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ORIGINAL ARTICLE



Vibroacoustic treatment to improve functioning and ability to work: a multidisciplinary approach to chronic pain rehabilitation

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ABSTRACT

Purpose: To study the use of Vibroacoustic treatment and an added self-care intervention for improving the functioning and ability to work of patients with chronic pain and potential comorbid depressive and anxious symptoms.

Materials and methods: A mixed methods study with four single cases. Participants received bi-weekly Vibroacoustic practitioner-led treatment sessions for five weeks, followed by a one-month washout period without treatments. Then, participants conducted four self-care vibroacoustic sessions per week for five weeks, followed by another month-long washout period. Participants kept diaries of their experiences during this time. Quantitative scales included the World Health Organization Disability Assessment Schedule 2.0, Visual Analogue Scales (pain, mood, relaxation, anxiety, and ability to work), Beck's Depression Inventory-II, and Hospital Anxiety and Depression Scale (Anxiety only). The use of physiological markers was also explored.

Results: The greatest improvement was from the practitioner-led sessions, but self-care was beneficial for pain relief and relaxation. Participants became more aware of sensations in their own bodies, and during washout periods noticed more clearly the treatment effects when symptoms returned. An added self-care phase to standard Vibroacoustic treatment could be beneficial for maintaining the effects from the more intensive Vibroacoustic treatment as part of multidisciplinary rehabilitation.

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Vibration; music; rehabilitation; chronic pain; mood disorders

► IMPLICATIONS FOR REHABILITATION

- Chronic pain and comorbid mood disorders negatively impact functioning and ability to work.
- Vibroacoustic treatment with a self-care phase could be beneficial for managing the symptoms of chronic pain if implemented within a naturalistic multidisciplinary rehabilitation context.
- In four single cases, this study shows functioning, pain, and depression improved after Vibroacoustic treatment with self-care.

Introduction

Painful musculoskeletal conditions affect 20–33% of the world's population [1]. They are the second greatest contributor to disability and, in addition to mobility restrictions, are linked to depression, early retirement, and a reduced ability to socially participate [2,3]. Chronic pain is subject to not only genetic factors, but is also influenced by our past experiences of pain and the context in which it occurs [4]. Our emotional state, anxiety, memories, and attention/distraction are all factors which augment or diminish our experience of pain [5] and therefore factors which also influence our ability to function.

The biopsychosocial model outlines that physical illnesses such as pain are a result of the interaction between physiological, psychological, and social factors, and mediated by socioeconomic factors, which may exacerbate the presentation of pain [4,6]. Interactions between emotional disorders, maladaptive cognition (e.g., poor coping skills), disability, physical deconditioning (due to decreased physical activity), disrupted social functioning, and nociceptive dysregulation suggests that approaches to chronic

pain management should focus on more than simply the pain sensation.

Multidisciplinary rehabilitation for symptom management

The goal of rehabilitation is to achieve optimal functioning. Building up one's resources supports this process by providing a facilitating environment, developing one's performance in interacting with their environment [7], regulating inappropriate adaptive stress responses posited to cause disorders such as depression and chronic fatigue syndrome [8], and reducing the calamitous impact poorly managed symptoms can have on healthcare systems [9]. Multidisciplinary approaches to pain management yield significant improvement in pain, physical and perceived functioning, emotional distress, pain acceptance and coping, and in the decreased use of maladaptive and passive coping strategies [10,11]. Coordinated interdisciplinary approaches offer the best clinical care for patients with chronic pain and are also the most cost-effective approach [12].

Vibroacoustic treatment in multidisciplinary rehabilitation

Vibroacoustic treatment is one example of a multi-modal approach to pain management. At Seinäjoki Central Hospital, Vibroacoustic treatment is delivered as part of multidisciplinary rehabilitation. It consists of three elements: low frequency sinusoidal sound vibration between 20–120 Hz, clients' preferred music, and practitioner support [13]. Described as a “two-pronged approach”, the tactile sinusoidal vibration elicits a relaxation response whilst the music listening element is beneficial for psychological symptoms [14]. Previous research has shown it is beneficial for eliciting a relaxation response, pain relief [14,15] and comorbid depression, anxiety, and insomnia [13], muscle tension and spasms [16], physical discomfort, fatigue, anxiety, and perceived general health [17], as well as being a suitable intervention to facilitate better outcomes in physiotherapy [13,18].

Applied within multidisciplinary care, Vibroacoustic treatment is part of an individually-tailored combination of standard pharmacological interventions as well as physiotherapy, (music) psychotherapy, and occupational therapy [19]. The team coordinates and develops the treatment plan based on a patient's needs, working towards improving patients' quality of working life or to work towards evaluation points assessing patients' capability of returning to work. Given the impact of chronic pain and comorbid mood-related symptoms on functioning, interventions applied to improve these symptoms could aid in improving one's functioning and ability to (return to) work.

Underlying mechanisms of vibroacoustic treatment

Although the underlying mechanisms of Vibroacoustic treatment are unknown, some theories exist. Stimulation of subcutaneous sensory mechanoreceptors (Pacinian corpuscles) sensitive to vibration and deep pressure [20] serves to potentially block afferent pain transmission [14,21]. Another theory relates to the relaxation response [22] and the concept of *sympathetic resonance*. Wigram [23] showed that applied vibrations are systematically felt in the same areas of the body (e.g., 40 Hz is commonly felt most strongly in the thigh muscles). Our bodies have natural resonant frequencies (e.g., each muscle) which may be activated or entrained through vibrotactile stimuli at the same frequency [24]. The vibration can stimulate sympathetic resonance through this matched oscillation, acting as a driving force [21]. In general, the higher the frequency within the low frequency range, the smaller the muscle and the closer to the head the frequency is perceived; i.e., 40 Hz is felt in the thighs, 60 Hz is felt in the chest [23]. Oscillatory dysfunction is suggested to play a significant role in developing and maintaining chronic pain [25], with disruption on the gamma band (around 40 Hz) related to thalamocortical dysregulation. This, in addition to clinical evidence and previous studies [15], supports the application of 40 Hz to act as a driving force for resolving this disrupted frequency band [21].

The second element of Vibroacoustic treatment – music listening – is also beneficial for pain relief, as well as reducing analgesic consumption [26] and physiological arousal, and is known to affect physiological parameters such as heart rate, respiration, and stress hormones [27]. It can be a directed approach to facilitating therapeutic change by manipulating or selecting music based on characteristics which will influence these variables, such as a tempo. Music perception is also influenced by our past experiences [28] and can elicit memories and images [29]. As pain perception is also influenced by past experiences thereof, music listening has the potential to influence how we perceive pain, altering our perception thereof through emotional responses.

Combined, the low-frequency sound vibration and the music listening can work towards altering the client's perception of pain, facilitated by the practitioner and the practitioner-client relationship.

Self-care as an element of rehabilitation

Orem [30] describes self-care as “an essential human regulatory function” [p. 33] and as it is inherent in one's daily activities, it should be viewed as an integral part of rehabilitation. The concept of self-care comprises an individual's responsibility towards healthy behaviours required for functioning, as well as those needed to manage chronic health conditions [9]. Barriers to conducting self-care are mostly related to having comorbidities, and include logistics of carrying out the practice, need for support, compound effects of conditions and medications, the emotional effects of the disease, and the physical limitations of conducting it [31]. The outcomes of self-care activities, on the other hand, include decreased pain, disability, and depressive symptoms [32], and improved cognitive symptom management, energy, fatigue, and self-rated health [33]. Although applications of low frequency sound vibration and music listening are generally afforded by a practitioner or therapist, Picard and colleagues [34] reported on a self-care approach to vibroacoustic treatment. Participants conducted sessions of combined music and pulsed vibration to manage their widespread pain and tenderness. Results showed improved indices of pain interference, relaxation, muscle tension, and energy levels [34].

As suggested by previous research of practitioner-led Vibroacoustic treatment, it can be effective for relieving both psychological and physiological symptoms [13,35,36]. The aim of this study was to assess the impact of Vibroacoustic treatment with a self-care element on functioning, chronic pain, and possible comorbid symptoms, implemented within a multidisciplinary rehabilitation context. The aim of this study was not to compare across participants, rather to gain insight into how this treatment could be beneficial to patients who are typically difficult-to-treat at this unit.

Materials and methods

The study was in ABA¹B¹ form. In Phase I, participants received bi-weekly Vibroacoustic practitioner-led treatment sessions for five weeks at a specialised rehabilitation unit at Seinäjoki Central Hospital followed by a month-long washout period (Phase II) without treatment. Thereafter, participants conducted four self-care Vibroacoustic sessions per week for five weeks at home (Phase III), followed by a second month-long washout period (Phase IV). The purpose of the washout periods was to assess the duration of treatment effect. Each participant served as his/her own control. As per standard practice at this unit, patients engage in various treatments (such as physiotherapy, [music] psychotherapy, and/or pharmacotherapy) concurrently or consecutively and this study took place within this naturalistic setting. Although a limitation in terms of comparison across participants, this study aimed to explore participants' responses to the treatment within the context of their individual rehabilitation programmes. Tampere University Hospital ethical committee granted ethics approval to conduct this study (ETL: R18007).

Phase I: Practitioner-led vibroacoustic treatment sessions

A Next Wave Physioacoustic chair is used at this facility (see Figure 1). Sonus Health Editor v3.26c software is used to play the low frequency treatment programme through loudspeakers located in the neck, back, thigh, and calf areas of the chair; the

frequency range of this software is 27–113 Hz. Participants received their bi-weekly practitioner-led sessions in this chair, with their preferred music playing through headphones, and interacting/discussing sensations and observations with the practitioner, JH, before and after the treatment programme. Participants were assisted in getting on/off the chair and told to inform the Practitioner if any discomfort were to arise during the stimulation.

