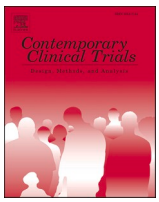
Contemporary Clinical Trials 120 (2022) 106880

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial



Lessons in Affect Regulation to Keep Stress and Pain UndeR control (LARKSPUR): Design of a randomized controlled trial to increase positive affect in middle-aged and older adults with fibromyalgia

Anthony D. Ong [a,c,*], Judith T. Moskowitz [d], Elaine Wethington [a,b,c], Elizabeth L. Addington [d], Mubarak Sanni [c], Selin Goktas [a], Erica Sluys [c], Sarah Swong [e], Patricia Kim [c], M. Carrington Reid [c]

[a] Department of Psychology, Cornell University, USA
[b] Department of Sociology, Cornell University, USA
[c] Division of Geriatrics and Palliative Medicine, Weill Cornell Medicine, USA
[d] Department of Medical Social Sciences, Northwestern Feinberg School of Medicine, USA
[e] Grossman School of Medicine, New York University, USA

ARTICLE INFO

Keywords:
Positive affect
Fibromyalgia
Chronic pain
Older adults
Skill-based training
Clinical trial
Intervention

ABSTRACT

Background: Fibromyalgia syndrome (FMS) is a leading cause of functional limitations and disability for which there is no cure. Positive psychological interventions for improving health have received increasing attention, but evidence of the feasibility, acceptability, and impact of such interventions in adult populations with FMS is limited.

Objectives: To describe the rationale and design of a 5-week, online positive affect skills intervention, LARKSPUR: Lessons in Affect Regulation to Keep Stress and Pain UndeR control.

Methods: FMS participants ($N = 90$) will be randomized to one of two conditions: (1) LARKSPUR or (2) emotion reporting/attention control. LARKSPUR is an online multicomponent intervention that targets eight skills to help foster positive affect: (1) noticing positive events, (2) savoring positive events, (3) identifying personal strengths, (4) behavioral activation to set and work toward attainable goals, (5) mindfulness, (6) positive reappraisal, (7) gratitude, and (8) acts of kindness. The primary outcomes include feasibility (i.e., recruitment, retention, adherence) and acceptability (i.e., helpfulness, usability, satisfaction). Secondary outcomes include pain intensity and pain interference.

Significance: If feasibility and acceptability metrics are met and reductions in pain outcomes are achieved, we will undertake future efficacy and effectiveness trials of LARKSPUR among older adults with FMS.

Trial Registration: NCT04869345.

1. Introduction

Fibromyalgia syndrome (FMS) is a chronic, musculoskeletal pain disorder characterized by diffuse pain and tenderness throughout the body, including the head, chest, abdomen, arms, legs, and back. Associated symptoms frequently include stiffness, fatigue, and impaired sleep. Affected individuals may report increased sensitivity to pain (hyperalgesia), as well as pain from a stimulus that does not normally provoke pain (allodynia) [1]. FMS predominantly affects women and is often accompanied by impaired physical functioning, depressed mood, as well as deficits in positive affect (PA) [2–4]. Conventional pharmacological treatments are considered only modestly effective, with many affected individuals experiencing undesirable side effects [5,6]. Standard behavioral therapies for FMS, such as cognitive-behavioral therapy for pain (CBT-P) [7] and mindfulness-based stress reduction (MBSR) [8], typically focus on reducing negative affective states (e.g., anxiety and depression) [9] and yield only modest treatment benefits [10]. Efforts are therefore needed to develop more effective approaches for FMS by identifying new targets for intervention.

A growing literature suggests that positive affective states (e.g., gratitude and happiness) play a unique role in promoting successful adjustment to chronic pain [11–14]. Positive affect has been theorized to facilitate adaptive coping by countering the effects of negative affect (NA) (e.g., fear and anxiety) [15], by reducing pain-related cognitions

* Corresponding author at: Department of Psychology, Cornell University, Ithaca, NY 14853-4401, USA.
E-mail address: anthony.ong@cornell.edu (A.D. Ong).

https://doi.org/10.1016/j.cct.2022.106880
Received 15 April 2022; Received in revised form 4 August 2022; Accepted 6 August 2022
Available online 11 August 2022

