageren afprøver hver øvelse et par gange.
3. Deltageren bedes udfører øvelserne (se nedenfor). Det pointeres, at alle øvelser skal udføres med god kontrol.
4. Deltageren instrueres i hjemmebrug af Bandcizer-sensoren.
5. Deltageren instrueres i hjemmebrug af træningsdagbogen, hvor antal gentagelser pr sæt noteres og vægtmodstand (elastikmodstand) noteres. Der er ikke afsat plads til hhv. blå og sort elestik i træningsdagbogen, men den kommunale fysioterapeut skal tilføje, hvis en blå eller stort elastik udleveres.

Sådan skal der instrueres i træning:
- De dynamiske øvelser (øvelse 2-4) skal udføres i et roligt og kontrolleret tempo: De udføres på tælling fra 2 i både koncentrisk og ekscentrisk fase.
- Alle deltagere skal starte med "Let sværhedsgrad".
- Når deltageren, med god kontrol og uden provokation af smerter, kan udføre 3 sæt med 15 gentagelser af øvelsen progredieres: Først ved at øge elastikstyrken og derefter ved at gå til øvelsens næste niveau.
- Under træning kan der forventes ømhed i skulderen. Dette er helt normalt. MEN hvis kendte smerter forværres, og smerterne ikke falder tilbage til det niveau, de var før træningsstart (indenfor max 1 time), skal deltageren gå ét niveau tilbage.
- Alle øvelserne skal udføres for begge skuldre.

Anbefalinger der gives til deltagerne om træningen:
Se hvad der står i træningsprogrammet, som udleveres til deltagerne. Se under "VEJLEDNING til hjemmetræningen".
- Øvelserne skal udføres ved 3-4 gange ugentlig som hjemmetræning gennem hele interventionsperioden (2-3 måneder), samt superviseret ved de 3 café-møder. Det anbefales desuden, at øvelserne bliver gennemført frem til follow-up tidspunktet (dvs. 3 måneder efter sidste café-møde).
- BandCizeren skal kun benyttes i interventionsperioden (herefter skal den returneres til Jeanette Trøstrup).
- Fysioterapeuten opfordrer deltagen til at finde ét tidspunkt på dagen, hvor det er lettest at huske at udføre øvelserne. Det kan fx være om morgenen lige inden tandbørstningen, eller om aftenen når aftensmad og praktiske ting er klaret derhjemme.
- Hvis deltageren har mulighed for at udføre øvelserne foran et spejl, opfordreres han/hun dertil, da han/hun herved bedre kan se, om øvelserne udføres korrekt.
- Varigheden af hjemmetræningen forventes at være cirka 15 min pr. gang.
- Træningen må gerne deles op i flere perioder om dagen, så deltageren fx træner øvelse 1 og 2 om morgenen og øvelse 3-4 til middag.

1 Klinisk skulderundersøgelse

Projektdeltager (navn) _____Deltager ID ___ ___ ___ ___ ___ ___ ___ ___
Dato: __ __ / __ __ - __ __ __ __ Fysioterapeutens initialer: ___ ___ ___

Anamnese

Hvor længe har smerterne stået på? (uge, mdr, år) _____

Er smerterne opstået som følge af traume: □ Nej
□ Ja

Andre symptomer: □ Nej
□ Ja, hvilke: vægttab /vejrtrækningsbesvær / hoste / opspyt / feber / svimmelhed/ kvalme / hovedpine / træthed

Aktuelle symptomer: nakke/skulderblad/skulder/overarm/albue/underarm/hånd hø/ve

Smerter: konstante/intermitterende/natlige _____

Hvad forværrer/forbedrer: _____

Smertestillende medicin: _____

Anden behandling: _____

Erhverv/sport/fritid: _____

Øvrige sygdomme: _____

Andet:_____

Undersøgelsesfund

Inspektion	**Hø**	**Ve**
Atrofi	□ Nej □ Ja, lokaliseret: □ Infraspinatus □ Supraspinatus □ Deltoideus □ Andet, beskriv:_____	□ Nej □ Ja, lokaliseret: □ Infraspinatus □ Supraspinatus □ Deltoideus □ Andet, beskriv:_____
Malalignment af skulder	□ Nej □ Ja, malalignment:_____	□ Nej □ Ja, malalignment:_____

Col. cerv.	**Hø**		**Ve**	
Bevægelighed	□ Normal	□ Nedsat □ Smerter Beskriv:_____	□ Normal	□ Nedsat □ Smerter Beskriv:_____
Foramen komp.test	□ Neg	□ Pos	□ Neg	□ Pos

Skulder	**Hø**		**Ve**	
Sc-hum rytme	□ Ingen scapula dyskinesi □ Scapula dyskinesi, beskriv:_____		□ Ingen scapula dyskinesi □ Scapula dyskinesi, beskriv:_____	
Smertebue	□ Neg □ Pos: □ 60-120° og/eller □ >120°		□ Neg □ Pos: □ 60-120° og/eller □ >120°	
AROM/PROM	□ AROM	□ PROM	□ AROM	□ PROM
Flex:	_____°	_____°	_____°	_____°
Abd:	_____°	_____°	_____°	_____°
Urot:	_____°	_____°	_____°	_____°
Irot:	□ Skulderblad	_____°	□ Skulderblad	_____°
	□ TH 12	_____°	□ TH 12	_____°
	□ Talje	_____°	□ Talje	_____°
	□ SI-led	_____°	□ SI-led	_____°
	□ Balle	_____°	□ Balle	_____°
	□ Lår	_____°	□ Lår	_____°

Palpation	**Hø**		**Ve**	
Ømhed	□ Nej		□ Nej	
	□ Ja, lokaliseret:	□ Sulcus □ Sternoclav-led □ AC-led □ GH-led □ Muskulatur: Trapez / levator scapula / infraspin. / suprapin. / pec.major / regio nuchae □ Anterolat hjørne af acromion	□ Ja, lokaliseret:	□ Sulcus □ Sternoclav-led □ AC-led □ GH-led □ Muskulatur: Trapez / levator scapula / infraspin. / supraspin. / pec. major / regio nuchae □ Anterolat hjørne af acromion

Kraftnedsættelse	**Hø**		**Ve**	
Elev/flex	□ Nej	□ Ja	□ Nej	□ Ja
Abd/add	□ Nej	□ Ja	□ Nej	□ Ja
Urot	□ Nej	□ Ja	□ Nej	□ Ja
Irot	□ Nej	□ Ja	□ Nej	□ Ja
Smerte ved bevægelse mod modstand	**Hø**		**Ve**	
Flex/ext	□ Nej	□ Ja	□ Nej	□ Ja
Abd/add	□ Nej	□ Ja	□ Nej	□ Ja
Urot	□ Nej	□ Ja	□ Nej	□ Ja
Irot	□ Nej	□ Ja	□ Nej	□ Ja
Specifikke tests	**Hø**		**Ve**	
Jobe's	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Hawkins	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Hawkins modificeret	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Neer's	□ Neg.	□ Pos.	□ Neg.	□ Pos.
O´Brien	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Cross over	□ Neg.	□ Pos.	□ Neg.	□ Pos.
SAT	□ Neg.	□ Pos.	□ Neg.	□ Pos.
SRT	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Tests som evt. udføres				
Yergason	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Apprehension	□ Neg.	□ Pos: _____°	□ Neg.	□ Pos: _____°
Relocation	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Sulcus	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Belly Pres	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Hornblower's	□ Neg.	□ Pos.	□ Neg.	□ Pos.
Evt. kommentar til tests:				

Kategorisering

□ SIS
□ Muskeløhmed
□ Frossen skulder
□ RC-ruptur
□ Mistanke om nerve afficering
□ AC-leds problematik
Instabilitet, betinget af:
□ Hypermobilitet
□ Traumatisk
□ Andet, skriv:_____

Plan

□ Træning
□ Ikke træning
□ Rådgivning om at søge egen læge

Kommentar

_____
_____
_____

Skulder-Café: Program for 1. møde

- Årsager til skuldersmerter
- Anatomi og biomekanik
- Smerter og øvelser
- Skulderundersøgelse
- Måling af skulderbelastninger

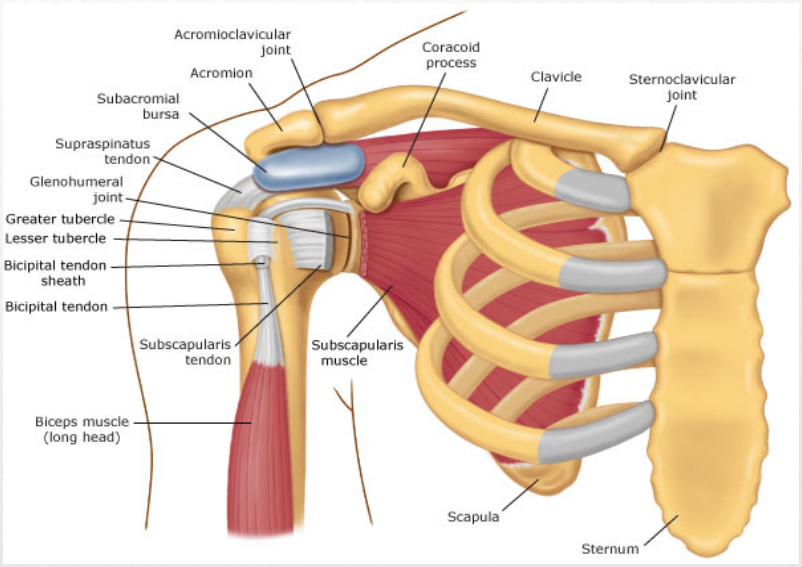
1

Årsager til skuldersmerter

- Alder, genetik, livsstil, arbejdsbelastninger
- Forskellige typer væv kan være smertegivende: led, muskler/sener, forkalkninger, slimsæk
- Muskelstabilitet og holdning omkring skulderen/skulderblad/øvre ryg

