

Protocol: Evaluation of a mind-body based application in combination with a graded movement program for the treatment of chronic/persistent pain

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Background

Chronic pain affects over 30% of people globally. In Canada, one in five individuals experience chronic pain, highlighting the need for effective management and productive treatment options (Health Canada, 2021). Pain is defined as “an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage” (IASP, 2020). Pain becomes chronic if it persists for over three months and can include primary or secondary chronic pain (Perrot et al., 2019). Primary chronic pain refers to the condition of chronic pain itself in which the pain is not associated with an underlying disease, and secondary chronic pain is associated with an underlying condition and becomes a symptom of that condition (Perrot et al., 2019). Pain is best understood through the biopsychosocial (BPS) lens, which acknowledges the influence that biology, psychology, and social factors have on one’s experience of pain (Gatchel et al., 2007). Previous treatments have focused on treating the biological aspect of pain, such as pharmacological interventions, which can temporarily numb pain, but are ineffective for long-term management and may cause harm, therefore highlighting the need for other treatments (Tankha et al., 2023; Thorn, 2020).

Canadians living with chronic health conditions are 61.6% more likely to utilize virtual consultations as they offer a more secure and convenient opportunity to access health care (Statistics Canada, 2023). Mobile applications have emerged in recent years to offer a new approach to treat chronic pain as they can employ BPS treatments such as mindfulness and cognitive behaviour therapy without physical manipulation, therefore allowing for an easier transition to effective virtual delivery (Devan et al., 2019; Thomson et al., 2024). Of the nineteen mobile applications evaluated in a systematic review by Devan and colleagues (2019), the mobile app under evaluation in the current trial was among the three apps recognized for including the largest number of self-management tools to help those manage chronic pain (Devan et al., 2019), and was among the top three scoring apps based on the MARS score (mobile app rating system) and based on its inclusion of evidenced based psychological components (MacPherson et al., 2022).

Recently, Thomson and colleagues (2024) conducted a six-week randomized controlled trial evaluating the mind-body mobile application (under investigation) for managing chronic pain. Engagement with the app resulted in significant improvements in physical, emotional, and cognitive aspects of pain including pain severity, interference with activities of daily living, negative emotional states and beliefs about chronic pain, when compared to usual care (Thomson et al., 2024). The app’s multimodal approach includes the use of BPS treatment modalities such as mindfulness, pain neuroscience education (PNE), cognitive-behavioral therapy (CBT), and pain reprocessing theory (PRT) (Ashar et al., 2022). Each of these modalities is associated with improved chronic pain management. Mindfulness helps patients develop awareness and acceptance of pain, by stimulating the vagus nerve to activate the parasympathetic nervous system, which reduces stress and can alleviate the impact of pain (Gerritsen & Band, 2018; Bawa et al., 2015). PNE improves pain understanding and reduces fear and catastrophizing (Louw et al., 2011; Salazar-Méndez et al., 2023). CBT provides coping strategies and alters unhelpful thinking to reduce pain intensity and severity (Lim et al., 2018; Thorn, 2020; Chen et al., 2023).

Lastly, PRT aims to retrain the brain's pain pathways to alter the perception of pain (Ashar et al., 2022; Tankha et al., 2023). The integration of these evidence-based strategies suggests the mind-body app as a flexible, accessible, and low-cost option for chronic pain management (Thomson et al., 2024), yet further investigation is needed to establish how to optimize its effectiveness in treating chronic pain.

The relationship between physical activity (PA) and chronic pain has been robustly researched as it provides many benefits while avoiding harm (Geneen et al., 2017). PA can directly relieve pain through endogenous opioid production and peripheral nerve regeneration, while also improving chronic pain indirectly by promoting weight loss, increasing muscle tone, and reducing joint load (Stagg et al., 2011; Messier et al., 2013). Additionally, regular PA enhances mental well-being and quality of life (QOL), which may further decrease pain intensity (Finan & Smith, 2013). Although patients are aware exercise will improve symptoms, adherence remains low (Leese et al., 2024).