[16], and by promoting neutral reappraisal processes [17]. A meta-analysis of 29 observational and experimental studies documented a protective effect of PA on pain severity in adults with chronic non-cancer pain [18]. These findings are in line with a systematic review and meta-analysis of randomized controlled trials (RCTs) showing beneficial effects of positive psychology interventions (PPI) in chronic pain treatment [19]. Thus, evidence supports applying PPIs in the treatment of chronic pain [19], yet the implementation of PPI approaches into clinical practice has been slow and varied [13]. Potential barriers include high patient burden associated with privacy concerns, time, and mobility or travel limitations [12].

Internet-delivered interventions for chronic pain have the potential to overcome some of the access barriers to traditional face-to-face care, while also assisting heath care providers in disseminating programs to a wider population [20]. A recent meta-analysis of 36 RCTs reported small effect sizes of internet-delivered cognitive and behavioral interventions for adults with chronic pain on measures of pain interference, depression, pain intensity, and pain catastrophizing [21]. Notably, few interventions focused on FMS ($n = 5$), and none explicitly targeted PA. Scalable interventions that can be delivered virtually are especially pertinent given calls for more research on the role of internet-based interventions for use with individuals 65 years and older [20] and with specific pain conditions, such as FMS [22]. Alternative delivery methods that can be personalized to the needs of middle-aged and older adults living with FMS are also imperative in light of social distancing concerns brought about by the COVID-19 pandemic [23]. To the best of our knowledge, internetinterventions that explicitly focus on skills for producing and maintaining PA have not been evaluated in adults with FMS; their effects on affect and pain regulation have not been examined; and evidence of underlying mechanisms and moderators of treatment effects remains unknown.

In the present research, we describe the rationale and design of the Lessons in Affect Regulation to Keep Stress and Pain UndeR control (LARKSPUR) study, a 5-week online intervention program. The program is a skills-based intervention designed to increase PA in adults with FMS. Two primary aims guide the study protocol. Aim 1 is to establish the feasibility and acceptability of LARKSPUR content and its method of delivery among middle-aged and older adults with FMS, a chronic pain population with known deficits in PA [2–4]. Aim 2 is to conduct a pilot randomized controlled trial to evaluate the preliminary impact of LARKSPUR on self-reported pain intensity and pain interference. We will also explore whether psychosocial variables (i.e., PA, depressive symptoms, physical functioning, stress appraisals) mediate the effects of LARKSPUR on pain outcomes and potential treatment moderation by demographic and clinical covariates. To date, the vast majority of trials have enrolled predominantly non-Hispanic White samples, so there is little outcome data for racial/ethnic minorities with FMS [24]. Here, we conduct a pilot randomized controlled trial of LARKSPUR among Hispanic, non-Hispanic African American and non-Hispanic other FMS adults.

Fig. 1 presents a conceptual representation of the hypothesized psychosocial mediators and moderators of LARKSPUR on chronic pain outcomes. The approach is based on the Positive Pathways to Health model [25], an integrative model of PA and health that draws from prior theoretical work on positive emotions [26], stress and coping [27], and positive activities [28] to guide positive psychological interventions. The model posits that increased positive emotion has a range of proximal benefits, such as prompting more adaptive coping strategies [29], reducing emotional reactivity to daily stress [30], and strengthening social relationships [31], which all lead to reduced depression. This reduction, in turn, predicts better physiological functioning (e.g., quicker autonomic recovery after a stressful event) [32] and greater adherence to recommended health behaviors [33] which ultimately lead to improved physical and psychological well-being.

