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Effects of an online program including mindfulness, exercise therapy and patient education compared to online exercise therapy and patient education for people with Patellofemoral Pain: protocol for a randomized clinical trial

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Abstract

Background   Patellofemoral pain (PFP) is a common knee disorder that causes persistent pain, lower self-reported function and quality of life. People with PFP also present with altered psychological factors, which are associated with higher levels of pain and dysfunction. Mindfulness-based interventions (MBI) generally consist of meditative practices developed to provide a holistic approach to chronic conditions. However, the effects of MBI on clinical and psychological outcomes for people with PFP remains understudied.

Methods   This assessor-blinded, parallel, two-arm randomized clinical trial aims to investigate the effects of adding an 8-week online MBI program to exercise therapy and patient education on clinical and psychological factors for people with PFP. We also aim to investigate whether psychological factors mediate changes in pain and function. Sixty-two participants with PFP will be recruited and randomized into one of two treatment groups (Mindfulness or Control group). Both groups will receive an 8-week intervention involving exercise therapy and education delivered through an online platform. The Mindfulness group will additionally receive a MBI component including formal and informal practices. Outcomes will be assessed online at baseline, intervention endpoint (follow-up 1) and 12 months after intervention completion (follow-up 2). Comparisons between groups will be performed at all time points with linear mixed models. A mediation analysis will be performed using a 3-variable framework.

Discussion   Exercise therapy and patient education are considered the "best management" options for PFP. However, unsatisfactory long-term prognosis remains an issue. It is known that people with PFP present with altered

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psychological factors, which should be considered during the evaluation and treatment of people with PFP. Adding a MBI to the current best treatment for PFP may improve short and long-term effects by addressing the underlying psychological factors.

Trial registration *Registro Brasileiro de Ensaios Clínicos* (ReBEC) RBR-4yhbqwk, registered in April 6, 2021.

Keywords Anterior knee pain, Psychological factors, Mindfulness, Education, Exercise therapy

Introduction

Patellofemoral pain (PFP) is characterized by the presence of pain around or behind the patella, exacerbated by activities that increase patellofemoral joint loading [1]. PFP is prevalent in young adults and adolescents (22.7% and 28.9%, respectively), with women being twice as likely to develop PFP than men [2]. People with PFP typically report reduced levels of physical activity [3], functional capacity [4, 5], and quality of life [6]. Evidence also indicates that symptoms can be long-lasting, with 50 to 91% of people with PFP experiencing persistent pain up to 18 years after the initial diagnosis [7].

According to the International Association for the Study of Pain (IASP) [8], the concept of pain encompasses more than just physical-chemical aspects of nociception. Sociocultural, emotional, and cognitive factors can also contribute to the worsening of pain and dysfunction [9–13]. This seems to apply to people with PFP as they present with altered psychological factors such as anxiety, depression, pain catastrophizing, and kinesiophobia [11]. Moderate correlations between psychological factors with pain and disability have also been reported in people with PFP [14].

Current recommendations on the "best management" for people with PFP are exercise therapy and patient education [15, 16]. Although effective in the short-term [16], unsatisfactory long-term prognosis remains an issue, with 57% of the people with PFP reporting unfavorable recovery at 5–8 years [17]. This could be a reflection of the lack of consideration for psychological factors during rehabilitation. Doménech et al. [18] have reported that patients who experience the largest decreases in pain catastrophizing, kinesiophobia, anxiety, and depression also experience greater improvement in pain and disability after a purely biomedical treatment. It has been suggested that the addition of co-interventions to address psychological factors, for example, cognitive-behavioral treatment, reassurance, and graded exposure to activity may enhance rehabilitation outcomes, such as pain and function, in individuals with PFP [18, 19]. The specific mechanisms by which changes in psychological factors influence physical function are not well known, however, positive coping cognitions and emotional states are thought to confer resilience to pain and resourcefulness to improve adherence to active treatments and physical activity [18, 19]. Therefore, further investigation is

required to understand the potential additional effects of interventions that may influence psychological factors to the current best management of PFP.

Mindfulness-based interventions (MBI) were developed to assist people in managing stress, anxiety and chronic pain [20]. This evidence-based program has been increasingly used for a variety of musculoskeletal disorders [21, 22]. Mindfulness is defined as a form of bringing attention, friendly curiosity, and non-judgmental awareness to body sensations, thoughts, and emotions in order to reduce suffering or distress and to increase wellbeing [23]. Previous studies have demonstrated specific brain modifications in neuroimaging evaluation in experience practitioners, such as increased grey matter volume in the frontal lobe and relatively decreased posterior cingulate cortex activity compared to novice practitioners [24–26]. This finding suggests an existence of a neural network responsible for the positive effects of MBI practices including, but not restricted to information processing, mind wondering regulation and adaptative behavior [24]. Therefore, as part of a rehabilitation program, mindfulness may promote a better focus on rehabilitation [20] and influence several psychological factors such as anxiety, pain catastrophizing and avoidance behaviors [27–29].

In this context, a recent study [30] has reported that adding an MBI to exercise therapy promoted lower levels of pain during running and stepping, less functional limitations and lower pain catastrophizing as compared to exercise alone in female runners with PFP. However, this study was performed exclusively on female recreational runners with PFP, which limits the generalizability to the general population with PFP. In addition, patient education was not provided in this study, which is of utmost importance to PFP [31]. As such, more studies are needed to investigate the effects of MBI in addition to exercise therapy and patient education in people with PFP.