At this facility, a typical treatment programme used for enabling relaxation and pain relief centres around 40 Hz, based on clinical experience and previous reports of this frequency discussed in section *Underlying mechanisms of Vibroacoustic treatment*. tailored the treatment programmes to suit the participants' individual needs, gradually increasing the volume as they became accustomed to the sensation. A treatment programme contains several steps and parameters such as *scan*, *cycle*, *strength*, *action*, and *time*. *Scan* modulates around the fundamental frequency, e.g., 31 Hz, by moving from this to a higher and lower frequency, e.g., 29–34 Hz, much akin to a radar, so that several scans of the fundamental frequency are completed during a two- to three-minute phase. *Cycle* or *pulsation* refers to the speed of the amplitude change – the time taken from silence to designated peak volume, e.g., 11 s. In practice, the longer the cycle and the wider the scanning range, the greater the relaxation effect. The wave-like sensation elicited through this pulsation may be compared to that of a massage chair. The *strength* of the programme can be adjusted both globally across all speakers and locally at individual speakers so that the programme strength can be increased and specific areas of the body can also be targeted. *Action* refers to the directional movement; either head-to-toe, vice versa, or no movement. The faster the *cycle*, the faster the *action* movement.

Although it is standard practice that a treatment programme of lower intensity is used at the beginning of a treatment phase with each new client, the rule of thumb otherwise is to tailor the treatment programmes to suit the needs of each individual. This means that if a client suffers more from shoulder pain, higher frequencies within the 20–120 Hz range are used whilst frequencies closer to 20 Hz would be used for patients whose pain is in larger muscle areas of the body. Given the individual nature of each treatment phase and each rehabilitation process for each client,

no direct comparison is possible; however, an idea of treatment responses of patients who receive VA treatment in addition to other therapies as part of their individual rehabilitation process can be gleaned. This is important in understanding how VA treatment may function in relation to other therapies offered as part of rehabilitation.

Phase III: Self-care sessions

Participants conducted their self-care sessions using a Taikofon FeelSound Player (see Figure 2), a small, cushion-like device with an in-built transducer, an audio cable, and Bluetooth function. The frequency range of Taikofon is 20–20 000 Hz. Participants used an android phone (Huawei Y5) to play the pre-installed Vibroacoustic treatment programme. The participants were free to place the cushion anywhere on their body, thereby offering targeted stimulation to e.g., the lower back.

All participants used the same 23-min, 40 Hz self-care treatment programme for each self-care session. The duration of the *cycle* or *pulsation* was 6.8 s. They could adjust the programme *volume/strength* using the phone's volume control.

Patients were instructed in how to use the self-care device using the Bluetooth function on both the Taikofon and the Huawei phone. They were instructed to use the device four times per week and to use it at the same time each day. If they had multi-site pain or wished to use the device in various places, participants were instructed to record where they placed the device in their diaries.

Participants

Participants were recruited following a purposive sampling method. Patients with chronic pain were contacted by JH regarding study participation; four patients gave informed consent. The mean age of the three females and one male was 43.25 (± 11.03) years (see Table 1 for an overview of demographics).

Participants 1 and 2 had pain in neck/shoulder areas, whilst Participant 1 also had pain in her thighs, and back, and tingling in both her feet. Participant 3 had pain in her hips, legs, feet, backside, as well as tingling in her left knee and soles of her feet. Finally, Participant 4 had pain in his calves as well as in his pain ranging from his right eyebrow back towards his neck, shoulders, and along his spine with tingling in his hands and along his back. As mentioned earlier, the aim of this study was not explicitly to compare the intervention across participants – as their profiles are so varied – rather to depict the variety of patients treated as



Figure 1. Physioacoustic recliner chair used in Phase I (practitioner-led) sessions. Dimensions 184 cm long, 78.5 cm wide, 120 cm high. Image reproduced with kind permission from the copyright holder: Next Wave Oy.



Figure 2. Taikofon FeelSound Player used in Phase III (self-care sessions). Dimensions: 48 cm long, 12 cm wide, 35 cm high. Image reproduced with kind permission from the copyright holder: Flexound Systems Oy.

Table 1. Participant demographics showing ICD-10* classifications and medications.

Participant	Sex	Age	Type of pain	Diagnoses (ICD-10)	Medications
1	Female	33	Musculoskeletal and neuropathic	M54.5 lower back pain; M54.6 Pain in thoracic spine; R29.8 Other unspecified symptoms and signs involving nervous and musculoskeletal systems; muscle weakness	Paracetamol; gabapentin; venlafaxine; amitriptyline; tramadol; tramadol including paracetamol
2	Female	37	Musculoskeletal and neuropathic	S13.4 Sprain and strain of the cervical spine; S44.3 Injury of axillary nerve; Nerve damage in right hand; Depression; neck/shoulder/back pain	Escitalopram; gabapentin; paracetamol
3	Female	58	Musculoskeletal	M79.7 Fibromyalgia; M47.8 Other spondylosis; lumbosacral spondylosis L4–L5	Buprenorphine; esomeprazole; paracetamol; pregabalin; amitriptyline
4	Male	45	Musculoskeletal	M79.7 Fibromyalgia; sleep apnea	Tramadol; paracetamol; amitriptyline; pregabalin; pantoprazole

*ICD-10 refers to the International Statistical Classification of Diseases and Related Health Problem.

this unit and how such a two-armed intervention could be received by difficult-to-treat patients such as these.

Data collection

A mixed-methods approach was taken consisting of participant diaries, questionnaires/scales, and physiological data. The data were collected in a concurrent-parallel design [37] such that each would support the others in exploring individual responses to both treatment conditions and the washout periods. The quantitative results comprise primary (functioning and ability to work), secondary (pain, mood, anxiety, and relaxation), and exploratory outcomes (physiological measures: [para-]sympathetic nervous system activity, galvanic skin response, and respiration rate). Participants wrote their diaries beginning at Phase I until the end of Phase IV. Quantitative outcomes were assessed at five measurement points. Measurement points 1 and 2 were the beginning and end of practitioner-led sessions in Phase I; Measurement Points 3 and 4 were the beginning and end of the self-care sessions in Phase III; Measurement Point 5 was follow-up, at the end of the second washout period in Phase IV. All quantitative scales/questionnaires and physiological measurements were completed at these time-points.

Qualitative data collection and analysis

Each participant wrote a diary to reflect their responses to the treatment conditions and washout periods, also reflecting on what they perceived to positively or negatively influence their symptoms. The instructions were rather open-ended to afford as rich and organic a description as possible. Each participant's diary was separately fully analysed with Qualitative Content Analysis [38] following an inductive approach. Inductive analysis allows findings to emerge from the raw data without pre-defined assumptions, theories, or hypotheses, but is still guided by evaluation objectives or research questions [39]. The diary transcripts for Participant 1 were first read through several times, based on which a coding frame was developed. The frame comprised the code label describing the code meaning, a description of this meaning, and illustrative text examples. Analytic memos were also written during the analysis process, which were used in developing the categories and themes. If new codes subsequently emerged from other participants' data, the coding frame was adjusted accordingly and applied to all data. Through this process, categories emerged developing into broader main themes and sub-themes. Similarities and differences between participants were explored and findings are tabulated according to the phase in which they were recorded by the participant.

Quantitative data collection and analysis

All quantitative data are presented as single cases, showing individual scores for each outcome at each measurement point. Interpretation guidelines for individual outcomes, as suggested by Dworkin and colleagues [40], referring to the smallest clinically relevant change in individual patients' outcomes, the Minimum Clinically Important Difference (MCID), were used where available for data analysis. Additionally, interpretation cut-off points for VAS outcomes that are available for pain [41] were also used. As these benchmarks for other VASs are unavailable, the pain cut-off points have been applied to all VAS outcomes as general indicators of each variable's current status. The interpretation guidelines are discussed for each scale separately.

World Health Organisation Disability Assessment Schedule (WHODAS)

The World Health Organization Disability Assessment Schedule 2.0 (WHODAS) is a 12-item self-complete scale used to standardise assessment of health and disability across all diseases with applications in both clinical and general populations. Cronbach's α was reported as ranging from 0.83–0.92 [42]. The MCID for WHODAS has not been established.

Visual Analogue Scales

Pain, mood, relaxation, anxiety, and ability to work were measured using Visual Analogue Scales (VAS). These scales are 100 mm horizontal lines with anchors on either end; the anchors in this case were 0 mm = unbearable pain, 100 mm = no pain, 0 mm = depressed, 100 mm = happy; 0 mm = tense, 100 mm = relaxed; 0 mm = anxious, 100 mm = no anxiety; and 0 mm = completely unable to work; 100 mm = best working ability. The polarities of these scales are used in this direction at this facility and, in order to retain coherence in their standard protocols, this formulation of the VAS was retained despite the usual format being, for example, 0 = no pain, 100 = unbearable pain. Participants were asked to mark the line to represent how they were feeling at that time. Test-retest reliability for pain was reported as $r = 0.94$ [43], $r = 0.82$ for mood [44], and $r = 0.59$ for anxiety [45]. For VAS for pain, the MCID is suggested as 10–20% reduction for minimal improvement, $\geq 30\%$ for moderate improvement, and $\geq 50\%$ corresponding to substantial improvement [40]. Interpretation VAS pain cut-off points applied to all VAS outcomes are 0–4 mm = severe [pain], 5–44 mm = moderate [pain], 45–74 mm = mild [pain], and 75–100 mm = no [pain] [41].

Beck's Depression Inventory-II

Beck's Depression Inventory-II (BDI-II) is a self-report, 21-item scale used to assess the severity of depressive symptoms. Scores range from 0–63 points and items are rated on a four-point scale from 0

(e.g., “I do not feel like a failure”) to 3 (e.g., “I feel I am a total failure as a person”). Scores can be interpreted as 0–13pts = minimal; 14–19pts = mild depression; 20–28pts = moderate depression; 29–63pts = severe depression. Cronbach’s α was reported as 0.92 for outpatients and 0.93 for college students [46]. A category change (e.g., from *moderate* to *mild* depression) and a 5-point reduction are used as MCID benchmarks here [40].