Our central hypothesis is that adults with FMS randomized to LARKSPUR (vs. attention control) will show high response rate, adherence, and acceptability and report improvements in pain outcomes from baseline to 1 month follow-up. Additionally, we hypothesize that the

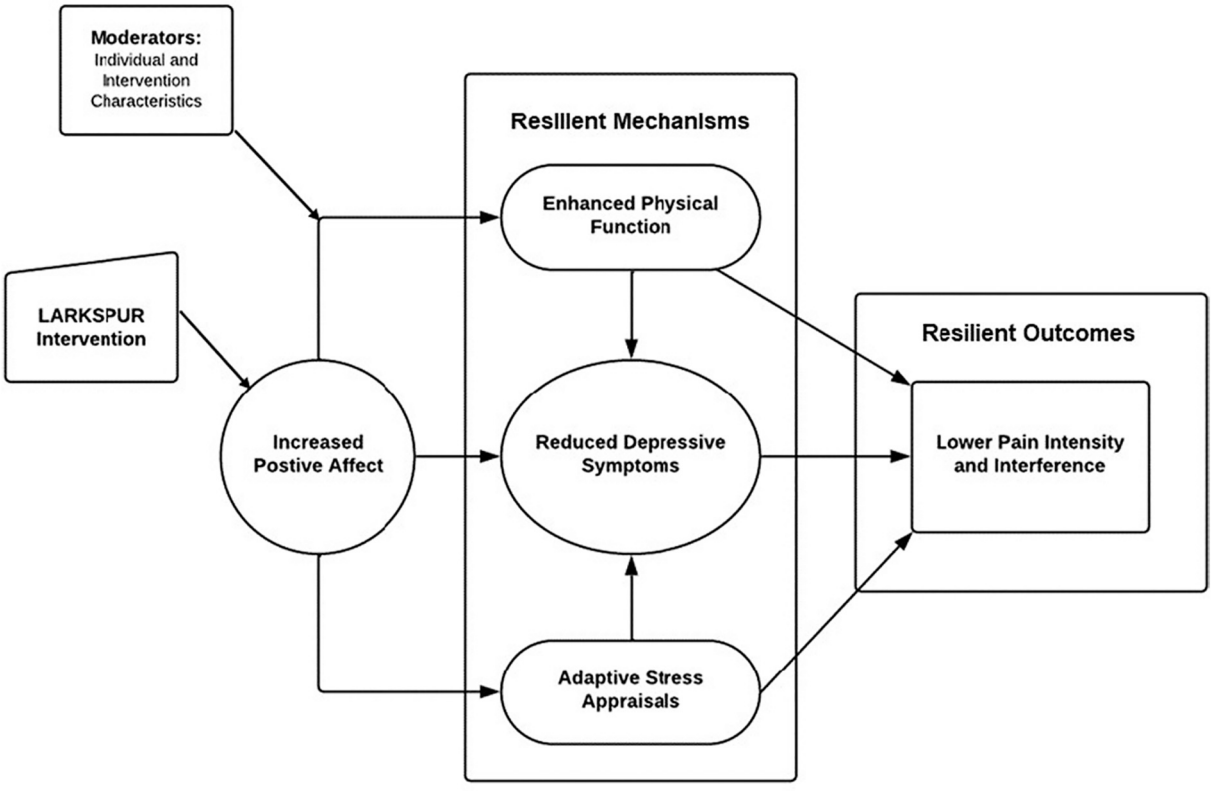


Fig. 1. Conceptual Model of LARKSPUR Intervention.

intervention will lead to increased levels of PA, which in addition to directly affecting depressive symptoms, will also have indirect effects through enhanced physical functioning and improved stress appraisals (*resilience mechanisms*). Decreased depressive symptoms, enhanced physical functioning, and improved stress appraisals, in turn, are hypothesized to lead to reduced pain intensity and pain interference (*resilience outcomes*). Individual characteristics such as demographics, pain medication use, and clinical comorbidities constitute potential moderators of intervention effects.

2. Materials and methods

2.1. Overview of study design

The LARKSPUR study (NCT04869345 on ClinicalTrials.gov) uses a 2-arm design to compare the effects of a 5-week PA skills-building intervention program to that of an emotion reporting/attention control group on self-reported pain intensity and pain interference following program completion and at 1-month follow-up. Fig. 2 presents the participant flow diagram. Participants will complete an online baseline assessment and be randomized to one of two self-.

guided online programs. The intervention program includes skills training exercises designed to increase the frequency of PA, beginning with basic skills for recognizing and savoring positive events and progressing to more complex skills such as goal-setting and acts of kindness. The control program will include daily emotion reporting during the 5-week intervention period. Participants in both arms will be assessed at baseline, post-intervention/control (approximately 11 weeks from baseline), and follow-up (approximately 16 weeks from baseline). Participants will be compensated for their time and incentivized to remain in the study with gift cards: $75 for baseline, post-intervention, and follow-up assessments; $42 for the diary assessments ($2 each for 21 days); and $25 for post-intervention feedback.