Kinesiophobia, the fear of movement due to perceived pain or reinjury, often leads to pain catastrophizing, resulting in a combination of pain and reluctance to engage in PA creating a vicious cycle that perpetuates chronic pain and functional disability (Asiri et al., 2021). This cycle emphasizes the need for new strategies to improve adherence to PA in this population (Asiri et al., 2021). Adding PNE to exercise programs can enhance outcomes, especially pain intensity, by reducing fear of harm and overcoming barriers like pain catastrophizing while engaging in exercise (Ma et al., 2023; Ryan et al., 2010). However, the impact of delivering the combination of PNE and exercise to patients with chronic pain virtually remains unexplored.

Somatic education offers a modality of exercise that trains both the mind and body and has been linked to improvements in pain perception, movement confidence, and stress reduction in individuals with chronic pain (Meehan & Carter, 2021; Huang & Babgi, 2022). Somatic education incorporates practices that increase sensory awareness, interoception, and proprioception through guided movement exploration and mindfulness (Hanna, 1988; Meehan & Carter, 2021). While research has concentrated on in-person somatic education programs (Huang & Babgi, 2022), recent interest in virtual delivery of treatment has increased due to and increase telehealth adoption post Covid-19 pandemic (Statistics Canada, 2023). Asynchronous virtual delivery of somatic education provides patients with chronic pain the freedom to complete the session at their own convenience when pain levels are tolerable, avoid unnecessary travel and complete exercise in the comfort of their own home. However, the efficacy of asynchronous somatic education programs within the chronic pain population remains limited.

While previous studies have supported both the mind-body app and somatic education independently, no research has evaluated the combined effects of a multimodal app and movement program. The current study aims to address this gap by investigating how adding virtual somatic education sessions while engaging with the mind-body app affects pain severity, pain interference, pain catastrophizing, QOL, depression, anxiety, stress, and kinesiophobia, over a six-week period in adults with mixed chronic pain. The broader objective is to establish an effective and accessible multimodal treatment plan to support long-term pain management.

Hypotheses

- i) Participants using the app and engaging in somatic education will report a reduction in pain severity and pain interference after the 6-week intervention (pre-post analysis).
- ii) Participants using the app and engaging in somatic education will report improvements in pain catastrophizing, quality of life, depression, anxiety, stress and kinesiophobia after the 6-week intervention (pre-post analysis).
- iii) Participants using the app and engaging in somatic education will report greater improvements in pain severity, pain interference, pain catastrophizing, quality of life depression, anxiety, stress than external (historical) participants from intervention arm (app-only) and control arm (usual care) from our recent study (Thomson et al, 2024).

Objectives:

Primary objectives: Comparison of current single arm trial with external control and intervention (app-only) arms from Thomson et al., (2024).

- i) To investigate the efficacy of a combined intervention employing a mind-body mobile app and somatic education (graded, gentle movement) on the experience of chronic pain relative to external study arms (waitlisted control group and app-only group). Outcomes include self-reported measures of pain severity and interference, perceptions/thoughts about pain, quality of life, and negative emotional states.

Secondary objectives: Pre-post comparison of all dependent variables, with the addition of a measure of kinesiophobia in the current, single arm study.

- ii) To explore whether intervention fidelity (frequency of app use and movement) is associated with changes in primary and secondary outcomes.
- iii) To explore whether changes (if any) in primary and secondary outcomes persist six weeks post-trial completion (12 weeks from baseline).

Primary outcomes:

- i) Pain severity and interference as measured using the Brief Pain Inventory (BPI) (Cleeland and Ryan, 1994).

Secondary outcomes:

- a. The following measures will be compared both pre and post intervention of the participants in the current study, as well as with the control group and app only intervention group from the previous study by Thomson et al, 2024.
 - Pain intensity as measured by the Patient-reported outcomes measurement information system (PROMIS) Pain Severity 3a Short Form measures severity over a 7-day time period.
 - Pain interference as measured by the PROMIS 8a Short Form (PROMIS Health Organization and Cooperative Group, 2012); (Kean et al., 2016).
 - Thoughts about pain as measured by Pain Catastrophizing Scale (PCS) score (Sullivan et al., 1995).
 - Quality of life as measured by the short-form (SF)-12 (Ware et al., 1996)

- Depression, anxiety, and stress as measured by the DASS-21 (Lovibond & Lovibond, 1995).
- Kinesiophobia as measured by the Tampa Scale of Kinesiophobia (TSK-17) (Roelofs et al., 2004). (Note: pre-post analysis only)
- b. The following exploratory analyses will be performed:
 - Correlations to explore relationship(s) between all outcomes and frequency of app usage and somatic education engagement.
 - 12-week follow-up analysis (6 weeks post trial end) to determine whether changes (if any) persist.
 - Pre-post analysis of Kinesiophobia.

