Positive effects of neuromuscular shoulder exercises with or without EMG-biofeedback, on pain and function in participants with subacromial pain syndrome – A randomised controlled trial

Birgit Juul-Kristensen[a,*], Camilla Marie Larsen[a,b], Henrik Eshoj[c], Trine Clemmensen[a,b], Anders Hansen[a,d], Peter Bo Jensen[a], Eleanor Boyle[a,e], Karen Søgaard[a,f]

[a] Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark
[b] Health Sciences Research Center, University College Lillebaelt, Odense, Denmark
[c] Quality of Life Research Center, Department of Haematology, Odense University Hospital, Odense, Denmark
[d] Research Unit for Rehabilitation, Institute of Clinical Research, University of Southern Denmark, Odense, Denmark
[e] Division of Epidemiology, Dalla Lana School of Public Health, University of Toronto, Toronto, Canada
[f] Department of Clinical Research, University of Southern Denmark, Odense, Denmark

ARTICLE INFO	ABSTRACT
	Background: The aim was to investigate the effect of Electromyography (EMG)-biofeedback guided exercises (BIONEX) on shoulder pain and function in participants with subacromial pain syndrome (SPS). *Methods:* Twenty-five women and 24 men (19–67 years), diagnosed with SPS, were randomised to BIONEX or the same exercises without EMG-biofeedback (NEX). Primary outcome was shoulder pain during the past 7 days (Numeric Pain Rating Scale (NPRS)). Secondary outcomes included self-reported (Disability of Arm Shoulder and Hand (DASH), Oxford Shoulder Score (OSS)), and measured shoulder function (surface EMG from upper trapezius, lower trapezius and serratus anterior) in mean and ratios of % of maximum voluntary EMG (%MVE) and onset time (msec), during arm tasks with 0, 1 and 3 kg. *Results:* There was no group difference (BIONEX versus NEX) in changed shoulder pain (NPRS, mean difference 0.18 (95% CI. −1.56; 1.19)), self-reported or measured shoulder function. Both groups, however, showed significant within-group improvements on self-reported outcomes (NPRS, DASH, OSS), only clinically relevant on NPRS (BIONEX 2.23 (SD 2.47); NEX 2.04 (SD 2.29)). *Conclusion:* BIONEX and NEX were both effective in reducing pain to a clinically relevant level, while EMG-biofeedback did not make a difference. The current neuromuscular shoulder exercise protocol is recommended.

1. Introduction

Shoulder pain is an important health and socioeconomic problem, with 23% of the European labour force having experienced pain in the neck/shoulder region or arms within the past year, accounting for the largest cause of work-related sickness absence, followed by back pain (Bevan, 2009).

Rotator cuff-related syndrome, synonymous with subacromial pain syndrome (SPS), is the most common shoulder disorder in the primary sector, causing pain, loss of general shoulder function, reduced strength and range of motion (Clausen et al., 2017). SPS is characterised by shoulder pain exacerbated by overhead activities that compress the subacromial structures, such as rotator cuff muscle tendons due to reduced subacromial space (Seitz and Michener, 2011). This condition

may be caused by inappropriate scapulo-humeral movements (most often reported as reduced scapula upward rotation and/or posterior tilt) with neuromuscular imbalance of the scapular muscles (Page, 2011). Muscular imbalance in SPS is often reported as higher muscle activity in the Upper Trapezius muscle (UT), lower activity in the Serratus Anterior (SA) and/or the Lower Trapezius (LT) muscle, and/or a higher ratio of the relative activation of UT and LT compared with healthy controls (Kinsella and Pizzari, 2017).

Recommended treatment guidelines for patients with SPS focus on decreasing pain, and increasing shoulder flexibility and function (Holmgren et al., 2012). This approach mostly includes exercises where muscle activity in the lower parts of the scapular stabilizing muscles (SA and LT) is increased, while activity in the upper parts of these muscles (UT) is decreased or maintained at the same level (Ellenbecker

and Cools, 2010; Saito et al., 2018). However, the foundation for these clinical guidelines is mostly studies with limited descriptions of the intervention and/or of moderate methodological quality (Saito et al., 2018). Further, relevant objective outcomes are sparse, primarily including isolated laboratory tests of limited translation to activities of daily living (Reijneveld et al., 2017).

Verbal and tactile feedback have shown to increase EMG amplitudes during selected shoulder exercises in young healthy individuals (Jones et al., 2018). Biofeedback in the form of visual electromyography (EMG) signals, seems promising for teaching individuals with or without shoulder pain to selectively activate different subparts of the scapular muscles (Larsen et al., 2014; Holtermann et al., 2010; Huang et al., 2013). However, adding EMG-biofeedback to a shoulder exercise protocol has not yet been studied in a randomised controlled trial (RCT) evaluating the effect on shoulder pain and function in patients with SPS.

Therefore, the aim was to investigate the effect of shoulder exercises and Electromyography (EMG)-biofeedback on shoulder pain, function and muscle activity in participants with SPS compared with the same exercises without EMG-biofeedback.

2. Methods

2.1. Design

A single-blinded two-group parallel superiority RCT was conducted, investigating the effect of 8 weeks of supervised EMG-biofeedback neuromuscular shoulder exercises (BIONEX group), versus neuromuscular shoulder exercises only (NEX group).

Baseline and follow-up testing after 8 weeks intervention included self-reported outcomes, placement of surface electrodes, performance of maximal voluntary isometric contractions (MVIC) for EMG normalisation, and standardised arm tasks. Randomisation was performed after baseline testing to avoid violation of the internal validity and the risk of bias, as described in the CONSORT statement for Randomised Controlled Trials (Boutron et al., 2008).

2.2. Subjects

Eligible participants were adults aged 19–67 years with a minimum amount of pain and actual pain. Pain amount was defined as shoulder/neck pain/discomfort for minimum 30 days within the past year as reported in the Nordic questionnaire for Musculoskeletal problems, a well validated and frequently used questionnaire (Kuorinka et al., 1987). For the actual pain, the included participants had to have a minimum of two positive impingement tests (Jobe, Neer, Hawkins, Apprehension tests) (Vind et al., 2011), and the ability to read and understand Danish. All testing procedures were standardised as previously described (Vind et al., 2011).

