

The Development of Mindful-Based Dance Movement Therapy Intervention for Chronic Pain: A Pilot Study with Chronic Headache Patients

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Author contribution statement

IMD was responsible for the conception and design of the study, data collection, interventions implementation, data analysis and interpretation, and writing the manuscript. VK were responsible for the conception and design of the study, contributed to the data analysis, interpretation and manuscript development. IM contributed to the interpretation of the data and manuscript development. All authors have approved the final version of the manuscript.

Keywords

dance movement therapy, mindfulness, Chronic Pain, Anxiety, Depression

Abstract

Word count: 274

Chronic pain is of significant global concern. There is growing evidence that body-mind therapies and psychological approaches can contribute towards changing chronic pain perceptions. This is the first model described in the literature that combines a mindfulness-based approach with dance movement therapy, and explores potential psychological and pain-related changes for this client population. In this paper results from the pilot study are presented involving patients with chronic headache recruited in an outpatient rehabilitation setting.

Methods: In this pilot study 29 patients (n=29) with chronic headache were randomized to either an MBDMT group or a waiting list control group (TAU). The MBDMT group was offered ten sessions in a clinical outpatient rehabilitation setting for five weeks. Data were collected pre- and post-intervention and 16 weeks after the intervention finished. The Hospital Anxiety and Depression scale (HADS), Patient Health questionnaire (PHQ-9), Five Facets of Mindfulness questionnaire (FFMQ) and Numeric Pain rating scale (NRS) were used as outcome measures.

Results: The working model of MBDMT identifies nine therapeutic mechanisms (safe therapeutic environment, mindfulness skills, body awareness, relaxation / releasing, distancing and staying with discomfort, meaning making, self-regulation, acceptance and integration, creative process). Per-protocol analysis reveals statistically significant reduction of pain intensity and depression scores in favor of the MBDMT group and these improvements were maintained in follow-up assessment.

Conclusions: Results suggest that MBDMT is a feasible and promising therapy approach for chronic pain patients. The pilot study offered sufficient information and preliminary results in the desirable direction to enable the researchers to move to an RCT stage in order to establish the efficacy of the intervention.

Trial registration: the study was registered in the www.researchregistry.com registry (5483).

Contribution to the field

This paper reports results of the development of Mindful-Based Dance movement therapy (MBDMT) approach for chronic pain patient population. Mindfulness is recognized as important component in dance movement therapy (DMT), but there has not been model which explores and integrates therapeutic mechanisms of both approaches - DMT and mindfulness-based interventions. The paper presents model of the MBDMT and results from pilot study where MBDMT intervention was offered to chronic headache patients recruited in an outpatient rehabilitation setting. In study design grounded theory was used to develop MBDMT model and quantitative strategy of pilot randomized controlled study was used to examine the effectiveness of the model. The preliminary results suggest that MBDMT is effective in reducing pain intensity and depression symptoms in comparison with TAU group. Also, important information was gained regarding recruitment and follow-up processes, intervention acceptability and participant satisfaction, outcome measure acceptability and performance. The pilot study offered sufficient information and preliminary results to enable the researchers to move to an RCT stage.

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- 10 Chronic pain is of significant global concern. There is growing evidence that body-mind therapies
- 11 and psychological approaches can contribute towards changing chronic pain perceptions. This is the
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- 15 headache recruited in an outpatient rehabilitation setting.
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- 17 MBDMT group or a waiting list control group (TAU). The MBDMT group was offered ten sessions
- 18 in a clinical outpatient rehabilitation setting for five weeks. Data were collected pre- and post-
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- 24 discomfort, meaning making, self-regulation, acceptance and integration, creative process). Per-
- 25 protocol analysis reveals statistically significant reduction of pain intensity and depression scores in
- 26 favor of the MBDMT group and these improvements were maintained in follow-up assessment.
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- 28 pain patients. The pilot study offered sufficient information and preliminary results in the desirable
- direction to enable the researchers to move to an RCT stage in order to establish the efficacy of the
- 30 intervention.
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- 32
- 33 1 Introduction

34 Chronic pain affects 20% of the worldwide population (Fayaz et al., 2016; Goldberg & McGee, 35 2011). 150 million Europeans suffer from moderate to severe chronic pain (Thematic Network on the Societal Impact of Pain, 2018)¹. This debilitating condition affects persons' physical, emotional and 36 37 social functioning, being a major source of suffering at the same time as it is a significant economic 38 burden and challenge for health care systems (IASP, 2019)². Since 2019 a significant change has 39 been made in the classification of chronic pain as the World Health Organization has adopted the 40 new edition of ICD-11. ICD-11 will be the first classification to include chronic pain as a health condition in its own right. This new classification differentiates chronic primary pain from chronic 41 secondary pain, with the former referring to pain in one or more anatomical regions that persists or 42 43 recurs for longer than three months. Furthermore, it recognizes that chronic primary pain is closely linked with significant emotional distress (anxiety, anger/frustration or depressed mood) and it 44 interferes with the activities of daily life and participation in social roles in ways in which cannot be 45 46 accounted for by another chronic pain condition (ICD-11, 2018)³. The new classification system is expected to promote research on the etiology and pathophysiology of these conditions and to improve 47 access to multimodal care for all patients with chronic pain (Treede et al., 2019). Several emotional 48 49 distress factors are regarded as mediators in the 'chronification' of pain, that is persistent pain with characteristic pain behavior and resistance to therapeutic intervention (Borsook et al., 2018). These 50 51 factors include pain catastrophizing, anxiety, and fear of pain and helplessness (Keefe et al, 2004). 52 Depression is also seen as a serious risk factor in the development of debilitating pain (Hülsebusch et 53 al., 2016). The psychological characteristics of chronic pain patients can involve abuse and neglect experiences in childhood (Davis et al., 2005), counter-dependency traits and alexithymia (Ak et al., 54 55 2004), with depression working as a mediator between chronic pain and alexithymia (Saariaho et al., 56 2013). These psycho-emotional characteristics of chronic pain patients make this patient population quite a heterogenous group. The large-scale cross-sectional study of chronic pain patients identified 57 four subgroups. They differ in aspects of pain intensity, duration and spreading, psychological strain 58 59 and social distress including lack of social support. Research confirms that all three components -60 bio-psycho-social – are important in chronic pain, but different constellations of these components form subgroups with different needs in pain treatment and indicate the need to design "tailor-made" 61 62 interventions (Bäckryd et al., 2018). 63 64 Epidemiology studies show that the prevalence of pain is higher in women: chronic primary headache, in particular, affects more women than men (Jiménez-Sánchez et al., 2012; Allais et al., 65

- 2020). Middle-age (40-59) has been reported as high-risk: people in this group appear to be less 66
- satisfied with their social life and are more often diagnosed with fibromyalgia. The older adult group 67
- 68 reported higher life quality scores, higher levels of satisfaction with marital and social life, and better
- mood, but they face more comorbidities and longer periods of pain (Rustøen at al., 2005). Seniors 69
- also report lower levels of pain severity and pain interference and greater levels of perceived control 70 71
 - over pain in comparison to younger people suffering from headaches (Lachapelle &
- 72 Hadjistavropoulos, 2005).
- 73