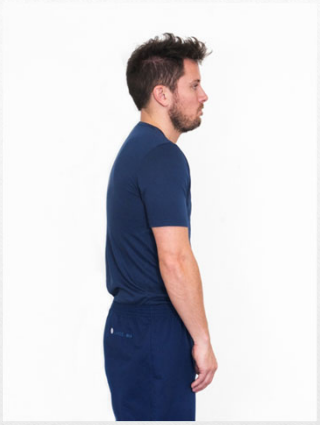
2

Skulderens anatomi



3

Kropsholdning



4

Smerter og øvelser

- De kendte smerter må ikke fremprovokeres eller forværres undervejs eller efter øvelser
- Ømhed i muskulaturen omkring skulderen er naturligt og forventeligt

5

Skulderundersøgelsen

- **Formål:**
- Grov-screening af jeres skulderproblem
- Sikre os, at I kan deltage i projektet
- Give kort individuel vejledning

6

Vejledning til hjemmetræningen

- Du skal træne 3-4 gange om ugen
- Træningen må gerne deles op i flere perioder om dagen
- Kropsholdningen (øvelse 1) skal du opretholde, mens du laver øvelse 2, 3 og 4.

7

Sværhedsgrader af øvelser

3 sværhedsgrader: let, middel og høj (øvelse 2, 3 og 4)
Start med let sværhedsgrad.

Du skal udføre så mange gentagelser, du kan.
Når du kan udføre > 3 x 15 gentagelser med en god kontrol og uden forværring af skuldersmerter → øge elastikstyrken.

Elastik farverne indikerer elastikkens styrke. Det er ikke sikkert, at du er på samme niveau ved hver øvelse.
Udfør øvelserne i roligt og kontrolleret tempo.

8

Smerter og ømhed under og efter træning

- Når du træner, kan du undervejs forvente ømhed i dine skuldermuskler.
- Hvis dine kendte skuldersmerter forværres og hvis smerterne ikke falder tilbage til startniveau (indenfor 1 time) træner du måske ved for højt niveau.
  - ➢ Gå derfor ét niveau tilbage.

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Baggrund | Axivity | Påsætning | Dagbog | Returnering

Belastninger i arbejde

Skulderbelastning:

- Arbejde med højtløftede arme
- Repetitive skulderbevægelser
- Kraftbetonede arbejdsfunktioner
- Håndarm-vibrerende værktøj

Måling af skulderbelastning:

- Via måleapparat Axivity
- 5 arbejdsdage
- Udfyldelse af dagbog

10

Baggrund | **Axivity** | Påsætning | Dagbog | Returnering

Hvordan måles skulderbelastning

Cuela-system | Inklinomter | Axivity

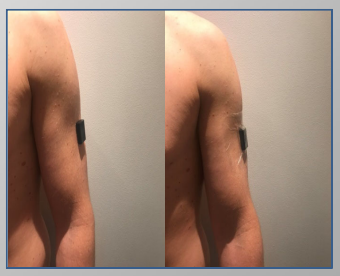
11

Baggrund | Axivity | **Påsætning** | Dagbog | Returnering

Påsætning og forholdsregler

Påsætning:

- Påsætning ca. 1-2 min
- Sættes under m. deltoideus via 2 stk. tape
- 5 arbejdsdage
- 24 timers målinger



Forholdsregler:

- Ikke gå i svømmehal
- Arbejd som du plejer!!!!
- Minimal risiko for kløe

12

Baggrund | Axivity | Påsætning | **Dagbog** | Returnering

Dagbog

Udfyldelse:

- Udfyld dagbog for hver arbejdsdag
- Dagbog omkring:
  - Mødetider
  - Kaffepause
  - Arbejdsopgaver
  - Kraftbetonede arbejdsfunktioner

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Arbejdsmiljø og Intelligent sundhedsfremme

Skulder-café
Program for 2. møde

Program:

- Sammenhænge mellem arbejdsmiljøbelastninger og skuldergener.
- Arbejdsmiljøforbedringer som kan reducere arbejdsrelaterede skulderbelastninger.
- Virksomhedsbesøgene – hvad og hvordan! Tilbud om virksomhedsbesøg og tilmelding.

Oplæg, debat og gruppearbejde. 45 minutter.

14

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Arbejdsmiljø og Intelligent sundhedsfremme

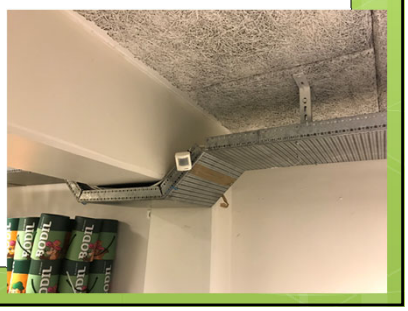
Skulderbelastende arbejde

1. Hvilke arbejdsopgaver er skulderbelastende i mit arbejde?

2. Hvad kan jeg selv gøre for at mindske mine skuldergener?

3. Hvad kan arbejdspladsen gøre for at undgå nedslidning af medarbejdere?

4. Hvad vil jeg gerne have hjælp til?



15

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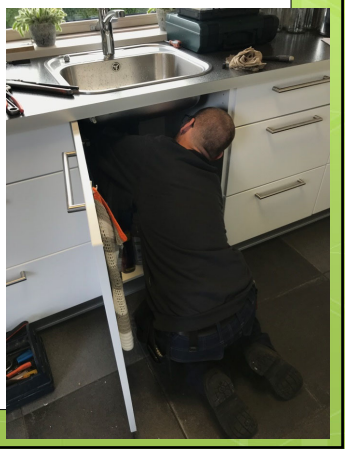
Arbejdsmiljø og Intelligent sundhedsfremme

Hvad er skulderbelastende arbejde?

Følgende forhold er skulderbelastende:

- Arbejde med højt løftede arme.
- Ensidigt gentagne bevægelser (EGA).
- Kraftbetonede arbejdsfunktioner (løft, bæring, træk, skub).
- Vibrationsudsættelser.



16

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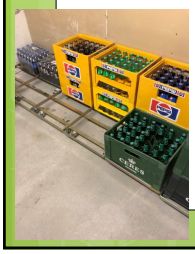
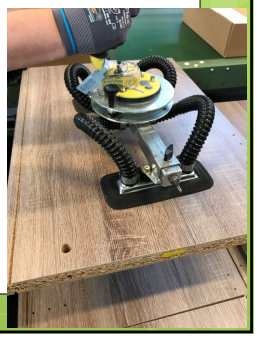
Arbejdsmiljø og Intelligent sundhedsfremme

Reduktion af skulderbelastninger

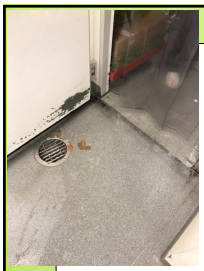
Overordnet går vi efter at:

- Nedsætte belastningen på skulderen i arbejdet (undgå løftede arme, mindre kraftanvendelse, undgå EGA, undgå vibrationer).
- Nedsætte tiden i belastende arbejdsopgaver.





17



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Arbejdsmiljø og Intelligent sundhedsfremme

Reduktion af skulderbelastninger

Forsøg at reducere belastninger fra "højt løftede arme", "ensidigt gentagne bevægelser", "kraftbetonet arbejde" og "vibrationer".

Det kræver ofte ændringer på flere niveauer:

- Organisatoriske indsatser.
- Pladsforhold optimeres.
- Tekniske hjælpemidler.
- Indretning af arbejdsområdet.
- Instruktion og oplæring.

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Arbejdsmiljø og Intelligent sundhedsfremme

Arbejdsmiljøloven

Arbejdsgiveren

§ 15. Arbejdsgiveren skal sørge for, at arbejdsforholdene er sikkerheds- og sundhedsmæssigt fuldt forsvarlige.

Lokallederen

§ 26. Arbejdslederen skal medvirke til, at arbejdsforholdene sikkerheds- og sundhedsmæssigt er fuldt forsvarlige inden for det arbejdsområde, som lederen har. Han skal herunder påse, at de foranstaltninger, der træffes for at fremme sikkerhed og sundhed, virker efter deres hensigt.

Ansatte

§ 27. De ansatte skal deltage i samarbejdet om sikkerhed og sundhed.

§ 28. De ansatte skal medvirke til, at arbejdsforholdene sikkerheds- og sundhedsmæssigt er fuldt forsvarlige inden for deres arbejdsområde, herunder at de foranstaltninger, der træffes for at fremme sikkerhed og sundhed, virker efter deres hensigt.

Uddrag fra lov om arbejdsmiljø lov nr. 784 fra 11/10 1999. Gælder stadig 17/6 2003.