Hospital Anxiety and Depression Scale – Anxiety subscale

The anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A) is a seven-item, self-complete scale used to assess the non-somatic cognitive and emotional aspects of anxiety in general medical populations. It is a four-point scale ranging from 0–3, (e.g., “I feel ‘wound up’”, 0 = not at all, 3 = most of the time). Scores can be interpreted as 0–7pts = normal; 8–10pts = borderline anxious; and 11–21pts = abnormal anxiety. Cronbach’s α ranges from 0.78–0.93 [46]. The MCID corresponds to a 1.57-point decrease in the HADS anxiety subscale [47].

Physiological data

Raw ECG signal, respiration, and galvanic skin response (GSR) data were recorded using the NeXus-10 physiological monitoring and biofeedback platform. BioTrace+ software was used to analyse the respiration rate and pain-related arousal respectively, and Kubios software was used to analyse the raw heart rate data recorded with ECG. All measurements were taken in the same soundproof treatment room with an ambient temperature of 22°C; the first and last self-care sessions were conducted at the facility to control for the measurement environment.

ECG/parasympathetic nervous system activity. The NX1-EXG2-Snap cable was used to detect heart rate data via ECG signal. ECG data pre-processing and analysis were performed using Kubios, version 3.1.0.1. The threshold-based method was used to remove artefacts. These are detected by comparing each beat-to-beat interval against a local average interval; if an interval differs more than a specified threshold from the local average, it is marked as an artefact. Kubios also adjusts these thresholds with mean heart rate. The minimum thresholds were selected to remove the artefacts without affecting the remaining data. The raw signals were de-trended using the smoothness priors method before analysis. Kubios analysis software provides indexes for autonomic nervous system assessment. Parasympathetic nervous system (PNS) activity, such as during resting or recovered states, decreases heart rate and increases heart rate variability. When we are stressed and the sympathetic nervous system (SNS) is activated, our heart rate increases and heart rate variability decreases [48]. The PNS index reflects Mean RR (mean of time interval between successive R-waves), RMSSD (root mean square of successive RR interval differences), and S1 (%), whilst for SNS these are Mean HR, Stress index, and SD2 (%). These indexes were used to evaluate participants’ stress responses at the five measurement points as an objective measure of pain [49]. A PNS/SNS value of zero refers to the mean population values, e.g., non-zero PNS values show how many standard deviations below (negative integers) or above (positive integers) the parameters are relative to normal population averages and vice-versa for SNS values.

The Taskforce of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology [50] recommends five-minute recordings for short-term HRV assessment. Five-minute segments were extracted from the beginning and end of the first and last practitioner-led sessions (Measurement Points 1 and 2) and the first and last self-care sessions (Measurement Points 3 and 4), and a five-minute measurement

was taken as follow-up (Measurement Point 5) at the end of the second washout period.

Galvanic skin response and respiration rate

The galvanic skin response sensor measures arousal through tracking sweat gland activity; expressed in microsiemens (μS), the value increases with the level of arousal, and normally decreases during relaxation. Ag-AgCl finger electrodes measure relative changes in skin responses [51]. The electrodes were placed on the distal phalanx of the digitus secundus and digitus medius of the participants’ left hands. The respiration sensor, consisting of an elastic belt worn around the navel, measures relative expansion of the abdomen during inhalation and exhalation. Mean galvanic skin response and respiration data values from the same five-minute segments as the ECG data were extracted for analysis using BioTrace+ software (V2017A).

Data integration

After both qualitative and quantitative data were separately analysed, these were integrated for each participant by exploring the qualitative findings’ parallel manifestations in the quantitative data. For example, changes in functioning described in participants’ diaries were compared and contrasted with WHODAS outcomes. Experiences of both qualitative and quantitative aspects were explored to ascertain whether the objective and subjective reports were congruent. Due to the parallel-convergent design of the data collection, the experiences participants reported either in their diaries or by completing the scales were recorded within the same timeframe (rather than successively) and may, therefore, afford a richer description of their overall experiences. The qualitative data also provided richer contextual information about how participants responded to the treatment sessions in between measurement points.

Presentation of results and findings

An overview of results and findings is first provided to give an impression of the general outcomes across all participants. However, the main focus is on the individual participants’ treatment responses and therefore an in-depth, integrated qualitative and quantitative presentation of each participant follows the general overview.

To simplify the quantitative data presentation and discussion, only the post-treatment data are shown (Figures 1–4), signifying the general change in variables over the course of the protocol (between sessions), rather than a detailed description of the within-session changes through the pre-/post-treatment outcomes. The quantitative results are narratively discussed using MCID [40] and interpretation guidelines [41] for interpretation purposes.

Results

Overall quantitative results

Primary outcomes

Participants 2, 3, and 4 showed an improvement in functioning during both treatment conditions. After the first washout period, Participants 2 and 4 reported worse functioning (Measurement Point 3) and all participants had worse functioning after the second washout period. For Participant 1, functioning appeared to have deteriorated throughout the process. The same was seen for participants’ ability to work; whilst this tended to improve

during the treatment conditions and deteriorate during the wash-out phases for Participants 2, 3, and 4, neither practitioner-led nor self-care sessions seemed to impact Participant 1's ability to work.

Secondary outcomes

Relaxation was the outcome which improved most substantially during both treatment conditions for each participant. The clearest effects were generally seen from Measurement Points 1-2, the practitioner-led sessions, and although the improvements from Measurement Points 3-4 were also substantial, the scores at the beginning of this self-care phase were also worse from not having received treatments for one month (e.g., Participant 3, Measurement Point 3). The effect of the Phase I and III sessions for BDI-II outcomes appear to have been generally worse after the second washout. Neither treatment condition seems to have had a strong impact on HADS-A outcomes; however, only Participant 3 recorded *abnormal anxiety* at the beginning of the study, and the effect was as a result greater for her compared to those beginning with *normal* or *borderline* level anxiety.

Exploratory outcomes

For all participants, physiological outcomes seem to indicate that the PNS activity increase and GSR decrease were associated with pain relief. Respiration rate, however, seems to contradict the expectation that slower respiration would be associated with a greater relaxation response. These exploratory outcomes, therefore, did not always support the other quantitative outcomes, as discussed later.

Overall qualitative findings

Four main themes, (1) *Pain as a barrier*, (2) *Adjusting to the new status quo*, (3) *Approaches to symptom management*, and (4) *Symptom nexus* emerged from the analysis of all four participants' diaries. Five sub-themes traversed all participants' experiences (see Table 2 for overview of overlapping main- and sub-themes). These – under the main theme titles – are displayed presently. Individual participants' qualitative findings are detailed in Tables 3–6.

Main theme 1: Pain as a barrier

Only one sub-theme, *Pain inhibits relief*, was individual to Participant 2, whilst *Pain inhibits functioning* was common to all

participants. Pain as an inhibitor to functioning was seen in activities such as lowered capacity to do housework/drive. Pain was a hindrance, also, in how Participants 2–4 were able to rest, e.g., waking up because of pain.

Main theme 2: Adjusting to the new status quo

Throughout the process, all participants became more aware of changes in their bodies or functioning by tracking progress whilst they actively engaged in the rehabilitation process. Although the level of functioning varied across participants, they became aware of sensations such as how long they could carry out activities before they started to feel pain. The experience of having better and worse days during the rehabilitation process was also evident for all participants.

Main theme 3: Approaches to symptom management

In addition to this awareness, actively trying to integrate the self-care practice during Phase III into their daily lives was a sub-theme for all participants, adjusting it to suit their own needs and schedules (e.g., changing its placement on the body when symptoms, for example, in the lower body were stronger, or conducting the practice in the mornings rather than the evenings). Relaxation was also a tool and outcome of the Vibroacoustic treatment sessions. It appeared for all stages that inducing a relaxation response afforded pain relief.

Main theme 4: Symptom nexus

This final main theme was manifest for only Participants 2 and 3, those with greater mood issues. They struggled with disability and the frustration they felt associated with this change in level of functioning. This was underlined in the emerging of the relationship between their symptoms (functioning, pain, and mood), and the sense of accomplishment and positive mood they associated with managing their pain. Possibly due to having an ambiguous diagnosis (fibromyalgia), meaning-making was important for Participant 3.

Integrated individual results and findings

Integrated outcomes for participant 1

Participant 1's low ability to work was interestingly not reflected in her WHODAS scores (see Figure 3), however it was seen in her diary entries (see Table 3), exemplified by entries such as "Came

Table 2. Overlap of the qualitative main themes with sub-themes across all participants.

Table 2: Overview of the quantitative main themes with sub themes across all participants								
	Theme							
	Theme 1: Pain as a barrier				Theme 2: Adjusting to the new status quo			
Participant	Pain inhibits functioning	Pain inhibits mood	Pain inhibits relief	Pain as a barrier to rest & recovery	Changes in level of functioning	Recognising needs/limitations /sensations	Rehabilitation as a dynamic process	
1	✓	✓				✓	✓	
2	✓	✓	✓	✓	✓	✓	✓	
3	✓			✓	✓	✓	✓	
4	✓			✓	✓	✓	✓	
	Theme 3: Approaches to symptom management				Theme 4: Symptom nexus			
	Participation to manage symptoms	Analgesic intervention	Relaxation to improve pain	Process of integrating and adjusting self-care practices	Intertwined relationship between symptoms	Success-dependent mood	Symptom genesis meaning-making	
1		✓	✓	✓				
2	✓	✓	✓	✓	✓	✓		
3		✓	✓	✓	✓	✓		
4			✓	✓			✓	

home, wasn't able to go for a walk (100m)" (Main theme: *Adjusting to the new status quo*). This related to her being aware of her needs and engaging in health behaviours, such as resting when needed. She recorded her daily activities according to distances walked (usually 1km), whether she did aerobics/swam that day, resting periods, and additional analgesics she took to manage her pain. For Participant 1, the sub-theme *Pain inhibits functioning* manifested in her pain-related physical limitations, "I could only do small bits [of aerobics] because of the pain". Her mood was rarely affected by lower functioning; her HADS-A scores improved by MCID during practitioner-led sessions, though generally her depression and anxiety scores were minimal.