Internet-based interventions have been recently promoted due to their potential to overcome geographical barriers, increase access to health services, and provide alternative means to continue treating patients whenever face-to-face encounters are precluded [32]. There is evidence supporting the use of internet-based interventions for the treatment of several conditions [33, 34] as they may provide similar improvements in pain and function

compared to face-to-face treatments [35, 36]. Furthermore, internet-based interventions may allow patients to assume a more active role in their rehabilitation, encouraging strategies as self-management and self-efficacy [33]. Online MBI has also been shown to be feasible and effective in reducing psychological factors such as stress, anxiety and depression [37]. However, few studies have investigated the effects of internet-based interventions for PFP, especially including components targeting psychological factors such as MBI.

The aims of this randomized clinical trial are:

(i) to investigate the immediate (8-week) and long-term (12-month) effects of adding the MBI program to an 8-week online intervention comprised of exercise therapy and patient education on self-reported recovery, pain, function, and psychological factors in people with PFP;

(ii) to investigate whether changes in psychological factors mediate changes in pain and function.

We hypothesize that people in the Mindfulness group will experience greater decreases in pain, as well as higher improvements in function at 8 weeks and 12 months. We also hypothesize that psychological factors such as kinesiophobia and pain catastrophizing will mediate changes in pain and function.

Methods
Protocol elaboration
This protocol is reported according to the SPIRIT statement (Standard Protocol Items: Recommendations for Interventional Trials) [38] and CONSORT Statement [39].

Study design
This is an assessor-blinded, parallel, two-arm randomized clinical trial with 12-month follow-up. All participants will receive an identical internet-based exercise therapy and patient education intervention, with one group receiving additional online MBI program. Details of participants time schedule according to the SPIRIT recommendations are available in Additional file 1.

Participants and consent
People with knee pain will be recruited through social media to participate in this study. All participants who meet the eligibility criteria will be informed about the nature of the research and receive an online consent form, prepared in accordance with the declaration of Helsinki [40] and the 466/12 resolution of the National Health Council.

Eligibility criteria
The eligibility criteria were designed according to the most recent PFP consensus statement on clinical examination of PFP [1] and will be completed through an online form. Participants' eligibility will be confirmed by a physiotherapist with >3 years of clinical experience managing people with PFP. All assessments, including eligibility criteria and outcomes measures (baseline, follow-up 1 and follow-up 2), will be performed through online forms. No face-to-face physical examinations will be performed. However, if further details are required to confirm the diagnosis, an online meeting between the physiotherapist and the participant will be performed.

Inclusion criteria
Participants will be required to meet the following criteria in order to be included in this study: (i) age between 18 and 40 years old; (ii) self-reported anterior knee pain (unilateral or bilateral) when performing at least two of the following activities: prolonged sitting, squatting, kneeling, running, ascending and descending stairs, jumping and landing [1]; (iii) self-reported anterior knee pain with insidious onset lasting at least 6 months [41]; (iv) worst self-reported pain in the previous month corresponding to at least 30 mm in a 100 mm visual analogue scale (VAS) [42].

Exclusion criteria
Participants will be excluded if they meet any of the following criteria: (i) self-reported anterior knee pain caused by trauma on the knee; (ii) self-reported history of patellar dislocation or subluxation; (iii) self-reported history of meniscal injury, ligament instability or patellar tendinopathy; (iv) history of osteoarthritis in any lower limb joint; (v) history of surgery on any lower limb joint; (vi) patient-reported rheumatic or neurologic disease; (vii) physiotherapy treatment for PFP during the preceding 6 months; (viii) answer "yes" on any questions on the PAR-Q physical activity readiness questionnaire [43]; (ix) history of current or past psychosis, major depressive episode, suicide attempt, post-traumatic stress disorder, bipolar disorder, manic episode, or substance dependency.

Randomization and blinding
The randomization list will be developed by an investigator who will not be involved in the recruitment and assessment of the participants. Randomization codes will be generated in blocks, using a custom list on the website (https://www.sealedenvelope.com/), and the participants will be randomized with a 1:1 allocation [44] to one of the two interventions. Sealed opaque envelopes, sequentially enumerated, will be used to conceal the allocation. After the baseline assessment, the investigator will open the envelope containing the participant's random code to ensure the allocation of the participant will be concealed. Due to the nature of the interventions, participants will

be informed about the type of intervention. Therefore, the study cannot be considered double-blind [44]. The assessor will be blinded to the allocation of participants.

Outcome measures
Outcome measures will be assessed online at baseline, intervention endpoint (8 weeks – follow-up 1), and 12 months after intervention completion (follow-up 2). Demographic data (e.g. age, gender, duration of symptoms) will be recorded at the baseline assessment.

Primary outcomes
Self-reported recovery The 7-point Likert global rating of change scale (GROC) is a measure of treatment effect that has been previously used in people with PFP [45, 46]. The participants will be asked "How would you describe your knee pain now, compared to before you began the treatment?" The answers are marked on a 7-point Likert scale (much better, better, a little better, no change, a little worse, worse, much worse). The answers will be dichotomized in "successful" and "unsuccessful". A successful outcome will be defined as being much better or better.

Pain Participants' self-reported pain level over the previous week will be measured with a 100 mm VAS [42]. The VAS consists of a 0 to 100 mm horizontal line, with 0 representing "no pain" (0 mm) and 100 representing "extreme pain". Participants will be instructed to draw a perpendicular line on the scale at the position that indicates the severity of usual and worst knee pain over the preceding week. The VAS is valid and reliable for assessing people with PFP [42].