2.2. Participant eligibility

Participant inclusion criteria include: (1) access to Wi-Fi Internet connection, (2) middle-aged and older adults (age $\geq$ 50 years), (3) English literacy via self-reports of fluency and reading and writing comprehension, and (4) meeting diagnostic criteria for FMS (overall score of $\geq$13 the American College of Rheumatology [ACR] Fibromyalgia Symptom several scale) [34] and/or physician confirmation of FMS. Participant exclusion criteria are kept to a minimum to maximize generalizability of the findings and include only factors that would impede study participation: (1) moderate or severe cognitive impairment (2 or more errors on 6-item Mini-mental state examination [MMSE]) [35], (2) current behavioral treatment for chronic pain, and (3) enrollment in another chronic pain trial.

2.3. Study procedures

The study procedures were reviewed and approved by the Institutional Review Board (IRB) at Weill Cornell Medicine (Trial Registration: NCT04869345).

Recruitment and Screening. Study participants will be recruited through referrals from clinicians practicing at the Center on Aging, an ambulatory care center serving middle-aged and older adults in New York City and part of the New York Presbyterian Healthcare System. Referring clinicians will not be compensated. Additional strategies will include posting study flyers throughout the New York Presbyterian Healthcare System, New York City-based senior centers, community centers, and online platforms (e.g., Facebook groups). Recruitment links will also be posted on clinicaltrials.gov (a web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported research), and emailed to potential participants via ResearchMatch, a national health volunteer research registry created by several U.S. based academic institutions and supported by the U.S. National Institutes of Health. In addition, IRB-approved recruitment letters will be mailed to participants who meet eligibility criteria based on information obtained from Epic medical records at the participating medical centers. Prospective participants will be screened by a trained interviewer to determine eligibility and assess interest in the study. Screening assessments include English literacy; a score of 3 or more on 6-item screener for cognitive impairment [35]; and willingness and availability to complete the program activities and assessments. Eligible persons who decide to participate will provide oral consent remotely via telephone or Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant Zoom visit. Eligible individuals are encouraged to discuss any questions or concerns with study staff prior to providing oral informed consent. Copies of each consent will be shared with the participant and study staff will record oral consent individually and store on secure servers not linked to study data.

Run-in Period and Randomization. Upon consenting to take part in the study, all participants will complete a staff-administered baseline questionnaire via Zoom or phone and enroll in a pre-randomization run-in period for 7 days during which they complete daily emotion reports. Each day during the run-in period, participants will receive an email with a link to a brief online survey of daily emotions using Research Electronic Data Capture (REDCap), a secure institutional data stored web platform for databases and surveys. Following the run-in period, participants will be randomized in a 1:1 ratio of intervention (LARKSPUR) to control (emotion reporting) using random block sizes of 2, 4, 6, or 8. Random allocation will be generated and implemented centrally by non-data collecting study staff. A computerized randomization program will assist in the development of the allocation sequence for study. Allocation concealment will be utilized to prevent selection bias and group assignment will be given to both the participant and selected

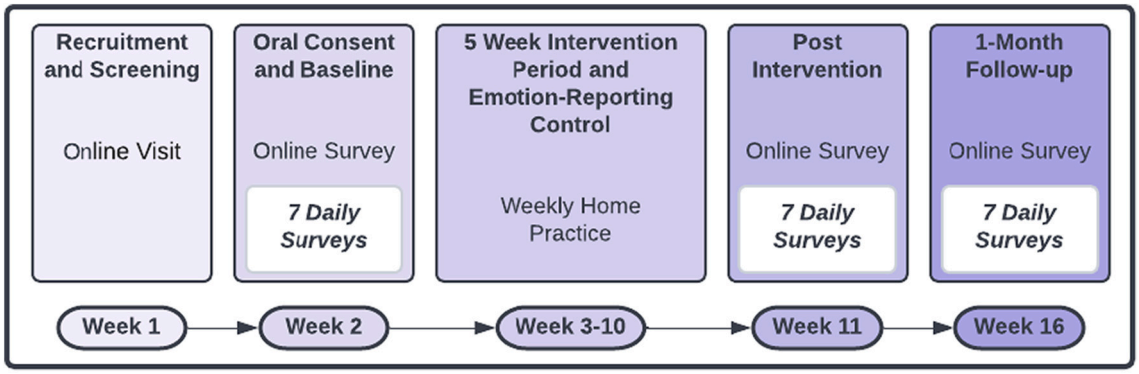


Fig. 2. Study flow diagram.

study staff only after completion of the baseline assessment.