Pain and relaxation scores varied from *mild* to *severe* but she recorded *moderate-substantial* improvements in both during Phases I and III; she also reported about this relaxation response from a practitioner-led session in her diary; "Relaxed a lot. Best experience, evening pains were less" (Main theme: *Approaches to*

symptom management). Relaxation was *moderate* at Measurement Point 1 and *mild* Measurement Point 2, and from *moderate* to *relaxed* from Measurement Point 3 to Measurement Point 4, suggesting there was a greater impact on level of relaxation during the self-care sessions. Pain improved from *moderate* (Measurement Point 1) to *mild* (Measurement Point 2) during practitioner-led sessions, but remained in the same category during the self-care phase. Contrary to the stable self-care scores, she noted in her diary that applying the self-care device to her legs helped the pain and at times she fell asleep. The general trend in SNS outcomes from Measurement Points 1–2 (Phase I) and Measurement Points 3–4 (Phase III) support the increased relaxation she experienced during both treatment periods.

She engaged in several approaches to symptom management – mostly analgesics, but also receiving other therapies such as physiotherapy – and she recognised that when she was more active than usual, she needed to take extra analgesics (Main

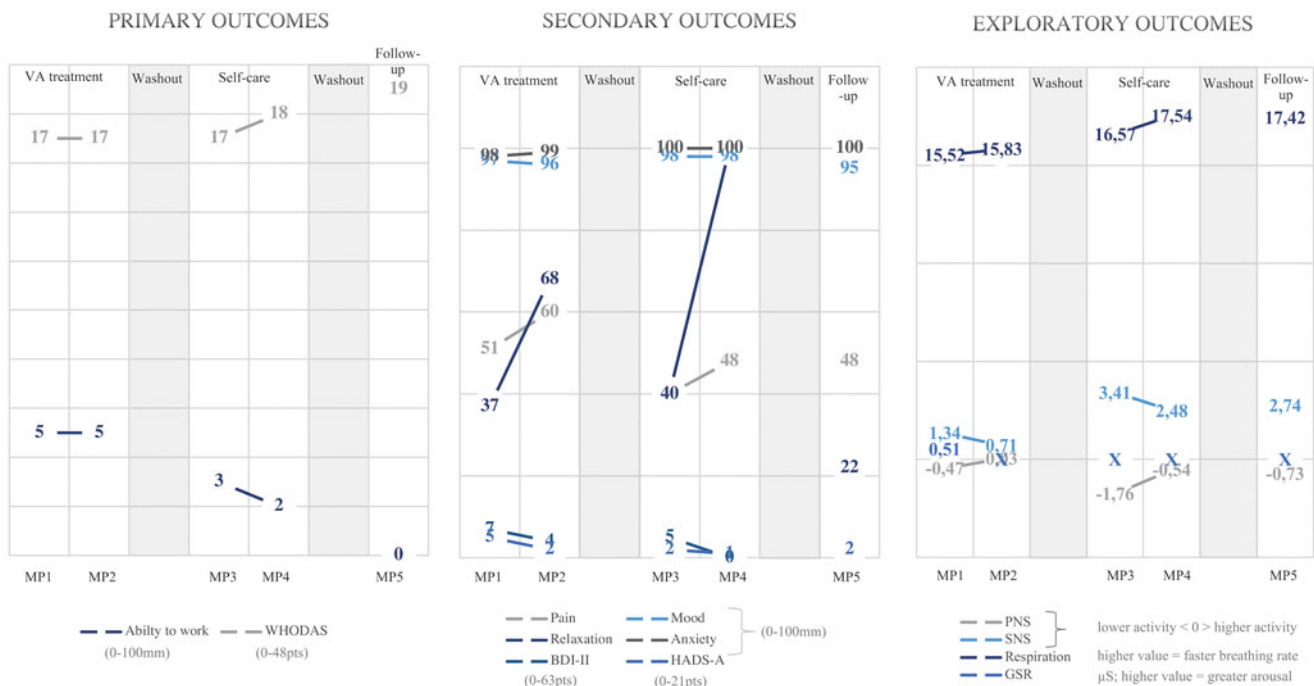


Figure 3. Primary, secondary, and exploratory quantitative outcomes for Participant 1 at Measurement Points 1–5. MP1–5: Measurement Points 1–5. Primary outcomes: WHODAS scores (raw 0–48 pts); 0 = no impaired functioning; Ability to work Visual Analogue Scale (0–100 mm); 0 = completely unable to work, 100 = best working ability; Secondary outcomes: Visual Analogue Scales (0–100 mm); Pain, mood, relaxation, anxiety; e.g., 0 mm = unbearable pain; 100 mm = no pain; Beck's Depression Inventory-II (0–63 pts); 0 = minimal depression; Hospital Anxiety and Depression Scale – Anxiety subscale only (0–21 pts); 0 = no anxiety; Exploratory outcomes: Parasympathetic nervous system; lower PNS activity < 0 > higher PNS activity; Sympathetic nervous system index; lower SNS activity < 0 > higher SNS activity; Galvanic skin response (arousal); microsiemens (µS); higher score = greater arousal (X = no reading); Respiration rate; higher score = faster breathing rate.

Table 3. Qualitative findings for Participant 1 showing protocol phase and illustrative quote.

Main theme	Sub-theme	Phase	Illustrative quote
Pain as a barrier	Pain inhibits functioning	II	Evening aerobics; I could only do small bits because of the pain.
	Pain inhibits mood	I	Until Friday, mood very high-spirited but the pain started to erode away at that on Friday.
Adjusting to the new status quo	Recognising limitations/needs/sensations	I	Came home, wasn't able to go for a walk (100 m).
	Rehabilitation as a dynamic process	I	Reduced [analgesic] in the morning – 300 mg (from 600 mg). Experience: noticed the lower dose in my back.
Approaches to symptom management	Analgesic intervention	II	From Wednesday-Saturday I was travelling and in pain and took extra medication. Immediately when I'm up for longer, it requires extra medication.
	Relaxation to improve pain	I	12:00 Vibroacoustic treatment "basic treatment". <u>Relaxed a lot.</u> Best experience, evening pains less.
	Process of integrating and adjusting self-care practices	III	Vibroacoustic treatment [self-care] on the legs, because they are so sore. [Next day] Vibroacoustic treatment from Friday helped a lot with the legs.

Phase I: Practitioner-led sessions; Phase II: Washout 1; Phase III: Self-care phase; Phase IV: Washout.

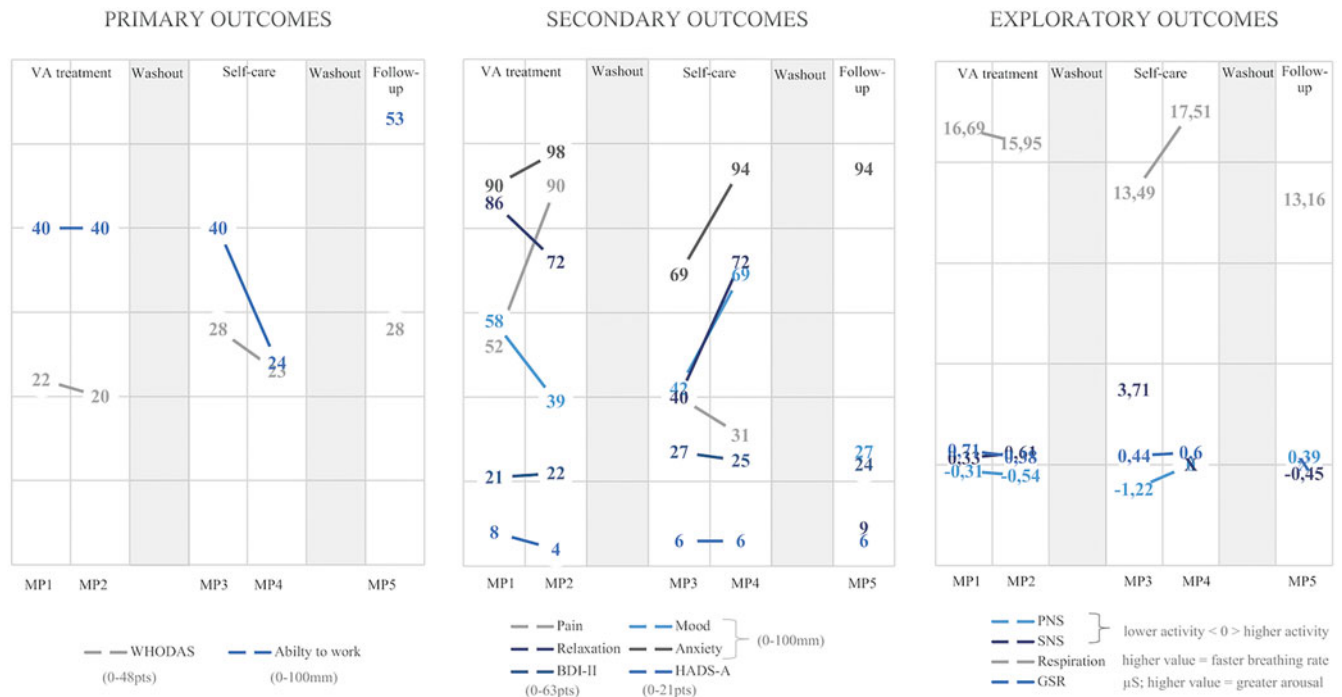


Figure 4. Primary, secondary, and exploratory quantitative outcomes for Participant 2 at Measurement Points 1–5. MP1–5: Measurement Points 1–5. Primary outcomes: WHODAS scores (raw 0–48 pts); 0 = no impaired functioning; Ability to work Visual Analogue Scale (0–100 mm); 0 = completely unable to work, 100 = best working ability; Secondary outcomes: Visual Analogue Scales (0–100 mm); Pain, mood, relaxation, anxiety; e.g., 0 mm = unbearable pain; 100 mm = no pain; Beck's Depression Inventory-II (0–63 pts); 0 = minimal depression; Hospital Anxiety and Depression Scale – Anxiety subscale only (0–21 pts); 0 = no anxiety; Exploratory outcomes: Parasympathetic nervous system; lower PNS activity < 0 > higher PNS activity; Sympathetic nervous system index; lower SNS activity < 0 > higher SNS activity; Galvanic skin response (arousal); microsiemens (μ S); higher score = greater arousal (X = no reading); Respiration rate; higher score = faster breathing rate.