Secondary outcomes
Self-reported function The Anterior Knee Pain Scale (AKPS) is a valid and reliable 13-item questionnaire that evaluates subjective function related to PFP [42]. Participants will complete the AKPS based on their perceived knee condition at the prior week. The total score for the AKPS ranges from 0 (maximal disability) to 100 (no disability), with the total score being used for statistical analysis.

Anxiety and depression The Hospital Anxiety and Depression Scale (HADS) is a 14-item questionnaire that evaluates the emotional state of the patient and identifies cases of mild, moderate and severe anxiety and/or depression disorders [47]. The HADS consists of two subscales, which assess anxiety (7 items) and depression (7 items) separately. Participants will be asked to answer each item on a 4-point Likert scale (0–3), with scores ranging from 0 to 21 for anxiety and 0 to 21 for depression. Scores between 0 and 7 are classified as normal, between 8 and

10 as mild, between 11 and 14 as moderate, and between 15 and 21 as severe [48].

Kinesiophobia The Tampa scale for kinesiophobia is a self-administered questionnaire that assesses pain-related fear associated with the avoidance behaviors, movements and physical activity [49, 50]. It contains 17 statements with answers in a 4-point Likert scale: [1] Strongly disagree, [2] Partially disagree, [3] Partially agree and [4] Totally agree[50]. Participants will be instructed to choose the option according to how much they agree with each statement. The score ranges from 17 to 68 and the higher the score, the higher the fear [49, 51].

Pain catastrophizing The Pain Catastrophizing Scale (PCS) is a 13-item questionnaire that consists of describing thoughts and feelings that individuals experience when they have pain [52]. Participants will be instructed to reflect on the experiences caused by pain in the past and indicate their perception on a 5-point Likert scale, where (0) represents "not at all" and [4] "all the time". The higher the score, the greater the pain catastrophizing [53].

Pain self-efficacy The Chronic Pain Self-Efficacy Scale (CPSS) is a 22-item self-administered questionnaire that assesses the perception of self-efficacy and the ability to deal with the consequences of pain in patients with chronic pain [54]. The CPSS contains 3 domains: pain control, physical function and symptom control. Participants will be asked to answer how much they agree with each of the items arranged on a Likert scale ranging from 10 to 100 points. The score ranges from 30 to 300, where the higher the score, the better the self-efficacy.

Self-reported physical activity level The International Physical Activity Questionnaire short form is a 9-item questionnaire that assesses how many days and hours the participants usually spent per week doing several activities [55]. The physical activity level will be determined by the total of vigorous and moderate exercise in the previous week and calculated according to previous studies [55, 56].

Interventions
After the baseline assessment, participants will receive immediate access to a WEB platform developed by one of the authors available at http://www.stepslab.com.br/ where the interventions will be delivered. An individualized online meeting will be performed between participants and a physiotherapist not involved in data analysis to guide them regarding platform usage, deadlines and the importance of committing to the intervention. Participants will have access to the online interventions for 8 weeks, which will be immediately ceased at the end of

the period. The exercise and education contents will be developed and pre-recorded by two physiotherapists with more than three years of clinical experience using evidence-based material. The MBI content will be developed and pre-recorded by a certified mindfulness teacher with more than 15 years of experience and revised by a psychologist to ensure psychological appropriateness. Details of the interventions according to the TIDier checklist [57] are available in Additional file 2.

Participants will only have access to content related to the group to which they were allocated (restricted area). Each session will be released for access on pre-defined dates relative to participants' entry into the trial (immediately after baseline assessment). This will be performed by an investigator who will not be involved in the recruitment and assessment of the participants. The system will only allow opening of the next session if the participant had ended the previous one. At the end of each session, participants will be required to report their current level of pain on an online VAS scale, if there was any adverse event during or after the intervention, the level of satisfaction and the level of perceived exertion on a 15-point Borg scale [58], ranging from 6 (no exertion at all) to 20 perceiving a (maximal exertion).

Participants will be instructed to not seek any other kind of knee pain treatment during the study, except in emergency cases. If necessary, participants will be able to contact the therapist through the platform's e-mail. An outline of the study procedures is summarized in Fig. 1.

Control group
Participants allocated to this group will receive two pre-recorded video classes per week according to their availability (e.g. on Tuesdays and Thursdays) with Exercise therapy and Patient education contents (lasting 35–50 min in total).

Exercise therapy The exercise therapy component will include the prescription of the exercises according to the American College of Sports Medicine Position Statement [59] and the PFP consensus [16, 19]. The mean duration of the exercise videos will be approximately 30 min. There will be a one-day break between the sessions, to respect recovery time.
Exercise therapy will aim to improve muscle performance, movement coordination and mobility [16, 19]. This intervention will target hip, knee, and ankle muscles. Exercises will be progressed in phases every two weeks (i.e., intensity, type of exercise, technique or repetitions). During the exercise, affirmative and encouraging audio messages will be displayed in order to motivate the participant to finish the session with as much effort as possible. The intensity of the exercises will be monitored through the Borg scale and must remain between 12 and

16 points. If the participant report exertion values outside this range, the exercise intensity will be modified. The full description of the exercises is available in Additional file 3.

Patient education Educational pre-recorded video classes will cover the following topics.
- Week 1: Understanding my knee: anatomy and biomechanics of the knee and the relationship between pain and injury.
- Week 2: Understanding my knee pain: incidence and prevalence of PFP; why my knee hurts; biomechanical and psychological factors of PFP; prognosis and diagnosis of PFP.
- Week 3: "Too Much, too soon": how high volume or high load intensity during daily activities or sports can lead to knee pain.
- Week 4: Myths and truths about my knee: Knee crepitus and movements considered harmful to the joint; fear of movement; and imaging exams.
- Week 5: Aspects of quality of life that influence pain: sleep quality, weight control, confidence, coping strategies, and mental health.
- Week 6: Taking care of my own pain: self-management of pain, motivation and responsibility for your own health.
- Week 7: Available treatment options: importance of adherence to active treatments, treatments that work, treatments that do not work and load management.
- Week 8: Take-home message: What should I do after the treatment? Motivation, habits change, behavioral change and the need to remain active (exercise/treatment).