Exclusion criteria were: ≥ 8 in shoulder pain/discomfort (Numeric Pain Rating Scale (NPRS) ranging from 0 to 10, 10 = worst) within the past 24 h, more than three additional regions with pain for minimum 30 days during the past 12 months, history of severe shoulder-neck pathology, trauma, or corticosteroid injection within the past 3 months, previous shoulder surgery, life threatening diseases, adverse psychosocial conditions or pregnancy, and positive signs of cervical radiculopathy as previously used (Larsen et al., 2014).

Participants were recruited from local specialised physiotherapy clinics, orthopaedic surgeons, rehabilitation departments, sports clubs, trade unions and through social media. Eligible participants received study information by email, a phone call for project information, and scheduling time for inclusion (Fig. 1).

The Committee on Biomedical Research Ethics for the Region of Southern Denmark, Denmark approved the study (Projects ID S-20090090). All participants gave written informed consent before data collection. The study conformed to the Declaration of Helsinki 2008

(World Medical 2013).

2.3. Interventions

Briefly, the intervention was scapula-focused, with the only group difference being EMG-biofeedback during exercises, where visual and verbal feedback from the activity levels was given on a computer screen to the BIONEX group. The feedback included feedback on increasing muscle activation of SA and LT and decreasing UT.

The program consisted of two periods. The first three weeks included exercises to (re)-activate the muscles to increase participant's awareness of shoulder function (scapula stabilisation during arm movement), including focus on LT and SA exercises. Muscle stretching exercises included pectoralis minor and the posterior shoulder capsule. The following five weeks consisted of transferring muscle awareness into daily activities, where LT and SA had to co-operate dynamically to succeed (see supplementary material).

2.4. Outcomes

Primary outcome was self-reported pain intensity during the past 7 days NPRS (Eshoj et al., 2017).

Secondary outcomes included further self-reported outcomes, such as pain intensity from NPRS for 'actual pain level' and 'pain level within the past 24 h', Disability of the Arm, Shoulder and Hand questionnaires (DASH), for changed symptoms over time. DASH contains 30 items, each rated on five-point Likert scale from 1 to 5 (1 = good function and/or no pain, 5 = poor function and/or considerable pain) (Schonnemann et al., 2011). DASH includes further two optional subdimensions (Work, Sports/Performing Arts activities), each with four items, rated as above. The total scores of each DASH dimension are calculated as follows: (total score/n answers) – 1 * 25, ranging from 0 to 100 for each dimension (Schonnemann et al. 2011). A further secondary outcome was the Oxford Shoulder Score (OSS), a 12-item scale rated on a five-point Likert scale from 0 to 4 (0 = poor function, 4 = good function) (Frich, Noergaard, and Brorson 2011). Daily pain and number of repetitions per exercise during home exercises were rated in the participants' diary. Demographic information included age, BMI, bodymass, height, weekly working hours, and workability.

Secondary outcomes further included objective measurements of surface electromyography (sEMG) signals from three scapular muscles: UT, LT and SA, during standardised arm task, with data extraction in the range of the painful arc (60° to 120° arm elevation) (Ludewig and Cook, 2000).

For the EMG recordings, bipolar sEMG-electrodes (Ambu "blue sensor M", A/S, Neuroline, 72001 k, Ballerup, Denmark) were placed on the participant's injured arm, for UT and LT in prone lying (arms beside the body), while for SA in standing. Electrodes of UT, were placed 20% medially to the midpoint between the acromion and the C7 vertebra, for LT, 33% medially to the midpoint between the medial scapular border and the 8th vertebra, while for SA on the bulky part of the 7th rib, following muscle fibre direction (Holtermann et al., 2010; Larsen et al., 2014). The sEMG-signals were sampled using Noraxon EMG-transmitters (Telemyo DTS System, USA), and data were transmitted to a belt receiver for further analysis.

2.5. Testing protocol

EMG signals were normalised to maximal voluntary EMG (MVE), subtracting resting signal of sEMG data collected for 30 s in prone lying. The participants performed minimum three (up to five) Maximum Isometric Contractions (MVICs), with verbal encouragement including 1 min rest in between, highest EMG value selected. All MVICs were performed with resistance during arm movement in the scapular plane (arm flexion in the plane of 45° to the sagittal plane of the truncus) as is the plane of movement for the scapula (Pearl et al. 1992)'. For the
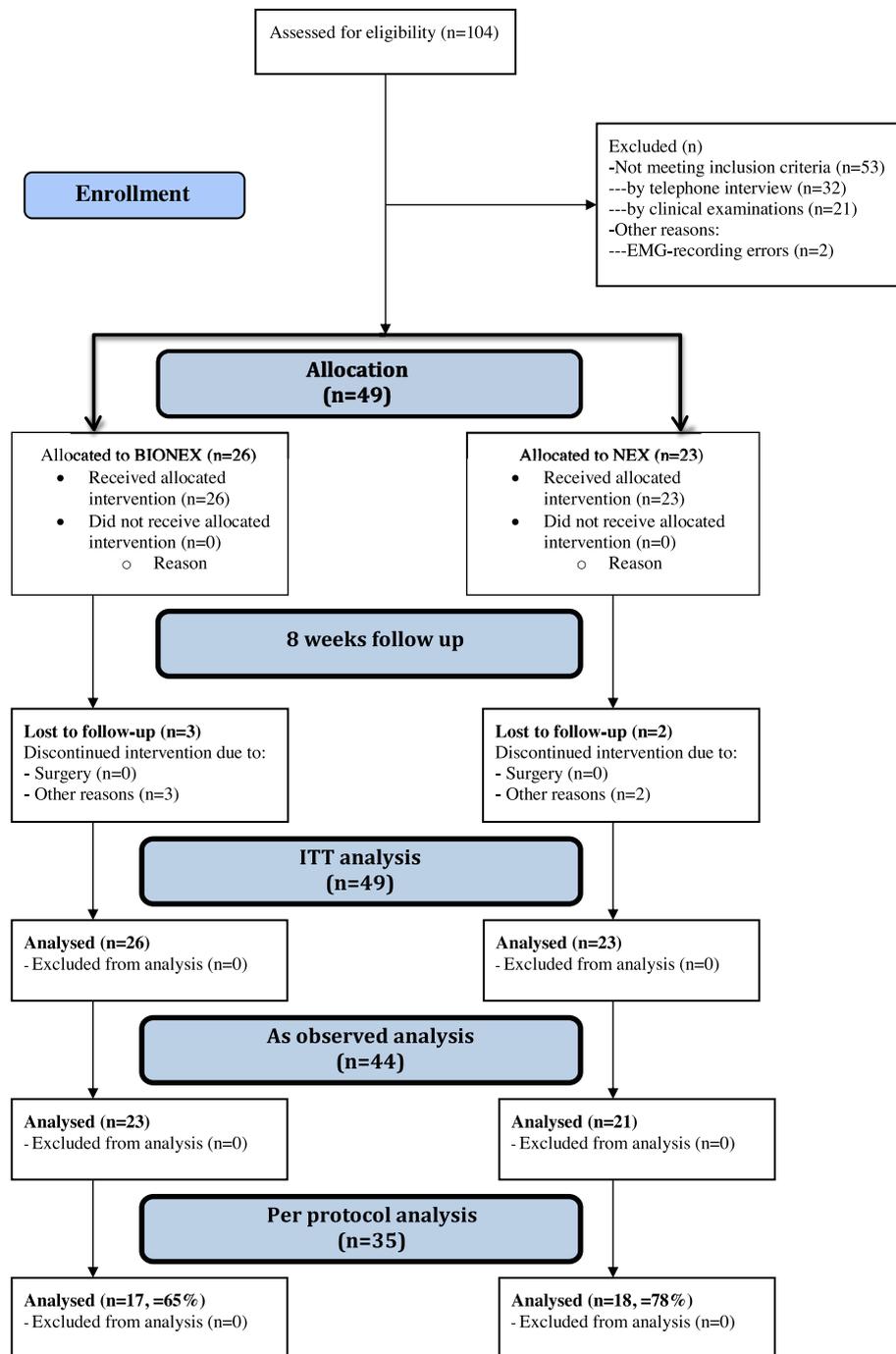
Fig. 1. Flow of the participants throughout the study. As observed analysis' means the population with imputed follow up data, while the 'per protocol analysis' means that only participants who were compliant according to the prespecified criteria (attendance of minimum 75% sessions (six of eight supervised sessions), and completion of minimum 75% of the scheduled home exercises) are in the analysis. '