theme: *Approaches to symptom management*). She wrote, however, that she “*did not really notice the effects of the [self-care] treatment*” and that she “*did not relax as well as in the [Physioacoustic] chair*”.

Integrated outcomes for participant 2

Participant 2 had a *moderate* ability to work (see Figure 4) throughout the study, however within this category her ability decreased by 50% from Measurement Points 3–4, the self-care phase, which corresponds to *substantial* change with the MCID [40] whereas there had been no change during the practitioner-led sessions. She reported improved functioning with WHODAS in both treatment conditions; despite a greater improvement during the self-care phase, the overall scores during Phase I were nonetheless better than during Phase III.

The immediate effects of the Phase I sessions are seen in the diary entries, also (see Table 4). Before the first Vibroacoustic session, she had difficulty driving because of her swollen and painful hands (Main theme: *Pain as a barrier*; “*The pain – mostly burning and neuralgia – was strong. It was very difficult to hold on to the steering wheel*”). The treatment relieved her pain and driving home was easier (Main theme: *Approaches to symptom management*; “*A wonderful feeling! Driving home was much better*”) indicating immediate positive results from the practitioner-led sessions.

During the self-care phase, she noted she was able to do more gardening than in previous years, indicating an increase in functioning, but also that she was in more pain because of this increased activity (Main theme: *Adjusting to the new status quo*; “*I nevertheless did more physical, heavier work outside in the garden and inside the house. Maybe my legs are reacting to this changing situation*”). WHODAS outcomes show that the improvement during Phase III was greater than during Phase I and that during the first washout period her functioning decreased, evidenced by the

increased WHODAS score at Measurement Point 3. The VAS for pain and WHODAS outcomes support the increase in pain and improvement in functioning during the self-care phase. VAS for ability to work, however, highlights a lesser ability to work during the self-care phase, which could be related to the increased pain as a result of having greater functioning.

Participant 2 explained that relaxation reduced the burning sensation in her neck/shoulder (sub-theme: *Relaxation to improve pain*). She also reported this relaxation response during the first self-care sessions, suggesting that pain relief was an auxiliary outcome to relaxation. The VAS outcomes for pain improved from *moderate* to *mild* during Phase I, and remained *moderate* during self-care, suggesting the practitioner-led sessions were more beneficial. Although relaxation improved from *moderate* to *mild* from Measurement Points 3–4, the post-treatment scores during the practitioner-led sessions were nonetheless consistently *mild*. The respiration rate outcomes further support her subjective response to the practitioner-led sessions, with decreased respiration rate from Measurement Points 1–2, however PNS activity increased and SNS activity decreased only during the self-care phase, suggesting less alert/stressed state during this time. Respiration rate also increased at Measurement Points 3–4. Arousal (GSR), pain, mood, depression, anxiety, and relaxation changes paralleled each other, on the other hand.

The reduced ability to work coincided with an increase in depression and anxiety, and linked to her adjusting to her lower level of functioning since the car accident: “*Anxious, angry, tired feeling which was somehow eased after psychotherapy. It again became overwhelming. Will I ever learn that my functioning will never again be 100% after the accident?*” (Main theme: *Adjusting to the new status quo*). Being unable to work also made her feel lonely: “*I miss adult company*”, suggesting that her lower functioning intertwined with her mood. After the first washout period,

Table 4. Qualitative findings for Participant 2 showing protocol phase and illustrative quote.

Main theme	Sub-theme	Phase	Illustrative quote
Pain as a barrier	Pain inhibits functioning	I	The pain – mostly burning and neuralgia – was strong. It was very difficult to hold on to the steering wheel
	Pain inhibits mood	II	I have finally resigned as the secretary of the shooting club, which wasn't possible because of my physical state ... It wasn't possible to write because of the pain. And "failing" always affected my mood
	Pain as a barrier to relief	III	Today I didn't do Taikofon. The pain meant I didn't have enough patience
	Pain as a barrier to rest & recovery	IV	I can't sleep any longer. Face is sore. I was tossing in bed in vain!
Adjusting to the new status quo	Changes in level of functioning	II	The first big drop into the ravine was having to stop playing the 5-row accordion, which I'd played since I was 7. Playing released feelings and endorphins ☺ ... It's difficult to change your activities/actions to become a listener
		III	I nevertheless did more physical, heavier work outside in the garden and inside the house. Maybe my legs [pain] are reacting to this changing situation
	Recognising limitations/needs/sensations	I	A new observation about my own body, is that the vibration treatment doesn't feel the same on both sides of my body. The program was changed slightly during the phase to be slightly stronger, i.e. more massage-like. The right side of my body doesn't function in the same way as the left. It feels missing
Approaches to symptom management	Rehabilitation as a dynamic process	II	Hands are again swollen. I decided not to be afraid of the pains. I already started to get pissed off with this illness, pain, low mood, and that nothing can be done. ☺ ☺ ☺ ☺ ☺
	Participation to manage symptoms	I	Mood was nevertheless positive and expectant. Research intrigued me. When I can be part of something, doing things with adults etc., everything feels good, when I don't have those possibilities now through working life
	Analgesic intervention	II	The trip to [location] was successful. Great! ☺ I managed the pains with analgesics. I tried to break up the standing, sitting, movement, so that my body wouldn't react to the pain. It was fairly successful
	Relaxation to improve pain	I	I was able to deeply relax, at least in the second half of the program. Relaxation clearly reduced the burning feeling in the neck/shoulder (from 75–35 mm). A wonderful feeling!
	Process of integrating and adjusting self-care practices	III	I carried it out lying on the bed, because there was no other peaceful place on offer. ... It's hard to find a quiet time in the evenings here Taikofon doesn't give the same relaxation as Vibroacoustics. Legs feel tense. Vibroacoustics also helped my legs. Taikofon doesn't. ... Taikofon helps with lighter relaxation, but when your whole body is shouting with tension and pain, the cushion isn't enough for that
Symptom nexus	Intertwined relationship between symptoms	III	Mind was somehow restless and relaxation didn't quite happen. The pain usually affects me like that. I get a restless feeling, even though I don't have big worries or the like
		II	Mood somehow good. It's probably because I was able to manage the pain and participate in the journey ☺
	Success-dependent mood	IV	This week I've been feeling quite blue, because the pains have been continuous and doing everything slowly and it still affects the pains

Phase I: Practitioner-led sessions; Phase II: Washout 1; Phase III: Self-care phase; Phase IV: Washout 2.

functioning, depression, and anxiety scores were also worse; the deterioration in BDI-II and HADS-A scores were also clinically relevant, implying that her overall situation had become worse after the practitioner-led treatments stopped.

Her ability to manage her symptoms was important for her, because it allowed her to participate and function in social events, which she noted was another means of symptom management: *"When I can be a part of something, doing things with adults etc., everything feels good"* (Sub-theme: *Participation to manage symptoms*). She was aware of both the connection between her pain and mood, and between being able to participate and her mood. When she was successful with pain management and participation, her mood was positive: *"The trip to [club event] was successful. Great! ☺ I managed the pains with analgesics. I tried to break up the standing, sitting, movement, so that my body wouldn't react to the pain. It was fairly successful"* (Main theme: *Approaches to symptom management*).

Integrated outcomes for participant 3

Although she recorded only a *mild* inability to work with VAS (see Figure 5), P3's functioning according to WHODAS was relatively poor. Pain was a barrier (see Table 4) to functioning and working ability, evidenced by having to leave work because of headaches (Sub-

theme: *Pain inhibits functioning*; *"pain continued during the night and next day, had to take migraine meds as well as leave work"*). When she felt less pain, she felt better and could manage to carry out more activities such as housework. A lesser ability to work paralleled worse pain, mood, relaxation, and anxiety levels, and she highlighted the pain-mood connection: *"Mood is good when I don't have any pain"* (Main theme: *Symptom nexus*). This is seen in the clinically relevant VAS (pain and mood), BDI-II, and HADS-A improvements. Her condition affected her mood when she felt despondent about the future: *"Mind a bit glum, I just feel that healthy days aren't coming or even a relatively good day"* (Sub-theme: *Success-dependent mood*), but she also acknowledged that her symptoms were gradually improving: *"even though, on the other hand, there have been [good days] and gradually, like, I've improved really slowly"* (Sub-theme: *Success-dependent mood*). The self-evaluated success of the rehabilitation process for her appeared to be related to having more healthy days and when she felt as though she did not have many, her mood was subsequently low. According to the VAS outcomes (see Figure 5), pain, mood, relaxation, and anxiety all improved after Measurement Point 1, the first three remaining in the *mild* category and anxiety as *no anxiety* until the end of the self-care phase.