The mean duration of the patient education videos will be approximately 6 min.

Mindfulness group
Participants allocated to this group will receive the same intervention as the control group and an additional pre-recorded video class with MBI content according to their availability (e.g. on Mondays and Wednesdays they receive exercise therapy and Patient education contents; on Fridays they receive mindfulness contents, lasting 35–50 min).

Mindfulness-based intervention The MBI component will be adapted from Mindfulness-Based Health Promotion (MBHP) model to suit patients with PFP and the online assessments of the present study. MBHP is an 8-week MBI developed in 2009 in the context of health promotion and quality of life [60]. Inspired by Jon Kabat-Zinn's original protocol—mindfulness-based stress reduction, MBSR (University of Massachusetts Medical Center, USA) [61,
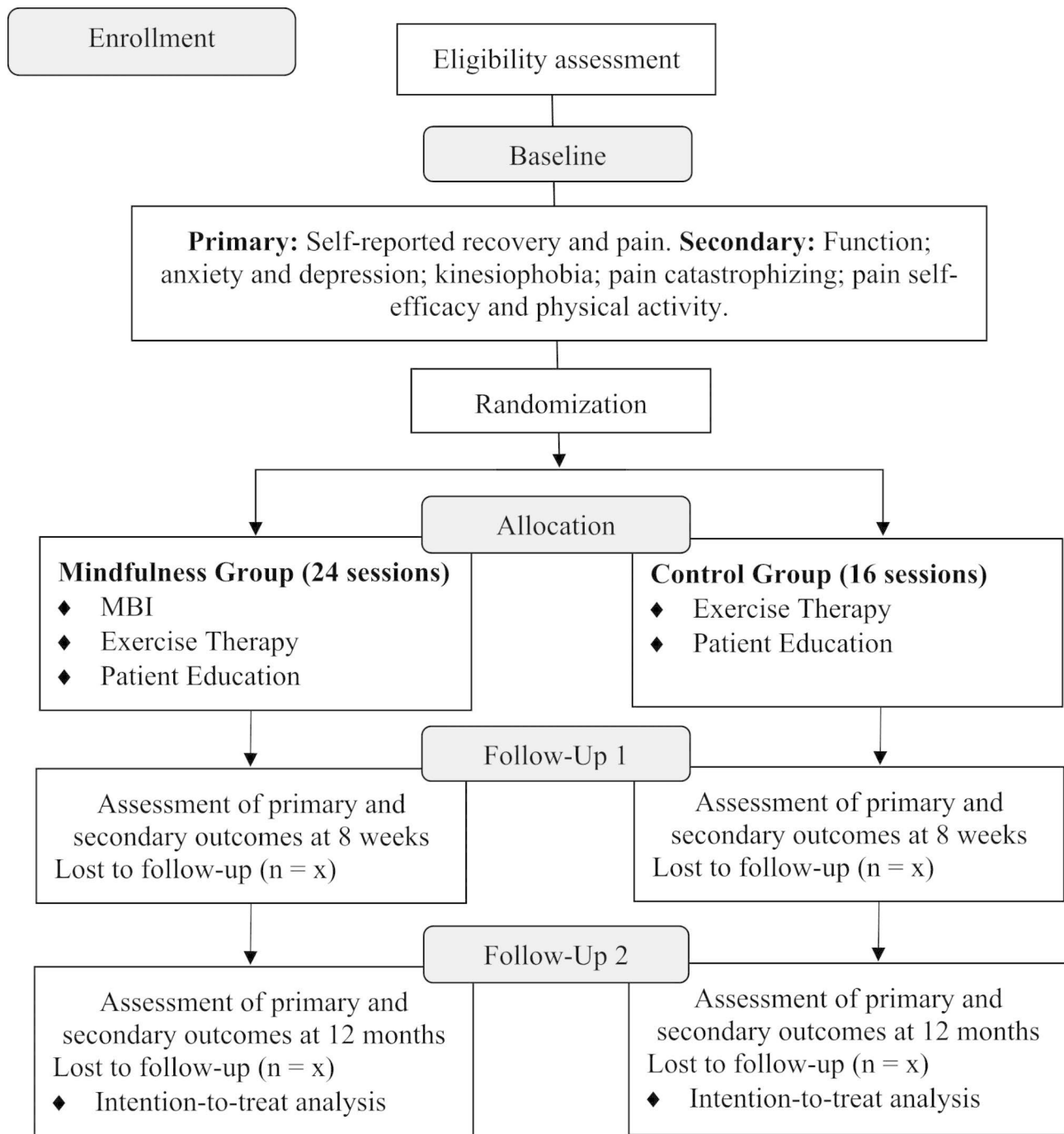
Fig. 1 Flow diagram of the study

62] —it also aggregates elements of other protocols, such as the MBCT (University of Toronto/Canada; University of Cambridge and Oxford University/United Kingdom) [63], the mindfulness programs of the Breathworks Institute (United Kingdom) [64], and mindfulness-based relapse prevention (MBRP, University of Washington, USA [65]. The MBHP has been extensively used in a variety of health conditions [66–68]. Video classes will include formal and informal mindfulness practices. The

description of the MBI is available in Additional file 4. The following themes will be covered.

