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Changes in pain, daily occupations, lifestyle, and health following an occupational therapy lifestyle intervention

a secondary analysis from a feasibility study in patients with chronic high-impact pain

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Clinical Pain Research

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Changes in pain, daily occupations, lifestyle, and health following an occupational therapy lifestyle intervention: a secondary analysis from a feasibility study in patients with chronic high-impact pain

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Abstract

Objectives: This study explored changes in pain-related parameters, occupational function, occupational balance, lifestyle factors, and self-perceived health status in adults with chronic high-impact pain participating in an occupational therapy lifestyle intervention.

Methods: This one-group longitudinal feasibility study was performed in three continuous feasibility rounds. The occupational therapists-led intervention targeted meaningful occupations, regular physical activity, and a healthy diet. The intervention contained individual and group sessions and was added to the standard multidisciplinary chronic

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pain treatment. Outpatients (n=40, 85% females, 46.6 ± 10.9 years old) participated in the study between April 2019 and December 2021. The analysis includes data for 31 participants.

Analysis of pre-post changes assessed after each feasibility round were performed for the outcomes: pain intensity, pain sensitivity and pain modulation (pressure pain threshold and tolerance, temporal summation of pain and conditioned pain modulation), pain self-efficacy, pain catastrophizing, motor and process skills, occupational balance, daily wake-time movement, daily walking steps, body mass index, waist circumference, blood pressure, and selfperceived health status.

Results: Improvements in motor skills (assessment of motor and process skills score=0.20 (1.37; 1.57), 95 % CI 0.01; 0.38) and temporal summation of pain (-1.19 (2.86; -1.67),

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95 % CI -2.16; -0.22), but a decrease in pain tolerance performanc (-7.110 (54.42; 47.32), 95 % CI -13.99; -0.22) were observed. related par Correlation analysis suggested moderate-to-very strong statistically significant relationships in several outcomes weren't pre-

related to pain, health, pain coping, occupational balance, occupational functioning, body anthropometrics, and pain sensitivity.

Conclusions: This study suggested that the lifestyle intervention would benefit motor skills while effects on other outcomes were unclear in adults with chronic pain. To confirm the findings, a randomized trial evaluating effectiveness is needed.

Ethical committee number: SJ-307 Reg. Clinicaltrials.gov: NCT03903900

Keywords: activities of daily living; evaluation study; health behaviour; healthy lifestyle; health-related quality of life; pain management

Introduction

Recent evidence suggests that multidisciplinary chronic pain treatment improves quality of life in people with chronic pain [1], but little is known about the optimal combination of chronic pain treatment modalities within these multi-modal programs [2]. Since the long-term success of pharmacological pain therapy is limited due to the high number needed to treat (NNT) and frequent adverse side effects [3], lifestyle management has been proposed as a novel nonpharmacological treatment for chronic pain [4–6]. A study of Danish outpatients with chronic pain demonstrated multiple lifestyle-associated risk factors and high motivation for initiating lifestyle changes [7], suggesting that a lifestyle focus might be appropriate. Therefore, a lifestyle management program for adults living with chronic pain (Redesign your EVEryday Activities and Lifestyle with Occupational Therapy (REVEAL(OT))) was developed as an add-on to the standard multidisciplinary treatment of chronic pain. Recently, the REVEAL(OT) intervention was tested for feasibility at a Danish hospital to prepare for a full-scale randomized controlled trial (RCT) [8]. The evaluation demonstrated satisfactory intervention feasibility regarding program adherence, patients' self-perceived relevance, timing and mode of delivery, and assessment procedure acceptance, with no adverse events causing discontinuation [9]. However, recruitment, retention and the fidelity of delivery needed improvement [9]. Pre-post analysis of selected outcomes showed no statistically significant change in self-perceived health-related quality of life (HRQoL), but statistically significant improvement in occupational

performance and satisfaction [9]. Pre-post change in painrelated parameters, occupational function, occupational balance, lifestyle factors, and self-perceived health status weren't previously reported.

This secondary analysis of the feasibility study aimed to investigate the pre-post change in pain intensity, pain sensitivity and pain modulation, pain self-efficacy, pain catastrophizing, motor and process skills, occupational balance, daily wake-time movement, daily walking steps, body mass index (BMI), waist circumference, blood pressure, and self-perceived health status in adults with chronic pain participating in REVEAL(OT). Additionally, we investigated the association between changes in the outcomes, to inform the assessment protocol adjustments for the RCT.

Methods

Study design

The outcomes in this pre-planned secondary analysis of a one-group longitudinal feasibility study were included in the protocol for the RCT (pre-registered at Clinicaltrials.gov NCT03903900). Both primary and secondary analyses aimed to inform a future randomized controlled trial (RCT).

The feasibility study followed the MRC framework [8]. The CON-SORT guidelines for reporting non-randomized pilot and feasibility studies guided this report (see Supplementary materials, Table S1) [10].

Settings

Occupational therapy unit (OTU) delivered the REVEAL(OT) intervention as an add-on treatment to standard multidisciplinary treatment for outpatients referred to the Multidisciplinary Pain Centre (MPC) at Naestved Hospital, Region Zealand, Denmark. Physicians, nurses, psychologists, physiotherapists, and a social worker provided the cognitivebehavioral therapy (CBT)-based standard treatment.