The immediate effects of the practitioner-led and self-care sessions are seen in this participant's diary entries (see Table 5). The relaxation response she felt during the practitioner-led sessions

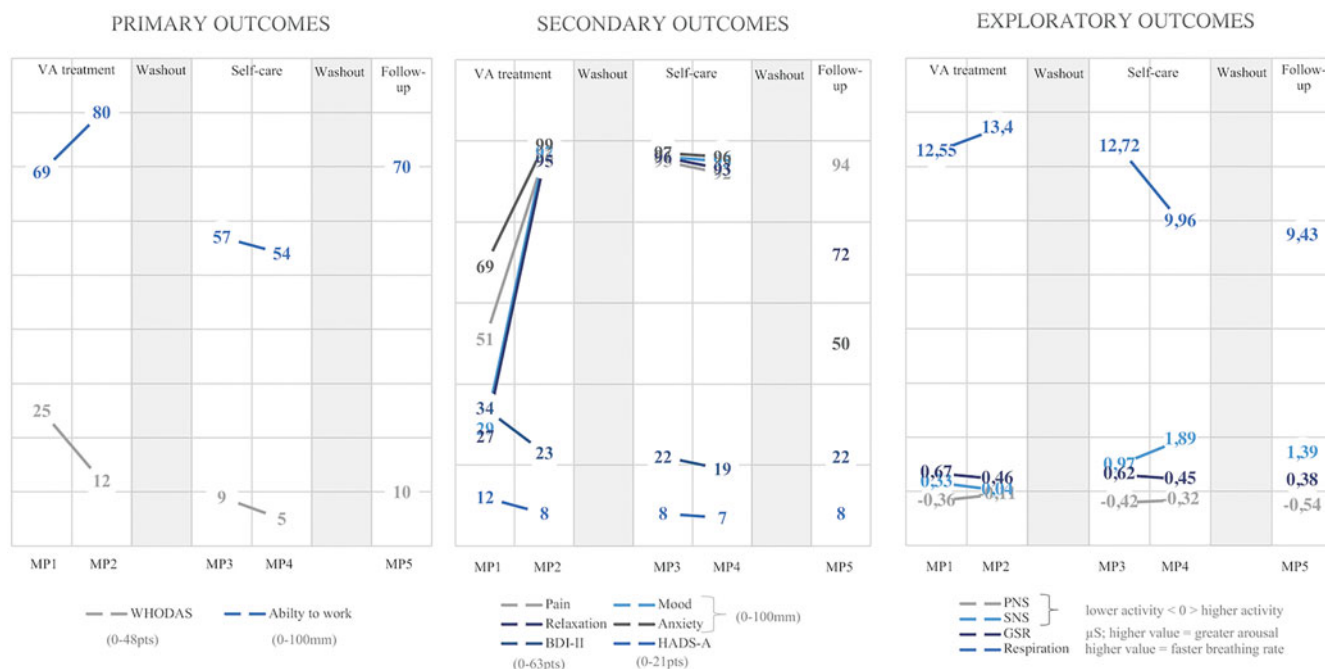


Figure 5. Primary, secondary, and exploratory quantitative outcomes for Participant 3 at Measurement Points 1–5. MP1–5: Measurement Points 1–5. Primary outcomes: WHODAS scores (raw 0–48 pts); 0 = no impaired functioning; Ability to work Visual Analogue Scale (0–100 mm); 0 = completely unable to work, 100 = best working ability; Secondary outcomes: Visual Analogue Scales (0–100 mm); Pain, mood, relaxation, anxiety; e.g., 0 mm = unbearable pain; 100 mm = no pain; Beck's Depression Inventory-II (0–63 pts); 0 = minimal depression; Hospital Anxiety and Depression Scale – Anxiety subscale only (0–21 pts); 0 = no anxiety; Exploratory outcomes: Parasympathetic nervous system; lower PNS activity < 0 > higher PNS activity; Sympathetic nervous system index; lower SNS activity < 0 > higher SNS activity; Galvanic skin response (arousal); microsiemens (μ S); higher score = greater arousal (X = no reading); Respiration rate; higher score = faster breathing rate.

Table 5. Qualitative findings for Participant 3 showing protocol phase and illustrative quote.

Main theme	Sub-theme	Phase	Illustrative quote
Pain as a barrier	Pain inhibits functioning	I	A heavy headache started the previous night, took several [analgesics], pain continued during the night and next day, had to take migraine meds as well as leave work.
		III	Pains reduced noticeably as well as the numbness, feeling better → mood better → can manage to do more
Adjusting to the new status quo	Pain as a barrier to rest & recovery	I	4.30 I got up to take a [analgesic]. Getting up at 7.00 somewhat helped the headache.
	Changes in level of functioning	IV	The “chair treatment” in the hospital was just wonderful; I was able to relax, not that much that I would fall asleep, pains disappeared, in the beginning this was for a few hours, then at the end they started to come back only the next day ... With the cushion I didn't experience big changes, maybe more from the music which helped to relax, but sure the vibrations felt wonderful on my back. ... Overall the pains are in my opinion less and changed a lot and are more tolerable, normally I don't notice them anymore, I just notice them if I want to go and do something e.g. housework, 1h is my limit after which the pain starts.
	Recognising limitations/needs/sensations	I	This week I had a new symptom when I sit or lie on the sofa, I get tingling in my legs (normally it's numbness). I didn't have this for a few years.
Approaches to symptom management	Rehabilitation as a dynamic process	III	Already when I think about this whole cushion phase the cushion + music somehow helped the pain, sometimes not, but there was a big effect on mood and also to concentration e.g. in the evening the last time I think I was able to concentrate on breathing and my thoughts didn't wander so much, afterwards I felt relaxed, calm and the pain was gone. I think sometimes I noticed if I were to get my own cushion the bad days would come just now and then. ... Certainly, doing the exercises which I do about 3 times a week, walking to work every day and in the evening little walks have also helped the pain and the physio, to which I've gone every week.
	Analgesic intervention	I	Backpain ... Had to take analgesics at work for the pain and in [Location] for the neuralgia.
	Relaxation to improve pain	I	Treatment was wonderful, few times almost fell asleep, good day, like before the pain, about 2 1/2 years ago.
Symptom nexus	Process of integrating and adjusting self-care practices	III	Cushion under calves, neuralgia in right calf, full volume Feeling wonderfully relaxed, tried to concentrate on breathing, no pain in calves, left toes were numb during the day, little pain in back, feeling also tired but still glum.
	Intertwined relationship between symptoms	II	Mood is good when I don't have any pain.
	Success-dependent mood	III	Mind a bit glum, just feel that healthy days aren't coming or even a relatively good day, even though on the other hand there have been and gradually, like I've improved really slowly
Symptom genesis	Symptom genesis	I	Tired in the morning, pains changing position and numbness, weather +1°, windy, cloudy, does the weather affect it?
	meaning making		

Phase I: Practitioner-led sessions; Phase II: Washout 1; Phase III: Self-care phase; Phase IV: Wash.

reminded her of a time before the pain started (“Treatment was wonderful, few times almost fell asleep, good day, like before the pain, about 2 1/2 years ago”, Main theme: Approaches to symptom management). The physiological outcomes also show an increase in relaxation response from Measurement Points 1–2 (practitioner-led sessions) with increased PNS and decreased SNS activity as