- Week 1: Breaking the automatism.
- Week 2: Body awareness.
- Week 3: Leaving the mind and inhabiting the body.
- Week 4: Raising awareness.
- Week 5: Letting go.
- Week 6: Dealing with challenges and letting go of resistance.

- Week 7: Mindfulness and self-care.
- Week 8: A look to the future.

In addition, participants included in this group will receive daily reminders and additional material (audios) to continue to practice formal and informal MBHP daily. The participants in this group will be encouraged to practice diaries.

Adherence

In order to improve the adherence to the treatments, before each session, participants of both groups will receive an automatic reminder via SMS and/or email before each session. Participants' adherence to the interventions will be monitored through the number of accesses (date and hour), time connected to the platform, sessions visualized, number of sessions finalized, number of drop outs and others.

Adverse events

At the end of each video class, in a pop-up window, all participants will report the intensity of their pain and if there were any adverse events during the session. Participants will be able to contact a therapist through the platform's email at any time. In case of a severe adverse event related to exercise therapy or MBI (e.g. strains, sprains, persistent severe pain, psychosis, mania, traumatic memories), the participant will be referred to a qualified healthcare professional for further investigation.

Sample size and power

The sample size calculation was performed based on the usual pain intensity data from Bagheri et al. [30]. Considering a difference between groups of 4.2 mm and a standard deviation of 5.4 mm, with an α of 0.05 and β of 0.20, 26 participants per groups are required (52 in total). We will recruit 31 participants per trial arm to allow for up to a 20% drop-out rate at 12 months.

Statistical analysis

Statistical analysis will be performed by the blinded assessor using SPSS software (IBM version 23, SPSS Inc., Chicago, Il). Descriptive statistics will be computed for all variables (e.g. mean, standard deviation). Data will be tested for normal distribution by the Shapiro-Wilk test. Chi-square tests will be performed to compare self-reported recovery (successful x unsuccessful) between groups. For continuous data, the effects of group, time and their interaction will be assessed with linear mixed models. Intraclass Correlation Coefficients will be used to determine the amount of variance explained by random effects [69]. The Bonferroni-adjusted *post hoc* test will be performed for multiple pairwise comparisons where appropriate. Effect sizes (95% CI) (Cohen's d) will also be calculated and interpreted as follows:

Cohen's = 0.2 'small effect'; = 0.5 'moderate effect'; = 0.8 'large effect' and = 1.3 'very large effect' [70]. Intent-to-treat analyses will be performed for all outcomes. Multiple imputation will be used to account for missing data if the proportion of missing data is > 5% [71]. For all tests, an α level of 0.05 two-tailed will be adopted to indicate statistical significance.

The mediation effects will be assessed following the 3-variable framework described by MacKinnon et al. [72]. In this model, the intervention condition is assumed to have both direct and indirect paths to the changes in clinical outcomes. The indirect path passes through the potential mediators (anxiety, depression, kinesiophobia, pain catastrophizing and pain self-efficacy). Three multiple regressions will be performed: [1] to test the association between the predictor (i.e., interventions) and the outcomes (i.e., pain and function); [2] to test the association between the predictor and the potential mediators and [3] to test the association between the potential mediators and the outcomes after controlling for the predictor. Then, it will be observed whether the association of the predictor with the outcome after controlling for potential mediators will be smaller than observed in the first regression.

Discussion

PFP is a common and often recalcitrant knee disorder, with symptoms persisting for many years [7]. Exercise therapy and patient education are considered the "best management" options for this population [15, 16]. However, unsatisfactory long-term prognosis remains an issue [17]. It is known that people with PFP present with altered psychological factors [11], which should be considered during the evaluation and treatment of people with PFP [19]. Recent studies suggest that MBI induces functional and structural brain modifications [24, 25]. As part of a rehabilitation program, MBI can help the patients to recognize and accept their condition, promoting a more effective focus on rehabilitation and facilitating pain relief [28, 73]. Therefore, adding a MBI program to the current best treatment for PFP may improve psychological outcomes, providing a better response to treatment at short and long-term. However, this hypothesis needs further investigation. The proposed trial will address this knowledge gap by evaluating the effects of adding an 8-week online MBI program to an online program of exercise therapy and patient education on self-reported recovery, pain, function and psychological factors and in people with PFP. If our hypotheses are confirmed, our findings will contribute to the discussion of a new perspective of treatment modality for people with PFP.

Limitations

This study investigates the additional effect of an online treatment based on mindfulness program to exercise therapy and patient education for people with PFP. Although exercise therapy and patient education are considered the cornerstones of PFP management [16, 19], the additional effect of the mindfulness intervention to all physical interventions of PFP is not investigated in the present study. Future studies in this area are warranted.

Abbreviations

AKPS	Anterior Knee Pain Scale
CPSS	Chronic Pain Self-Efficacy Scale
GROC	global rating of change scale
HADS	Hospital Anxiety and Depression Scale
IASP	International Association for the Study of Pain
MBHP	Mindfulness-Based Health Promotion
MBI	Mindfulness-based interventions
PCS	Pain Catastrophizing Scale
PFP	Patellofemoral pain
ReBEC	*Registro Brasileiro de Ensaios Clínicos*
SPIRIT	Standard Protocol Items:Recommendations for Interventional Trials
VAS	visual analogue scale.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-023-06491-x.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

Acknowledgements
Not applicable.

Authors' contributions
LP is the scholarship holder and conceived of the study. LP drafted the paper. VP, RB, LF, JS, AA, EP and FA contributed to the study design. FL developed the WEB platform used to deliver the online interventions. OM developed the MBI. All investigators revised this protocol critically for important intellectual content. LP and VP will be responsible for the implementation.