³ ICD-11, 2018: https://icd.who.int/browse11/l-m/en

¹ Thematic Network on the Societal Impact of Pain, 2018:

https://ec.europa.eu/health/sites/health/files/policies/docs/ev 20181112 co07 en.pdf ² IASP. 2019: https://www.iasp-

pain.org/PublicationsNews/NewsDetail.aspx?ItemNumber=8340&navItemNumber=643

74 Treatment strategies which are regarded as clinically effective, and cost-efficient, tend to be

multidisciplinary and are based on the biopsychosocial model of pain (Gatchel et al., 2007),

- acknowledging psychological risk factors (Nicholas et al, 2011) and offering holistic approaches to
- multimodal pain management (Kress et al., 2015). The biopsychosocial model of pain recognizes that
 pain has three facets: cognitive-evaluative, sensory-discriminative, and affective-motivational aspects
- pain has three facets: cognitive-evaluative, sensory-discriminative, and affective-motivational aspects
 (Melzack, 1999). All of these need to be included in a treatment package. From a wide range of
- 80 psychological therapies, Cognitive Behavioral therapy (CBT) and Acceptance and Commitment
- 81 Therapy (ACT) present the strongest evidence for decreasing depression, pain-related anxiety and
- 82 catastrophizing, and for increasing self-efficacy (Williams et al., 2012; Veehof et al., 2016). Also,
- 83 studies on Mindfulness-Based Stress Reduction programme (MBSR) report decreasing pain intensity
- 84 and disability (Cramer et al., 2012). MBSR was a programme created and introduced by John Kabat-
- 85 Zinn, who defines mindfulness as: "the awareness that emerges through paying attention on purpose,
- 86 in the present moment, and nonjudgmentally to the unfolding of experience moment to moment"
- 87 (Kabat-Zinn, 2003, p.145). Mindfulness allows patients to relate to their physical and psychological
- symptoms in a different, more skillful way, with a positive effect on developing a realistic sense of
 control and appropriate strategies in becoming adaptive (Grossman et al., 2010; Kabat-Zinn et al.,
- 90 1986). Other Mindfulness-Based Interventions (MBI) show positive impact on perceived pain
- 91 control, pain acceptance and quality of life (Bawa et al., 2015). In MBIs the indirect effect on pain is
- 92 due to an increased acceptance; this buffers the intensity of perceived pain as a stressful event
- 93 (Shapiro et al., 2006). Analysis of the content of MBIs reveal meditation practice, exercises that
- 94 support the change of habits, simple yoga exercises and psychoeducation as some of the main
- 95 structural components of the intervention (Majore-Dūšele et al., 2018). Furthermore, monitoring
- 96 attention and acceptance are the central mechanisms in mindfulness training programmes;
- 97 these interact to improve stress, affect, and health outcomes (Lindsay & Creswell, 2017).
- 98

99 However, these interventions are limited in their capacity to approach the person as a whole, 100 prioritizing often the cognitive domain as the route through which change may occur. They 101 require considerable cognitive and linguistic skills from the client/patient and acknowledgment of 102 psychological difficulties and mental health concerns in their physical symptoms. As chronic pain 103 patients experience the physical nature of their symptoms, and may perceive their mental health 104 concerns as stigma, they may refuse cognitive-based interventions (Pavne & Brooks, 2018). With 105 chronic pain being situated in the body, there is a danger that cognitive-based interventions are 106 missing the opportunity to validate the physical suffering and work with the body in order to find 107 therapeutic solutions. They also make limited use of the connection between the body and the mind 108 as a means through which change may occur, ignoring the role movement can play as a holistic, 109 creative, and thus therapeutic, tool. For a body-based condition such as chronic pain, there may be 110 value in the development of a body-mind intervention with a holistic/creative character. Dance 111 Movement Therapy (DMT) is one such intervention.

- 112
- DMT is defined as "the therapeutic use of movement to further the emotional, cognitive, physical, spiritual and social integration of the individual. Somatic awareness and kinesthetic empathy, movement as creative self-expression and dance as non-verbal interaction, are the core components of DMT (European Association of Dance Movement Therapy 2013, p.1)⁴.
- 117

⁴ European Association of Dance Movement Therapy, 2013: <u>https://www.eadmt.com/?action=article&id=22</u>

118 There is growing evidence that Dance Movement Therapy (DMT), a creative body-mind form of

- 119 psychotherapy, may have a positive psychological impact on the psychological states of patients with 120 somatic concerns. Dance and movement, being key elements in the therapeutic alliance between
- patient and therapist, can provide the means for the self-expression and communication of unspoken
- 122 concerns amongst this client population. The latest meta-analyses show that DMT is helpful in
- 123 health-related psychological outcomes, improving wellbeing, mood, affect, quality of life, body
- image and interpersonal competence, and reducing clinical symptoms such as anxiety and depression
- 125 for different patient groups (Koch et al., 2014; Koch et al., 2019; Meekums et al., 2015; Karkou et
- al., 2019). DMT has shown promising improvements in functioning for fibromyalgia patients
 (Bojner-Horwitz et al., 2003) and patients with medically unexplained symptoms (Payne & Brooks,
- 2020; Payne & Brooks, 2017; Payne & Brooks, 2016). However, until now, there has been limited
- research on the effectiveness of DMT with patients suffering chronic pain. One of the few studies
- 130 with this client population comes from Shim (2015; Shim, et al., 2017) who found that the ten-week
- 131 DMT process increased resilience, decreased 'kinesiophobia' (i.e. fear of movement) and showed a
- 132 beneficial impact on pain intensity.
- 133

Regardless of the type of psychological therapy, there are arguments that the mechanisms of change in each therapeutic intervention need to be considered specifically for each client population (Kazdin,

136 2009; Burns, 2016). In pain treatment *mindfulness, acceptance* and *self-efficacy* are recognized

- mechanisms in pain regulation (Turner et al., 2016). In DMT work with chronic pain patients,
 increasing *self-compassion* has been set as a main principle of the work, which is facilitated through
- alternating between states of acceptance and inspiration (Erber, 2015). The BodyMind Approach®
- (TBMA) (an approach that has derived from DMT) has identified five key factors as responsible for
- 141 successful self-management of patients with medically unexplained symptoms. These are: body with
- 142 mind connections, importance of the facilitator, positive benefits, preparedness for change, self-

acceptance and compassion (Payne & Brooks, 2020). The DMT model for building resilience in pain

- patients by Shim et al, (2017) recognizes the mechanisms of *activating self-efficacy, connecting to* self, connecting to others, enhancing emotional intelligence, and reframing as important. In earlier
- 146 models of DMT for chronic pain patients (Shim, 2015), four therapeutic factors were identified:
- *kinesthetic awareness* (articulation, noticing, widening), *enactment* (mobilization & motivation,
- 148 kinesthetic imagining, reinforcement & reframing), *expressivity* (externalizing & symbolization,
- emotional restoration and management, creativity & ability to play), and *making connections* (mind-
- 150 body integration, meaning-making & identity reconstruction, interpersonal connection).
- 151

Despite the discussion in DMT literature that mindfulness is an important component of DMT (Koch et al., 2019), there has been no prior study that integrates these two approaches and explores potential psychological and pain-related changes for this client population. In this paper the development of

the working model of the Mindful-Based DMT (MBDMT) is presented, along with results from the

156 pilot study that has been completed, before conducting a large RCT that will examine the efficacy of

- 157 MBDMT for chronic pain patient population.
- 158
- The objectives of the pilot study were to: (1) establish recruitment and follow-up processes; (2)
- 160 <u>explore initial outcome results of MBDMT intervention; (3) examine intervention acceptability</u>,
- 161 participant <u>adherence and (4) test adherence to the MBDMT protocol.</u> This current paper will present
- and discuss how these objectives were met.