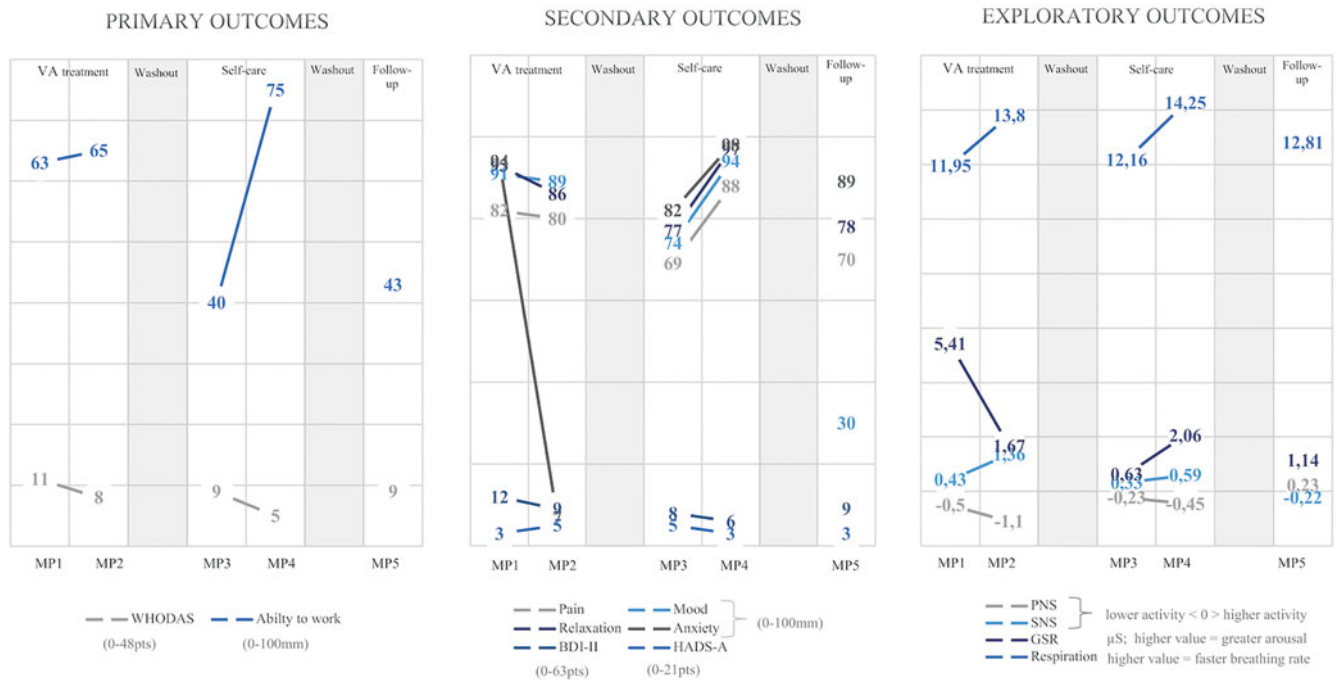


Figure 6. Primary, secondary, and exploratory quantitative outcomes for Participant 4 at Measurement Points 1–5. MP1–5: Measurement Points 1–5. Primary outcomes: WHODAS scores (raw 0–48 pts); 0 = no impaired functioning; Ability to work Visual Analogue Scale (0–100 mm); 0 = completely unable to work, 100 = best working ability; Secondary outcomes: Visual Analogue Scales (0–100 mm); Pain, mood, relaxation, anxiety; e.g., 0 mm = unbearable pain; 100 mm = no pain; Beck's Depression Inventory-II (0–63 pts); 0 = minimal depression; Hospital Anxiety and Depression Scale – Anxiety subscale only (0–21 pts); 0 = no anxiety; Exploratory outcomes: Parasympathetic nervous system; lower PNS activity < 0 > higher PNS activity; Sympathetic nervous system index; lower SNS activity < 0 > higher SNS activity; Galvanic skin response (arousal); microsiemens (μ S); higher score = greater arousal (X = no reading); Respiration rate; higher score = faster breathing rate.

well as decreased arousal (GSR) and increased PNS activity also at Measurement Points 3–4. PNS activity increased and GSR decreased to a greater degree during the practitioner-led sessions, suggesting that the self-care sessions were not as relaxing as the practitioner-led sessions. Contrary to this, respiration rate decreased much more during the self-care phase. Although there appeared to be a negative trend in the physiological outcomes, she wrote: “Already when I think about this whole cushion phase, the cushion and music somehow helped the pain, sometimes not, but there was a big effect on mood and also concentration” (Main theme: *Adjusting to the new status quo*), highlighting that although she did not experience pain relief during self-care sessions comparable to that of practitioner-led treatments, she experienced other positive effects. She marked improvement for the concentration item of WHODAS, as she found concentration *slightly difficult* at the beginning of the study and *not at all difficult* at the end, also supported by the qualitative findings that she was less distracted: “I think I was able to concentrate on breathing and my thoughts didn't wander so much” (Sub-theme: *Rehabilitation as a dynamic process*).

Throughout the process, she became conscious of new sensations, or those that had returned after years of absence: “This week I had a new symptom when I sit or lie on the sofa, I get tingling in my legs (normally it's numbness). I didn't have this for a few years” (Sub-theme: *Recognising limitations/needs/sensations*). In comparing the practitioner-led and self-care sessions, she noted that her pain stayed away longer as Phase I continued (“I was able to relax, not that much that I would fall asleep, pain disappeared; in the beginning this was for a few hours, then at the end it [pain] started to come back only the next day”, sub-theme: *Changes in level of functioning*). She noticed that her pain was generally less frequent as the process continued (“Overall the pain is, in my opinion, less, and it changed a lot and is more tolerable,

normally I don't notice it anymore, I just notice it if I want to go and do something e.g., housework, one hour is my limit after which the pain starts”, Sub-theme: *Changes in level of functioning*). Ability to work VAS scores improved too during the self-care sessions and at the end of the process she discussed increasing her working hours with her MD – further supporting her ability to work had improved.

Integrated outcomes for participant 4

Participant 4's positive response to the practitioner-led treatment sessions (see Figure 6) was most clearly seen in improved functioning, pain, relaxation, and mood. During the first session, he experienced pain relief (nerve pain in his head), however it returned as soon as he left the treatment room (see Table 6). It was a large adjustment for him, as the difference between the pain and no-pain was so noticeable: “I felt quite anxious then [when the pain came back] because the contrast was so big” (Sub-theme: *Changes in level of functioning*). However, as this phase continued, he noticed the pain stayed away for longer: “It helped my legs a lot!! They were lighter and I was painless for many days” (Sub-theme: *Rehabilitation as a dynamic process*). He also noticed other changes. He usually applied cooling gel to reduce night-time leg pain, but could reduce the amount of gel he applied during Phase I (Main theme: *Adjusting to the new status quo*). Although the general trend of respiration rate and PNS/SNS activity suggest he was less relaxed from Measurement Points 1–2 and Measurement Points 3–4, arousal (GSR) was greatly reduced during the practitioner-led sessions. Relaxation (VAS) showed a slight decrease from Measurement Points 1–2, however the score still fell within the *mild tension* category at Measurement Point 2. BDI-II improvement during Phase I was clinically relevant, as was the improvement in the HADS-A score during Phase III.

Table 6. Qualitative findings for Participant 4 showing protocol phase and illustrative quote.

Main theme	Sub-theme	Phase	Illustrative quote
Pain as a barrier	Pain inhibits functioning	I	I was in more pain than usual. I wasn't able to do anything in the evening. I felt as though I had a heavy cold and I was frozen solid under a blanket. I woke to a heavy cramp in my leg during the night.
Adjusting to the new status quo	Pain as a barrier to rest & recovery	II	I've had a lot of pain. Sleeping poorly at night and back and legs have been painful. I'm constantly getting electric shock in my legs.
	Changes in level of functioning	I	The pains returned quite quickly. I felt quite anxious then because the contrast was so big.
		I	Relaxed again really well [during the treatment]. I was able to put less creams on my legs when I go to bed (cooling gel etc).
	Recognising limitations/needs/sensations	I	I relaxed again much deeper. If I relax properly, I'm in more pain in the evening. The night was again rather good.
Approaches to symptom management	Rehabilitation as a dynamic process	I	It helped my legs a lot!! They were lighter and painless for many days. It's terrible that it's stopping almost like in the middle of the treatment, now that it's beginning to help the pain!!!
	Relaxation to improve pain	I	I relaxed well again. After the treatment, my strength was rather gone, but returned quickly. Nerve pain in my head was less.
	Process of integrating and adjusting self-care practices	III	It has worked with varying success. I intermittently put it on my neck when going to sleep. Relaxed quite well and I'm able to fall asleep better. The same music is already starting to be irritating. I have tried to use the cushion religiously. If I use it too late, the only effect is tiredness. I don't notice great changes to the pain. Able to manage to relax.

Phase I: Practitioner-led sessions; Phase II: Washout 1; Phase III: Self-care phase; Phase IV: Washout.

Participant 4 did not notice a great change in his pain when conducting the self-care sessions, however his pain was in the *mild* category at all Measurement Points. He reported in his diary that he was able to relax using the self-care device, noticing some pain relief (Theme: *Approaches to symptom management*). This can also be seen in the VAS pain outcomes, with improved pain from Measurement Points 3–4.

The quantitative results show that all outcomes were worse after the treatments stopped, at Measurement Point 5. He noted: *"After the treatments stopped, I had a lot more pain. Nerve pain in my head and legs has returned. I have been sleeping worse"* (Sub-theme: *Process of integrating and adjusting self-care practices*). Although Phase III improvement margins were comparatively narrower than during Phase I sessions, his condition during self-care was also better than before the study began. He more easily noticed the benefit of the self-care sessions after the treatments had ended, because his symptoms deteriorated at that point; this is also supported by the quantitative Measurement Point 5 scores.

Discussion

This study aimed to assess the impact of practitioner-led Vibroacoustic treatment sessions and self-care on functioning, chronic pain, and possible comorbid mood disorders within a multidisciplinary rehabilitation setting. As self-care is a part of regulatory function inherent in one's daily activities and to be viewed as an integral part of rehabilitation [30], the self-care phase was introduced to the Vibroacoustic treatment protocol as a means of protracting patients' rehabilitation processes. As in previous research of Vibroacoustic treatment [13–15,17], participants in this study experienced pain, mood, and insomnia relief. The outcomes from the limited applications of Vibroacoustic as a self-care intervention [34] support these participants' experiences of increased energy and relaxation. The comparatively greater improvement in relaxation scores by participants in this study are also in line with previous research [13–15]. Patients receiving Vibroacoustic treatment within multidisciplinary care, as with the participants in this study, also reported relaxation as the variable of greatest improvement, even by those previously unable to reach a state of relaxation using other methods [52].

Although relaxation was greatly improved in the patients presented here, as there was no comparison with other relaxation techniques or the possibility to explore the specific active agent within the VA treatment triad which elicited the relaxation response, this is an area for future research and investigation.

Self-care as an integral part of a rehabilitation process

Self-care as a concept adheres to several principles: attributes, such as one's ability to perform self-care, and decision-making; antecedents, such as social support, perceived and actual physical and psychological health condition, prior experiences, and self-efficacy; and outcomes, including improved functioning, coping, and physiological and psychological symptoms [30]. These elements can be seen in the participants' experiences presented here. As self-care is intrinsically involved in rehabilitation and one's daily health behaviours, the emerging self-care-related behaviours were noted already during the practitioner-led phase, laying the foundation for these to become fully realised during the self-care phase.

Awareness of change

Improved symptoms noticed by participants (such as concentration) contributed to how they perceived improved functioning and their increased ability to work, evidenced by Participant 3's gradual increase in working hours. Awareness, as one of the attributes of self-care described by Orem [30], was also exhibited by other participants. As perceived disability and emotional distress negatively influence one's ability to work [53], Participant 3's awareness of her improved symptoms could have been a boost towards affording her a sense of self-efficacy and control over her symptoms. Participant 3 also noticed improvement in cognitive functioning, a reported effect of self-care practices [33]. The quantitative outcomes support the improvement in mood which could have afforded this positive change.