Funding
LP is funded by São Paulo Research Foundation (FAPESP) with a scholarship (number: 2020/12475-7). The financial sponsor of the scholarship played no role in the design, execution, analysis and interpretation of data, or writing of the study.

Data Availability
Not applicable.

Declarations

Competing interests
The authors declare that they have no competing interests.

Ethics approval and consent to participate
The study protocol has been approved by the Sao Paulo State University Human Research Ethics Committee (number 4.606.720) and registered with the *Registro Brasileiro de Ensaios Clínicos* (ReBEC) number RBR-4yhbqwk. All methods will be carried out in accordance with relevant guidelines and regulations. Informed consent will be obtained from all subjects.

Consent for publication
Not applicable.

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References
1. Crossley KM, van Middelkoop M, Callaghan MJ, Collins NJ, Rathleff MS, Barton CJ. 2016 Patellofemoral pain consensus statement from the 4th International Patellofemoral Pain Research Retreat, Manchester. Part 1: Terminology, definitions, clinical examination, natural history, patellofemoral osteoarthritis and patient-reported outcome m. Br J Sports Med. 2016;50(14):844–52.
2. Boling M, Padua D, Marshall K, Guskiewicz K, Pyne S, Beutler A. Gender differences in the incidence and prevalence of patellofemoral pain syndrome. Scand J Med Sci Sport. 2010;20(5):725–30.
3. Glaviano NR, Baellow A, Saliba S. Physical activity levels in individuals with and without patellofemoral pain. Phys Ther Sport. 2017;27:12–6.
4. Nakagawa TH, Serrão FV, Maciel CD, Powers CM. Hip and knee kinematics are associated with pain and self-reported functional status in males and females with patellofemoral pain. Int J Sports Med. 2013;34(11):997–1002.
5. Ferrari D, Briani RV, de Oliveira Silva D, Pazzinatto MF, Ferreira AS, Alves N, et al. Higher pain level and lower functional capacity are associated with the number of altered kinematics in women with patellofemoral pain. Gait Posture. 2018;60(July 2017):268–72.
6. Coburn SL, Barton CJ, Filbay SR, Hart HF, Rathleff MS, Crossley KM. Quality of life in individuals with patellofemoral pain: a systematic review including meta-analysis. Phys Ther Sport. 2018;33:96–108.
7. Stathopulu E, Baildam E. Anterior knee pain: a long-term follow-up. Rheumatology. 2003;42(2):380–2.
8. Merskey H. In: Bogduk N, editor. Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. 2nd ed. Int Assoc Study Pain Press; 1994.
9. Carr DB, Eisenberg E, Fricton JR, Giamberardino MA, Goh CR, Jadad AR, et al. Pain and Philosophy of the mind. Int Assoc Study Pain Pain Clin Updat. 2007;15(5):1–4.
10. Powers CM, Witvrouw E, Davis IS, Crossley KM. Evidence-based framework for a pathomechanical model of patellofemoral pain: 2017 patellofemoral pain consensus statement from the 4th international Patellofemoral Pain Research Retreat, Manchester, UK: part 3. Br J Sports Med. 2017. bjsports-2017-098717.
11. Maclachlan LR, Collins NJ, Matthews MLG, Hodges PW, Vicenzino B. The psychological features of patellofemoral pain: a systematic review. Br J Sports Med. 2017;bjsports-2016-096705.
12. Crofford LJ. Chronic Pain: where the body meets the brain. Trans Am Clin Climatol Assoc. 2015;126:167–83.
13. Vlaeyen JWS, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. Pain. 2000;85(3):317–32.
14. Domenech J, Sanchis-Alfonso V, López L, Espejo B. Influence of kinesiophobia and catastrophizing on pain and disability in anterior knee pain patients. Knee Surg Sport Traumatol Arthrosc. 2013;21(7):1562–8.
15. JOSPT Infographic. Diagnosing and treating Patellofemoral Pain. J Orthop Sports Phys Ther. 2021;51(6):316.

16. Collins NJ, Barton CJ, van Middelkoop M, Callaghan MJ, Rathleff MS, Vicenzino BT, et al. 2018 Consensus statement on exercise therapy and physical interventions (orthoses, taping and manual therapy) to treat patellofemoral pain: recommendations from the 5th International Patellofemoral Pain Research Retreat, Gold Coast, Australia, 2017. Br J Sports Med. 2018;52(18):1170–8.

17. Lankhorst NE, van Middelkoop M, Crossley KM, Bierma-Zeinstra SMA, Oei EHG, Vicenzino B, et al. Factors that predict a poor outcome 5–8 years after the diagnosis of patellofemoral pain: a multicentre observational analysis. Br J Sports Med. 2015;50(14):bjsports–2015.

18. Doménech J, Sanchis-Alfonso V, Espejo B. Changes in catastrophizing and kinesiophobia are predictive of changes in disability and pain after treatment in patients with anterior knee pain. Knee Surg Sports Traumatol Arthrosc. 2014;22(10):2295–300.

19. Willy RW, Hoglund LT, Barton CJ, Bolgla LA, Scalzitti DA, Logerstedt DS, et al. Patellofemoral pain clinical practice guidelines linked to the international classification of functioning, disability and health from the academy of orthopaedic physical therapy of the american physical therapy association. J Orthop Sports Phys Ther. 2019;49(9):CPG1–95.

20. Bishop SR, Lau M, Shapiro S, Carlson L, Anderson ND, Carmody J, et al. Mindfulness: a proposed operational definition. Clin Psychol Sci Pract. 2004;11(3):230–41.