injured side a solid band was used, fixed to a plate on the floor and mounted proximally to the elbow joint. For the non-injured side manual resistance was used in an outward rotated shoulder position (Larsen et al. 2014). There was no data sampling on unjured side since we only wanted data on the injured side. Bilateral resistance was performed to ensure that participants did not perform any potentially harmful asymmetrical resistance movement, and to provide the highest EMG amplitude as possible. For MVE of UT and SA, participants were standing with the upper extremities at 90° and 135° shoulder flexion (scapular plane), elbows extended, wrists in neutral, performing maximum isometric shoulder flexion pressing upwards against the resistance. For MVE of LT, participants were prone lying, arms in 180°

flexion (scapular plane), performing maximum isometric horizontal shoulder abduction pressing against the resistance. Participants were encouraged to perform each MVE within tolerable pain.

The arm elevation task was performed in scapular plane during three conditions in the following order: hands holding no external load (0 kg), 1 kg dumbbell and 3 kg dumbbell. The scapular plane was guided with markings on the floor showing 45° angle towards a wall (arm aligned with the wall). The arm task was performed with extended elbows from 0° to maximum arm elevation (concentrically/up) during 2 s, followed by lowering (eccentrically/down) to 0° during 2 s (Ludewig and Cook, 2000), then 4 s rest. Each movement was standardised, guided by a metronome, repeated five times with one-minute

rest between each load (0-1-3 kg). Verbal instruction of performing maximal shoulder flexion (0-180-0°) was given, verified by Inclinometer (Noraxon, USA), attached to the participant's wrist.

2.6. Compliance, randomisation, allocation and blinding procedures

To measure compliance, number of attended sessions supervised by the treating physiotherapist was registered, in addition to the participant-registered home-based exercises in a diary. Satisfactory compliance included attendance of minimum 75% sessions (six of eight supervised sessions), and completion of minimum 75% of the scheduled home exercises.

A list of random numbers (1:1) (equal number for each group) was prepared prior to study start stating to which group each individual would be allocated. After baseline testing, participants were randomised to either BIONEX or NEX by drawing an opaque, sealed, sequentially numbered envelope. After group allocation the envelope was stored in a locker not accessible by the assessors. The participant's name and telephone number were forwarded to the treating physiotherapist for scheduling exercise appointments.

The same four assessors (in two pairs), blinded to group allocation, not involved in treatment, carried out testing. Before actual inclusion the assessors and treating physiotherapists were thoroughly trained in how to administer the outcomes, assess and train the participants. The treating physiotherapists were blinded to the baseline data, and participants were encouraged not to reveal their treatment assignment at follow-up testing. Baseline and follow-up testing in addition to the interventions were carried out in separate facilities at the XXX.

2.7. Data analysis

EMG signals were amplified with gain of 400 (Telemyo DTS Telemetry with analogue output module, Noraxon, USA) and analogue band pass filtered with a 2nd order Butterworth filter, with cut-off frequencies at 10–480 Hz, then sampled at 1000 Hz, converted in digital form by a 12bit A/D-converter and stored on a disk (CED 1401, Spike2 software, Cambridge Electronic Devices, UK). Raw data of EMG measurements were sent to an impartial data engineer before statistical analysis. EMG amplitude was calculated by root mean square (RMS) with a moving window (1 s duration and moving in 100 ms steps) throughout the entire EMG recording.

Onset of muscle activity was based on visual inspection of the activity and by using the inclinometer. The time period for arm movements between 60° – 120° part of the 180° swing during elevation and lowering was selected for analysis, due to this range often being the most painful, this is known as the "painful arc" (Michener et al., 2009). This period lasted 0.7 s, with start 0.7 s after the visually determined onset (upwards), and 0.7 s from the most elevated point of motion, detected by the inclinometer (downwards), respectively (Larsen et al., 2014).

Peak RMS value recorded during MVE was used for EMG normalisation (% MVE) (Larsen et al., 2014), and the final analysis of % MVE was based on the mean of the three middle trials of five (2, 3 and 4) of 0–1-3 kg. Mean normalised muscle activity during arm elevation and lowering (% MVE) of each muscle and each load, and muscle activity ratios between the muscles or subparts (UT/LT, UT/SA, LT/SA) were calculated for the periods of painful arc (60° to 120°) during arm elevation and lowering (Ludewig and Cook, 2000). Further, muscle onset difference was defined as delay between pairs of muscles (UT-SA, UT-LT, LT-SA), with negative values representing initial activity of the first mentioned muscle or muscle subparts, and positive values represented initial activity of the last mentioned muscle.