Participants

The MPC outpatient cohort ≥18<65 years old with chronic non-malignant pain lasting more than three months were screened for eligibility and asked about their interest in participating. Individuals with acute/subacute pain; cancer-related pain; unstable medicine intake over the past four weeks; daily opioid intake >30 mg; headache/migraine; current depression or substance misuse; severe psychiatric illness; poor Danish proficiency; inability to walk a distance of 100 m independently or attending other specialized chronic pain treatments were excluded.

Intervention

The REVEAL(OT) had a three-fold focus on meaningful activities, healthy eating, and daily physical activity guided by occupational science [11, 12], occupational lifestyle management research [13], the World Health

Organisation's physical activity guidelines for adults [14] and the advice on healthy nutrition from the Ministry of Food, Agriculture and Fisheries in Denmark [15]. The REVEAL(OT) consisted of 2-4 1-h individual sessions and 4-8 2-h group sessions over 12-15-weeks. Each group comprised max. six participants. The protocolized and manualized intervention contents included: (a) brief didactic presentations on the topics, such as occupation for health and well-being, benefits of daily physical activity, meals and eating habits, occupational balance and time management, productivity/domestic and out-of-home activities, ergonomics at home and work, flow experience, hobbies, and leisure; (b) group discussions; (c) individual reflection prompts; and (c) building up personal experience. In addition, the participants monitored their lifestyle-related health behavior by wearing an activity tracker which detected daily physical activity, energy expenditure, and step counts and making diary notes. Assistive devices were available for loan during the intervention course.

Occupational therapist contact was provided at least every second week or on demand. Intervention occupational therapists (OTs) had 14 years of professional experience each. Weekly and on-demand supervision of the intervention delivery was provided to the OTs by the principal investigator who had completed online courses within the Life Management Series at The USC Mrs. T.H. Chan Division of Occupational Science and Occupational Therapy (University of Southern California, USA), 12 contact hours in total. In addition, a one-day course and supervision in the Canadian Occupational Performance Measure interviewing technique and practice were provided by A.E. Larsen, Ph.D. and lector from the University Colledge Copenhagen. After completing the intervention, the participants continued their standard treatment plan at the MPC. A detailed description of the intervention is available in previous publication [9, 16].

Patient and public involvement

The outcomes were informed by our previous research on the outpatient cohort of the MPC, which provided us with clinically relevant information on their HRQoL, health, pain, lifestyle factors, and motivation for changing lifestyle [7]. Qualitative mid-term evaluation with focus groups of patients and clinicians informed further research activities [16].

Data collection

The assessment procedure contained two modules performed by trained assessors in the clinic, and by patients' self-reports at home. The assessments were carried out 1-2 weeks before and max. 2 weeks after the intervention to capture the pre-post change in the outcomes.

Self-reports (at-home assessment): The participants self-reported their sociodemographics, pain intensity, pain catastrophizing, pain spreading, pain self-efficacy, occupational balance, sleep quality, health, and HRQoL using an at home online questionnaire in the national Danish clinical chronic pain registry PainData [17].

Health: EuroQoL questionnaire (EQ-5D-5L, EuroQol reg. ID 28126) assessed self-perceived health on the day of the assessment on a visual 0-100-point analog scale (EQ5D VAS), with 0 for the worst imaginable health and 100 for the best imaginable health [18].

Sociodemographics: Gender and age were calculated from each participant's personal Danish ID number containing relevant identifiers. Selfreports registered education level and marital status.

Pain intensity: The participants rated worst and average pain in the last 24 h using the Brief Pain Inventory Short Form (BPI-sf) [19]. The pain intensity levels ranged from 0 (no pain) to 10 (worst pain imaginable) on a Numeric Range Scale (NRS).

Pain spreading: Participants registered their painful body areas on a body pain chart representing 71 anatomic regions in anterior and posterior views and allowing for pain spreading quantification [20]. The method permitted marking multiple painful body areas.

Pain catastrophizing: Catastrophic thinking related to pain was reported using the Pain Catastrophizing Scale (PCS), 13 items: scores 0-52 (higher is worse) [21, 22].

Pain acceptance: Acceptance of chronic pain was reported using the Chronic Pain Acceptance Questionnaire (CPAQ), eight items: scores 0–48 (higher is better) [23-25].

Pain self-efficacy: Self-perceived confidence in functioning despite the pain and regarding domestic shores, socializing, work, and medicationfree pain coping was assessed using the Pain Self Efficacy Questionnaire (PSEQ), 10 items: scores 0-60 from 0 (not confident) to 6 (completely confident) (higher is better) [26].

Occupational balance: Satisfaction with the amount and variation of occupations was reported using the Occupational Balance Questionnaire (OBQ), 13 items, four-step ordinal scales: scores 13-52 from 1 (disagree) to 4 (agree) (higher is better) [27].

Sleep quality: Self-reported sleep quality was registered by the adapted Karolinska Sleep Questionnaire (KSQ), four items subscale for sleep disturbance frequency, frequency of difficulties in falling asleep, frequency of early awakenings, and frequency of night-time awakenings accompanied with difficulty in falling asleep again: scores 4-20, from 1 (every night or almost every night) to 5 (never) (higher is better) [28].