21. Hilton L, Hempel S, Ewing BA, Apaydin E, Xenakis L, Newberry S, et al. Mindfulness Meditation for Chronic Pain: systematic review and Meta-analysis. Ann Behav Med. 2017;51(2):199–213.

22. Cherkin DC, Sherman KJ, Balderson BH, Cook AJ, Anderson ML, Hawkes RJ, et al. Effect of mindfulness-based stress reduction vs cognitive behavioral therapy or usual care on back pain and functional limitations in adults with chronic low back pain: a randomized clinical trial. JAMA - J Am Med Assoc. 2016;315(12):1240–9.

23. Crane RS, Brewer J, Feldman C, Kabat-Zinn J, Santorelli S, Williams JMG, et al. What defines mindfulness-based programs? The warp and the weft. Psychol Med. 2017;47(6):990–9.

24. Boccia M, Piccardi L, Guariglia P. The meditative mind: A comprehensive meta-Analysis of MRI studies. Biomed Res Int. 2015;2015.

25. Brewer JA, Garrison KA. The posterior cingulate cortex as a plausible mechanistic target of meditation: findings from neuroimaging. Ann N Y Acad Sci. 2014;1307(1):19–27.

26. Fox KCR, Nijeboer S, Dixon ML, Floman JL, Ellamil M, Rumak SP, et al. Is meditation associated with altered brain structure? A systematic review and meta-analysis of morphometric neuroimaging in meditation practitioners. Neurosci Biobehav Rev. 2014;43:48–73.

27. Desbordes G, Gard T, Hoge EA, Hölzel BK, Kerr C, Lazar SW et al. Moving beyond Mindfulness: Defining Equanimity as an Outcome Measure in Meditation and Contemplative Research Gaëlle. Mindfulness (N Y). 2015;6(2):356–72.

28. Schütze R, Rees C, Preece M, Schütze M. Low mindfulness predicts pain catastrophizing in a fear-avoidance model of chronic pain. Pain. 2010;148(1):120–7.

29. Garland E, Gaylord S, Park J. The role of mindfulness in positive reappraisal. Explor J Sci Heal. 2009;5(1):37–44.

30. Bagheri S, Naderi A, Mirali S, Calmeiro L, Brewer BW. Adding mindfulness practice to Exercise Therapy for female recreational runners with Patellofemoral Pain: a Randomized Controlled Trial. J Athl Train. 2021;56(8):902–11.

31. de Oliveira Silva D, Pazzinatto MF, Rathleff MS, Holden S, Bell E, de Azevedo FM et al. Patient education for Patellofemoral pain: A Systematic Review. J Orthop Sport Phys Ther. 2020.

32. LG F, BT S. To what extent can telerehabilitation help patients in low- and middle-income coutries? Brazilian J Phys Ther. 2020.

33. Wang X, Hunter DJ, Vesentini G, Pozzobon D, Ferreira ML. Technology-assisted rehabilitation following total knee or hip replacement for people with osteoarthritis: A systematic review and meta-analysis. BMC Musculoskelet Disord. 2019;20(1).

34. van Egmond MA, van der Schaaf M, Vredeveld T, Vollenbroek-Hutten MMR, van Berge Henegouwen MI, Klinkenbijl JHG, et al. Effectiveness of physiotherapy with telerehabilitation in surgical patients: a systematic review and meta-analysis. Physiother (United Kingdom). 2018;104(3):277–98.

35. Jiang S, Xiang J, Gao X, Guo K, Liu B. The comparison of telerehabilitation and face-to-face rehabilitation after total knee arthroplasty: a systematic review and meta-analysis. J Telemed Telecare. 2018;24(4):257–62.

36. De Oliveira Silva D, Pazzinatto MF, Crossley KM, Azevedo FM, Barton CJ. Novel stepped Care Approach to provide Education and Exercise Therapy for Patellofemoral Pain: feasibility study. J Med Internet Res. 2020;22(7):e18584.

37. Krusche A, Cyhlarova E, Williams JMG. Mindfulness online: an evaluation of the feasibility of a web-based mindfulness course for stress, anxiety and depression. BMJ Open. 2013;3(11):1–10.

38. Chan A, Tetzlaff JM, Gotzche P, Altman DG, Mann H, Berlin JA et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346–e7586.

39. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340.

40. Kong H, West S, Principles G. Declaration of Helsinki. Ethical principles for medical research involving human subjects. J Indian Med Assoc. 2009;107(6):403–5.

41. Finnerup NB, Scholz J, First MB, Barke A, Cohen M, Smith BH, et al. Chronic pain as a symptom or a disease: the IASP classification of chronic pain for the international classification of diseases (ICD-11). Pain. 2018;160(1):19–27.

42. Crossley KM, Bennell KL, Cowan SM, Green S. Analysis of outcome measures for persons with patellofemoral pain: which are reliable and valid? Arch Phys Med Rehabil. 2004;85(5):815–22.

43. Pescatello L, Arena R, Riebe D, Thompson P. Guidelines for Exercise Testing and prescription. Med Sci Sport Exerc. 2014;23(10):482.

44. Kim J, Shin W. How to do random allocation (randomization). Clin Orthop Surg. 2014;6(1):103–9.

45. Collins N, Crossley K, Beller E, Darnell R, McPoil T, Vicenzino B. Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomised clinical trial. BMJ. 2008;337(7677):1034–6.

46. Matthews M, Rathleff MS, Claus A, Mcpoil T, Nee R, Crossley KM et al. Does foot mobility affect the outcome in the management of patellofemoral pain with foot orthoses versus hip exercises ? A randomised clinical trial. 2020;1416–22.