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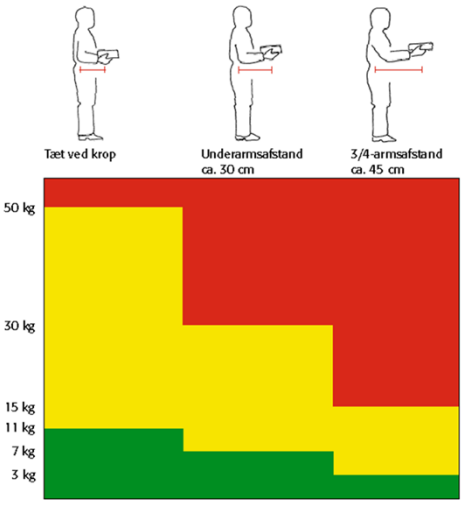
Arbejdsmiljø og Intelligent sundhedsfremme

Vurdering af løft



- Klart sundhedsskadeligt
- Risiko for sundhedsskade - kræver helhedsvurdering
  - ✓ *Arbejdsstillinger/-bevægelser*
  - ✓ *Mulighed for greb*
  - ✓ *Pladsforhold*
  - ✓ *Organisering*
  - ✓ *Uventede hændelser*
  - ✓ *Tekniske hjælpemidler*
- Normalt ikke sundhedsskadeligt

Kilde: At-vejledning. Arbejdets udførelse D.3.1. Løft, træk og skub. September 2005.

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Vurdering af træk og skub med tekniske hjælpemidler

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Arbejdsmiljø og Intelligent sundhedsfremme

Følgende elementer skal indgå i vurderingen:
– Transportmateriellets design (Transportmateriellet skal passe til de byrder, der skal transporteres, og stedet, hvor transporten skal foregå.)
– Transportmateriellets vedligeholdelse
– Underlagets beskaffenhed
– Pladsforhold
– Synsforhold
– Uforudsete hændelser
– Vægt og stabilitet af materiel og byrde/læs (under 200 kg sjældent et problem ved kortvarig transport på jævnt, vandret, kørefast underlag og under gode pladsforhold. Er totalvægten på mellem 200 og 500 kg, kan det være kritisk, mens totalvægte på 500 kg eller derover næsten altid vil være problematiske)
– Hastigheds- og retningsændringer
– Arbejdsmetode (træk/skub, byrden foran/bag ved personen)
– Arbejdsstillinger og –bevægelser (Ved skrå arbejdsstillinger er der risiko for at glide, snuble, falde og miste kontrollen. En skrå stilling af kroppen vil ofte være tegn på, at kraftkravet er for stort)
– Arbejdets frekvens og varighed.

Kilde: AT-vejledning arbejdets udførelse – D.3.1 Løft, træk og skub. AT, september 2005

21

Ensidigt gentaget arbejde (EGA)

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Arbejdsmiljø og Intelligent sundhedsfremme

Der er tale om **ensidigt, gentaget arbejde (EGA)**, når ensartede arbejdsbevægelser gentages med stor hyppighed en væsentlig del af arbejdsdagen som led i det daglige arbejde. Arbejdet vurderes ikke som ensidigt, gentaget, hvis de ensartede bevægelser udføres mindre end ca. ti pct. sammenlagt af den tid, det pågældende arbejde udføres. Derimod kan arbejdet godt være ensidigt, belastende, som det er tilfældet ved fx overvågningsarbejde og langturschaufførarbejde.

Gener og helbredsskader efter EGA er især knyttet til nakke, skuldre og arme.
Hovedelementerne i vurderingen af EGA er:
– Varigheden af de enkelte arbejdscykluser eller procentdelen af cyklustiden/ observationstiden med gentagne bevægelser
– Varigheden af arbejdet pr. dag/pr. uge
– Tilstedeværelsen af forværrende faktorer.

Arbejdet klassificeres som høj- eller lavrepetitivt ud fra enten cyklustiden eller procentandel af cyklustid/observationstid med ensartede bevægelser.

Kilde: AT-vejledning arbejdets udførelse – D.3.2 Ensidigt, belastende arbejde og ensidigt, gentaget arbejde. AT, August 2002

22

Model til kortlægning af EGA

Højrepetitivt: Hvis arbejdscyklustiden er mindre end 30 sek. eller hvis ensartede bevægelser gentages mere end 50 pct. af arbejdscyklustiden.

Lavrepetitivt: Hvis arbejdscyklustiden er mellem 30 sek. og 5 min. eller hvis ensartede bevægelser gentages mellem 50 pct. og 10 pct. af arbejdscyklustiden.

Tid: Ensidigt, gentaget arbejde, der udføres mere end halvdelen af arbejdstiden eller tre-fire timer dagligt, skal altid kortlægges og vurderes. Det vurderes, om der arbejdes under tidspres.

Forværrende faktorer

Kraftanvendelse: Fx i forbindelse med brug af håndværktøj, betjeningshåndtag, håndtering eller bearbejdning af arbejdsemner eller materialer.

Arbejdsstilling: Uhensigtsmæssigt ergonomisk indrettet arbejdsplads og/eller fastlåst arbejdsstilling uden mulighed for variation.

Opmærksomhed/ koncentration, syns- eller hørekrav: Fx ved præcisionsarbejde eller sorteringsarbejde.

Handlemuligheder: Lille mulighed for påvirkning af arbejdet, herunder arbejdsbetingelser, tempo, indhold, arbejdsmetoder og arbejdsteknik.

Kilde: AT-vejledning arbejdets udførelse – D.3.2 Ensidigt, belastende arbejde og ensidigt, gentaget arbejde. AT, August 2002

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Forebyggelse af arbejdsrelateret besvær

Indsatser rettes mod:

- Arbejdsstedets indretning
- Tekniske hjælpemidler
- Manuel håndtering
- Arbejdets tilrettelæggelse
- Personlige værnemidler
- Forebyggelse af problemer i det psykiske arbejdsmiljø

https://www.bam-bus.dk/
http://www.bygergo.dk/faggrupper/

Kilde: AT-vejledning arbejdets udførelse – D.3.4 Arbejdsrelateret muskel- og skelet besvær. AT, maj 2005

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ID-nummer: |_|_|_|_|_|_|

Reduktion af skulderbelastende arbejde og skulderproblemer

Spørgeskema A

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

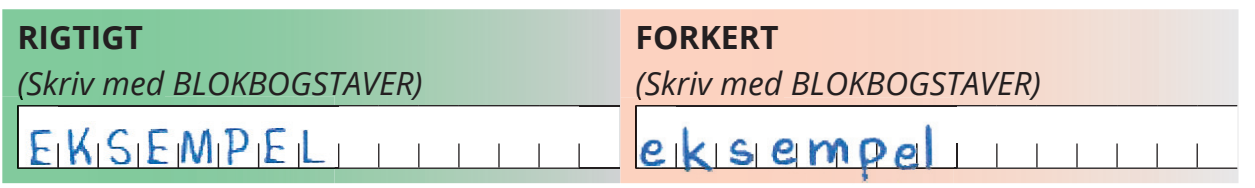
VEJLEDNING

Du kan besvare spørgeskemaet ved at udfylde dette papirskema eller ved at svare online.

Hvis du vælger at svare online, skal du benytte det link, som du har fået tilsendt. Ønsker du at besvare online, men har ved en fejl ikke modtaget et link, bedes du sende en mail herom til: jeatro@rm.dk (Jeanette Trøstrup).

Sådan udfylder du spørgsmålet

Vi beder dig om at svare på spørgsmålene efter de anvisninger, der er angivet i spørgeskemaet. Brug venligst en **sort** eller **blå kuglepen**. Sæt kryds og skriv tal så de er nemme at tolke, som vist i nedenstående eksempler:

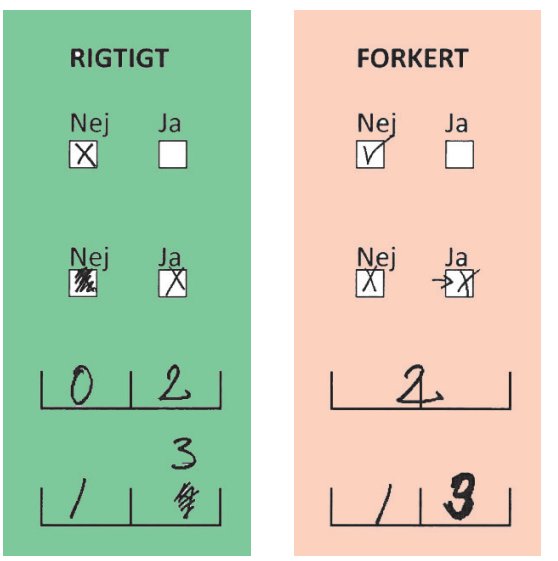


Sæt tydelige X

Hvis et felt er **udfyldt forkert**, skraveres det (pågældende kasse), og krydset sættes det rigtige sted

Tallene skrives i felterne

Tallene rettes ved at overskrive det forkerte tal og skrive det rigtige henover



Nogle af spørgsmålene i dette skema har du besvaret før. Vi vil bede dig svare igen, for at vi kan følge dit forløb over tid.

Hvis du har spørgsmål om spørgeskemaet
Du er velkommen til at stille spørgsmål om spørgeskemaet til:

Jeanette Trøstrup, Regionshospitalet Silkeborg på tlf. 24 75 91 53 (hverdage 9-15) eller på e-mail: jeatro@rm.dk.