In-clinic assessment

Motor & process skills: Activities of daily living (ADL) function related to the observed effort and/or fatigue, efficiency, safety, and independence in the performance of habitual daily activity tasks were measured using the standardized Assessment of Motor and Process Skills (AMPS) instrument [29, 30]. Occupational performance together with body anthropometrics and metabolic health factors may reflect a change in lifestyle habits [31].

Qualified OTs conducted the AMPS assessment allowing each patient to pre-determine and perform two relevant personal or instrumental ADL (PADL or IADL) with individually adjusted difficulty levels. The AMPS evaluates the overall quality of personal motor and process skills on a four-point ordinal scale, capturing the interaction between the person, occupation, and environment [32]. Two scores in log-odds probability units (logits) for personal ADL function reflecting motor and process skills, adjusted for task complexity and rater severity, were derived. The AMPS has previously demonstrated its broad validity in different diagnoses, including chronic pain [33].

BMI: BMI was calculated digitally by the TANITA DC-360 weight scale using a person's height in cm and weight in kg (BMI=kg/m²) to estimate whether body weight was healthy (BMI ranged from 18.5 to 24.9), underweight, overweight, or obese [34].

Waist circumference: The certified stretch-resistant measuring tape was used to measure waist circumference to help identify possible abdominal obesity, i.e., waist circumference >80 cm for women and >102 cm for men, which increases disease risk and mortality [35]. Assessors measured the participants' waist circumferences by placing the measuring tape parallel to the floor at the midpoint between the lowest palpable rib and the top of the iliac crest, with the participants standing up with arms at the side, no clothes around the abdomen and normal breathing. The measurements were repeated twice, and the average value was calculated. The two measures exceeded 1 cm.

Blood pressure: The assessors received training in the unified protocolized method to perform the BP assessment and measured the participants' BP according to the protocol after appx. 30 min physically non-strenuous activity (the COPM interview) using a licensed medical sphygmomanometer [36]. Two values in millimeters of mercury (mm Hg) were obtained for the systolic BP (while the heart beats) and diastolic BP (while the heart is relaxed). BP norm was defined as a systolic BP≤120 mm Hg and a diastolic BP≤80 mm Hg. High BP (hypertension) may increase the risk of cardiovascular diseases and stroke and can be prevented by lifestyle changes, e.g., healthy eating and physical activity.

Pain sensitivity: Quantitative sensory testing (QST) aims to decrease researcher bias assessing sensory functioning of neural system. A range of different techniques are available. Primary pressure hyperalgesia is assessed by pressure pain thresholds (PPTs). Decreased PPTs outside known painful area might reflect secondary pressure hyperalgesia [37, 38]. Temporal summation of pain (TSP) is the proxy assessment for wind-up [39, 40] and is believed to assess dorsal horn neuron excitability. Conditioned pain modulation (CPM) is a proxy assessment for diffuse noxious inhibitory control [41] and believed to assess the function of the descending pain inhibitory systems [37, 38].

Deep tissue pain sensitivity was evaluated by cuff pressure stimuli using a computer-controlled cuff algometer (Cortex Technology and Aalborg University, Denmark), including a 13-cm wide tourniquet cuff (VBM, Sulz, Germany) and an electronic VAS (Aalborg University, Denmark) for the recording of the pain intensity [42]. The cuff was placed over the head of the gastrocnemius muscle at the dominant side. Patient was in a half-sitting position. The continuous electronic VAS (sliding resistor) was 10 cm long and sampled at 10 Hz. Zero reflected no pain and 10 cm – worst pain imaginable. Cuff algometry is a reliable assessment for pain pressure thresholds, TSP, and CPM [43, 44].

The pressure of the cuff was increased by 1 kPa/s, and the patient was instructed to rate the pain intensity continuously on the electronic VAS until the tolerance level was reached. At this point, the patient was instructed to press a stop button. The cuff pressure pain detection threshold (cPDT) was defined as the pressure at which the VAS score exceeded 1 cm as in previous studies [45, 46]. The cuff pressure pain tolerance threshold (cPTT) was defined when the patient pressed the stop button. The measurements were conducted once on both legs. Ten short-lasting stimuli (1 s each) at the level of the cPTT were given at the right lower leg with a 1 s break between stimuli. The participants were

instructed to continuously rate the pain intensity of the sequential stimuli using the electronic VAS and not return to zero during the breaks. Each cuff pressure stimulus was accessed by a VAS score. TSP was calculated as the absolute difference between the last three stimuli and the first three stimuli, as in previous studies [46, 47]. The CPM magnitude was assessed as the absolute changes in cPDT with and without a cuff conditioning stimulus. Then, the conditioning stimulus was applied to the left lower leg, and the cPDT was assessed on the right lower leg as described above. The conditioning stimulus was applied as a constant stimulus with an intensity of 70 % of the pain tolerance level on the contralateral leg [46]. The CPM effect was calculated as the absolute difference in conditioned and unconditioned cPDT (i.e., cPDT conditioned minus cPDT unconditioned).