Methods

Participants

Inclusion: Participants aged 19 to 75 years who have non-malignant chronic or persistent pain. Chronic pain is generally defined as persistent pain that has lasted for more than 3 months (Treede et al., 2015). Our study will include participants that have had ongoing pain for at least 6 months, and participants must experience pain at least half the days in the last 6 months (Deyo et al., 2014). Pain can include bodily pain and/or head pain (migraine/headache). According to the classifications described above by Treede et al., (2015), our study will include participants with primary chronic pain, head/orofacial pain, visceral pain, post-surgical, and musculoskeletal pain.

Exclusions: The following participants are excluded from participation. Self-reported history of any of the following:

- Psychotic illness or manic episode
- Substance use disorder or problematic substance use within 6 months of start date
- Metastasizing cancers
- Cognitive impairment (that could interfere with using the application)
- Previous experience with the mind-body app under study.
- Previous, regular (at least once a week) engagement with a somatic movement program (e.g., Feldenkrais, Hanna Somatics, Somatic Yoga, Tai Chi, Pilates)

Procedures

Intervention

Participants qualifying for study inclusion will participate in a combined intervention that involves use of a 6-week free trial of a mind-body focused mobile application and engagement in virtual, asynchronous, audio-guided Somatic Education sessions. Participants will complete baseline questionnaires and a follow-up set of questionnaires at 6 weeks (same as baseline, minus the demographics and pain history sections). All questionnaires and frequency logs will be completed through surveymonkey.com. To link surveys with frequency logs participants will be given a unique alphanumeric identifier.

Participants will be provided free 6-week access to a pain-specific, mind-body mobile application (app). The app includes activities that are evidence-based and informed to treat the biopsychosocial model of pain (also referred to as the mind-body approach). The app is self-directed and includes activities in brain training (cognitive behavioural therapy), meditation, pain education, and expressive writing (journaling). The app also includes links to podcasts that include interviews with scientific experts in chronic pain, pain psychologists, and recovery stories. Participants will receive a 6-week free trial of the app and will also be given a brief introductory video (made by Dr. Thomson) to orient them to the app and provide guidelines and tips. Participants will be asked to engage with the app at least 4 times per week.

Participants will also be asked to participate in a low intensity 20-30-minute audio-guided somatic education (gentle movement) sessions at least three times per week. Audio-guided somatic education sessions will be led by UFV faculty member Brian Justin who is a licensed somatic education instructor (and has worked with pain populations). Movements will be led in a gentle, flow style with planned progressions from week to week. All movements will be instructed by asynchronous audio recordings to improve accessibility (e.g., audio can be downloaded and used without internet connection) allowing participants to engage in spaces and at times of their choosing. In week 1 of programming, participants will be provided an introductory visual guide in the form of a demonstration (images and a brief video of the exercises) to ensure participants have a general idea of what they are supposed to be doing. Throughout the audio recordings, the instructor will provide detailed instructions, helping them safely engage in the target movements. The movements included in the somatic education sessions include Week 1: Arch and flatten, Week 2: Flower, Week 3: Back lift, Week 4: Side bend, Week 5: Wash rag and Week 6: All of them.

A weekly frequency log will be sent to participants via email (with a link to survey monkey) to record number of times they used the app as well as the number of times they engaged with somatic education sessions in the previous 7 days.

Historical use of data for control group and comparison group

Data from the current study (mind body app and somatic education) will be compared to the control group and app use only group from Thomson et al, (2024) in which the participants followed the protocol as follows.

Control group: Participants in Thomson et al (2024) control group were asked to continue with usual pain treatments, gained access to the app following study completion. They completed baseline and 6-week questionnaires, along with a weekly log to track any changes in usual care for pain.

App-only group: Participants in Thomson et al, (2024) were provided free 6-week access to the same mind-body mobile application (app). Participants were given a brief introductory video (same one that will be used in the current trial) to orient them to the app and provide guidelines and tips. Participants were asked to engage with the app at least 4 times per week. A weekly log will be sent to participants via email (with a link to survey monkey) to record number of times they used the app in the previous 7 days.