Participants randomized to the intervention group will receive self-paced internet-supported instruction and practice in skills for increasing their daily experience of positive emotion. At the beginning of each week, participants will receive instructional materials that introduce the week's skill(s) and are asked to practice each skill as "home practice" every day until the next weekly session. Home practice for the control group will consist of completing daily emotion reports over the 5 weeks of the intervention.

Run-out Period and Follow-up. As with the run-in period, immediately after the intervention (run-out period) and at 1-month post intervention (follow-up), participants will complete online daily emotion reports every day for seven days. In addition to daily emotion reports, participants also will complete measures of daily stressors.

2.4. Intervention program

The PA skills intervention on which LARKSPUR is based was developed by J. Moskowitz and has been widely tested by her team in 13 studies with >300 participants (ages 16 to 78) coping with various life stressors—from diagnosis with a serious illness to normative daily stress [36–38]. The program has been implemented in person (individually and in groups), and most recently, has been delivered online as a self-guided program with people with type 2 diabetes.[39], depression [40–42], HIV [43], cancer [44,45], and among the general public coping with COVID-19 [46]. The intervention teaches participants eight PA skills over five weekly learning modules. Each module is designed to be completed within 1 week; however, to allow for variations in individual schedules and self-pacing, participants are given a total of 6 weeks to complete the LARKSPUR program. A description of the intervention content is summarized in Table 1. The eight skills in the intervention are: (1) noticing positive events [47,48], (2) savoring positive events [49,50], (3) identifying personal strengths [51,52], (4) behavioral activation to set and work toward attainable goals [53,54], (5) mindfulness [8,55], (6) positive reappraisal [27,56], (7) gratitude [57,58], (8) acts of kindness [59,60]. Each skill is associated with a home practice exercise, and participants are encouraged to spend approximately 10 min each day reviewing the skill and completing home practice. Participants may also revisit previous weeks' skills and home practice exercises. The online intervention will be supplemented by support from research staff via telephone and email. The support offered will be minimal and involve reminders to complete program activities and administrative or technical assistance. After completion of the course, participants will be able to access the course materials on the website indefinitely, allowing them to review the skills learned or continue with their home practice.

Table 1
Intervention content.

Week 1	1. Positive Events	1. Learning how to notice and appreciate positive events
	2. Savoring	2. Activities to help amplify experience of positive events
Week 2	3. Strengths	3. Identifying and being aware of personal strengths by listing the strengths in your daily life
	4. Activation	4. Emphasis on setting small, attainable goals and working up to challenging goals gradually
Week 3	5. Mindfulness	5. Using present-focused awareness to combat rumination about chronicity of pain and pain-related limitations and using acceptance to tolerate unpleasant situations with less negative emotion
Week 4	6. Positive Reappraisal	6. Seeing the "silver lining" or finding out that things were not as bad as they could have been
	7. Gratitude	7. Becoming aware and appreciative of things to be grateful for in life
Week 5	8. Acts of Kindness	8. Small prosocial acts that can be performed even if one is relatively socially isolated or has limited mobility

Positive Events and Savoring (Skills 1 and 2). Everyday positive events, such as chatting with a friend or taking a walk, are strongly linked to PA and mental and physical health [61–63]. Further, savoring through reminiscing about or sharing positive events with close others is associated with increased personal and relational well-being [64–66]. In the current intervention, participants are asked to keep a journal in which they note, write about, and reflect on a positive event each day throughout the week.