Physical wake-time activity (PWTA): The participants wore thighmounted three-axial accelerometers for 4 days to monitor the variations of physical activity (PA) and sedentary behavior during their wake time [48]. PWTA was calculated in hours (non-sedentary, between 6 a.m. and 11 p.m.), hours in walking activity, and number of steps per day.

Sample size

Feasibility studies are not designed to evaluate effects, and there is no definitive approach to estimating their correct sample size [49]. Therefore, we did not perform a formal sample size calculation and our results can only be used to guide future trials in the field, not as proof of effect or lack of effect.

Analysis

We estimated means and standard deviations (SD) for continuous variables and frequency distributions for categorical variables in the descriptive statistical analysis. We tested the assumption of normality of distribution using the Shapiro-Wilk W test and histograms to determine whether parametric or nonparametric statistics should be applied. The pre-post difference in an outcome was calculated by subtraction of its baseline score from post-intervention score. The pre-post differences were presented as means and 95 % confidence intervals (CI). The positive pre-post difference in EQ 5D VAS health, CPAQ pain acceptance, PSEQ self-efficacy, OBQ occupational balance, KSQ sleep quality, AMPS motor and process skills, PWTA physical activity scores, and walking steps (higher scores are better) was interpreted as an improvement and negative pre-post difference - as a decline. Negative pre-post-difference in the inverse assessments (lower is better), i.e., BPI-sf pain intensity and PCS pain catastrophizing, was interpreted as an improvement, and positive pre-post difference - as a decline. As higher scores in BMI, waist circumference, and blood pressure may indicate poorer metabolic health compared to the lower scores, their pre-post differences were treated as the inverse assessment scales. Negative pre-post differences TSP (as expression of the nervous system's pain excitability) and positive pre-post differences in CMP conditioned pain modulation (as expression of the nervous system's pain inhibitory capacity) were interpreted as improvements. We performed t-tests of the pre-post differences in the outcomes using the data from the complete datasets. Participants with missing outcomes were not included in the specific analyses.

Pearson's correlation analysis evaluated the magnitude and direction of the association between the change estimates. Additionally, occupational performance and satisfaction previously assessed by the Canadian Occupational Performance Measure (COPM, a higher score is better) [9] was included in the correlation analysis, to provide a complete comparison of the outcomes. The correlation coefficients 0.01-0.09 described a negligible, 0.10-0.29 - week, 0.30-0.49 - moderate, 0.50-0.69 - strong, and 0.70-0.99 - very strong correlation [50]. Stata© 17.0 software (Stata Statistical Software: Release 21. College Station, TX: StataCorp LLC) assisted with the statistical analysis.

Results

Of 40 patients with chronic pain enrolled in the feasibility study between January 2019 and October 2020, there were 32 completers (80%). One participant was excluded from the analysis because of receiving the entire content of the standard treatment before starting in the REVEAL(OT), which deviated from the study protocol. See the previously published study flow diagram [9] in Supplementary Materials (Figure S1). Completing at-home assessment was a difficult task for most participants. Efforts were made to prevent missing data by up to five reminders (phone calls and e-mails). Technical assistance was available on demand during the assessment period.

Three feasibility rounds (REVEAL(OT) 1.0-3.0) were performed between April 2019 to July 2021 with structural adjustments to the needs of the participants, and clinical practice between the rounds, according to the feedback received, while the intervention concept, topics and procedures remained. We completed the final data collection June 2021.

The sociodemographic data (Table 1) illustrated that most participants were aged 35 or older (80.7%), had not entered the higher education system (74.1%), received social-supportive economic benefits (77.8%), and experienced more than 50 % of the body regions affected by pain (70.4%). The participants reported 11 years of pain experience and a pain intensity score of 6.5 (0-10 scale) on average.

Table 2 demonstrates pre-post changes in self-perceived health status, motor and process skills, occupational balance, pain intensity, pain sensitivity, pain catastrophizing, pain self-efficacy, pain acceptance, sleep quality, PWTA, BMI, waist circumference, and BP. This study identified a statistically significant improvement in motor skills (mean=0.20, 95 % CI 0.01; 0.38; p=0.0357) that reached the MCID for AMPS of 0.3 logits in 35.7% of the participants [51]. A statistically significant decrease in the cPTT level for the right leg (mean=-7.11, 95 % CI -13.99; -0.22; p=0.0436) accompanied a statistically significant decrease in TSP (mean=-1.19, 95%) CI -2.16; -0.22; p=0.0184) post-intervention. No other statistically significant pre-post changes were identified.

Table 3 presents the results of Pearson's correlation analysis of change in the outcome. Statistically significant Table 1: Sociodemographics and pain-related characteristics of the study sample.