A similar situation occurred for Participant 2; in becoming aware of the gradual increase in sensation in her right leg during the practitioner-led sessions, although she was not yet at the stage where she could return to work, she only noticed this asymmetrical sensation during Vibroacoustic treatment, and it became a way of tracking treatment progress.

Participant 4 noticed how beneficial self-care had been when symptoms returned during the second washout period. Although the effects were subtler than the comparatively greater effects he felt from the practitioner-led sessions, he exhibited awareness of the changes from the treatments, and then as a result of their absence.

With greater awareness, one potentially begins to recognise potential barriers. All participants noticed some barriers to functioning and self-care, including influence from comorbidities such as mood, also shown elsewhere [31]. Improvements recorded during self-care included decreased pain and depression, and improved functioning, which were also previously reported [32].

Mourning one's past identity

Patients with persistent pain are also commonly emotionally impacted by the chronic illness (as seen with Participants 2 and 3) and the link between pain and poor mental wellbeing, sometimes mourning the loss of their former selves [54]. Frustration with poor functioning, loneliness, inadequacy resultant of the new experience of low functioning, and embarrassment due to non-working status are all aspects of this emotional impact. Participant 3 felt that Vibroacoustic treatment reminded her of a time before her pain; her mood was low, fearing that she would not return to this former self. Patients often feel disappointed when they realise that they must settle for symptom reduction rather than a cure [54]. This supports Participant 2's struggle to accept that her functioning would never again be at 100%. Patients with chronic pain also often believe that a change in functioning corresponds to a complete loss of functioning, as was the case for Participants 2 and 3 [55]. They at times struggled to accept the new level of functioning as they had been accustomed to more activity, social functioning, and participation before the onset of their pain.

Social functioning

Participant 2 understood the importance of socialising to her rehabilitation process, noticing improvement in her pain and mood when she was able to participate in social events. In contrast, Participant 1 may have not felt the need to return to work because of her support system outside the workplace which was lacking for Participant 2 whilst on disability leave. One's ability to participate is influenced by one's biological functioning, which refers to the general physical functioning and the extent to which this limits one's activities [56]. Social functioning is an important element predicting pain self-efficacy and pain severity [57], with lower social functioning and biological functioning predicting higher pain severity. The importance of being able to retain or regain one's social functioning is underscored by Participant 2's experiences and need for socialising. The fact the self-care was at home, without the same level of professional support, was an issue for her. Despite the intensive rehabilitation offered at the hospital, she wished for a longer Vibroacoustic treatment period, having found the bi-weekly sessions beneficial from the social point-of-view as well as the physical treatments. When psychological symptoms were greater (e.g., feeling low because of disability), participants' feelings of control over their symptoms was impacted. Prior experiences of greater functioning resulted in frustration with the current level, as described in previous research [55]. Their negative responses to pain or inability to conduct day-to-day activities affected their health-related behaviours (e.g., skipping self-care sessions) and disability negatively impacted their social interactions (inability to attend birthday parties/club events).

Comparing objective and subjective reports

The differences between the qualitative and quantitative data were seen in instances where, for example, Participant 4 reported the self-care intervention was ineffective for pain relief, but the VAS for pain indicated otherwise. The improvement in pain during self-care was clinically relevant, however he felt the effects were much weaker than the practitioner-led sessions in which there was no clinically important difference. His pain at Measurement Point 4 was objectively better than Measurement Point 1, but he only noticed the deterioration in symptoms after the self-care had ended. The effects from self-care were perceived as subtler than those of the practitioner-led sessions. The physiological outcomes were mixed. He reported decreased PNS and SNS activity, however increased arousal (GSR), during the practitioner-led phase. During the self-care sessions, SNS activity increased, supporting his claims that these sessions were not as relaxing as the previous treatment condition. Higher RMSSD (vagal tone) scores are associated with higher pain intensity in those with chronic pain compared to controls without chronic pain [57]. This was also seen, for example, at Measurement Point 4 for Participant 4; his RMSSD score at the beginning of the treatment phase was 28.5 ms (VAS pain 69 mm), and 26.6 ms (VAS pain 88 mm) at the end of the treatment phase. Patients with fibromyalgia, such as Participant 4, have been shown to exhibit decreased PNS activity and increased SNS activity compared to controls [58]. This could explain Participant 4's increased SNS level at Measurement Point 1 when his pain was *mild* and the decreasing PNS during the practitioner-led sessions when his VAS pain score was worse. From a within-session perspective, although not the focus of this present study, those entering a relaxation response have been shown to exhibit increased heart rate and decreased respiration whilst meditating [59]. Participant 4's physiological outcomes showed an increase in heart rate from 69 to 71 beats per minute and a decrease in respiration rate from 15 to 13 breaths per minute at Measurement Point 2. He also marked *relaxed* on the VAS for relaxation. Arousal also reduced from 2.08–1.67 μ S during this session. The within-session changes may indicate a general trend over time such that the decreased respiration rate from 3–4 and increased SNS activity (including heart rate) may represent a relaxation response over time. Galvanic skin response (GSR), as a physiological measure of arousal and mental/emotional states, has been shown to reduce with meditation and music listening as so-called stress-relieving methods, but may also indicate the level of concentration; if one is disturbed when engaging in these activities, GSR peaks [60]. This could account for higher mean GSR levels (e.g., Measurement Point 4, Participant 4), possibly resulting in difficulty reaching a more relaxed state during the comparatively short self-care treatment time.

Anxiety is potentially another confounding variable. It has been shown that the relationship between pain and anxiety is not always unidirectional, in that when anxiety is not related to experimental pain, the pain is perceived as less intense compared to when anxiety is associated with the pain source [61]. The music, despite being participant-chosen, may have influenced physiological responses. Music chosen by participants has been shown to arouse autonomic nervous system responses (e.g., heart rate, muscle tension) even though participants reported reduced anxiety and an increase in relaxation [62]. This could partly explain the disparity between the physiological, VAS, and verbal reports.

Similarly, in assessing subjective and objective reports of activity in patients with chronic lower back pain [63], self-report measures did not correlate with the objective measurement of physical

activity. There were strong correlations, however, between objective and subjective reports in controls who were asymptomatic. Comparison with asymptomatic controls is not possible in the present study; however, symptoms such as pain (as suggested by van Weering and colleagues [63]) may account for the disparity in subjective and objective records.

These conflicting reports emphasise the complex interactions between physiological responses and perceptual experiences of the multi-modal experience of chronic pain and multidisciplinary approaches to its management.

Limitations

As this study took place within a naturalistic setting, participants were receiving various other interventions either concurrently or successively. To some degree, the qualitative findings show some pre- and post-treatment changes, however the overall effect of both treatment conditions is compounded by additional therapy regimens. This has both positive and negative attributes. The efficacy of the interventions cannot be assessed using this approach. However, as Vibroacoustic treatment is delivered to difficult-to-treat patients with various diagnoses receiving various treatments at this unit, adding this self-care intervention to the naturalistic setting gives a more accurate representation of how it would work in practice, therefore assessing effectiveness. Effectiveness studies look at clinical practice and the real-life circumstances. The “ideal” unidimensional scale for measuring pain is the VAS [64], because it is independent of language, however, a mix of subjective and objective reports should be used given the disparity in what a patient or researcher/healthcare giver may evaluate as a successful intervention. As perceived functioning and chronic pain are subjective to each individual patient, their experiences of this approach - relative to their standard care - is, in essence, the most important tool for intervention evaluation. In addition to the other treatment participants were receiving, medication changes were also a compounding variable for Participant 1 because she changed medication dosage during the protocol. Although it is also a part of one's rehabilitation process, this influences her pain and may account for the relatively little pain reported with VAS.

In relation to the study design, although comparison across individual cases is not possible, the outline aimed to give impressions of how participants with various levels of functioning may respond to Vibroacoustic treatment with added self-care. Barlow and colleagues [65] expressed the necessity of non-RCT studies in evaluating processes, as such studies are required to explore whether the resources needed to conduct larger, randomised studies are justified. The present study serves as a way of exploring the potential responses of a highly varied target group, and whether chronic pain patients with possibly comorbid mood disorders may benefit from this “two-pronged” approach. As the field is still small, these more in-depth studies are needed before larger studies can be considered. This was, however, an issue for outcome measures, as the small sample meant quantitative analyses could not be conducted. On the other hand, the mixed methods design highlighted the complexity of the individual chronic pain experience. As Morgan and Morgan [66] succinctly wrote: “No amount of research in the nomothetic tradition can effectively reveal the likelihood of successful treatment in an individual case” (p. 185).

The comparatively lower intensity of the Phase III sessions compared to the Phase I sessions was also discussed by participants. Although the self-care device is indeed much smaller than the Physioacoustic chair, the aim of this study was not to

compare efficacy of one approach to the other, rather to explore whether a self-care phase could be useful as an additional intervention for patients at home.

Conclusion

Outcomes from a self-care phase added to standard Vibroacoustic treatment protocol at the multidisciplinary rehabilitation unit at Seinäjoki Central Hospital indicate that both interventions may be beneficial for improving functioning, pain, mood, and relaxation. Participants found the effects from the practitioner-led sessions were more distinctly manifested by the end of that phase; the self-care sessions appear to have been beneficial for less severe pain and related symptoms. This self-care approach could be applied directly after practitioner-led sessions to prolong the effects, or as an intervallic or intermediate intervention applied between intensive practitioner-led phases. The mentality and skills developed during a rehabilitation process may support prolonged relief, potentially helping to avoid relapse. As previous research has supported the combination of Vibroacoustic treatment and physiotherapy [13,17], the self-care device could be implemented as a way to improve physiotherapy outcomes when conducting exercises at home.

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Declaration of interest

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