Dato

1. Dato for udfyldelse af spørgeskemaet

Skriv dato:

dag	måned	år

Arbejde

2. Hvordan er din <u>nuværende</u> arbejdsevne, sammenlignet med da den var bedst?
Forestil dig at din arbejdsevne er 10 point værd, når den er bedst. Hvor mange point vil du give din nuværende arbejdsevne? 0 betyder, at du ikke kan arbejde for tiden.

Sæt ét X.

Ude af stand til at arbejde	0	1	2	3	4	5	6	7	8	9	10	Bedste arbejdsevne
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

3. Hvor stor indflydelse har du normalt på tilrettelæggelsen og udførelsen af dit arbejde?

Sæt ét X.

Meget stor	Ret stor	Moderat stor	Ikke så stor	Ret lille	Meget lille
☐	☐	☐	☐	☐	☐

4. Hvor krævende synes du alt i alt, dit arbejde er?

Sæt ét X.

Særdeles krævende	Meget krævende	Ret krævende	Noget krævende	Ikke så krævende	Meget lidt krævende
☐	☐	☐	☐	☐	☐

5. Hvilken form for løn får du for tiden?

Sæt ét X.

	Nej	Ja
Fast løn	☐	☐
Fast løn med mulighed for overarbejdsbetaling	☐	☐
Gruppebonus	☐	☐
Enkeltmandsbonus	☐	☐
Gruppeakkord	☐	☐
Enkeltmandsakkord	☐	☐
Anden	☐	☐

6. Hvis du har problemer på dit arbejde, kan du så få den nødvendige hjælp og støtte fra din ledelse?

Sæt ét X.

Altid	Næsten altid	Som regel	Ofte	Af og til	Sjældent/aldrig
☐	☐	☐	☐	☐	☐

7. Hvis du har problemer på dit arbejde, kan du så få den nødvendige hjælp og støtte fra dine kolleger?

Sæt ét X.

Altid	Næsten altid	Som regel	Ofte	Af og til	Sjældent/aldrig
☐	☐	☐	☐	☐	☐

8. Medfører dit arbejde i løbet af en typisk arbejdsdag, at du ...

Sæt ét X i hver linje.

	Nej	> 0 min til < ½ time	½ time til < 1 time	1 time til < 2 timer	2 til < 4 timer	Mindst 4 timer
Arbejder med én eller begge **albuer** løftet over skulderhøjde?	☐	☐	☐	☐	☐	☐
Udfører de samme bevægelser med **hænder** eller **arme** flere gange i minuttet fx ved samlebånd? Se bort fra computerarbejde.	☐	☐	☐	☐	☐	☐
Løfter genstande på **10 kg** eller derover med hænderne? (10 kg er cirka som en fyldt gulvspand med vand, én kasse med tomme ølflasker eller et 1-årigt barn).	☐	☐	☐	☐	☐	☐
Bruger vibrerende værktøj, som du holder med hænderne fx pladevibrator eller vinkelsliber?	☐	☐	☐	☐	☐	☐

9. Hvor fysisk anstrengende er dit arbejde generelt for dine arme?

Skriv ét tal.

Ved vurdering af anstrengelse bedes du skrive det tal, der svarer til, hvor tungt og belastende du oplever, at arbejdet **generelt** er for dine arme.

0 betyder, at du ikke føler nogen som helst anstrengelse i armene.

10 er det mest anstrengende, du nogensinde oplever for dine arme.

Skriv tal:

0	*Overhovedet ingen*	
0,3		
0,5	*Ekstremt svag*	*Knapt mærkbar*
0,7		
1	*Meget svag*	
1,5		
2	*Svag*	*Let*
2,5		
3	*Moderat*	
4		
5	*Stærk*	*Tung*
6		
7	*Meget stærk*	
8		
9		
10	*Ekstremt stærk*	*"Maksimal"*
11		
∑		
•	*Absolut maksimum*	*Højest mulige*

10. Har du nogensinde i dit liv skiftet arbejde, arbejdsmetoder eller arbejdsopgaver helt eller delvist på grund af skulderproblemer?

Nej	☐ → Gå til spørgsmål 11
Ja	☐ → Besvar nedenstående spørgsmål

Hvis ja:

Hvilke arbejdsmæssige ændringer er der sket?

Sæt ét eller flere X.

Jeg har ikke noget arbejde nu	☐
Jeg har skiftet arbejde	☐
Jeg har skåret ned på min arbejdstid	☐
Jeg undgår visse opgaver	☐
Jeg har ændret mine arbejdsmetoder	☐
Andre ændringer	☐

Skulder

11. I løbet af de sidste 4 uger …
Har du haft problemer med højre og/eller venstre skulder?

Sæt ét X.

Nej	☐
Ja, højre	☐
Ja, venstre	☐
Ja, begge – især højre	☐
Ja, begge – især venstre	☐
Ja, begge – lige meget	☐

De følgende spørgsmål (12 - 26) handler om den skulder, du især har problemer med.

Hvis du har lige store problemer med højre og venstre skulder, bedes du tænke på højre skulder, når du svarer.

12. Hvor længe har du haft dine nuværende skulderproblemer?

Cirka: ☐☐ år og ☐☐ måneder

13. I løbet af de sidste 4 uger …
Hvordan vil du beskrive den <u>værste</u> smerte du har haft i *din skulder*?

Sæt ét X.

Ingen	Mild	Moderat	Svær	Uudholdelig
☐	☐	☐	☐	☐

14. I løbet af de sidste 4 uger …
Har du haft svært ved at tage tøj på, på grund af din skulder?

Sæt ét X.

Intet besvær	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

15. I løbet af de sidste 4 uger …
Har du haft svært ved at komme ind og ud af en bil eller ved at bruge offentlig transport på grund af din skulder?

Sæt ét X.

Intet besvær	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

16. I løbet af de sidste 4 uger …
Har du været i stand til at bruge kniv og gaffel – *på samme tid*?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

17. I løbet af de sidste 4 uger …
Kunne du *selv* klare de daglige indkøb?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

18. I løbet af de sidste 4 uger …
Kunne du bære en bakke med en tallerken med mad gennem et lokale?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

19. I løbet af de sidste 4 uger …
Kunne du børste/rede dit hår med den dårlige arm?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

20. I løbet af de sidste 4 uger …
Hvordan vil du beskrive den smerte, du normalt har haft i din skulder?

Sæt ét X.

Ingen	Mild	Moderat	Svær	Uudholdelig
☐	☐	☐	☐	☐

21. I løbet af de sidste 4 uger …
Kunne du hænge dit tøj op i en garderobe, *med din dårlige arm*?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

22. I løbet af de sidste 4 uger …
Har du været i stand til at vaske og tørre dig selv under begge arme?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

23. I løbet af de sidste 4 uger …
Hvor meget har smerten fra din skulder forstyrret dit normale arbejde (inkl. husligt arbejde)?

Sæt ét X.

Slet ikke	En lille smule	Moderat	Meget	Totalt
☐	☐	☐	☐	☐

24. I løbet af de sidste 4 uger …
Har du været besværet af smerter i din skulder i din seng om natten?

Sæt ét X.

Ingen nætter	1 til 2 nætter	Nogle nætter	De fleste nætter	Hver nat
☐	☐	☐	☐	☐

25. Hvilken grad af smerter har du i din skulder i dag, når du sidder *med armen helt i ro*?

Sæt ét X.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Værst tænkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

26. Inden for de sidste 24 timer…
Hvad var den værste grad af smerter i din skulder *ved brug af armen*?

Sæt ét X.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Værst tænkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

27. De følgende udsagn handler om, hvor meget fysiske aktiviteter som at bukke sig, løfte, gå eller køre påvirker eller ville påvirke *dine* skuldersmerter.

Sæt ét X i hver linje ved det tal, der passer bedst til din opfattelse af udsagnet.

	Helt uenig			Hverken uenig eller enig			Helt enig
Fysisk aktivitet forværrer mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Fysisk aktivitet kan skade min skulder	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg burde ikke udføre fysiske aktiviteter, som (måske) forværrer mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg kan ikke udføre fysiske aktiviteter, som (måske) forværrer mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

28. De følgende udsagn handler om, hvordan dit sædvanlige arbejde påvirker eller ville påvirke *dine* skuldersmerter.

Sæt ét X i hver linje ved det tal, der passer bedst til din opfattelse af udsagnet.

	Helt uenig			Hverken uenig eller enig			Helt enig
Mine smerter opstod som følge af mit arbejde eller ved en ulykke på mit arbejde	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde har forværret mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde er for hårdt for mig	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde forværrer eller ville forværre mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde kan skade min skulder	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg burde ikke udføre mit sædvanlige arbejde med mine nuværende smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg tror ikke, at jeg er vendt tilbage til mit sædvanlige arbejde inden for 3 måneder	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

29. I løbet af de sidste 4 uger …
Hvor ofte har du på grund af dine skulderproblemer taget smertestillende medicin?

Flere gange om dagen	1 gang om dagen	2-6 gange om ugen	1-4 gange om måneden	Mindre end 1 gang om måneden	Aldrig
☐	☐	☐	☐	☐	☐

Helbred

Spørgsmål 30 - 35 handler om dine symptomer og din evne til at udføre forskellige aktiviteter inden for de sidste 7 dage.

Hvis du ikke har udført en bestemt aktivitet inden for de sidste 7 dage, bedes du angive det svar, du mener, vil dække bedst.