Variable	n (%) or mean	(median; range)
	Completers (n=31)	Non-completers (n=9)
Females		
Completers	25 (80.7)	9 (100)
Age, years		
Completers	46.8 (11.1; 23–62)	45.7 (10.5; 33–64)
Age groups, years old		
18–24	1 (3.2)	0 (0)
25–34	5 (16.1)	1 (11.2)
35–44	6 (19.4)	3 (33.3)
45–54	9 (29.0)	3 (33.3)
55–64	10 (32.3)	2 (22.2)
Social status	· · ·	, , , , , , , , , , , , , , , , , , ,
Married/cohabiting	17 (54.8)	6 (66.7)
Single	9 (29.1)	3 (33.3)
Not answered	5 (16.1)	0 (0)
Education	- ()	- (-)
Primary and lower secondary	7 (22.6)	4 (44.5)
school	, (22.0)	1(11.5)
Secondary school	1 (3.2)	0 (0)
Vocational education	12 (38.7)	2 (22.2)
Short-cycle higher education	4 (12.9)	2 (22.2)
Medium-cycle higher education	2 (6.5)	1 (11.1)
Other	1 (3.2)	0 (0)
Not answered	4 (12.9)	0 (0)
	4 (12.9)	0(0)
<i>Economic support basis</i> Earned income (regular	6 (19.4)	0 (0)
conditions)	0 (19.4)	0(0)
Earned income (flexible	2 (6.4)	1 (11 2)
conditions)	2 (0.4)	1 (11.2)
Sickness benefit	6 (19.4)	2 (22 2)
		2 (22.2) 1 (11.1)
Unemployment benefit Cash benefit	0 (0) 7 (22.6)	
		0 (0) 2 (22.2)
Resource course benefit	4 (12.9) 2 (6.4)	2 (22.2) 2 (22.2)
Pension (regular or early, age- induced)	2 (0.4)	2 (22.2)
,	4 (12 0)	1 (11 1)
Not answered	4 (12.9)	1 (11.1)
Years with pain	0 (25 0)	
<5	8 (25.8)	5 (55.6)
5-9	6 (19.4)	2 (22.2)
10-14	2 (6.5)	1 (11.1)
15-19	5 (16.1)	1 (11.1)
≥20	5 (16.1)	0 (0)
Not answered	5 (16.1)	0 (0)
Pain intensity, 0–10 NRS	27 (6 40 2 40)	
Average ^a	27 (6.48; 3–10)	9 (6.7; 5–8)
Strong ^a	27 (8.11; 5–10)	9 (7.4; 7–8)
Pain spreading, % of the 71 body		.
<25	3 (9.7)	0 (0)
25-50	5 (16.1)	4 (44.5)
50-75	7 (22.6)	3 (33.3)
≥75	12 (38.7)	2 (22.2)
Not answered	4 (12.9)	0 (0)

^aExclusive non-responded completers, n=4.

Variable (n observations)	Count (%) (median		Pro	e-post (difference
	Baseline	Follow- up	Mean	SD	95 % CI
Health status (n=22)					
EQ-5D VAS 0-100	46.55	54.14	7.59	24.30	-3.18; 18.36
BPI-sf pain (n=21)					
Worst, NRS	8.38 (6;	7.76 (4;	-0.61	1.75	-1.41; 0.18
	10)	9)			
Average, NRS	6.67 (3;	6.00 (3;	-0.67	1.62	-1.41; 0.72
	10)	9)			
AMPS occupational fu	nction (n=28	9			
Motor skills	1.37	1.57	0.20 ^a	0.47	0.01; 0.38
Process skills	1.59	1.67	0.82	0.36	-0.06; 0.22
OBQ occupational	31.57	34.86	3.29	7.55	-1.07; 7.64
balance (n=14)					
PCS catastrophizing	23.86	23.14	-0.71	14.31	-7.23; 5.80
(n=21)					
PSEQ pain self-	23.30	28.45	5.15	16.86	-2.74; 13.04
efficacy (n=20)					
CPAQ pain accep-	20.48	20.62	0.14	10.06	-4.44; 4.72
tance (n=21)					
KSQ sleep (n=21)	8.71	8.14	-0.57	5.18	-2.93; 1.79
PWTA time (hours	1.52	1.58	0.07	0.60	-0.21; 0.35
daily) (n=20)					
Walking steps (n	5,710	5,458	-252	1.527	-988; 484
daily) (n=19)					
BMI (n=28)	30.78	31.06	0.29	1.01	-0.10; 0.68
	(100)	(100)			
Waist circumference	101.30	99.63	-1.67	4.76	-3.52; 0.18
(n=28)					
BP (n=28)					
Systolic	130.96	130.50	-0.46	12.74	-5.40; 4.47
Diastolic	80.93	80.86	-0.07	9.61	-3.80; 3.65
Pain sensitization (n=					
cPDT, R	23.88	21.30	-2.58	13.57	-8.18; 3.02
cPDT, L	22.77	24.26	1.50	12.04	-3.47; 6.47
cPTT, R	54.42	47.32	-7.11ª	16.68	-13.99; -0.22
cPTT, L	49.90	47.16	-2.74	11.80	-7.62; 2.13
CPM	-0.22	5.11	5.33	21.54	-3.56; 14.23
TSP	2.86	1.67	–1.19 ^a	2.36	-2.16; -0.22

 Table 2: The pre-post change in outcomes related to health, pain, daily occupations, and lifestyle.