163 2 Methods

164 2.1. Recruitment procedure and participants

- 165 The present study recruited patients with chronic headache (tension-type headache and/or migraine
- with or without aura, diagnosed by neurologist). Patients with chronic headache were prioritized in 166
- 167 this study because of easy access to this population in the first instance. Inclusion and exclusion
- 168 criteria were established prior to the commencement of the study. Inclusion criteria for the study
- 169 were: (1) primary headache lasting more than three months (headaches needed to be the primary 170 cause for seeking medical help); (2) being between 20 and 55 years old; (3) increased depression
- 171 and/or anxiety measures (PHQ-9 \geq 5; HADS \geq 7). Exclusion criteria were: (1) patients who had a
- 172 disease based on an infectious process, autoimmune or metabolic pathology, traumatic injury,
- 173 neoplastic process (primary tumor or metastasis) or internal organ pathology which can be connected
- 174 with pain: (2) movement limitations not related to the diagnosis of chronic pain (eg cerebral palsy.
- 175 spinal injuries, etc.); (3) pregnancy.
- 176 The recruitment strategy involved: (i) the neurologists of the rehabilitation setting who were
- 177 informed at their quarterly meeting about the aims and structure of the intervention, and the inclusion
- 178 and exclusion criteria of the pilot study; (ii) participation in the research and DMT groups was
- 179 advertised through social media in a closed group of the headache patient's association. Interested
- 180 participants allowed their neurologist to send contact information to the principal investigator (first
- 181 author of this paper). Alternatively, they were given the option to contact the principle investigator
- 182 themselves through email or SMS. The principal investigator made an initial phone call to each
- 183 interested individual to inform them about the study, to answer any questions, and to gain verbal
- 184 consent for participation in the study. Potential participants were informed about randomization, and
- 185 were also informed that members of the control group could participate in the DMT group after the
- intervention group process was complete. Following this, all participants were sent by email written 186 information about the study, the consent form and all measures for the baseline assessment. The 187
- recruitment process and all aspects of the study gained ethical approval by the Ethics Committee of
- 188 Riga Stradins University (02/28/2019 Nr.6-3/2/43).
- 189
- 190 Over the ten weeks of the recruitment period (Aug-Nov 2019), 39 women (n=39) expressed interest
- 191 in participating in the study; 19 were recommended for participation by their neurologists, while the
- 192 other 20 were recruited through the headache patient's association. Although no prevalence or
- 193 restrictions were identified in inclusion criteria regarding sex, only female participants came forward
- 194 to participate in the study. After the baseline assessment, 29 patients (n=29) were eligible for
- 195 inclusion. These patients were randomly assigned to the MBDMT intervention or the waiting list
- 196 control group using the random number generator that produced two sets of 15 unique numbers from 197 1-30.
- 198
- 199 All participants in the study received treatment as usual (TAU), continuing in their rehabilitation
- 200 outpatient setting. TAU for chronic headache patients was pharmacological treatment ordered by a
- 201 neurologist along with physical and/or physiotherapy input (Table 1).
- 202 Figure 1 Recruitment flow diagram (insert here)
- 203 2.2. Outcome measures
- 204 Assessments were performed at baseline (T1), post treatment (T2; 2 months after baseline) and four 205 months post-intervention (T3; 4-month follow-up).

- 206 *Demographic information* was collected through a self-completed questionnaire created by the
- 207 researcher, which gathered information about the gender, age and pain characteristics pain duration,
- 208 pain etiology, and types of pain control strategies.
- 209 A numeric rating scale (NRS) was used as a scale for pain intensity measurement. This is an 11-point
- scale where the end points are the extremes of no pain (0) and worst possible pain (10). The NRS can
- 211 be graphically or verbally presented, and can be self-assessed. This method of assessing pain is
- 212 widely recommended as a core outcome measure in clinical trials of chronic pain treatment
- 213 (Dworkin, et al., 2005; Farrar, et al., 2001).
- The Hospital anxiety and depression scale (HADS; Zigmond & Snaith, 1983) evaluates the severity of anxiety and depression symptoms in non-psychiatric inpatients. It is composed of seven items that assess anxiety symptoms and seven for depression symptoms. Each item contains a scale of four points (from 0 to 3) with total scores ranging from 0 to 21 for anxiety and depression in three categorical levels: normal (0–7); borderline abnormal (8–10); abnormal (11–21). Higher scores mean greater severity. Psychometric properties for the Latvian version showed a good internal consistency (Cronbach's alpha 0.892) (Šmite & Ancāne, 2010). In the present study, the internal consistency at T1 was Cronbach's $\alpha = 82$ for depression scale and $\alpha = 80$ for anxiety scale; at T2 $\alpha = 79$ and $\alpha =$
- 221 <u>T1 was Cronbach's $\alpha = .82$ for depression scale and $\alpha = .80$ for anxiety scale; at T2 $\alpha = .79$ and $\alpha = .222$.82; at T3 $\alpha = .74$ and $\alpha = .73$.</u>
- *The 9-items Patient Health Questionnaire* (PHQ-9; Kroenke & Spitzer, 2002) is a self-administered dual-purpose instrument that can establish provisional depressive disorder diagnoses as well as grade depressive symptom severity. Each of the nine items is scored 0 to 3, providing a severity score ranging from 0 to 27. Severity of depression was assessed by the PHQ-9 depression severity score and graded as none/minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19), and severe (20-27). In the present study, the internal consistency of <u>T1</u> data was Cronbach's $\alpha = .79$; <u>T2 α </u> =.74; T3 $\alpha = .70$
- 230

231 *The Five facets of mindfulness questionnaire* (FFMQ; Baer et al., 2006) is composed of 39 items.