Strengths and Activation (Skills 3 and 4). Recognizing one's personal strengths and progress toward goals are a form of self-affirmation that can increase PA and psychological adjustment to physical illness [67]. Evidence indicates that positive psychological interventions that focus on leveraging individual strengths can increase pain self-efficacy and reduce loss of functioning among individuals with chronic pain [68]. Behavioral activation, a core treatment component in CBT programs for chronic pain [69], targets pleasant activities and seeks to create opportunities for positive reinforcement by highlighting the impact of pleasant activities on mood and symptoms. Moreover, evidence from intervention studies support the use of behavioral activation as a stand-alone pain management strategy [12,70]. Participants in the intervention arm of the current study are asked to reflect on a personal strength, set attainable goals, and note progress each day.

Mindfulness (Skill 5). Mindfulness, defined as the process of openly attending to the present moment [71], is a widely used and empirically supported psychosocial treatment for chronic pain [72]. Importantly, the practice of mindfulness has been theorized to enhance PA and attenuate pain [14] by (1) fostering decentering or attentional disengagement from pain [16], (2) broadening the scope of momentary cognition to encompass nonpainful experiences [15], and (3) motivating adaptive coping strategies, such as increased prosocial behavior [73]. In the current intervention, participants are asked to spend 10 min each day practicing a guided breath awareness and meditation exercise.

Positive Reappraisal (Skill 6). Positive reappraisal is a form of coping that involves changing one's personal construal of stressful events either through disputing negative cognitions or recognizing potential benefits ("silver linings") [56]. As a PA-enhancing strategy, positive reappraisal predicts reduced pain catastrophizing and perceived stress [16] and is a core therapeutic focus of mindfulness-based cognitive treatment for pain [74]. As part of the current study, participants are asked to keep a week-long journal, noting a relatively minor stressor each day then listing the ways in which the event can be positively reappraised.

Gratitude (Skill 7). This activity asks participants to keep a daily gratitude journal. It is based on evidence that people who report feeling gratitude have higher levels of PA and more favorable physical health outcomes than people who do not regularly experience gratitude [75]. Gratitude is associated with enhanced quality of life among those living with chronic pain conditions, including arthritis and FMS [76,77]. In the current study, intervention participants are asked to notice and record each day things for which they feel grateful.

Acts of Kindness (Skill 8). This activity asks participants to practice daily acts of kindness toward others. Practicing kindness and prosocial behavior is linked to increased PA [78] and longevity [60]. There is also evidence that interventions containing prosocial elements (e.g., performing random acts of kindness) yield improve pain outcomes (i.e., reduced pain intensity; lower pain interference) independently of the effects of pain medication use [12]. During the week in which participants learn and practice this skill, they are asked each day to perform a small act of kindness toward someone and note it in their daily journal.

2.5. Control program

The control program consists of completing daily emotion reports during the 5-week intervention period. Participants in the emotion reporting-control group are asked to log onto the study website daily,

where they are promoted to report on their emotions over the past 24 h.

2.6. LARKSPUR and control program delivery

Both the LARKSPUR and control programs were tailored for internet-based delivery via customized website built on BrightOutcome, a patient-centered healthcare application used by practitioners and health researchers worldwide. BrightOutcome is recognized as secure, and all communications on the website use industry-standard transport layer security or secure sockets layer encryption. The BrightOutcome platform allows for all intervention content to be viewable on handheld, tablet, and laptop devices. Data from the BrightOutcome platform include number of logins, completed home exercises, number of skills completed week by week, and data from the daily emotion and pain surveys.

2.7. Assessments and measures

Primary outcomes. The primary outcomes include feasibility and acceptability. Feasibility will be assessed through recruitment, retention, and adherence established by conducting frequency and descriptive statistics for enrollment rates, number of sessions completed, and number of weeks required to complete the intervention. Acceptability will be assessed at post-intervention. Participants will be asked to provide feedback on perceived helpfulness, usability, and overall satisfaction with the program. Additionally, participants will be asked to rate how much they would recommend the program to someone else with chronic pain using a 10-point Likert scale, ranging from 1 = *definitely not* to 10 = *definitely yes*.