6

AMPS, assessment of motor and process skills; BMI, body mass index; BP, blood pressure; BPI-sf, brief pain inventory – short form; CI, confidence interval; CPAQ, chronic pain acceptance questionnaire; cPDT, cuff pressurepain detection threshold (kPA); CPM, difference between conditioned and unconditioned pain perception; cPTT, cuff pressure pain tolerance threshold (kPA); h, hours; L, left leg; n, number; NRS; numeric range scale; OBQ, occupational balance questionnaire; PCS, pain catastrophizing scale; PSEQ, pain self-efficacy questionnaire; PWTA, physical wake-time activity; R, right leg; SD, standard deviation; TSP, temporal summation of pain. ^aStatistically significant change at 0.05 level.

positive correlations at a moderate level or over (r>0.3) were observed within the same assessment tools, i.e., BPI-sf, AMPS, COPM, PWTA, and pain sensitivity. Additionally, an

improved PSEQ pain self-efficacy significantly correlated with improved OBQ occupational balance (r=0.58). An improvement in CPAQ pain acceptance significantly correlated with PSEO pain self-efficacy (r=0.52) and COPM satisfaction with occupational performance (r=0.55). An improvement in KSO sleep quality significantly correlated with an improvement in CPAQ pain acceptance (r=0.43). A high positive correlation between OBQ occupational balance and COPM satisfaction with occupational performance (r=0.52) did not reach the 0.05 level of statistical significance. Moreover, positive change (i.e., a decrease) in waist circumference was significantly correlated with an improvement in COPM occupational performance (r=-0.40), OBO occupational balance (r=-0.53), and CPAO pain acceptance (r=-0.48), while higher CPM scores (i.e., as an indicator for an improved pain inhibition) were significantly correlated with a decrease in BMI (r=-0.60).

At the same time, an improved PSEQ pain self-efficacy and an improved CPAQ pain acceptance were significantly correlated with an increased PCS pain catastrophizing (r=0.67 and r=0.54, respectively). An improvement in KSQ sleep quality was significantly correlated with a decline in AMPS motor skills (r=-0.58). Lower diastolic blood pressure was significantly correlated with a decline in OBQ occupational balance (r=-0.71). Higher TSP scores (i.e., as an indicator for pain excitability) were significantly correlated with improved AMPS motor skills (r=0.45).

Discussion

This secondary analysis of outcomes from a lifestyleoriented program added to standard multidisciplinary chronic pain treatment showed that the participants improved their motor skills while their cuff pressure pain tolerance and temporal summation of pain decreased. No statistically significant pre-post changes were identified in self-perceived health status, process skills, occupational balance, pain intensity, cuff pressure pain tolerance thresholds, temporal summation of pain, pain catastrophizing, pain self-efficacy, pain acceptance, sleep quality, physical activity, BMI, waist circumference, and blood pressure. Statistically significant correlations were identified between several outcomes.

The findings added to the previous report on a statistically significant change in the COPM occupational performance and satisfaction with occupational performance postintervention [9]. A statistically significant association between change in occupational performance and self-efficacy has previously been identified [52, 53]. However, painrelated self-efficacy changes were statistically insignificant

the outcome variables.
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t change
pre-post
between
Correlations
Table 3:

									ر	סנובומתה	correlation coefficients, r	IS, r											
Variables	EQ-5D VAS health	BP-sf worst pain	BP-sf average pain	COPM performance	COPM satisfaction	AMPS motor	AMPS process	OBQ	PCS	PSEQ	CPAQ KS	KSQ PWTA (h daily)	/TA (h Steps (n daily) daily)	(n BMI y)	_	Waist circumference s	BP systolic (BP diastolic	cPDT, R	cPDT, L	cPTT, R	cPTT, L	CPM
BP-sf worst pain BP-sf average	0.43 0.45 ª	0.87																					I
pain		l																					
COPM	0.08	0.01	-0.02																				
performance																							
COPM	0.26	0.22	0.16	0. 7 9 ^b																			
satisfaction																							
AMPS motor	0.01	-0.07	-0.08	0.35	0.34																		
AMPS process	0.31	0.03	-0.00	0.17	0.26	0.53 ^a																	
ово	0.39	0.47	0.27	0.19	0.52	-0.12	-0.16																
PCS	-0.03	0.09	0.05	0.01	0.21	-0.33	-0.31	0.41															
PSEQ	0.34	0:30	0.29	0.16	0.40	-0.26	-0.15	0.58 ^a	0.67 ^a														
СРАQ	0.02	0.08	0.14	0.40	0.55 ^a	-0.33	-0.30	0.45	0.54 ^a	0.52 ^a													
ksq	0.33	0.13	0.37	-0.16	-0.02	- 0.58 ^a	-0.32	0.16	0.23	0.40	0.43 ^a												
PWTA (h daily)	-0.03	0:30	0.18	-0.26	-0.22	-0.22	-0.17	0.01	-0.13	-0.02	-0.09 0.35	35											
Steps (n daily)	0.06	0.25	0.11	-0.01	0.19	0.23	0.13	0.13	-0.29	-0.10	-0.06 -0.04		0.70 ^a										
BMI	0.12	0.14	0.18	0.10	-0.04	0.15	0.09	0.06	-0.28	0.04	-0.13 -0.02		0.09 -0.04	4									
Waist	-0.11	-0.19	-0.05	-0.31	-0.40 ^a	0.12	0.23	- 0.53 ª	-0.23	- 60.0-	-0.48 ^a -0.10		-0.27 -0.18	8 0.12	2								
circumference																							
BP systolic	0.20	-0.21	-0.01	0.18	0.19	0.17	0.37	-0.16	-0.05	0.25	0.10 0.	0.16 –0.	-0.16 -0.31	31 0.26	<u>1</u>	1.16							
BP diastolic	-0.18	-0.17	0.10	0.10	0.02	0.14	0.28	-0.71 ^a	-0.11	-0.15	0.06 0.08		0.19 0.24	24 0.03	33	0.07	0.34						
cPDT, R	-0.21	-0.01	-0.03	-0.23	-0.24	0.08	-0.30	0.20	-0.09	-0.07	-0.30 -0.23		0.24 0.17	17 0.08	8	-0.12	-0.11	-0.23					
cPDT, L	0.23	-0.10	-0.14	-0.05	-0.11	0.23	0.19	0.21	-0.39	-0.42	-0.31 -0.09		0.10 0.08	80.0- 80	8	-0.30	-0.07	-0.18	0.36				
cPTT, R	0:30	-0.13	-0.17	-0.10	-0.06	0.19	0.23	0.18	-0.28	-0.33	-0.30 -0.29		-0.02 0.18	18 0.18	∞	-0.17	0.07	-0.13	0:30	0.51 ^a			
cPTT, L	0.38	-0.25	-0.31	-0.05	-0.06	0.05	0.13	0.18	-0.14	-0.03	-0.42 -0.05		-0.01 -0.14	4 0.30	0	-0.11	0.23	-0.33	0.34	0.49 ^a	0.56ª		
CPM	-0.20	-0.19	-0.15	-0.34	-0.33	-0.19	-0.26	-0.18	0.14	-0.02	-0.08 0.04		0.03 -0.15	15 - 0.60 ^a)å	0.10	-0.16	-0.23	0.46 ^a	0.17	0.03	-0.06	
TSP	0.40	0.09	0.17	0.17	0.09	0.45 ^a	0.28	0.23	-0.25	0.02	-0.17 -0.09		-0.15 0.18	8 0.28	80	0.26	0.17	-0.16	0.07	0.28	0.20	0.31	-0.26
AMPS, assessment of motor and process skills; BMI, body mass index; BP, blood pressure; BPI-sf, brief pain inventory-short form; COPM, Canadian occupational performance measure; CPAQ, chronic pain acceptance questionnaire; cPDT, cuff pressure-pain detection threshold (kPA); CPM, and inference between conditioned and unconditioned pain perception; cPTT, cuff pressure pain tolerance threshold (kPA); h, hours; L, left leg; n,	nent of mc cPDT, cuff	otor and pr f pressure-	ocess skills; E pain detectio	3MI, body m n threshold	lass index; B (kPA); CPM,	P, blood pi , difference	essure; Bl between	PI-sf, b condit	rief pai	in inver and und	itory-sho	rt form; C ed pain p	OPM, Cané erception;	idian oc cPTT, ci	ccupatio uff press	nal perfoi sure pain	mance toleran	measure ce thresl	e; CPAQ hold (kF), chron PA); h, ŀ	ic pain a	accepta , left leç	nce ; n,
number; OBQ, occupational balance questionnaire; PCS, pain catastrophizing scale; PSEQ, pain self-efficacy questionnaire; PWTA, physical wake-time activity; R, right leg; TSP, temporal summation of pain. ^a Statistically significant change at 0.01 level. Bold values reached statistical significance at min. 0.05 level.	occupatio	nal balanc 5 level; ^b st	e questionna atistically sigi	ire; PCS, pai nificant chaı	n catastroph nge at 0.01	iizing scale level. Bold	scale; PSEQ, pain self-efficacy questionnaire; PWTA, physical v Bold values reached statistical significance at min. 0.05 level	in self- ached	efficac statistic	y quest	ionnaire; ificance a	PWTA, ph	iysical wak	e-time	activity; l	R, right le	g; TSP, I	empora	l summ	lation o	f pain. ^a	Statistic	ally

in the current study. Moreover, change in pain self-efficacy revealed no correlation with the change in COPM scores, but both correlated significantly with pain acceptance. Higher self-perceived acceptance of living with chronic pain was among the outcomes reported by the participants at a previous qualitative evaluation of the REVEAL(OT) intervention [16]. Improved pain acceptance also had a statistically significant correlation with improved sleep quality in this study. At the same time, pain self-efficacy and pain acceptance showed a strong inverse correlation with pain catastrophizing which is surprising, because the crucial role of reduced catastrophic thinking for successful pain selfmanagement is known [54, 55]. These correlations shall be investigated further.

Multiple reports have highlighted the benefits of improved occupational performance for daily functioning in different populations [56–58], underscoring the importance of approaching meaningful everyday occupations in the chronic pain population. A strong interrelationship between occupational performance and satisfaction, occupational balance, pain self-efficacy, and pain acceptance, detected in this study suggested an ability to impact pain coping capacity. However, this study was not powered to analyze possible causal relationships which have to be investigated closer, to avoid misinterpretations. Future studies shall also investigate the role of body anthropometrics, e.g., BMI, waist circumference, and blood pressure, in occupational therapy lifestyle management of chronic pain.