Each item is rated on a 5-point Likert scale (1 = "never or very rarely true"; 5 = "very often or always

- true"). Five scales: "Observing" is the ability to notice or attend to internal and external experiences
- such as sensations, thoughts, or emotions. "Describing" means to label internal experiences with
- words. "Acting with awareness" refers to focusing on one's activities in the moment as opposed to
- behaving mechanically. "Non-judging of inner experience" means taking a non-evaluative stance
 toward thoughts and feelings and "non-reactivity to inner experience" refers to allowing thoughts and
- feelings to come and go, without getting caught up in or carried away by them. Higher scores on the
- FFMQ reflect greater mindfulness skills. The Latvian version of this scale has shown good reliability
- and internal consistency (Cronbach's alpha 0.9; Majors, 2013). In the present study, the internal
- 241 consistency of T1 data was Cronbach's $\alpha = .89$; T2 $\alpha = .86$; T3 $\alpha = .91$.
- 242 Intervention
- 243 The Mindful-Based Dance Movement Therapy (MBDMT) intervention model <u>used in this study</u> was
- grounded on the contribution of five expert informants. It involved nine therapeutic
- 245 mechanisms/components of change, <u>which were structured in a developmental process with each</u> 246 component supporting the next one.
- 1. Safe therapeutic environment. This is a common factor in any counselling or psychotherapy
- process. Its main characteristics are warm relationships built on empathy, support, validation and the
- acceptance of the patient as he/she is emotionally, physically, and cognitively. These are also

- 250 known as the person-centered facilitative conditions (Lambert & Barley, 2001). The therapeutic
- 251 environment is a safe holding space for the other factors in the therapy process.
- 252 2. *Mindfulness skills*. The patient will be supported to focus and regulate their attention to different
- 253 realms of perception: their own sensations, emotions, thoughts and images, and to cultivate kindness,
- 254 compassion and a non-judgemental attitude towards their self. The development of mindfulness skills 255 will serve as gateway into the creative process.
- 256 3. Body awareness. The patient will pay attention toward their body sensations, not reacting
- 257 negatively or emotionally but with an explorative interest. Attention toward interaction between
- 258 sensation, emotions and thoughts, experience of body-mind connectivity.
- 259 4. Relaxation / releasing. Through creative activities, verbalization and sharing, the patient will 260 express themselves safely and release physical tension. This will open them up for new experiences
- 261 and perceptions of themselves and others.
- 262 5. Distancing and staying with discomfort. Instead of persisting with fear and avoidance reactions,
- 263 the patient will use creative tools (props) and aesthetic distance to focus on pain. This will help them
- 264 to explore their relationship with their symptoms, and to build tolerance and the ability to manage 265 their discomfort.
- 266 6. *Meaning making*. The patient will be invited to respond to the question: 'Why is this happening to
- 267 me?' In-depth exploration of symptoms in the context of one's personal life and possible insights into 268 the cause-effect relationship of symptom development.
- 269 7. Self-regulation. The patient will practice self-management, recognizing and releasing physical
- 270 tension and dealing with any emotionally intense feelings which may arise.
- 271 8. Acceptance and integration. As a result of the therapeutic process, the patient may gain a deeper 272
- understanding of themselves, as well as an acceptance of their physical and emotional state.
- 9. The *Creative process* permeates all of the above factors in the model, as they are delivered through 273
- 274 creative activities. Imagery, symbolism and movement metaphors are core aspects of dance
- 275 movement therapy.
- 276
- 277 The therapy model described above shows that MBDMT is a purposefully organized therapeutic
- 278 process where, through the use of creative activities, the development of mindfulness skills, and an
- 279 exploration of bidirectional processes, the relationship between body and mind is explored and self-
- 280 management and self-regulation skills are learned (Majore-Dūšele et al., 2019).
- 281

282 Figure 2 Mindful-Based Dance Movement therapy intervention model (insert here)

283

- 284 The protocol of the MBDMT intervention is organized as a short-term focused therapeutic process
- 285 taking into the account the short-term organization structure of rehabilitation settings in Latvia. It
- 286 includes ten sessions, twice a week, for a five-week period. Each session lasts 90 minutes and
- 287 follows a similar structure: (1) check-in and physical warm-up; (2) body-scan (sitting, lying,
- 288 standing, or walking); (3) work with themes – safety, pleasure, personal borders, body-mind
- 289 connection, relationship with pain, resources; (4) closure and homework.
- 290 Two therapeutic groups took place, with seven/eight participants in each group. Three participants
- 291 were lost early in the process, leaving a group of twelve (n=12) from whom the data was derived.
- 292 The groups were facilitated by a dance movement therapist in training (3rd year professional Masters
- 293 student in arts therapies with specialization in dance movement). The facilitator had been licensed as
- 294 a psychotherapist prior to training as a dance movement therapist, had more than five years practice
- 295 working with mental health issues and adult groups, had previous mindfulness practice training (8
- 296 weeks programme), received training in delivering the MBDMT intervention (24 hrs) and had

supervision during the intervention period by a qualified supervisor. MBDMT intervention training
 included personal experience with the MBDMT model and facilitating skills training.

299 2.3. Analysis

300 Data were analyzed using the Statistical Package for Social Science – Version 23 (SPSS-23, IBM 301 SPSS Statistics for Macintosh, Version 23.0. Armonk, NY, United States: IBM Corp.). Descriptive 302 statistics were used to present the characteristics of the sample. The Kolmogorov-Smirnov test 303 indicated that the distribution departed from normality and the small sample size limited the power of 304 statistical analysis, so the Mann-Whitney U test was used to analyze baseline group differences of the 305 interval data (ie socio-demographic and clinical characteristics), while the Pearson Chi-Square test or 306 Fisher's Exact Test was used for categorical variables (localization and duration of pain and pain 307 control strategies). The Mann-Whitney U test was also used to conduct a between-group comparison 308 of the change in scores from baseline (T1) to the post treatment (T2) and follow up (T3) for all the 309 outcome measures with p < 0.05 being the accepted level of statistical significance. Although 310 medians (interquartile range) were used for the calculation of averages, also means and standard B11 deviations were presented. Taking into account the small sample size of this pilot study, the statistical 312 analysis was performed Per Protocol (PP) instead of performing Intention To Treat (ITT) analysis. 313 PP included patients who completed the intervention according to the protocol only along with data 314 collected from the control group. In all cases, missing data were not included in the calculation. 315 B16 The Reliable Change Index (RCI; Jacobson & Truax, 1991) was calculated for PHQ-9, HADS and **B**17 pain measures to assess the impact of the intervention at the individual level. RCI was used as an 318 indicator of clinical significance of change because it allowed a determination of whether an 819 individual change score (between pre-intervention and post-intervention assessment) was 820 significantly greater than a difference that could have occurred due to random measurement error 321 alone (Guhn et al., 2014). Cut-off points dividing clinical and non-clinical patient groups were ≥ 10 322 for PHQ-9 and ≥ 8 for HADS as the most frequently recommended ones in the literature (Manea et 323 al., 2012; Hansson et al., 2009; Bjelland et al., 2002). Participants whose PHQ-9 and HADS scores 324 were below the cut-off point at the pre-treatment measurement (T1) were excluded from the RCI 325 calculation. RCI were calculated at 95% confidence. If a participant's RCI was below -1.96 and 326 passed the cut-off point, the participant was classified as recovered. If the RCI was below -1.96 but 327 did not passed the cut-off point, the participant was classified as *improved*. If the participant's RCI was between -1.96 and 1.96, the participant was classified as unchanged. If the participant's RCI 328 329 was above 1.96, the participant was classified as *deteriorated*. For pain measures the RCI were 330 calculated based on the minimal clinically important difference being 2-points on a 10-point rating 331 scale as reported in previous studies (Hägg et al., 2003). 332

Power calculation was performed for the primary outcome measure – depression (PHQ-9), to detect
 the adequate sample size for future RCT.