47. Pais-Ribeiro J, Silva I, Ferreira T, Martins A, Meneses R, Baltar M. Validation study of a portuguese version of the hospital anxiety and Depression Scale. Psychol Heal Med. 2007;12(2):225–37.

48. Zigmond AS, Snaith RP. The Hospital anxiety and Depression Scale. Acta Psychiatr Scand. 1983;67(6):361–70.

49. French DJ, France CR, Vigneau F, French JA, Evans RT. Fear of movement/(re)injury in chronic pain: a psychometric assessment of the original English version of the Tampa scale for kinesiophobia (TSK). Pain. 2007;127(1–2):42–51.

50. De Souza FS, Marinho Cda S, Siqueira FB, Maher CG, Costa LO. Psychometric testing confirms that the brazilian-portuguese adaptations, the original versions of the fear-avoidance beliefs Questionnaire, and the Tampa Scale of Kinesiophobia have similar measurement properties. Spine (Phila Pa 1976). 2008;33(9):1028–33.

51. Kori K, Miller R, Todd D. Kinesiophobia: a new view of chronic pain behaviour. Pain Manag. 1990;3:35–43.

52. Sehn F, Chachamovich E, Vidor LP, Dall-Agnol L, de Souza IC, Torres IL, et al. Cross-cultural adaptation and validation of the brazilian portuguese version of the Pain Catastrophizing Scale. Pain Med. 2012;13(11):1425–35.

53. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and validation. Psychol Assess. 1995;7(4):524–32.

54. De Góes Salvetti M, De Mattos Pimenta CA. Validação da Chronic Pain self-efficacy scale para a língua Portuguesa. Rev Psiquiatr Clin. 2005;32(4):202–10.

55. Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-Country reliability and validity. Med Sci Sports Exerc. 2003;35(8):1381–95.

56. Briani RV, Pazzinatto MF, De Oliveira Silva D, Azevedo FM. Different pain responses to distinct levels of physical activity in women with patellofemoral pain. Brazilian J Phys Ther. 2017;21(2):138–43.

57. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348(March):1–12.

58. Cabral LL, Nakamura FY, Stefanello JMF, Pessoa LCV, Smirmaul BPC, Pereira G. Initial Validity and Reliability of the Portuguese Borg Rating of Perceived Exertion 6–20 Scale. Meas Phys Educ Exerc Sci. 2020 Apr 2;24(2):103–14.

59. Garber CE, Blissmer B, Deschenes MR, Franklin BA, Lamonte MJ, Lee IM, et al. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: Guidance for prescribing exercise. Med Sci Sports Exerc. 2011;43(7):1334–59.

60. Demarzo M, Garcia-Campayo J. Manual Prático de mindfulness: curiosidade e aceitação. 1st ed. Sao Paulo: Palas Athena; 2015. p. 256.

61. Kabat-Zinn J. Mindfulness-based stress reduction (MBSR). Constr Hum Sci. 2003;8(2):73–107.

62. Kabat-Zinn J. Full catastrophe living: using the wisdom of your body and mind to face stress, apin and illness. Full catastrophe living. Ed Bantam; 2018. p. 722.
63. Kuyken W, Watkins E, Holden E, White K, Taylor RS, Byford S, et al. How does mindfulness-based cognitive therapy work? Behav Res Ther. 2010;48(11):1105–12.
64. Cusens B, Duggan G, Thorne K, Burch V. Evaluation of the breathworks mindfulness-based pain management programme. Clin Psychol Psychother. 2010;63–8.
65. Hendershot CS, Witkiewitz K, George WH, Marlatt GA. Relapse prevention for addictive behaviors. Subst Abus Treat Prev Policy. 2011;6(1):17.
66. Salvo V, Curado DF, Sanudo A, Kristeller J, Schveitzer MC, Favarato ML, et al. Comparative effectiveness of mindfulness and mindful eating pro-grammes among low-income overweight women in primary health care: a randomised controlled pragmatic study with psychological, biochemical, and anthropometric outcomes. Appetite. 2022;177:106131. (July 2021).
67. Trombka M, Demarzo M, Campos D, Antonio SB, Cicuto K, Walcher AL, et al. Mindfulness Training improves Quality of Life and reduces depression and anxiety symptoms among police officers: results from the POLICE Study—A Multicenter Randomized Controlled Trial. Front Psychiatry. 2021;12(February):1–16.
68. de Lima-Araujo GL, de Sousa Júnior GM, Mendes T, Demarzo M, Farb N, de Araujo DB, et al. The impact of a brief mindfulness training on interoception: a randomized controlled trial. PLoS ONE. 2022;17(9 September):1–18.
69. Nakagawa S, Johnson PCD, Schielzeth H. The coefficient of determination R2 and intra-class correlation coefficient from generalized linear mixed-effects models revisited and expanded. J R Soc Interface. 2017 Sep 1;14(134).
70. Sullivan GM, Feinn R. Using effect size - or why the P value is not enough. J Grad Med Educ. 2012;4(3):279–82.
71. Dong Y, Peng CYJ. Principled missing data methods for researchers. Springer-plus. 2013;2(1):1–17.
72. Mackinnon DP, Fairchild AJ, Fritz MS. Mediation Analysis. 2007;58(593).
73. Lange K, Gorbunova A, Christ O. The influence of mindfulness on different aspects of Pain Perception and Affective Reactivity to Pain - Feasibility of a Multimethodical Approach. Mindfulness (N Y). 2012;3(3):209–17.

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