Pain alleviation remains one of the most important outcomes from the patient's perspective [59]. A slight but insignificant reduction in the worst and average pain intensity was observed in this study. Chronic pain is multifactorial, but studies indicate that the nervous system's sensitivity is linked to chronic pain [38, 60]. However, prepost data on pain sensitivity demonstrated contradicting findings with a potential reduction in temporal summation of pain and a potential decrease in pain tolerance thresholds following the intervention. These unexpected results and the difference between pain tolerance levels in the right vs. left leg at follow-up may originate from a lack of side difference in pain, diseases allocated to knees and legs, or leg dominance. Alternatively, a more positive mindset in patients after pain rehabilitation might result in PDT and PTT registered at lower pressure levels which led to lower TSP [61]. These parameters may be relevant in future studies. Additionally, previous evidence shows that specific chronic pain sub-groups, e.g., those with fibromyalgia, offer a more explicit response to the temporal summation test but may need substantially lower pain stimuli than the controls [62]. A control group and sub-group phenotyping could help nuance the findings of this study. Moreover, this study observed that more efficient pain inhibition correlated with higher BMI scores. At the same time, we know from previous research that being overweight is associated with higher pain, and a negative relationship would be expected [63]. These conflicting results should be interpreted carefully and further explored in future studies.

While planning future research applying the QST methods, the researchers should be attentive to large intrapersonal variability in QST measures [64]. This intrapersonal variability might be associated with other pain-related parameters such as pain catastrophizing [65], sleep quality [47], or immune response [66]. Studies demonstrate conflicting results regarding conditioned pain modulation before and after pain-relieving therapies, likely due to the complexity of factors interfering with QST results [67–69]. On the other hand, pre-treatment QST parameters could predict treatment outcomes following pharmacological and surgical interventions [70]. Thus, QST methods in future studies shall include supportive assessment methods and a set of relevant parameters.

This study suggested that occupational performance, occupational balance, and pain sensitivity would help interpret the results of occupational therapy lifestyle intervention for adults with chronic pain. Occupational performance, as an outcome tightly connected with everyday life, may help detect positive health behavior changes in the short term, e.g., after the appx. four monthslong REVEAL(OT) program. Other outcomes appealing to more abstract constructs, such as pain catastrophizing and pain acceptance, would probably need a longer time than the max. 15-week REVEAL(OT) intervention to develop a statistically significant effect. Randomized controlled trials shall confirm the explanatory potential of the outcome measures for a lifestyle-oriented approach to chronic pain.

Limitations

This study operated with outcomes measuring health, pain, daily occupations, lifestyle, and quality of life, according to the recommendations for outcome assessment in chronic pain studies [71, 72], and used validated assessment tools, which improved the validity. However, the findings must be interpreted with caution. The most important limitation is the one-armed design and a rather small study sample, which precludes any firm conclusions on the effects of the intervention. Additionally, the relatively high number of daily walking steps in the participants at baseline and the insignificant pre-post change observed suggest a degree of participant bias when the participants, after mounting the accelerometer, adjusted their physical activity behavior according to self-perceived expectations of the research. Thus, monitoring physical activity status before allocation to the intervention would be helpful to prevent this type of bias.

It shall also be considered whether the outcomes, such as BMI, waist circumference, and blood pressure, shall be included in the assessment battery for the RCT. Clinically meaningful and sustainable change in those would need a specific strategy targeting weight loss and hypertension, which was not a part of the REVEAL(OT) intervention [73].

This study illustrated that timely self-assessment using an online questionnaire was a difficult task for the participants, which confirmed previously detected challenges with participant retention to the intervention [9]. Repetitive reminders could only partly support the adherence to the assessment procedure, indicating the need for more assistance, e.g., by placing the entire assessment routine in the clinic facilities.

Considering the high heterogeneity of chronic pain treatment approaches [74] and contextual dependence of healthcare interventions [8], the pragmatic setup of this study and the add-on intervention adapted to the specific Danish pain center may have reduced the generalizability of the results. As the representation of males in this study was lower than expected for the typical gender distribution in the chronic pain population, a larger representation of males in further studies would also improve the generalizability. Moreover, the participants' satisfaction was only represented by the COPM score for satisfaction with occupational performance [9]. Satisfaction with the treatment as an outcome, proposed for assessment in chronic pain trials, should be included in future RCT [75, 76].

Implications

This study proposes to consider the following while planning future research in lifestyle-oriented approach to chronic pain treatment:

- Robust study design, possibly including pain phenotyping.
- A combination of several pain sensitivity test methods.
- Investigation into how occupational performance and occupational balance may correlate with pain copingrelated parameters, such as pain catastrophizing, pain acceptance and pain self-efficacy, and pain sensitivity.
- Measures of body anthropometrics may assist studies that expect metabolic changes in the participants, e.g., weight-loss studies for chronic pain.

Conclusions

This study suggested that a lifestyle-oriented approach in chronic pain rehabilitation was beneficial for motor skills in adults with chronic pain, while effects on other outcomes were unclear. However, the findings need careful interpretation and robust fully-powered randomized trials to make firm conclusions on the effects of the intervention.

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Research ethics: This study has been approved by the Regional Committee on Health Research Ethics in Region Zealand (Reg. SJ-703) and the Data Protection Authority for Region Zealand (REG-052-2018) in Denmark.

Informed consent: Informed consent has been obtained from all the participants in this study.

Author contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

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