335 **3 Results**

336

337

3.1. Recruitment and follow-up feasibility

B38 During the 2.5-month enrollment period, 39 women expressed an interest in participating in the study

and 29 met the eligibility criteria. Both recruitment strategies (i) by the neurologists and (ii) by

headache patients' association were similarly effective, attracting 50% and 50% of study participants.

As the study flow diagram shows (see Figure 1), post-treatment measures used immediately after the

- 342 intervention were completed by all the members of the control group and all those from the
- intervention group who attended for the whole duration of the programme. Three participants who
- did not complete therapy discontinued early in the study. Follow-up measures were completed by
- 345 100% of the intervention group completers and 71% (10/14) of the control group.
- 346
- 347 Sample characteristics
- 348
- All the participants in the study were female and between 26 and 55 years of age (M = 36.7,
- 350 SD=7.4). 56.7% of the patients had suffered from pain (headache, migraine) for more than ten years.
- 351 60% of the patients suffered from other types of pain in addition to headache and migraine. The
- 352 participants in the intervention and control group were compared by demographic characteristics in 353 order to establish whether there were differences between them at baseline. The participants in the
- intervention group were older (M = 40.9, SD= 6.9) than participants in the control group (M = 32.6, SD= 5.0). There were no differences between the two groups in the duration of pain experience and
- variabilities of pain type or pain control strategies (Table 1).
- Table 1: Baseline participant demographic and clinical characteristics in intervention and control
 groups (insert here).
- 360 3.2. Treatment outcome results: changes in intervention group versus control group
- Table 2 Means, standard deviation, medians of clinical outcome measures; between group
 comparison of the pre/post and pre/follow up change scores (per-protocol analysis) (insert here).
- 363 comp
- 364 The means, standard deviation and medians of the outcome measures, as well as between group
- 365 comparison of the baseline/post (T1/T2) and baseline/follow up (T1/T3) change scores are presented
- in Table 2 at three measurement points. Results indicate that, at baseline (T1), there were no
- 367 statistically significant differences between groups in the measurements of pain, PHQ-9, HADS or
- FFMQ. For each of the scales with clinical cut-offs the selected population baseline mean was above the clinical cut-offs, PHQ-9 (M= 8.1, SD=4.3), HADS-A (M=9.8, SD= 4.1), HADS-D (M= 5.34, 3.8)
- respectively, indicating mild to moderate symptoms of anxiety and depression for both groups.
- 371
- A Mann-Whitney *U* test was conducted to look for <u>statistically</u> significant differences in the reduction of pain, depression and anxiety scores across treatment conditions. The test identifies a significant difference in the change score (T1/T2) of perceived pain between the MBDMT group
- Mdn = -1) and control group (Mdn = .00), U= 128.5, p = .02. The change remained statistically significant in T1/T3 between the intervention group (Mdn = -1.5) and the control group (Mdn = .00), U= 81.5, p = .04.
- 5/1 U=8
- 378
- The reduction of PHQ-9 scores indicates that there were changes in symptoms for the intervention group (Mdn = -2) which was different from the control group in a statistically significant way (Mdn = -1), U = 40.5, p = .02. in T1/T2 comparison. The difference was not statistically significant when T1/T3 was calculated, U = 35.5, p = .18.
- 383
- 384 On HADS measures the change score for anxiety and depression was greater than for the control 385 group in both post intervention time points with reduced scores post intervention for the MBDMT
- intervention group, but this change did not reach statistical significance (HADS-A, T1/T2: Mdn = -2) $M_{1} = 0$ $M_{2} = 0$ $M_{2} = 0$ $M_{2} = 0$
- 387 vs Mdn =.00, U = 121.00, p = .06; T1/T3: Mdn = 4 vs Mdn= -1, U = 78.5, p = .08; HADS-D,

388 T1/T2: Mdn = -1.5 vs Mdn = .00, U = 118.5, p = .07; T1/T3: Mdn = -1 vs Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = 76.5, p = .07; T1/T3: Mdn = .00, U = .00; T1/T3: Mdn = .00; T1/T3: Mdn = .00; T1/T3: Mdn = .00; U = .00; T1/T3: Mdn = 389 .11). 390

- 391 No significant differences between groups was found for Five Facets of Mindfulness scores as 392 indicated in Table 2. 393
- 894 Table 3 Reliable change of intervention group using 95% CI for outcome measures pre-intervention 395 to follow-up (insert here) 396
- 397 With reference to Table 3, 50% (6/12) of the intervention group participants experienced a reliable
- 398 change in pain reduction of at least 2-points. For the other 50% their pain level stayed unchanged. 399 For 92% (11/12) of participants, their anxiety level reached the clinical cut-off point at baseline for
- 400 HADS-A, but follow up measures demonstrated reliable improvement for 73% (8/11) of the
- 401 participants. 28% (3/11) of the participants' anxiety levels changed from clinical to non-clinical
- 402 population valuables. Only four participants' depression levels reached clinical cut-off points at
- 403 baseline by both measures PHO-9 and HADS-D, but at follow up three of these patients (75%)
- 404 demonstrated a reliable improvement with regard to depression, changing from the clinical to the
- 405 non-clinical population. One patient, from the intervention group included in RCI calculations,
- 406 demonstrated a significant increase in anxiety. 407
- 408 As this pilot study demonstrated statistically significant decrease in depression, the PHQ-9 measure
- 409 of depression was used as a primary outcome of the intervention. Based upon the follow up data,
- 410 using the means and standard deviation, sample size calculation for a larger RCT was performed.
- 411 Calculation for continuous outcome superiority trial with 80% power at an alpha level of .05
- 412 suggestes that a total sample of 86 participants was needed to detect clinically important difference
- 413 between means. To allow for attrition between end of trial and follow-up, the aim was to recruit 120
- 414 patients for an RCT.
- 415 3.3. Intervention acceptability, participant adherence and satisfaction
- 416 Of the 15 patients who began to participate in the MBDMT group, twelve completed the therapy course and attended at least eight sessions. The three participants who did not complete the treatment 417 418 discontinued early in the study: one moved to a new residence, and two concluded after the first 419 session that the intervention was not appropriate for them. Four patients completed all ten sessions, 420 three patients nine sessions and five completed eight sessions.
- 421 3.4. Adherence relative to MBDMT protocol
- 422 Adherence to the treatment protocol from the dance movement therapist in training was evaluated
- 423 through a selection of video recordings from the sessions, looking at different stages of the work
- 424 (warm-up, working and closing stage). This was also discussed during regular supervision sessions.
- 425 Substantial diversion from the protocol was not observed. The nine working mechanisms that
- informed the structure of the intervention were found to be logical and supportive of the development 426
- 427 of the group therapy process. There was, however, some difficulty in the timing of the sessions: the
- 428 therapist in training found that more time was needed at the beginning and end of the sessions to
- 429 allow for the participants' verbal discussion.
- 430 On the whole, the treatment protocol was easy to follow and responsive to group dynamics offering 431 alternative choices of techniques.