Det er uden betydning, hvilken hånd eller arm du anvender til at udføre aktiviteten; dit svar skal afspejle din evne til at udføre selve handlingen, uanset hvordan du gør det.

30. Vurder venligst, hvordan din evne til at udføre følgende handlinger har været i den forløbne uge.

Sæt ét X i hver linje.

	Ikke vanskeligt	Lidt vanskeligt	Noget vanskeligt	Meget vanskeligt	Umuligt
Åbne et (marmelade) glas med stramt låg	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre tungt husarbejde (fx vaske vægge, vaske gulve)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Bære en indkøbspose eller en mappe	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vaske dig selv på ryggen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Bruge en kniv til at skære mad ud	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Fritidsaktiviteter, som sender en vis kraft eller stød gennem din arm, skulder eller hånd (fx golf, slag med hammer, tennis, osv.)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

31. Hvor *vanskeligt* har det været for dig i den forløbne uge, at omgås familie, venner, naboer og grupper pga. din arm, skulder eller hånd?

Sæt ét X.

Slet ikke	Lidt	En del	Temmelig meget	Virkelig meget
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

32. Har du i den forløbne uge været hæmmet i at udføre dit arbejde eller andre gøremål pga. din arm, skulder eller hånd?

Sæt ét X.

Slet ikke hæmmet	Lidt hæmmet	En del hæmmet	Meget hæmmet	Ude af stand til
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

33. Vær venlig at angive sværhedsgraden af følgende symptomer i den forløbne uge.

Sæt ét X i hver linje.

	Ingen	Lidt	En del	Svær	Ekstrem
Smerte i din arm, skulder eller hånd når du laver noget bestemt	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Prikken i din arm, skulder eller hånd	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

34. Hvor vanskeligt har det i den forløbne uge været for dig, at sove pga. smerter i din arm, skulder eller hånd?

Sæt ét X.

Ikke vanskeligt	Lidt vanskeligt	Noget vanskeligt	Meget vanskeligt	Så vanskeligt at det forhindrer mig i at sove
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

35. De følgende spørgsmål drejer sig om påvirkningen af din arbejdsevne pga. din arm, skulder eller hånd (inklusive husarbejde, hvis det er din hovedbeskæftigelse).

Sæt ét X i hver linje.

	Ikke vanskeligt	Lidt vanskeligt	Noget vanskeligt	Meget vanskeligt	Umuligt
Bruge din sædvanlige fremgangsmåde i dit arbejde?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre dit sædvanlige arbejde pga. smerter i din arm, skulder eller hånd	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre dit arbejde så godt, som du gerne ville?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre dit arbejde på den tid du plejer?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

36. Angiv, ved at sætte X i én af kasserne i hver gruppe, hvilke udsagn, der bedst beskriver din helbredstilstand i dag.

Bevægelighed

Jeg har ingen problemer med at gå omkring	☐
Jeg har nogle problemer med at gå omkring	☐
Jeg er bundet til sengen	☐

Personlig pleje

Jeg har ingen problemer med min personlige pleje	☐
Jeg har nogle problemer med at vaske mig eller klæde mig på	☐
Jeg kan ikke vaske mig eller klæde mig på	☐

Sædvanlige aktiviteter
(fx arbejde, studier, husarbejde, familie- eller fritidsaktiviteter)

Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter	☐
Jeg har nogle problemer med at udføre mine sædvanlige aktiviteter	☐
Jeg kan ikke udføre mine sædvanlige aktiviteter	☐

Smerter/ubehag

Jeg har ingen smerter eller ubehag	☐
Jeg har moderate smerter eller ubehag	☐
Jeg har ekstreme smerter eller ubehag	☐

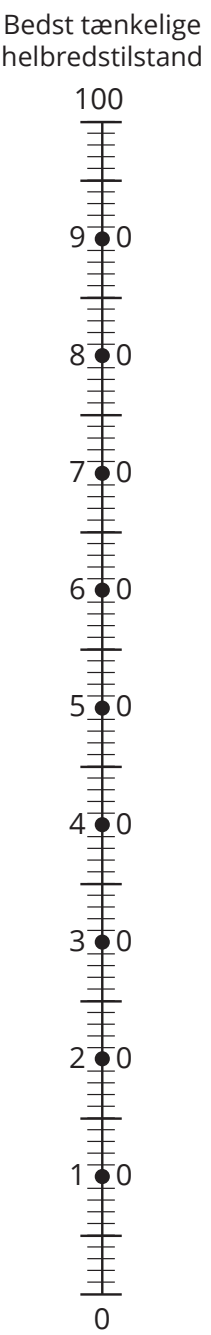
Angst/depression

Jeg er ikke ængstelig eller deprimeret	☐
Jeg er moderat ængstelig eller deprimeret	☐
Jeg er ekstremt ængstelig eller deprimeret	☐

37. Din egen helbredstilstand i dag

For at hjælpe folk med at sige, hvor god eller dårlig en helbredstilstand er, har vi tegnet en skala (næsten ligesom et termometer), hvor den bedste helbredstilstand, du kan forestille dig, er markeret med 100, og den værste helbredstilstand, du kan forestille dig, er markeret med 0.

Vi beder dig angive på denne skala med en tydelig streg i det punkt, hvor du mener din egen helbredstilstand er i dag.



Baggrund

38. Er du højre- eller venstrehåndet?

Sæt ét X.

Højrehåndet	☐
Venstrehåndet	☐
Bruger begge hænder lige godt	☐

39. Ryger du?

Sæt ét X.

Nej, jeg er holdt op	☐
Nej, jeg har aldrig røget	☐
Ja	☐

40. Hvor høj er du?

Angiv i cm.

Hvor høj er du (uden sko)? ⌊___|___|___⌋ cm

41. Hvad vejer du?

Angiv i kg.

Hvad vejer du (uden tøj)? ⌊___|___|___⌋ kg

Tak for din besvarelse

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

ID-nummer: |__|__|__|__|__|__|

Navn: _____

Reduktion af skulderbelastende arbejde og skulderproblemer

Spørgeskema B

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

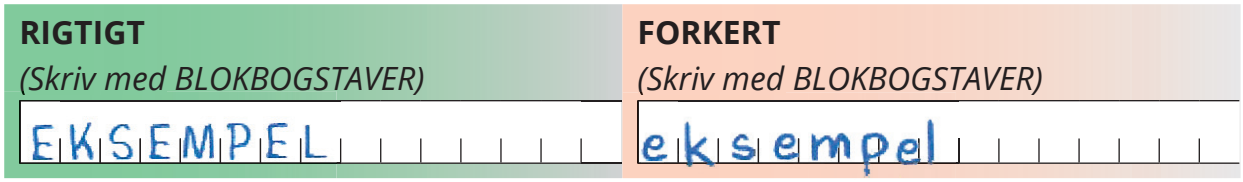
Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

Kære projektdeltager

Det er nu 3 måneder siden, at din deltagelse i skulderprojektet sluttede. Vi vil derfor bede dig udfylde dette spørgeskema

Sådan udfylder du spørgeskemaet

Vi beder dig om at svare på spørgsmålene efter de anvisninger, der er angivet i spørgeskemaet. Brug venligst en **sort** eller **blå kuglepen**. Sæt kryds og skriv tal så de er nemme at tolke, som vist i nedenstående eksempler:

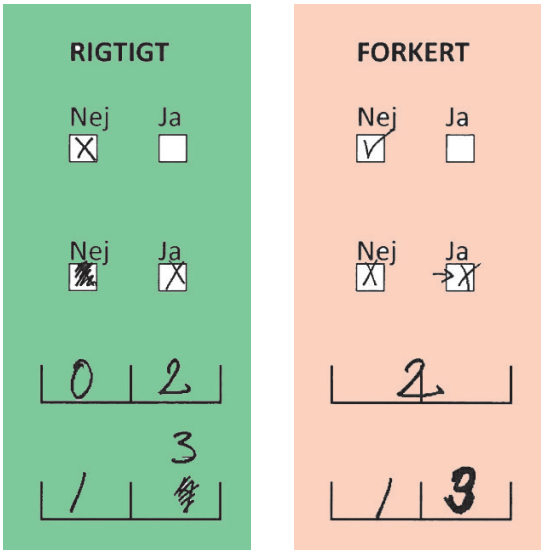


Sæt tydelige X

Hvis et felt er **udfyldt forkert**, skraveres det (pågældende kasse), og krydset sættes det rigtige sted

Tallene skrives i felterne

Tallene rettes ved at overskrive det forkerte tal og skrive det rigtige henover



Nogle af spørgsmålene i dette skema har du besvaret før. Vi vil bede dig svare igen, for at vi kan følge dit forløb over tid.

Hvis du har spørgsmål om spørgeskemaet
Du er velkommen til at stille spørgsmål om spørgeskemaet til:

Jeanette Trøstrup, Regionshospitalet Silkeborg på tlf. 24 75 91 53 (hverdage 9-15) eller på e-mail: jeatro@rm.dk.

Dato

1. Dato for udfyldelse af spørgeskemaet

Skriv dato:

	/	/
dag	måned	år

Arbejde

2. I løbet af <u>de sidste 3 måneder ...</u>
Har du skiftet arbejde, arbejdsmetoder eller arbejdsopgaver helt eller delvist på grund af skulderproblemer?