2.8. Statistical analysis

Primary and secondary outcomes were analysed according to the intention-to-treat (ITT) principle; missing follow-up data replaced by baseline values (carried forward), while missing baseline data replaced by mean baseline values of the whole group. Per protocol analyses were performed for those fulfilling the criteria for compliance. The calculated sum scores of the secondary outcomes (DASH, OSS) were treated as continuous variables.

Residuals from the final statistical model of each outcome were found to be normally distributed. A linear regression model was used to analyse data representing mean changes in continuous end points of self-reported and measured EMG outcomes. For each dependent variable the model included the dependent avariables of change values (difference between baseline and follow-up), and independent variables of exposure (BIONEX, NEX), sex, BMI, age and baseline value of the relevant variable.

A multilevel linear mixed model was used to analyse group differences in overall change scores of the weekly NPRS data, as registered daily in diaries, by repeated measures. This means that the model included the dependent variable of change value (NPRS difference between baseline and follow-up), and independent variables of exposure (BIONEX, NEX), sex, BMI, age and baseline NPRS value. Further, group differences in demographics and baseline values were tested with t-tests, and within-group changes with paired t-tests.

All ITT analyses were performed blinded to group allocation carried out according to pre-established analysis plan (Juul-Kristensen et al., 2017), with an external epidemiologist performing the analysis for the primary outcome, and all co-authors approving and signing the blinded interpretation (Jarvinen et al., 2014).

A sample size of 10 participants per group was required to detect a difference of two NPRS points (standard deviation of 1.5, 80% power, alpha level 0.05) (Salaffi et al. 2004). For detecting EMG between-group differences of minimum 25% improvement in % MVE (standard deviation of 42% in % MVE, 80% power, alpha level 0.05), minimum 22 participants per group was required (Ludewig and Cook 2000). To account for drop-outs, 50 participants were included.

An alpha-level of 0.05 was considered statistically significant (p < 0.05, two- sided). Finally, results are expressed as the difference between group means with 95% Confidence Intervals and their associated p-values. Statistical analyses were performed using SPSS (IBM, Armonk NY, USA, version 24.0).

3. Results

3.1. Participant characteristics

A total of 104 participants volunteered; however, 55 participants were excluded (Fig. 1), leaving 49 participants for randomisation, BIONEX (26) and NEX (23) (ITT population), with three participants in BIONEX and two in NEX lost to follow-up.

Generally, the two groups were comparable on demographics, baseline values for self-reported outcomes (Table 1a) and measured EMG values, only shown for 3 kg load (Table 1b). Number of females were 13 (50%) in BIONEX, and 12 (52%) in NEX.

Sensitivity analyses showed no differences in demographics and baseline outcomes between participants lost to follow-up and those from the complete dataset (data not shown).

3.2. Primary analysis

BIONEX improved 0.18 points (95% CI. −1.56; 1.19) more than NEX in primary outcome, NPRS (pain within the past seven days), however, non-significantly.

3.3. Secondary analyses

Likewise, no group difference in the remaining change scores of self-reported outcomes (e.g. DASH total −0.61 (-5.32; 6.55); OSS 0.36

Table 1a
Baseline demographics and primary and secondary self-reported outcomes (Mean, SD) for participants with subacromial impingement syndrome, for the participants allocated to the BIONEX or NEX group.

Variables	BIONEX Group	NEX Group
	Mean (SD)	Mean (SD)
	(n = 26)	(n = 23)
Demographics		
Age (yrs)	41.0 (11.7)	45.1 (13.0)
BMI	26.3 (3.5)	24.2 (4.1)
Bodymass (kg)	81.9 (17.3)	73.7 (16.1)
Height (cm)	175.7 (9.5)	173.7 (7.8)
Work/week (hrs)	35.4 (11.6)	35.0 (10.3)
Workability (level)	6.5 (2.6)	7.2 (2.1)
Primary self-reported outcome		
NPRS within past 7 days	5.1 (2.2)	4.8 (2.1)
Secondary self-reported outcomes		
NPRS now	3.4 (2.2)	2.6 (2.1)
NPRS within the past 24 h	4.3 (2.2)	3.7 (2.3)
DASH total	27.0 (12.4)	26.8 (15.3)
DASH work	25.7 (26.4)	24.8 (22.4)
DASH sport	37.6 (28.0)	45.2 (19.6)
OSS	35.1 (5.6)	34.1 (7.4)

Abbreviations: BIONEX EMG-biofeedback neuromuscular shoulder exercise group; **NEX** neuromuscular shoulder exercise group ; **BMI** Body Mass Index; **NPRS** Numeric Pain Rating Scale (0–10, 10 = worst pain); **DASH** Disability of Arm Shoulder and Hand (1–5, 5 = worst); **OSS** Oxford Shoulder Score (0–4, 0 = worst).
base = significant effect of baseline values; w = significant within group-differences from baseline to follow-up.

Table 1b
Baseline values (Mean, SD) on secondary objective EMG outcomes, for the arm elevation and lowering task of 3 kg (mean relative activity in %MVE, muscle activation ratios and onset time) for participants with subacromial impingement syndrome, for the participants allocated to the BIONEX or NEX group.

Variables	BIONEX Group	NEX Group
	Mean (SD)	Mean (SD)
	(n = 26)	(n = 23)
Secondary objective outcomes		
EMG (%MVE)		
UT elevation, 3 kg	42.6 (22.6)	49.4 (27.8)
UT lowering, 3 kg	23.6 (11.3)	30.4 (18.7)
LT elevation, 3 kg	21.8 (12.5)	28.6 (17.1)
LT lowering, 3 kg	15.4 (8.8)	19.1 (11.3)
SA elevation, 3 kg	31.9 (18.8)	34.3 (20.8)
SA lowering, 3 kg	21.0 (13.0)	23.3 (16.1)
EMG (ratio)		
UT/SA elevation, 3 kg	1.6 (0.9)	1.6 (0.6)
UT/SA lowering, 3 kg	1.7 (1.9)	1.6 (1.1)
UT/LT elevation, 3 kg	2.9 (4.4)	2.0 (1.0)
UT/LT lowering, 3 kg	2.2 (1.8)	2.0 (1.5)
LT/SA elevation, 3 kg	0.9 (0.5)	0.9 (0.3)
LT/SA lowering, 3 kg	0.9 (0.6)	0.9 (0.3)
EMG (onset time, ms)		
UT-SA elevation, 3 kg	−0.06 (0.1)	−0.09 (0.1)
UT-LT elevation, 3 kg	−0.06 (0.1)	−0.06 (0.1)
LT-SA elevation, 3 kg	−0.02 (0.1)	−0.02 (0.1)

Abbreviations: BIONEX EMG-biofeedback neuromuscular shoulder exercise group; **NEX** neuromuscular shoulder exercise group ; **EMG** Electromyography; **%MVE** percentage of Maximum Voluntary EMG; **UT** Upper Trapezius; **LT** Lower Trapezius; **SA** Serratus Anterior.