432 4 Discussion

- 433 This pilot study suggested that MBDMT was a useful intervention for reducing the pain, depression
- 434 <u>and anxiety</u> symptoms of chronic pain patients participating in the study. <u>Results indicate that</u>
- 435 offering a DMT group intervention in addition to the usual medical treatment of chronic pain
- 436 improved the psychological aspects and reduced pain more than just medical treatment and
- 437 <u>physiotherapy.</u> Viewing the results of the present study within the context of other DMT and
 438 mindfulness-based intervention studies, the study offers an interesting addition to the literature,
- 438 mindfulness-based intervention studies, the study offers an interesting addition to the interature, 439 especially with regards to pain reduction. Results from systematic reviews show that MBIs are
- 439 especially with regards to pain reduction. Results from systematic reviews show that MBIs are440 inconsistent in terms of their effect on pain reduction. Results vary from medium to weak
- 441 effectiveness, but do reveal a positive impact on perceived pain control with a moderate effect size (g
- 42 = 0.58 (Cramer et al., 2012; Bawa et al., 2015). Note: the goal of MBIs is not to reduce the intensity
- 443 of the pain but to improve the patient's functioning and reduce their general distress; being mindful
- 444 has a therapeutic value in its own right (Reiner et al., 2013).
- 445 Results from this MBDMT study, however, do suggest a statistically significant reduction in pain
- 446 intensity, in contrast with the mindfulness measure where no significant change was observed. While
- 447 pain reduction is not the primary goal of the MBDMT intervention, the pain experience of the patient
- is validated and the relationship with pain is addressed in the work phase of the therapeutic process.
- For 50% of MBDMT participants pain reduction was at least two points on the NRS scale; this is
- 450 considered to be a reliable and clinically important change (Farrar et al., 2001). These results are
- 451 consistent with the earlier research in DMT for chronic pain patients, in which the theme of working
- 452 with the meaning of pain was part of the therapeutic process, and the reduction in pain intensity was 453 observed (Shim et al., 2017).
- The MBDMT intervention <u>preliminary</u> results <u>also suggest</u> that reduction in depression and anxiety symptoms is possible at least for the small sample of participants with chronic pain involved in this
- 456 study. Individual analysis of reliable change for the intervention group indicated reliable
- 457 improvement in anxiety symptoms for 73% of patients. For those four patients with moderate and
- 458 severe depression, improvement was clinically significant, allowing them to move to a non-clinical
- 459 population. These results are consistent with previous research with a similar patient group with
- 460 medically unexplained symptoms, including medically unexplained pain, where 65% of participants
- 461 involved in a (TBMA) group demonstrated reliable improvement on depression or anxiety measures
- 462 (Payne & Brooks, 2017; Payne et al., 2017). These results can also support results from a large-scale 463 clinical trial on DMT and depression (Hyvönen et al., 2020) and meta-analyses on DMT for
- depression (Meekums et al., 2015; Karkou et al., 2019) Also, potentially they add to results from
- 465 generic meta-analyses on DMT (Koch et al, 2019). The latter study argues that DMT can improve
- 466 psychological conditions by decreasing depression and anxiety levels for patients with somatic
- 467 concerns. Results from the current study suggest that this was also true for the participants of the
- 468 MBDMT group.
- 469
- Findings from this current study may be biased, due to the small sample size and the possibility of a
 type II error (low power to detect true effects). However, it is important to mention that the follow-up
- type II error (low power to detect true effects). However, it is important to mention that the follow-up
- 472 measurement (T3) took place two weeks after the beginning of the Covid-19 pandemic in Latvia (Margh 2020) and that an averall atmosphere of foor and we contain the second se
- 473 (March 2020), and that an overall atmosphere of fear and uncertainty may have influenced the
- 474 participants' psycho-emotional state. This, in turn, may have been reflected in the results of the
- 475 <u>follow-up</u> anxiety, depression <u>and also pain</u> measures. <u>Also, it is important to acknowledge that 60%</u>
- 476 <u>of the study participants had comorbid pain states, which may also have influenced the study results.</u>
- 477 The comorbidity of other pain and mental states (depression and anxiety) are characteristic of women

- 478 with migraine diagnosis and has been reported in previous chronic pain studies (Allais et al., 2020;
- 479 Xu et al., 2020), suggesting that mechanism of central sensitization may be a substrate or
- 480 consequence of comorbidity (Ashina et al., 2018).
- 481 Patients found the experience of being in the MBDMT group to be useful. This was reflected in the
- 482 acceptability of the intervention by the participants, which was evaluated as good; 80% of the
- 483 participants assigned to the treatment group stayed in the process and attended at least eight out of
- ten therapy sessions. <u>The literature suggests that other body-based interventions also show high</u>
- 485 completion rates. TBMA, for example, reported a completion rate of 95 percent (Payne & Brooks,
- 486 2017), and the resilience-building DMT approach for chronic pain patients was evaluated as helpful
- 487 <u>and supporting of a body-mind orientated approach by 68% of participants (Shim et al., 2017).</u>
- 488 Still, in the current study, since two patients did not find the intervention appropriate for them and
- dropped out of the intervention group after the first therapy session, an assessment of the
- intervention's suitability is needed. Although statistical tests showed no significant difference in
 baseline measures between those dropping out and those completing the intervention. HADS anxiety
- 491 baseline measures between those dropping out and those completing the intervention, HADS anxiety 492 scores indicate that there were some differences worthy of further analysis. The mean score of
- 472 scores indicate that there were some differences worthy of further analysis. The mean score of 493 anxiety (9.95) for the group completing the intervention can be seen as borderline with the mean
- 494 score of the dropout group (14.00) being a clear outlier. It is possible that the patients with the high
- 495 anxiety scores perceived the creative group intervention of MBDMT as too unusual, and involvement
- 496 in the therapeutic group as emotionally overwhelming. In a clinical context, an individual dance
- 497 movement therapy approach could have been more suitable for these patients.
- 498 The evaluation of *acceptability of outcome measures* indicated that in comparison with HADS, PHQ-
- 9 could show a higher sensitivity in assessing symptoms of depression for this patient group. The
- 500 construction of the HADS relies on anhedonia, not on somatic symptoms, and it is sensitive to mild
- distress as it excludes symptoms of severe mental illness. PHQ-9 is constructed as a diagnostic tool
- for clinical depression and strongly correlates with mental and physical health difficulties (e.g. self-
- reported disability days and clinical visits) (Anderson et al., 2011) making it an appropriate tool for use within this study. Furthermore, PHQ-9 was evaluated by patients with unexplained medical
- 505 use within this study. <u>Furthermore, PHQ-9 was evaluated by patients with unexplained medical</u> conditions as a more appropriate measurement tool than CORE or HADS in a TBMA pilot study
- 506 (Payne, personal communication, December 2020). Finally, chronic pain patients are often more
- 507 interested in the physical representation of their difficulties than the emotional aspects. It therefore,
- appeared that PHO-9 was a more suitable measure of depression for this study, as it captured changes
- 509 in the somatic aspects of psycho-emotional distress.
- 510
- 511 512 Similary, the General Anxiety Disorder (GAD-7) scale was considered a good tool to assess the
- 513 <u>anxiety level for the chronic pain patient group. GAD-7 has good psychometric properties and is</u>
- 514 sensitive as a clinical outcome measure (National IAPT Programme Team, 2011). Both GAD-7 and
- 515 PHQ-9 were also used as measurement tools for depression and anxiety in previous research with a
- 516 similar population in The BodyMind Approach (Payne & Brooks, 2017; Payne & Brooks, 2016). It
- 517 <u>was therefore decided to use this tool along with PHQ-9 instead of HADS for the larger scale clinical</u> 518 trial following the pilot.
- 519
- 520 Somatic sensitivity may also be relevant to the mindfulness measure. In the present study the FFMQ
- 521 was used to assess changes in mindfulness aspects. The FFMQ evaluates the components of
- 522 dispositional mindfulness, i.e. the tendency to express mindful attitudes and behaviors in everyday
- 523 life (observing experience, using language to describe experience, acting with awareness, being non-