Sæt ét X.

Nej	☐ → Gå til spørgsmål 3
Ja	☐ → Besvar nedenstående spørgsmål

Hvis ja:

Hvilke arbejdsmæssige ændringer er der sket?

Se bort fra ændringer med hensyn til sygemelding.

Sæt ét eller flere X.

Jeg har ikke noget arbejde nu	☐
Jeg har skiftet arbejde	☐
Jeg har skåret ned på min arbejdstid	☐
Jeg undgår visse opgaver	☐
Jeg har ændret mine arbejdsmetoder	☐
Andre ændringer	☐

3. Hvordan er din <u>nuværende</u> arbejdsevne, sammenlignet med da den var bedst?

Forestil dig at din arbejdsevne er 10 point værd, når den er bedst. Hvor mange point vil du give din nuværende arbejdsevne?
0 betyder, at du ikke kan arbejde for tiden.

Sæt ét X.

Ude af stand til at arbejde	0	1	2	3	4	5	6	7	8	9	10	Bedste arbejdsevne
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Skulder

De følgende spørgsmål (4 - 17) handler om den skulder, du har fået foretaget målinger på, mens du arbejdede.

I løbet af de sidste 4 uger ...

4. Hvordan vil du beskrive den værste smerte du har haft i *din skulder*?

Sæt ét X.

Ingen	Mild	Moderat	Svær	Uudholdelig
☐	☐	☐	☐	☐

5. I løbet af de sidste 4 uger...
Har du haft svært ved at tage tøj på, på grund af din skulder?

Sæt ét X.

Intet besvær	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

6. I løbet af de sidste 4 uger ...
Har du haft svært ved at komme ind og ud af en bil eller ved at bruge offentlig transport på grund af din skulder?

Sæt ét X.

Intet besvær	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

7. I løbet af de sidste 4 uger ...
Har du været i stand til at bruge kniv og gaffel – *på samme tid*?

Sæt ét X.

Ja, let	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

8. I løbet af de sidste 4 uger …
Kunne du *selv* klare de daglige indkøb?

Sæt ét X.

Ja, let	Lidt besvær	Besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

9. I løbet af de sidste 4 uger …
Kunne du bære en bakke med en tallerken med mad gennem et lokale?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

10. I løbet af de sidste 4 uger …
Kunne du børste/rede dit hår med den dårlige arm?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

11. I løbet af de sidste 4 uger …
Hvordan vil du beskrive den smerte, du normalt har haft i din skulder?

Sæt ét X.

Ingen	Mild	Moderat	Svær	Uudholdelig
☐	☐	☐	☐	☐

12. I løbet af de sidste 4 uger …
Kunne du hænge dit tøj op i en garderobe, *med din dårlige arm*?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

13. I løbet af de sidste 4 uger ...
Har du været i stand til at vaske og tørre dig selv under begge arme?

Sæt ét X.

Ja, let	Lidt besvær	Nogen besvær	Meget besvær	Umuligt
☐	☐	☐	☐	☐

14. I løbet af de sidste 4 uger ...
Hvor meget har smerten fra din skulder forstyrret dit normale arbejde (inkl. husligt arbejde)?

Sæt ét X.

Slet ikke	En lille smule	Moderat	Meget	Totalt
☐	☐	☐	☐	☐

15. I løbet af de sidste 4 uger ...
Har du været besværet af smerter i din skulder i din seng om natten?

Sæt ét X.

Ingen nætter	1 til 2 nætter	Nogle nætter	De fleste nætter	Hver nat
☐	☐	☐	☐	☐

16. Hvilken grad af smerter har du i din skulder i dag, når du sidder *med armen helt i ro*?

Sæt ét X.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Værst tænkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

17. Inden for de sidste 24 timer...
Hvad var den værste grad af smerter i din skulder *ved brug af armen*?

Sæt ét X.

Ingen smerter	0	1	2	3	4	5	6	7	8	9	10	Værst tænkelige smerter
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

18. De følgende udsagn handler om, hvor meget fysiske aktiviteter som at bukke sig, løfte, gå eller køre påvirker eller ville påvirke *dine* skuldersmerter.

Sæt ét X i hver linje ved det tal, der passer bedst til din opfattelse af udsagnet.

	Helt uenig			Hverken uenig eller enig			Helt enig
Fysisk aktivitet forværrer mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Fysisk aktivitet kan skade min skulder	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg burde ikke udføre fysiske aktiviteter, som (måske) forværrer mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg kan ikke udføre fysiske aktiviteter, som (måske) forværrer mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

19. De følgende udsagn handler om, hvordan dit sædvanlige arbejde påvirker eller ville påvirke dine skuldersmerter.

Sæt ét X i hver linje ved det tal, der passer bedst til din opfattelse af udsagnet.

	Helt uenig			Hverken uenig eller enig			Helt enig
Mine smerter opstod som følge af mit arbejde eller ved en ulykke på mit arbejde	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde har forværret mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde er for hårdt for mig	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde forværrer eller ville forværre mine smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Mit arbejde kan skade min skulder	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg burde ikke udføre mit sædvanlige arbejde med mine nuværende smerter	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
Jeg tror ikke, at jeg er vendt tilbage til mit sædvanlige arbejde inden for 3 måneder	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Helbred

Spørgsmål 20-25 handler om dine symptomer og din evne til at udføre forskellige aktiviteter inden for de sidste 7 dage.

Hvis du ikke har udført en bestemt aktivitet inden for de sidste 7 dage, bedes du angive det svar, du mener, vil dække bedst.

Det er uden betydning, hvilken hånd eller arm du anvender til at udføre aktiviteten; dit svar skal afspejle din evne til at udføre selve handlingen, uanset hvordan du gør det.

20. Vurder venligst, hvordan din evne til at udføre følgende handlinger har været i den forløbne uge.

Sæt ét X i hver linie.

	Ikke vanskeligt	Lidt vanskeligt	Noget vanskeligt	Meget vanskeligt	Umuligt
Åbne et (marmelade) glas med stramt låg	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre tungt husarbejde (fx vaske vægge, vaske gulve)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Bære en indkøbspose eller en mappe	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vaske dig selv på ryggen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Bruge en kniv til at skære mad ud	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Fritidsaktiviteter, som sender en vis kraft eller stød gennem din arm, skulder eller hånd (fx golf, slag med hammer, tennis, osv.)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

21. Hvor *vanskeligt* har det været for dig i den forløbne uge, at omgås familie, venner, naboer og grupper pga. din arm, skulder eller hånd?

Sæt ét X.

Slet ikke	Lidt	En del	Temmelig meget	Virkelig meget
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

22. Har du i den forløbne uge været hæmmet i at udføre dit arbejde eller andre gøremål pga. din arm, skulder eller hånd?

Sæt ét X.

Slet ikke hæmmet	Lidt hæmmet	En del hæmmet	Meget hæmmet	Ude af stand til
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Vær venlig at angive sværhedsgraden af følgende symptomer i den forløbne uge.

Sæt ét X i hver linje.

23. Smerte i din arm, skulder eller hånd når du laver noget bestemt

Ingen	Lidt	En del	Svær	Ekstrem
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

24. Prikken i din arm, skulder eller hånd

Ingen	Lidt	En del	Svær	Ekstrem
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

25. Hvor vanskeligt har det i den forløbne uge været for dig, at sove pga. smerter i din arm, skulder eller hånd?

Ikke vanskeligt	Lidt vanskeligt	Noget vanskeligt	Meget vanskeligt	Så vanskeligt at det forhindrer mig i at sove
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

26. De følgende spørgsmål drejer sig om påvirkningen af din arbejdsevne pga. din arm, skulder eller hånd (inklusive husarbejde, hvis det er din hovedbeskæftigelse).

Sæt ét X i hver linje.

	Ikke vanskeligt	Lidt vanskeligt	Noget vanskeligt	Meget vanskeligt	Umuligt
Bruge din sædvanlige fremgangsmåde i dit arbejde?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre dit sædvanlige arbejde pga. smerter i din arm, skulder eller hånd	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre dit arbejde så godt, som du gerne ville?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Udføre dit arbejde på den tid du plejer?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

27. Angiv, ved at sætte X i én af kasserne i hver gruppe, hvilke udsagn, der bedst beskriver din helbredstilstand i dag.

Bevægelighed

Jeg har ingen problemer med at gå omkring	☐
Jeg har nogle problemer med at gå omkring	☐
Jeg er bundet til sengen	☐

Personlig pleje

Jeg har ingen problemer med min personlige pleje	☐
Jeg har nogle problemer med at vaske mig eller klæde mig på	☐
Jeg kan ikke vaske mig eller klæde mig på	☐

Sædvanlige aktiviteter
(fx arbejde, studier, husarbejde, familie- eller fritidsaktiviteter)

Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter	☐
Jeg har nogle problemer med at udføre mine sædvanlige aktiviteter	☐
Jeg kan ikke udføre mine sædvanlige aktiviteter	☐

Smerter/ubehag

Jeg har ingen smerter eller ubehag	☐
Jeg har moderate smerter eller ubehag	☐
Jeg har ekstreme smerter eller ubehag	☐

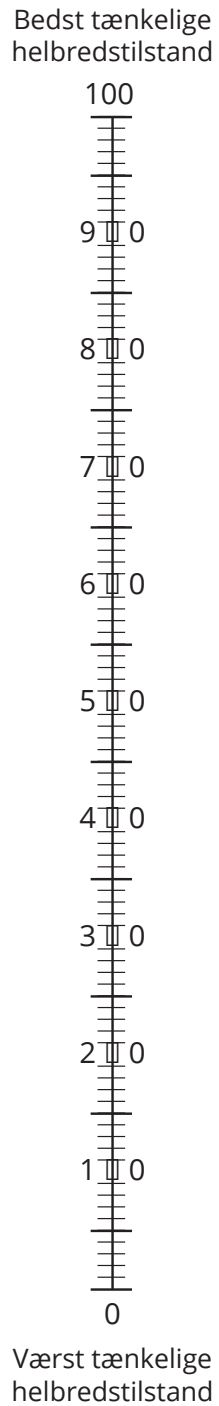
Angst/depression

Jeg er ikke ængstelig eller deprimeret	☐
Jeg er moderat ængstelig eller deprimeret	☐
Jeg er ekstremt ængstelig eller deprimeret	☐

28. Din egen helbredstilstand i dag

For at hjælpe folk med at sige, hvor god eller dårlig en helbredstilstand er, har vi tegnet en skala (næsten ligesom et termometer), hvor den bedste helbredstilstand, du kan forestille dig, er markeret med 100, og den værste helbredstilstand, du kan forestille dig, er markeret med 0.