Secondary outcomes (baseline, post-intervention, 1 month). Secondary outcomes include pain intensity and pain interference measured by the PROMIS-SI and PROMIS-PI scales at baseline, post-intervention, and 1-month follow-up. The scales were selected to best match pain symptomatology conceptually predicted by previous research [19]. The PROMIS-SI includes 3 items that ask participants to rate pain intensity over "the past 7 days" and "right now" using a 0 = *no pain* to 4 = *very severe* rating scale [79]. The PROMIS-PI includes 6 items that ask participants to self-report on the consequences of pain on relevant aspects of life using a 0 = *never* to 4 = *always* rating scale [80]. Composite scores for both scales will be computed by averaging responses, with higher scores indicating worse pain and greater pain interference, respectively.

Hypothesized psychosocial mediators (baseline, post-intervention, 1 month). Psychosocial variables that serve as potential mechanisms by which the LARKSPUR intervention could improve pain outcomes will be assessed.

Positive and negative affect will be assessed with the Positive and Negative Affect Scale (PANAS) [81]. The 20-item scale asks respondents to rate how they feel "in general" using a 5-point Likert-type scale, ranging from 1 = *very slightly* or *not at all* to 5 = *extremely*.

Depressive symptoms will be assessed by the Center for Epidemiologic Studies Depression Scale Revised (CESD-R-10) [82]. The 10-item version of the CES-D asks for participants to rate how often over the past week they experienced symptoms associated with depression on a 4-point scale, ranging from 0 = *rarely or none of the time* to 3 = *most or almost all the time*.

Physical functioning will be assessed using the PROMIS-PF [83] and PROMIS F-SF [84]. The PROMIS-PF includes ten items that assess abilities and limitations with respect to everyday physical activities, such as climbing the stairs, carrying groceries, and being able to sit on and get up from the toilet. Respondents are asked to report limitations and abilities to perform activities on a five-point scale, ranging from 1 = cannot/unable do to 5 = *not at all/without any difficulty*. The PROMIS F-SF is a 6-item instrument that assesses level of fatigue over a 7-day recall period. Respondents are asked to report fatigue on a scale on a five-point scale, ranging from 1 = *not at all* to 5 = *very much*.

Stressor appraisals will be assessed with the 10-item Perceived Stress Scale [85]. Respondents report how often they have experienced perceived stress on a five-point scale, ranging from 1 = *never* to 5 = *very often*.

Daily positive and negative affect will be assessed with the modified Differential Emotions Scale (mDES) [86]. The 20-item scale asks respondents to rate how often they felt 10 positive and 10 negative emotions "during the past 24 hours" using a 5-point Likert-type scale, ranging from 0 = *never* to 5 = *most of the time*.

Daily stressors will be assessed with the Daily Inventory of Stressful Events (DISE) [87]. The self-report instrument asks participants to report whether each of seven types of stressors (e.g., network stressors, stressors at work) occurred in the past 24 h.

Demographic and clinical covariates will be assessed and explored as potential moderators of treatment effects. A baseline survey will assess participant demographic characteristics including sex, age, race/ethnicity, income, education, and marital status. Pain medication will be assessed with two items: "During the past 30 days, how often have you taken prescription/non-prescription medication for pain?" and "During the past 30 days, how often have you taken non-prescription medication for pain? This may include aspirin (e.g., Bayer), acetaminophen (e.g., Tylenol), ibuprofen (e.g., Advil, Motrin), other NSAIDs (e.g., naproxen a.k.a. Aleve), or something else?" Chronic comorbid medical conditions will be assessed using an interviewer-administered version of the Charlson Comorbidity Index [88].

2.8. Statistical analysis and data management

We will summarize baseline demographic data overall and by treatment arm to provide descriptive statistics of the study participants. We will calculate means, standard deviations, and the interquartile range for continuous variables (e.g., income, age), and calculate percentages and list frequency counts for categorical variables (e.g., sex, race and ethnicity). Prior to conducting analyses, we will evaluate distributions to ensure that they meet assumptions of planned analyses, including detection of outliers.