524 reactive, and being non-judgmental). However, the FFMQ does not distinguish between attention 525 directed to exteroception, interoception or thoughts (Hanley et al., 2017). Since body awareness is 526 one of the basic components of the MBDMT intervention, a measurement that detects aspects of 527 interoceptive body awareness may be more appropriate in future studies. The Multidimensional 528 Assessment of Interoceptive Awareness (MAIA, Mehling et al., 2012) is one such example: it allows 529 an assessment of awareness of the body's physiological condition alongside the evaluative 530 interpretations arising in tandem with that awareness (Mehling, 2016). Mehling (2012) also states 531 that the MAIA can be helpful in researching mind-body interventions, where the multidimensional 532 assessment of body awareness can be used to understand which aspects of body awareness contribute 533 to improvements in clinical outcomes. MAIA has been used as a body awareness assessment tool in 534 previous research on use of DMT for chronic pain patients (Shim, 2015). 535 536 Mindfulness scores did not show statistically significant changes after the five-week-long MBDMT 537 intervention. The most commonly used structure in MBI research is eight weeks, with a group 538 session once a week and an emphasis on regular practice at home (Bawa et al., 2015). The present 539 length of the MBDMT intervention may not be enough to develop sustainable mindfulness skills. 540 The 'dosage' of this DMT intervention might have been insufficient to create quantitatively 541 observable changes in mindfulness outcome measures. Another possible interpretation is that the 542 working mechanisms of the MBDMT model were more closely connected with active therapeutic 543 factors in DMT than with mindfulness interventions. To research this hypothesis future studies should involve qualitative and quantitative analysis of therapeutic mechanisms. Future research may 544 545 also attempt to answer questions present in the DMT literature (Koch et al., 2019): what do DMT and 546 mindfulness-based interventions have in common? Additional mindfulness principles that have been 547 incorporated in DMT through the practice of authentic movement such as the concept of

- 548 bodymindfulness (Payne & Brooks, 2019) or "bodyfulness" (Caldwell, 2014) can be further considered in future research studies.
- 549

550 551 At the time of writing, this is the first pilot clinical trial to explore a mindfulness-based model in 552 DMT for the specific patient group. There are several publications available at the time of writing 553 this paper: a published case analysis, in which the principles of mindfulness are used within the 554 context of somatic psychotherapy and DMT as a pathway towards embodiment (Tantia, 2013); a 555 research study, showing mindfulness skill training as one of the guiding principles of therapeutic intervention for patients with depression (Pylvänäinen et al., 2015); and therapy models that offer the 556 557 perspective of mindfulness meditations, mindful movement practices, e.g. tai chi and yoga as an 558 important aspect of the DMT intervention (Olmedo, 2020; Sanchez, 2012; Barton, 2011). The 559 BodyMind Approach (TBMA)[®] created by Helen Payne (2009a,b) is an integrative approach 560 underpinned by principles of experiential learning cycles, dance movement psychotherapy and 561 mindfulness research, created and researched for patients with medically unexplained symptoms

562 (Payne et al., 2020). However, the MBDMT is the first model in DMT to be adapted for chronic pain

patients which employs aspects from other models in a unique way. The model uses mindfulness as 563 564 an integral part of the therapeutic process, in which the methodology of mindfulness practice and the

- 565 understanding of the working mechanisms are integrated within the creative process of DMT. The
- 566 MBDMT model adopts a bi-directional body-mind approach, in which awareness of the body is used

567 as a physical portal to consciousness (Eddy, 2016), and awareness of the mind is seen as a

metacognitive state - ability to observe, explore and gain the understanding of the processes and 568

- 569 relationships between mind and body, with both aspects (ie body awareness and meta-cognitive
- 570 aspects) of mindfulness being equally important (Majore-Dusele & Karkou, 2018). In comparison
- 571 with other mindfulness-based interventions, the advantage of the MBDMT is that mindfulness is put

into action through creative activity, and creative methods enable the participant to fully experienceand to be able to observe the experience at the same time.

574 575

Limitations and future research directions

576 577 The first limitation of the study is the small sample size (n=29) that reduces the generalizability and 578 statistical power of calculations, and questions the reliability of the quantitative findings. Qualitative 579 data were used to complement the findings coming from quantitative data and to strengthen the 580 conclusions regarding the study's feasibility and the impact of the intervention on specific self-581 reported measures completed by the participants. The use of self-reported scales is another limitation 582 of this study. One of the clinical characteristics of the chronic pain patients includes alexithymia – a 583 decreased ability to identify and describe emotional states and differentiate them from bodily 584 sensations. This questions the participants' ability to evaluate their own psycho-emotional states 585 properly. Although the validity and reliability of the self-report scales used were high, in future 586 research both subjective and objective measures should be incorporated to increase the validity of the 587 research findings. Another limitation is the fact that there were only female participants in the study, 588 questioning the external validity of the study and suggesting a potential selection bias. Also, the 589 length of the intervention (10 sessions), and the fact, that the therapeutic process was directed by a 590 dance movement therapist in training, should be considered as possible limitations of the study and as 591 factors with capacity to influence the results of the study.

592

In contrast, the strength of the study is based on the use of randomization and the presence of
 homogeneity of the study's sample. Further strengths can be assigned to the careful development of
 the intervention integrating the two practices.

- Conclusions
- 597 598

596

599 The MBDMT is a feasible and promising intervention for chronic pain patients. The participants in 600 the MBDMT group reported a significant decrease in pain intensity in comparison with the TAU 601 control group in both post-intervention measures. A decrease in depression symptoms was significant 602 in post-intervention measurement. Anxiety also changed in the expected direction for the MBDMT 603 group. Although results did not reach statistical significance, there was reliable improvement for 73 604 per cent of the patients attending the intervention group. Scores on mindfulness measures changed in 605 the expected direction for the MBDMT group, but did not reach statistical significance when 606 compared with scores from the control group on the same measures.