Vi beder dig angive på denne skala med en tydelig streg i det punkt, hvor du mener din egen helbredstilstand er i dag.



29. Hvordan vil du beskrive <u>din generelle tilstand i skulderen nu</u>, hvis du sammenligner med, hvordan du havde det for cirka 5 måneder siden?

Sæt ét X.

Meget bedre	☐
Bedre	☐
Lidt bedre	☐
Uændret	☐
Lidt værre	☐
Værre	☐
Meget værre	☐

Behandling

30. I løbet af de sidste 4 uger …
Hvor ofte har du på grund af dine skulderproblemer taget smertestillende medicin?

Sæt ét X

Flere gange om dagen	1 gang om dagen	2-6 gange om ugen	1-4 gange om måneden	Mindre end 1 gang om måneden	Aldrig
☐	☐	☐	☐	☐	☐

31. I løbet af de sidste 4 uger …
Hvor ofte har du udført dine skulderøvelser?

Sæt ét X.

5-7 gange om ugen	2-4 gange om ugen	1 gang om ugen eller midre	Slet ikke
☐	☐	☐	☐

32. I løbet af de sidste 3 måneder …
Hvor mange gange har du på grund af dine skulderproblemer været behandling hos….
Skriv antal gange. Hvis du ikke har været hos pågældende behandler, skriv 0.

Skriv ét tal i hver linje.

Læge?	Cirka:	☐☐	gange
Fysioterapeut?	Cirka:	☐☐	gange
Kiropraktor?	Cirka:	☐☐	gange
Anden behandler?	Cirka:	☐☐	gange

Hvis anden behandler, hvilken?
Skriv med BLOKBOGSTAVER.

_____

33. I løbet af de sidste 3 måneder …
Har du på grund af dine skulderproblemer fået behandling med …

Skriv ét tal i hver linje.

	Nej	Ja	Ved ikke
Indsprøjtning i skulderen (blokade)?	☐	☐	☐
Skulderoperation?	☐	☐	☐

Din deltagelse i projektet

34. Har du ved deltagelse i projektet fået tilstrækkelig viden om, hvordan du kan håndtere dine skulderproblemer?

Sæt ét X.

I høj grad	I nogen grad	I mindre grad	Slet ikke	Ved ikke
☐	☐	☐	☐	☐

35. Har du ved deltagelse i projektet fået tilstrækkelig viden om, hvordan du kan træne din skulder?

Sæt ét X.

I høj grad	I nogen grad	I mindre grad	Slet ikke	Ved ikke
☐	☐	☐	☐	☐

36. Har du ved deltagelse i projektet fået tilstrækkelig viden om, hvordan du kan få nedsat belastningerne af din skulder på arbejdet?

Sæt ét X.

I høj grad	I nogen grad	I mindre grad	Slet ikke	Ved ikke
☐	☐	☐	☐	☐

37. Har du oplevet nogle ulemper – fx muskelømhed – ved deltagelse i projektet?

Nej	☐
Ja	☐

Hvis ja, hvilke?

_____

_____

_____

_____

38. Lavede du dine skulderøvelser, mens du deltog i projektet?

Nej	☐
Ja	☐

Hvis nej, hvorfor lavede du ikke øvelserne?

_____

_____

_____

_____

Hvis ja, hvorfor lavede du øvelserne?

39. Hvor enig er du i følgende udsagn?
Jeg er alt i alt tilfreds med min deltagelse i projektet 'Reduktion af skulder-belastende arbejde og skulderproblemer'.

Sæt ét X.

Helt enig	Enig	Hverken enig eller uenig	Uenig	Helt uenig
☐	☐	☐	☐	☐

40. Har du ideer til, hvordan projektet kan blive bedre?

Tak for din besvarelse

Grafisk Service 3748

Center for Planlagt Kirurgi
Regionshospitalet Silkeborg
Hospitalsenhed Midt

Arbejdsmedicinsk Klinik
Aarhus Universitetshospital

Arbejdsmedicinsk Klinik
Regionshospitalet Herning
Hospitalsenheden Vest

Spørgeskema C vedr. forskningsprojektet "Reduktion af skulderbelastende arbejde og skulderproblemer"

Kære _____

Jeg vil starte med at takke dig for din deltagelse i projektet "Reduktion af skulderbelastende arbejde og skulderproblemer".

Det er nu cirka 12 måneder siden, du kom med i projektet. Det er vigtigt for projektet, at du udfylder dette spørgeskema, så vi kan undersøge, om indsatsen har effekt.

Spøgeskemaet tager ca. 8 minutter. Tryk "indsend", når du har færdiggjort din besvarelse.

Hvis du har spørgsmål eller kommentarer, er du velkommen til at kontakte mig på telefon 24 75 91 53 eller e-mail jeatro@rm.dk.

Venlig hilsen

Jeanette Trøstrup, Fysioterapeut, ph.d.-studerende, Center for Planlagt Kirurgi, Regionshospitalet Silkeborg

Skriv dit navn _____

Dato

1. Dato for udfyldelse af spørgeskemaet _____

Arbejde

2. Hvad er din aktuelle beskæftigelse

- ◯ I arbejde på normale vilkår (som ansat eller selvstændig)
- ◯ I arbejde på særlige vilkår (aktivering, skånejob, fleksjob)
- ◯ Sygemeldt fra arbejde (heltids- eller deltidssygemeldt)
- ◯ Sygemeldt fra arbejdsløshed
- ◯ På orlov (fx barsels-, forældre- eller uddannelsesorlov)
- ◯ Arbejdsløs
- ◯ Elev, lærling
- ◯ Studerende
- ◯ Aftjener værnepligt
- ◯ Folkepensionist, efterlønsmodtager eller førtidspensionist
- ◯ Andet

3. Hvad er din nuværende stillingsbetegnelse?
Vær så præcis som muligt. Skriv fx "montør for køkkenfirma" i stedet for "montør" eller "fabriksarbejder på møbelfabrik" i stedet for "fabriksarbejder".

Skriv stillingsbetegnelse på dansk : _____

4. Hvad er din ugentlige arbejdstid?

Her tænkes på den aftalte arbejdstid ifølge overenskomst eller anden aftale - fx 37 timer per uge. Hvis du har flere job, tænkes der på det samlede antal timer.
Rund op til nærmeste hele timetal.

Skriv antal timer per uge _____

5. Hvordan er din nuværende arbejdsevne, sammenlignet med da den var bedst?

Forestil dig at din arbejdsevne er 10 point værd, når den er bedst. Hvor mange point vil du give din nuværende arbejdsevne?

0 betyder, at du ikke kan arbejde for tiden.

◯ 0, Ude af stand til at arbejde ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9
◯ 10, Bedste arbejdsevne

Skulder

De følgende spørgsmål (6-19) handler om den skulder, du har fået foretaget målinger på i projektet.

6. I løbet af de sidste 4 uger ...
Hvordan vil du beskrive den værste smerte du har haft i din skulder?

◯ Ingen ◯ Mild ◯ Moderat ◯ Svær ◯ Uudholdelig

7. I løbet af de sidste 4 uger ...
Har du haft svært ved at tage tøj på, på grund af din skulder?

◯ Intet besvær ◯ Lidt besvær ◯ Besvær ◯ Meget besvær ◯ Umulig

8. I løbet af de sidste 4 uger ...
Har du haft svært ved at komme ind og ud af en bil eller ved at bruge offentlig transport på grund af din skulder?