(-3.09; 2.37)) was found (Table 2). However, both groups showed significant within-group improvements from baseline to follow-up (Table 2).

For the weekly NPRS scores (Fig. 2), there was no significant group difference across the 8 weeks, but over time, there was a significant reduction in pain for the total group (p < 0.001). Furthermore, there was significant effect of NPRS baseline values (p < 0.001; higher baseline values improved mostly), and sex (p = 0.018; larger pain for females than for males).

Groups did not differ in changed EMG outcomes, for any of the muscles or muscle subparts during the arm tasks, with only few significant within-group differences (Table 3, only shown for 3 kg load).

3.4. Attendance and compliance

General attendence of supervised sessions and home exercises corresponded to 86% for BIONEX and 88% for NEX with no significant group difference. For the per protocol analyses, a total of 17 (65%) participants in BIONEX and 18 (78%) in NEX were compliant according to pre-established criteria. The same pattern of non-significant group differences were seen in change scores in the per protocol analyses.

4. Discussion

With an equal and satisfactory compliance, the current study showed that following an 8-week shoulder exercise protocol with EMG-biofeedback was not superior in reducing shoulder pain and improving self-reported shoulder function compared with no EMG-biofeedback. Neither was there superior relief of shoulder pain with EMG-biofeedback across all 8 weeks. However, both groups improved significantly with a clinically important change of minimum 2.0 in pain and most of the remaining self-reported shoulder function outcomes. There was no superior effect of BIONEX in changed EMG outcomes for any of the muscles or muscle subparts, as also confirmed by per protocol analyses.

4.1. Primary analysis

The expected larger change in pain in the EMG-biofeedback group relied on an improved balanced muscle activation. Since group differences in changed EMG outcomes were absent, it was not surprising that the effect on changed pain between the two groups was also absent. Previous experimental studies have shown that few sessions with EMG-biofeedback were able to reduce UT/LT and UT/SA ratios more than with no EMG-biofeedback (Huang et al., 2013), and improve selective activation of LT and UT (Larsen et al., 2014). Since this would improve muscle function, neuromuscular control, and self-management of pain, it was anticipated that shoulder pain would be reduced, as previously showed with scapula-focused training (without control groups) (Worsley et al., 2013; De Mey et al., 2012). This is the first clinical RCT study investigating the effect of 8 weeks of EMG-biofeedback.

One of the reasons for the lacking effect on EMG outcomes may be the different procedures (positions, exercise types) used for EMG-biofeedback between the experimental studies and the current clinical study (Larsen et al., 2014; Huang et al., 2013). Also, the type of EMG biofeedback may result in different outcomes. In this study visual EMG biofeedback only during exercise sessions, as opposed to continuous EMG feedback throughout the day. In the present study the physical therapists were also allowed to use verbal and tactile feedback in both groups, as previously used (Jones et al., 2018), however, without influencing group differences of EMG levels.

Another reason may be that the current exercise protocol used standardised as opposed to individualised intense progressions (De Mey et al., 2012; Hotta et al., 2018), potentially insufficiently challenging the neuromuscular system. However, as some participants were unable to complete arm elevation tasks with 3 kg due to pain, progression criteria seemed reasonable. Further, the current study aimed primarily

Table 2

Primary and secondary self-reported outcomes (Mean ± SD, and 95% Confidence Intervals (CI)) from baseline to eight-week follow-up, in change scores (baseline minus follow up) for participants with subacromial impingement syndrome, and between-group differences (BIONEX minus NEX), for the participants allocated to the BIONEX or NEX group, intention-to-treat population.

Variables	BIONEX group	NEX group	Between-Group	p-value
	Change (95% CI)	Change (95% CI)	difference (95% CI)	
	(n = 26)	(n = 23)		
Primary self-reported outcome				
NPRS past 7 days	2.23 (1.23; 3.22)[w]	2.04 (1.06; 3.03)[w]	0.18 (−1.56; 1.19)	0.73[base]
Secondary self-reported outcomes				
NPRS now	1.27 (0.34; 2.20)[w]	1.17 (0.13; 2.22)[w]	0.10 (−1.46; 1.27)	0.53[base]
NPRS past 24 h	2.08 (0.96; 3.20)[w]	1.00 (−0.27; 2.27)	1.08 (−2.72; 0.56)	0.40[base]
DASH total	8.00 (4.45; 11.55)[w]	8.61 (3.51; 13.72)[w]	−0.62 (−5.32; 6.55)	0.73[base]
DASH work*	10.11 (1.16; 19.06)[w]	5.19 (−2.63; 13.01)	4.92 (−16.64; 6.80)	0.39[base]
DASH sport**	5.43 (−6.28; 17.14)	12.05 (3.19; 20.91)[w]	−6.62 (−7.99; 21.23)	0.32
OSS	−3.88 (−5.72; −2.04)[w]	−4.25 (−6.39; −2.10)[w]	0.36 (−3.09; 2.37)	0.99[base]

Abbreviations: BIONEX EMG-biofeedback neuromuscular shoulder exercise group; **NEX** neuromuscular shoulder exercise group; **NPRS** Numeric Pain Rating Scale (0–10, 10 = worst pain); **DASH** Disability of Arm Shoulder and Hand (1–5, 5 = worst); **OSS** Oxford Shoulder Score (0–4, 0 = worst); significant effect of baseline values (=base); significant within group-differences from baseline to follow-up (=w).

* n = 24 for BIONEX, n = 19 for NEX.