507 Still, it <u>was</u> concluded that the pilot study offered sufficient information and preliminary results to 608 enable the researchers to move to an RCT stage. It is expected that a larger sample, the inclusion of 609 an active control, the replication of the group to more than one site delivered by more than one 610 therapist, and the inclusion of additional somatic outcome measures, will strengthen this pilot study

611 enabling generalizable findings on the effectiveness of this approach to people with chronic pain.

612 5 Ethics statement

- 613 This study gained approval by the Ethics Committee of Riga Stradins University with written
- 614 informed consent from all subjects. All subjects gave written informed consent in accordance with
- 615 the Declaration of Helsinki.

616 **6** Author contributions

- 617 IMD was responsible for the conception and design of the study, data collection, interventions
- 618 implementation, data analysis and interpretation, and writing the manuscript. VK were responsible
- 619 for the conception and design of the study, contributed to the data analysis, interpretation and
- 620 manuscript development. IM contributed to the interpretation of the data and manuscript
- 621 development. All authors have approved the final version of the manuscript.

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- The authors declare that the research was conducted in the absence of any commercial or financial
 relationships that could be construed as a potential conflict of interest.

633 9 Footnotes

634

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Table 1 Baseline participant demographic and clinical characteristics in intervention and control groups

Characteristics	Intervention group	Control group	р	
	(n=15)	(n=14)		
Age M (SD)	40,9 (6,97)	32,2 (4,98)	.001 ^a	
Localization of pain	N (%)	N (%)		
Headache, migraine	15(100)	14(100)		
Lower back pain	8(53.3)	5(35.7)	.340 ^b	
Musculoskeletal	7(46.7)	2(14.3)	.109°	
Fibromyalgia	2(13.3)	1(6.7)	1.0 ^c	
Duration of pain			.431°	
until 1 year	1(6.7)	2(14.3)		
1-3 years	2(13.3)	0(0)		
3-5 years	0(0)	1(7.1)		
5-10 years	2(13.3)	4(28.6)		
more than 10	10(66.7)	7(50.00)		

Pain control strategies			
Medication	14(93.3)	13(85.7)	.598°
Physiotherapy/massage	9(60.0)	5(35.7)	.191 ^b
Daily exercise	3(20.0)	2(14.3)	1.0 ^c
Physical procedures	5(33.3)	4(28.6)	1.0 ^c
Relaxation/meditation	1.0 ^c		
^a Mann-Whitney U test; ^b Pearson Cl	ni-Square; ^c Fisher Exact test		

 Table 2 Means, standard deviation, medians of clinical outcome measures; between group comparison of the pre/post and pre/follow up change scores.

Variables		Intervention a	group (n=12)	Control group (n=14)		Mann-Whitney U / p - value		
(Chronbah's α)	Time	Mean (SD)	Mdn (IQR)	Mean (SD)	Mdn (IQR)			
Pain (NRS)	T1	6.00 (1.28)	6 (2)	6.33 (1.22)	6 (3)	102.5 / .35		
	T2	4.83 (1.34)	5 (1)	6.22 (1.56)	6 (2)			
	Т3	4.67 (1.44)	4 (2)	6.00 (1.23)	6 (2)			
	(Δ)T1 to T2	- 1.17 (.83)	- 1.00 (1.75)	11 (1.17)	.00 (1.5)		39.5 / .02*	
	(Δ)T1 toT3	- 1.33(.98)	-1.5 (1.75)	33 (1.0)	.00 (1.5)			26.5 / .04*
PHQ-9	T1	8.08 (4.64)	6 (5)	8.67 (4.53)	8 (6)	86.00 / .92		
(.80)	T2	4.58 (2.61)	4.5 (4)	8.33 (4.21)	9 (6)			
	Т3	4.17 (1.75)	4.5 (2)	6.78 (3.03)	8 (6)			
	(Δ)T1 to T2	-3.5 (6.19)	-2.00 (3.00)	33 (2.96)	- 1 (2)		40.5 / .02*	
	(Δ)T1 to T3	-3.91 (4.12)	-2.5 (3.75)	-1.89 (3.59)	-2 (3.5)			35.5 / .18
HADS- Anx	T1	10.83 (4.39)	11.5 (6)	9.22 (3.89)	9 (5)	56.00 / .15		
(.82)	T2	8.08 (3.91)	7.5 (7)	8.56 (3.21)	9 (5)			
	Т3	8.17 (2.72)	8.5 (3)	9.22 (3.93)	9 (6)			
	(Δ)T1 to T2	-2.75 (3.67)	-2 (3.75)	67 (2.24)	.00 (3)		121.0 / .06	
	(Δ)T1 to T3	-2.67 (3.31)	-4 (4.75)	.00 (3.46)	-1 (7)			78.5 / .08
HADS- Depr	T1	6.25 (3.72)	5 (5)	4.57 (3.81)	4.5 (5.8)	64.00/ .30		
(.80)	T2	4.75 (3.17)	5 (4)	4.22 (2.77)	4 (5)			
	Т3	4.42 (2.61)	4 (3)	3.44 (2.83)	3 (6)			
	(Δ)T1 to T2	-1.5 (3.70)	-1.5 (3.75)	.44 (1.94)	.00 (6)		118.5 /.07	

Running Title

	(Δ)T1 to T3	-1.83 (2.72)	-1 (4)	33 (2.00)	.00 (3)			76.5 / .11
FFMQ_full scale	T1	129.25 (20.04)	127 (32.3)	138.67 (15.35)	141 (49)	92.5/.67		
(.89)	T2	136.92 (17.05)	135 (15)	137.11 (9.21)	136 (10.5)			
	Т3	134.75 (18.69)	136.5 (22.3)	137.11 (21.99)	141 (31.5)			
	(Δ)T1 to T2	-7.67 (22.69)	-2.5 (21.25)	1.55 (7.52)	2 (8.5)		108.5 /.21	
	(Δ)T1 to T3	-5.5 (16.63)	-4 (26)	1.55 (10.97)	2 (16.5)			65.00 / .43

969 IG – intervention group; CG – control group; (Δ) was computed by subtracting pretest from posttest and

970 pretest from follow up scores; positive values signify an increase and negative values a decrease in the

971 dependent measure. Results from NRS – Numerous pain rating scale; PHQ-9 – Patient health questionnaire;

972 HADS – Hospital anxiety and depression scale; FFMQ – Five facets of mindfulness questionnaire – full scales

973 results. ***p< 0.05**

974 Table 3 Reliable change of intervention group using 95% CI for outcome measures pre-intervention 975 to follow-up.

Outcome variables	Recovered	Improved	Deteriorated	Unchanged
Pain (NRS) n=12	0%	50% (6/12)	0%	50% (6/12)
PHQ-9 n= 5	80% (4/5)	0%	0%	20% (1/5)
HADS-D n=4	75% (3/4)	25% (1/4)	0%	0%
HADS-A n=11	28% (3/11)	45% (5/11)	9% (1/11)	18% (2/11)

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