◯ Intet besvær ◯ Lidt besvær ◯ Besvær ◯ Meget besvær ◯ Umulig

9. I løbet af de sidste 4 uger ...
Har du været i stand til at bruge kniv og gaffel - på samme tid?

◯ Ja, let ◯ Lidt besvær ◯ Besvær ◯ Meget besvær ◯ Umulig

10. I løbet af de sidste 4 uger ...
Kunne du selv klare de daglige indkøb?

◯ Ja, let ◯ Lidt besvær ◯ Besvær ◯ Meget besvær ◯ Umulig

11. I løbet af de sidste 4 uger ...
Kunne du bære en bakke med en tallerken med mad gennem et lokale?

◯ Ja let ◯ Lidt besvær ◯ Nogen besvær ◯ Meget besvær ◯ Umulig

12. I løbet af de sidste 4 uger ...
Kunne du børste/rede dit hår med den dårlige arm?

◯ Ja, let ◯ Lidt besvær ◯ Nogen besvær ◯ Meget besvær ◯ Umulig

13. I løbet af de sidste 4 uger ...
Hvordan vil du beskrive den smerte, du normalt har haft i din skulder?

◯ Ingen ◯ Mild ◯ Moderat ◯ Svær ◯ Uudholdelig

14. I løbet af de sidste 4 uger ...
Kunne du hænge dit tøj op i en garderobe, med din dårlige arm?

◯ Ja, let ◯ Lidt besvær ◯ Nogen besvær ◯ Meget besvær ◯ Umulig

15. I løbet af de sidste 4 uger ...
Har du været i stand til at vaske og tørre dig selv under begge arme?

◯ Ja, let ◯ lidt besvær ◯ Nogen besvær ◯ Meget besvær ◯ Umulig

16. I løbet af de sidste 4 uger ...
Hvor meget har smerten fra din skulder forstyrret dit normale arbejde (inkl. husligt arbejde)?

◯ Slet ikke ◯ En lille smule ◯ Moderat ◯ Meget ◯ Totalt

17. I løbet af de sidste 4 uger ...
Har du været besværet af smerter i din skulder i din seng om natten?

◯ Ingen nætter ◯ 1 til 2 nætter ◯ Nogle nætter ◯ De fleste nætter ◯ Hver nat

18. Hvilken grad af smerter har du i din skulder i dag, når du sidder med armen helt i ro?

◯ 0, Ingen smerter ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, Værst tænkelige smerter

19. Inden for de sidste 24 timer ...
Hvad var den værste grad af smerter i din skulder ved brug af armen?

◯ 0, Ingen smerter ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, Værst tænkelige smerter

20. De følgende udsagn handler om, hvor meget fysiske aktiviteter som at bukke sig, løfte, gå eller køre påvirker eller ville påvirke dine skuldersmerter.

Sæt ét kryds i hver linje ved det tal, der passer bedst til din opfattelse af udsagnet.

	0 Helt uenig	1	2	3 Hverken uenig eller enig	4	5	6 Helt enig
Fysik aktivitet forværrer mine smerter	◯	◯	◯	◯	◯	◯	◯
Fysisk aktivitet kan skade min skulder	◯	◯	◯	◯	◯	◯	◯
Jeg burde ikke udføre fysiske aktiviteter, som (måske) forværrer mine smerter	◯	◯	◯	◯	◯	◯	◯
Jeg kan ikke udføre fysisk aktiviteter, som (måske) forværrer mine smerter	◯	◯	◯	◯	◯	◯	◯

21. De følgende udsagn handler om, hvordan dit sædvanlige arbejde påvirker eller ville påvirke dine skuldersmerter.

Sæt ét kryds i hver linje ved det tal, der passer bedst til din opfattelse af udsagnet.

	0 Helt uenig	1	2	3 Hverken uenig eller enig	4	5	6 Helt enig
Mine smerter opstod som følge af mit arbejde eller ved en ulykke på mit arbejde	◯	◯	◯	◯	◯	◯	◯
Mit arbejde har forværret mine smerter	◯	◯	◯	◯	◯	◯	◯
Mit arbejde er for hårdt for mig	◯	◯	◯	◯	◯	◯	◯
Mit arbejde forværrer eller ville forværre mine smerter	◯	◯	◯	◯	◯	◯	◯
Mit arbejde kan skade min skulder	◯	◯	◯	◯	◯	◯	◯
Jeg burde ikke udføre mit sædvanlige arbejde med mine nuværende smerter	◯	◯	◯	◯	◯	◯	◯

Jeg tror ikke, at jeg er vendt tilbage til mit sædvanlige arbejde inden for 3 måneder	◯	◯	◯	◯	◯	◯	◯

22. Hvordan vil du beskrive din generelle tilstand i skulderen nu, hvis du sammenligner med, hvordan du havde det for cirka 12 måneder siden?

◯ Meget bedre ◯ Bedre ◯ Lidt bedre ◯ Uændret ◯ Lidt værre ◯ Værre ◯ Meget værre

23. I løbet af de sidste 12 måneder ...
Hvor ofte har du lavet skulderøvelser?

◯ 5-7 gange om ugen
◯ 2-4 gange om ugen
◯ 1 gang om ugen eller mindre
◯ Slet ikke

24. I løbet af de sidste 12 måneder...

Har du på grund af dine skulderproblemer fået behandling med...

Sæt ét X i hver linje.

	Nej	Ja	Ved ikke
Indsprøjtning i skulderen (blokade)?	◯	◯	◯
Skulderoperation?	◯	◯	◯

25. Hvor enig er du i følgende udsagn?
Jeg er alt i alt tilfreds med min deltagelse i projektet "Reduktion af skulderbelastende arbejde og skulderproblemer"

◯ Helt enig ◯ Enig ◯ Hverken enig eller uenig ◯ Uenig ◯ Helt uenig

26. Jeg giver samtykke til, at projektgruppen må indhente data fra offentlige registre om sundhedsforbrug og sygefravær, hvis projektet skulle have behov for dette.

◯ Nej ◯ Ja

27. Har du kommentar, er du velkommen til at skrive dem her:

_____

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Declaration of co-authorship concerning article for PhD dissertations

Full name of the PhD student: Jeanette Trøstrup

This declaration concerns the following article/manuscript:

Title:	Reducing shoulder complaints in employees with high occupational shoulder exposures: study protocol for a cluster randomised controlled study (The Shoulder-Café Study)
Authors:	Trøstrup J, Mikkelsen LR, Frost P, Dalbøge A, Høybye MT, Casper SD, Jørgensen LB, Klebe TM, Svendsen SW

The article/manuscript is: Published ☒ Accepted ☐ Submitted ☐ In preperation ☐

If published, state full reference: Trials (2019) 20:627 (https://doi.org/10.1186/s13063-019-3703-y)

If accepted or submitted, state journal:

Has the article/manuscript previously been used in other PhD or doctoral dissertations?

No ☒ Yes ☐ If yes, give details:

Your contribution

Please rate (A-F) your contribution to the elements of this article/manuscript, **and** elaborate on your rating in the free text section below.

A. Has essentially done all the work (>90%)
B. Has done most of the work (67-90 %)
C. Has contributed considerably (34-66 %)
D. Has contributed (10-33 %)
E. No or little contribution (<10%)
F. N/A

Category of contribution	Extent (A-F)
The conception or design of the work:	B
Free text description of PhD student's contribution ***(mandatory)*** Together with my supervisors I developed and designed the study	
The acquisition, analysis, or interpretation of data:	B
Free text description of PhD student's contribution ***(mandatory)*** I did the analyses and the interpretation of data together with my supervisors	
Drafting the manuscript:	A
Free text description of PhD student's contribution ***(mandatory)*** I wrote the first manuscript draft	
Submission process including revisions:	A

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Free text description of PhD student's contribution ***(mandatory)***
I submittet the manuscript, was the corresponding author and communicated with the journal regarding the revisions

Signatures of first- and last author, and main supervisor

Date	Name	Signature
22.11.2021	Jeanette Trøstrup	Jeanette Trøstrup
25.11.2021	Susanne Wulff Svendsen	Susanne Wulff Svendsen
22/11/21	Mette Trep Høybye	Mette Trep Høybye

Date: 22/11 - 21

Jeanette Trøstrup

Signature of the PhD student

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The article/manuscript is: Published ☐ Accepted ☐ Submitted ☒ In preperation ☐

If published, state full reference:

If accepted or submitted, state journal: Physical Therapy & Rehabilitation Journal

Has the article/manuscript previously been used in other PhD or doctoral dissertations?

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Submission process including revisions:	A

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Free text description of PhD student's contribution ***(mandatory)***
I submittet the manuscript and I am the corresponding author

Signatures of first- and last author, and main supervisor

Date	Name	Signature
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25.1.2021	Susanne Wulff Svendsen	Susanne Wulff Svendsen
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Jeanette Trøstrup

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Declaration of co-authorship concerning article for PhD dissertations

Full name of the PhD student: Jeanette Trøstrup

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Title:	Increased shoulder pain across an exercise session and subsequent shoulder exercise – a cohort study
Authors:	Trøstrup J, Svendsen SW, Dalbøge A, Mikkelsen LR, Høybye MT, Jørgensen LB, Klebe TM, Frost P

The article/manuscript is: Published ☐ Accepted ☐ Submitted ☐ In preperation ☒

If published, state full reference:

If accepted or submitted, state journal: l

Has the article/manuscript previously been used in other PhD or doctoral dissertations?

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Your contribution

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Free text description of PhD student's contribution ***(mandatory)*** I wrote the first manuscript draft	
Submission process including revisions:	A

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Free text description of PhD student's contribution ***(mandatory)***
I have prepared the manuscript for submission

Signatures of first- and last author, and main supervisor

Date	Name	Signature
22.11.2021	Jeanette Trøstrup	Jeanette Trøstrup
22.11.21	Poul Frost	Poul Frost
22.11.21	Mette Trep Høybye	Mette Trep Høybye

Date: 22/11 - 21

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