** n = 15 for BIONEX, n = 12 for NEX.
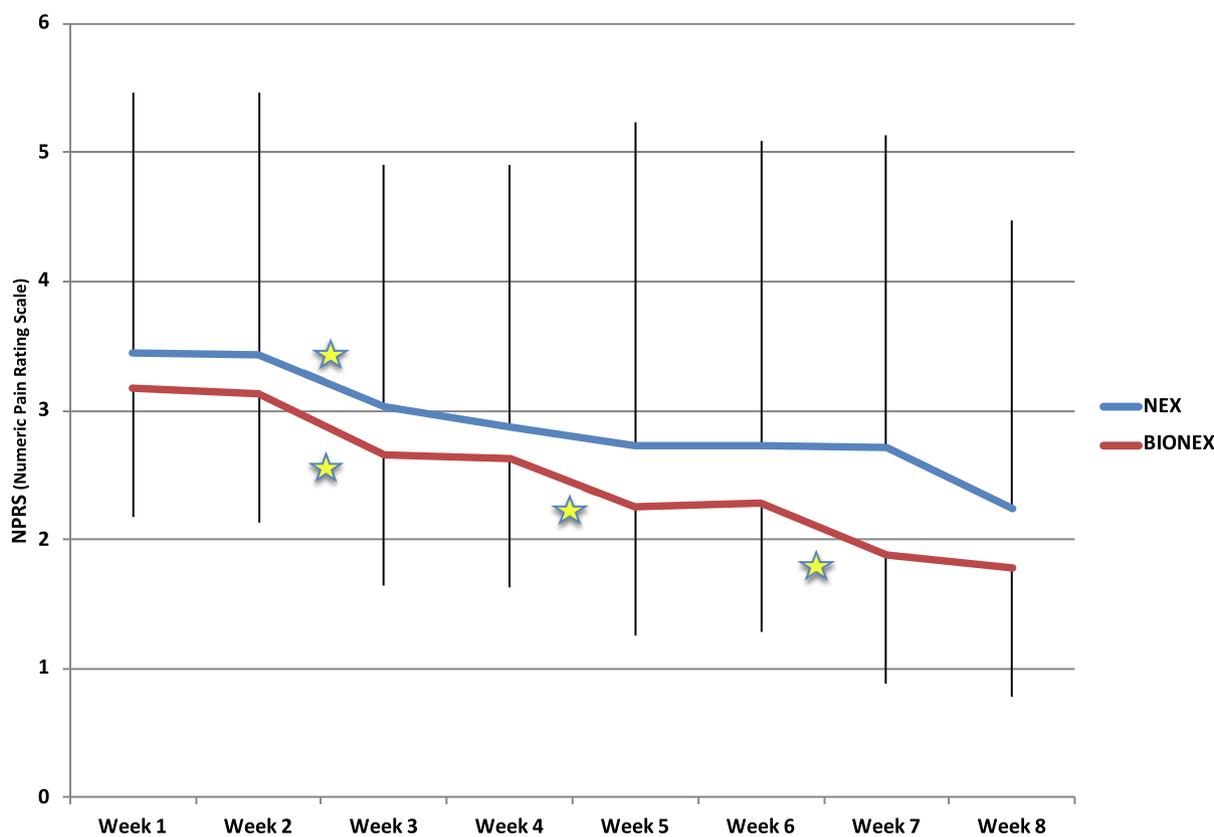
Fig. 2. Secondary self-reported outcome of Numeric Pain Rating Scale (NPRS) at baseline and each week (week 1–8) after baseline for BIONEX vs. NEX among participants with subacromial impingement syndrome (ITT population). Data points represent means and error bars indicate 95% CI/SD. * (stars) denote significant within-group changes between two week numbers.

at improving muscle coordination and not just strength, which was the rational for using relatively low loads. Other reasons may be larger number than one weekly supervised session (Struyf et al., 2013; Holmgren et al., 2012; Shah etal., 2014; Baskurt et al. 2011; Moezy et al., 2014; Osteras et al., 2010), and longer treatment periods than 8 weeks (Struyf et al., 2013; Holmgren et al., 2012; Bennell et al., 2010).

4.2. Secondary analyses

The effect of the exercise program in both groups is in line with similar exercise interventions, showing positive effects on pain and physical function in participants with SPS (McClure et al., 2004; De Mey et al., 2012; Worsley et al., 2013; Reijneveld et al., 2017). Although the content of exercise protocols vary across studies, all exercises are scapula-focused.

Table 3

Secondary objective EMG outcomes (Mean ± SD, and 95% Confidence Intervals (CI)) for the arm elevation and lowering task of 3 kg (mean relative activity in % MVE, muscle activation ratios and onset time) from baseline to eight weeks follow-up as change scores (baseline minus follow up) for participants with subacromial impingement syndrome, and between-group differences (BIONEX minus NEX), for the participants allocated to the BIONEX or NEX group, intention-to-treat population.

Variables	BIONEX group	NEX group	Between-Group	p-value
	Change (SD)	Change (SD)	difference (95% CI)	
	(n = 26)	(n = 23)		
Secondary outcomes				
EMG (%MVE)				
UT elevation, 3 kg	−2.15 (−5.74; 1.44)	−0.70 (−5.72; 4.31)	−1.45 (−4.45; 7.34)	0.55[base]
UT lowering, 3 kg	0.82 (−2.39; 4.04)	3.29 (−0.85; 7.41)	−2.46 (−2.57; 7.49)	0.33[base,a]
LT elevation, 3 kg	−2.30 (−5.64; 1.03)	2.55 (−1.38; 6.48)	−4.85 (−0.13; 9.84)	0.19[base]
LT lowering, 3 kg	−0.22 (−3.42; 2.97)	−0.53 (−4.32; 3.25)	0.31 (−5.10; 4.48)	0.70[base]
SA elevation, 3 kg	−0.38 (−5.96; 5.20)	1.73 (−3.48; 6.93)	−2.11 (−5.39; 9.60)	0.75[base,a]
SA lowering, 3 kg	2.83 (−1.95; 7.62)	−1.13 (−6.18; 3.92)	3.96 (−10.74; 2.82)	0.07[base]
EMG (activation ratio)				
UT/SA elevation, 3 kg	0.15 (−0.30; 0.59)	−0.05 (−0.26; 1.16)	0.20 (−0.70; 0.30)	0.56[base,a]
UT/SA lowering, 3 kg	0.18 (−0.63; 0.10)	0.26 (−0.01; 0.52)	−0.07 (−0.81; 0.96)	0.44[base]
UT/LT elevation, 3 kg	−0.73 (−2.46; 1.00)	−0.03 (−0.43; 0.37)	−0.70 (−1.14; 2.53)	0.97[base]
UT/LT lowering, 3 kg	0.10 (−0.57; 0.77)	0.41 (−0.08; 0.90)	−0.32 (−0.51; 1.14)	0.30
LT/SA elevation, 3 kg	0.05 (−0.14; 0.23)	−0.01 (−0.14; 0.12)	0.05 (−0.28; 0.18)	0.86[base,a]
LT/SA lowering, 3 kg	−0.13 (−0.43; 0.16)	−0.01 (−0.19; 0.17)	−0.12 (−0.23; 0.47)	0.48
EMG (onset time, msec)				
UT-SA elevation, 3 kg	−0.01 (−0.04; 0.03)	−0.04 (−0.08; −0.01)[w]	0.04 (−0.08; 0.01)	0.23
UT-LT elevation, 3 kg	−0.05 (−0.09; −0.002)[w]	−0.03 (−0.08; 0.03)	−0.02 (−0.05; 0.09)	0.34[base]
LT-SA elevation, 3 kg	0.02 (−0.03; 0.07)	0.002 (−0.05; 0.06)	0.01 (−0.09; 0.06)	0.48[base]