All procedures will remain consistent with the previous trials. These include drafts of original email communications, screening forms, survey prompts, and weekly check ins. The following changes were made to the surveys: removal of medication use given that this data was too heterogeneous to analyze and the addition of the kinesiophobia measure to use in the pre-post comparison of the current single arm trial. Inclusions and exclusions are the same, except the requirement for participants to not currently be participating in somatic training programming. We will employ many of the same recruitment methods in an effort to recruit a similar sample.

Measures

All participants (control and intervention) will complete baseline questionnaires (detailed below) and a follow-up set of questionnaires at 6 weeks (same as baseline, minus the demographics and pain history sections). All questionnaires and frequency logs will be completed through surveymonkey.com. To link pre- and post-surveys along with frequency logs, participants will be given a unique alphanumeric identifier. We will do an additional follow-up survey at 12 weeks in the combined intervention group. This survey will be similar to the survey at 6 weeks, but will also inquire whether participant continued with app usage.

Measures:

The questionnaires will include the following:

1. Demographics: We will collect data on gender, age, socioeconomic status (education, income), residence, relationship status, dependents, employment status.
2. Pain history: Participants will provide information on their pain condition. This will include location, diagnosis, date of onset, average frequency, changes in employment due to pain. Other details regarding pain are captured in the questionnaires that follow.
3. Brief Pain Inventory Short Form (BPI-SF) - this includes items about location of pain, intensity of pain, current treatments, and interference with daily activities (Cleeland & Ryan, 1994)
4. PROMIS Pain Intensity Scale (Adult Short form) - 3 items (PROMIS Health Organization and Cooperative Group, 2012).
5. PROMIS Pain Interference Scale (Adult Short form) - 8 items (PROMIS Health Organization and Cooperative Group, 2012).
6. Pain Catastrophizing Scale (Sullivan et al., 1995).
7. DASS-21 (Depression, Anxiety, Stress Scale) - 21 items (Lovibond & Lovibond, 1995).
8. QoL questionnaire- SF 12 (Ware et al., 1996).
9. Tampa Scale of Kinesiophobia (TSK-17) (Roelofs et al., 2004).

Data Analysis

Power analysis: We have estimated a small effect size of $f = 0.2$ (Cohen's $d = 0.4$) given the lack of data on the effects of somatic education interventions. We expect an effect due to the mobile app use based on our previous trial and others. For example, a meta-analysis of mobile app-based interventions for the treatment of chronic pain (Pfeifer et al., 2020) reported a small effect at Cohen's $d = 0.4$ and the effect size for the primary outcome (pain severity) in our recent trial was small to medium, at $d = 0.43$ (Thomson et al., 2024). Given that we do not have a

comparable reference for somatic education programming, we are aiming to achieve similar group sizes as our previous trial ($n = 98$ to 100 per arm). Using G-power (Erdfelder et al., 2009) calculation with an estimated power of $f = 0.2$ a comparison between three groups at two time-points, a total sample size of $n = 199$ (~ 66 participants per group) would be required to achieve 80% power (at alpha = .05). We will aim to enroll $n = 100$ participants in the current single arm trial.

Statistical analysis: Our primary aim is to compare the current intervention arm with historical control and intervention arms from Thomson et al., (2024). Previous data was analyzed using a linear mixed model for repeated measures (MMRM) with maximum likelihood (ML) estimation. Data from the current study will be compared with two external arms: usual care control and intervention (app-only) arms. We will first employ weighting derived from individual propensity scores (PS) to reduce bias of prognostic factors between comparison groups (given the lack of randomization in the single arm trial). Propensity scores are calculated using logistic regression, estimating the probability of being in the treatment group based on factors like pain severity. Weighted PS scores will then be compared between the three study arms (control, app-only, combined) using linear mixed modelling to enable intention to treat analysis.

Additional analysis: The study is the basis for a 4th year directed study (Ms. Courtney Snell), and the student will perform and present results from a simplified analysis: pre-post effects of a single arm, combined intervention. This analysis will employ dependent (paired) t -tests for each dependent variable (baseline to 6 weeks), along with correlation analysis to explore whether intervention fidelity relates to outcome measures.

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