Abbreviations: BIONEX EMG-biofeedback neuromuscular shoulder exercise group; **NEX** neuromuscular shoulder exercise group ; **EMG** Electromyography; **%MVE** percentage of Maximum Voluntary EMG; **UT** Upper Trapezius; **LT** Lower Trapezius; **SA** Serratus Anterior; Significant effects of age (=a), gender (=g), BMI, Body Mass Index (=B); baseline values (=base); significant within-group differences from baseline to follow-up (=w).

5. Limitations

As described the current age criteria were selected to represent the general population, in contrast with previous studies (De Mey et al., 2012; Huang et al., 2013) (eg. current 42–50 years versus previous athletic populations of about 25 years). Further, the current study used the diagnostic criteria for SPS on which the patho-etiology was based and not scapular muscle imbalance, since muscle imbalance may be invisible and even non-symptomatic (Belling Sorensen and Jorgensen, 2000).

A major strength is the rigid design with appropriate sample size, standardised tests for inclusion (Juul-Kristensen et al., 2006; Vind et al., 2011), and procedures for electrode placement, normalisation of EMG signal, experimental testing (Holtermann et al., 2010; Ludewig and Cook, 2000), besides the random allocation to intervention groups with blinded assessors during data sampling and analyses.

6. Conclusion

In summary, EMG-biofeedback did not seem to make a difference. As both BIONEX and NEX were effective in reducing pain to a clinically relevant level, the current neuromuscular shoulder exercise protocol can be recommended to patients with subacromial pain syndrome.

Future research should focus on subgroup analyses on those participants with the most altered shoulder neuromuscular strategies at baseline, besides further development of biofeedback procedures for use in clinical practice.

Financial disclosure

Declaration of Competing Interest

The authors declared that there is no conflict of interest.

Acknowledgements

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jelekin.2019.07.009.

References

Baskurt, Z., Baskurt, F., Gelecek, N., Ozkan, M.H., 2011. The effectiveness of scapular stabilization exercise in the patients with subacromial impingement syndrome. J. Back Musculoskelet Rehabil. 24, 173–179.

Belling Sorensen, A.K., Jorgensen, U., 2000. Secondary impingement in the shoulder. An improved terminology in impingement. Scand. J. Med. Sci. Sports 10, 266–278.

Bennell, K., Wee, E., Coburn, S., Green, S., Harris, A., Staples, M., Forbes, A., Buchbinder, R., 2010. Efficacy of standardised manual therapy and home exercise programme for chronic rotator cuff disease: randomised placebo controlled trial. BMJ 340, c2756.

Bevan, Stephen. 2009. Fit for Work?: Musculoskeletal Disorders in the European Workforce (Work Foundation).

Boutron, I., Moher, D., Altman, D.G., Schulz, K.F., Ravaud, P., 2008. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann. Intern. Med. 148, 295–309.

Clausen, M.B., Witten, A., Holm, K., Christensen, K.B., Attrup, M.L., Holmich, P., Thorborg, K., 2017. Glenohumeral and scapulothoracic strength impairments exists in patients with subacromial impingement, but these are not reflected in the shoulder pain and disability index. BMC Musculoskelet Disord 18, 302.

De Mey, K., Danneels, L., Cagnie, B., Cools, A.M., 2012. Scapular muscle rehabilitation exercises in overhead athletes with impingement symptoms: effect of a 6-week training program on muscle recruitment and functional outcome. Am. J. Sports Med. 40, 1906–1915.

Ellenbecker, T.S., Cools, A., 2010. Rehabilitation of shoulder impingement syndrome and

rotator cuff injuries: an evidence-based review. Br. J. Sports Med. 44, 319–327.

Eshoj, H., Bak, K., Blond, L., Juul-Kristensen, B., 2017. Translation, adaptation and measurement properties of an electronic version of the Danish Western Ontario Shoulder Instability Index (WOSI). BMJ Open 7, e014053.

Frich, L.H., Noergaard, P.M., Brorson, S., 2011. Validation of the Danish version of Oxford shoulder score. Dan. Med. Bull. 58, A4335.

Holmgren, T., Bjornsson Hallgren, H., Oberg, B., Adolfsson, L., Johansson, K., 2012. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study. BMJ 344, e787.

Holtermann, A., Mork, P.J., Andersen, L.L., Olsen, H.B., Sogaard, K., 2010. The use of EMG biofeedback for learning of selective activation of intra-muscular parts within the serratus anterior muscle: a novel approach for rehabilitation of scapular muscle imbalance. J. Electromyogr. Kinesiol. 20, 359–365.

Hotta, G.H., Santos, A.L., McQuade, K.J., de Oliveira, A.S., 2018. Scapular-focused exercise treatment protocol for shoulder impingement symptoms: three-dimensional scapular kinematics analysis. Clin Biomech (Bristol, Avon) 51, 76–81.

Huang, H.Y., Lin, J.J., Guo, Y.L., Wang, W.T., Chen, Y.J., 2013. EMG biofeedback effectiveness to alter muscle activity pattern and scapular kinematics in subjects with and without shoulder impingement. J. Electromyogr. Kinesiol. 23, 267–274.

Jarvinen, T.L., Sihvonen, R., Bhandari, M., Sprague, S., Malmivaara, A., Paavola, M., Schunemann, H.J., Guyatt, G.H., 2014. Blinded interpretation of study results can feasibly and effectively diminish interpretation bias. J. Clin. Epidemiol. 67, 769–772.

Jones, S.A., Pamukoff, D.N., Mauntel, T.C., Blackburn, J.T., Myers, J.B., 2018. The influence of verbal and tactile feedback on electromyographic amplitude of the shoulder musculature during common therapeutic exercises. J. Sport Rehabil 27, 424–430.

Juul-Kristensen, B., Kadefors, R., Hansen, K., Byström, P., Sandsjî, L., Sjögaard, G., 2006. Clinical signs and physical function in neck and upper extremities among elderly female computer users: the NEW study. Eur. J. Appl. Physiol. 96, 136–145.

Juul-Kristensen, B., CM. Larsen, H.; Eshøj, TH. Clemmensen, A. Hansen, PB. Jensen, E. Boyle, and K. Søgaard. 2017. "Statistical Analysis Plan (SAP): Effect of eight weeks' training with or without EMG-biofeedback, on shoulder pain and function in patients with subacromial impingement - an assessor-blinded randomised controlled trial." In https://findresearcher.sdu.dk:8443/admin/files/129144582/BJK_SAP_RCTBIONEX_081117_final.pdf, 20. Odense, Denmark: University of Southern Denmark.

Kinsella, R., Pizzari, T., 2017. Electromyographic activity of the shoulder muscles during rehabilitation exercises in subjects with and without subacromial pain syndrome: a systematic review. Shoulder Elbow 9, 112–126.

Kuorinka, I., Jonsson, B., è Kilbom, A., Vinterberg, H., Biering-Sõrensen, F., Andersson, G., Jõrgensen, K., 1987. Standardised Nordic questionnaires for the analysis of musculoskeletal symptoms. Appl. Ergo. 18, 233–237.

Larsen, C.M., Juul-Kristensen, B., Olsen, H.B., Holtermann, A., Sogaard, K., 2014. 'Selective activation of intra-muscular compartments within the trapezius muscle in subjects with Subacromial Impingement Syndrome. a case-control study. J. Electromyogr. Kinesiol. 24, 58–64.

Ludewig, P.M., Cook, T.M., 2000. Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. Phys. Ther. 80, 276–291.

McClure, P.W., Bialker, J., Neff, N., Williams, G., Karduna, A., 2004. Shoulder function and 3-dimensional kinematics in people with shoulder impingement syndrome before and after a 6-week exercise program. Phys. Ther. 84, 832–848.

Michener, L.A., Walsworth, M.K., Doukas, W.C., Murphy, K.P., 2009. Reliability and diagnostic accuracy of 5 physical examination tests and combination of tests for subacromial impingement. Arch. Phys. Med. Rehabil. 90, 1898–1903.

Moezy, A., Sepehrifar, S., Solaymani Dodaran, M., 2014. The effects of scapular stabilization based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlled randomized clinical trial. Med. J. Islam Repub. Iran 28, 87.

Osteras, H., Torstensen, T.A., Osteras, B., 2010. High-dosage medical exercise therapy in patients with long-term subacromial shoulder pain: a randomized controlled trial. Physiother. Res. Int. 15, 232–242.

Page, P., 2011. Shoulder muscle imbalance and subacromial impingement syndrome in overhead athletes. Int. J. Sports Phys. Ther. 6, 51–58.

Pearl, M.L., Jackins, S., Lippitt, S.B., Sidles, J.A., Matsen 3rd., F.A., 1992. Humeroscapular positions in a shoulder range-of-motion-examination. J. Shoulder Elbow Surg. 1, 296–305.

Reijneveld, E.A., Noten, S., Michener, L.A., Cools, A., Struyf, F., 2017. Clinical outcomes of a scapular-focused treatment in patients with subacromial pain syndrome: a systematic review. Br. J. Sports Med. 51, 436–441.

Saito, H., Harrold, M.E., Cavalheri, V., McKenna, L., 2018. Scapular focused interventions to improve shoulder pain and function in adults with subacromial pain: a systematic review and meta-analysis. Physiother. Theory Pract. 34, 653–670.

Salaffi, F., Stancati, A., Silvestri, C.A., Ciapetti, A., Grassi, W., 2004. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur. J. Pain 8, 283–291.

Schonnemann, J.O., Larsen, N., Hansen, T.B., Soballe, K., 2011. reliability and validity of the Danish version of the disabilities of arm, shoulder, and hand questionnaire in patients with fractured wrists. J. Plast Surg. Hand Surg. 45, 35–39.

Seitz, A.L., Michener, L.A., 2011. Ultrasonographic measures of subacromial space in patients with rotator cuff disease: a systematic review. J. Clin. Ultrasound 39, 146–154.

Shah, M., Sutaria, J., Khant, A., 2014. Effectiveness of scapular stability exercises in the patient with the shoulder impingement syndrome. Indian J. Phys. Ther. 2, 79–84.

Struyf, F., Nijs, J., Mollekens, S., Jeurissen, I., Truijen, S., Mottram, S., Meeusen, R., 2013. Scapular-focused treatment in patients with shoulder impingement syndrome: a randomized clinical trial. Clin. Rheumatol. 32, 73–85.

Vind, Mikkel, Bogh, Søren Bie, Larsen, Camilla Marie, Knudsen, Hans Kromann, Søgaard, Karen, Juul-Kristensen, Birgit, 2011. Inter-examiner reproducibility of clinical tests and criteria used to identify subacromial impingement syndrome. BMJ open 1.

World Medical, A. . 2013. 'World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects', JAMA, 310: 2191-4.

Worsley, P., Warner, M., Mottram, S., Gadola, S., Veeger, H.E., Hermens, H., Morrissey, D., Little, P., Cooper, C., Carr, A., Stokes, M., 2013. Motor control retraining exercises for shoulder impingement: effects on function, muscle activation, and biomechanics in young adults. J. Shoulder Elbow Surg. 22, e11–e19.

Birgit Juul-Kristenen (PT, PhD, associate professor) at University of Southern Denmark, Department of Sports Sciences, Research Unit for Musculoskeletal Function and Physiotherapy. Her field of research includes mechanisms, prevention and treatment of muscle/joint diseases, in the shoulder and neck.