Primary analyses will adhere to an intent-to-treat principle and will be performed using SAS or Stata. We will assess changes in primary outcomes using restricted maximum likelihood estimation with a longitudinal mixed modeling framework, under the assumption of missing at random and using all available outcome data for comparison. Models will include fixed effects for program (LARKSPUR vs. control), time (baseline, post-intervention, 1-month follow-up), and the interaction between program and time. Exploratory analyses will also examine treatment moderation by demographic and clinical covariates. Finally, we will tests whether hypothesized psychosocial variables (e.g., PA, depressive symptoms, physical functioning, stressor appraisal) mediate the effects of the intervention on primary outcomes using bootstrapping analyses.

Missing data and power. Missing data will be addressed using multiple imputation, and sensitivity analyses will explore the impact of nonignorable nonresponse (missing not a random) using "auxiliary variables" [89]. Given that the primary purpose of this study is to assess the feasibility of methods and procedures to be used in a larger, fully powered trial of LARKSPUR, sample size was chosen based on feasibility indicators (recruitment, retention, adherence) rather than on formal power calculations, as appropriate for the pilot nature of the study [see 90]. For quantitative pilot studies, sample sizes of 30 per treatment arm have been proposed to establish feasibility [91]. To allow for attrition between end-of-trial and follow-up, we aimed to recruit 45 per group (intervention and control). Analyses will be exploratory with the aim of hypothesis generation. Findings from subgroup analyses should therefore be interpreted with caution and call for further confirmatory randomized trials [92].

3. Discussion

LARKSPUR is a 2-arm pilot randomized controlled trial designed to

rigorously evaluate the effects of PA skills training among adults with FMS. Strengths of LARKSPUR include: (1) theoretically-grounded, empirically-supported strategies for increasing PA [93–95], (2) measurement-burst design incorporating a range of intensive longitudinal daily diary assessments and multi-wave follow-ups, (3) self-paced online delivery format, and (4) adapted content for adults with FMS. To date, few studies have examined the feasibility of internet-based intervention programs for adults with FMS [for a discussion, see 21], and none have explicitly targeted PA. The present study will be the first to assess the feasibility, acceptability, and preliminary efficacy of LARKSPUR to support PA maintenance among middle-aged and older adults living with FMS.

In addition, this trial will evaluate potential underlying mechanisms and moderators of treatment effects, which may have import for how to deliver, translate and scale LARKSPUR. Further, the trial includes a 1-month follow-up, which will provide vital information about the initial and short-term effects of LARKSPUR. Finally, LARKSPUR is a remotely delivered, low-intensity, and flexible intervention that supports sustainability and dissemination, which will be particularly salient in the context of the COVD-19 pandemic.

In summary, LARKSPUR is a brief, multicomponent PA skills intervention that targets pain intensity and interference in adults with FMS. If shown to be feasible and acceptable, these skills will make LARSKPUR potentially scalable, and easy to disseminate across a variety of healthcare settings. These findings should be of interest to primary health care providers who serve vulnerable older adult populations, whose physical impairment and chronic pain may make access to traditional face-to-face clinical care difficult. Further, results will inform a larger, fully powered effectiveness or efficacy trial, including examination of LARKSPUR compared with other behavioral therapies for FMS, such as CBT-P and MBSR. Finally, the results of this single-site feasibility trial may support the conduct of future network-wide studies that could significantly impact care and treatment of individuals living with FMS.

Funding acknowledgements

This research was supported, in part, by grants (U24AG058556, P30AG022845) from the National Institute on Aging.

CRediT authorship contribution statement

Anthony D. Ong: Conceptualization, Methodology, Writing – review & editing. **Judith T. Moskowitz:** Conceptualization, Methodology, Writing – review & editing. **Elaine Wethington:** Conceptualization, Methodology, Writing – review & editing. **Elizabeth L. Addington:** Methodology, Writing – review & editing. **Mubarak Sanni:** Data curation, Supervision. **Selin Goktas:** Writing – review & editing. **Erica Sluys:** Data curation. **Patricia Kim:** Data curation, Data curation, Supervision. **M. Carrington Reid:** Conceptualization, Methodology, Writing – review & editing.

Declaration of Competing Interest

The authors declare that there is no conflict of interest.

Data availability

No data was used for the research described in the article.

Acknowledgements

We are extremely grateful to Sabrina Feldman, Sidney Gibson, Usha Kaul, Ethan Low, Isel Vazquez-Carbajal, and Rebecca Wartels for their assistance with data collection.

References

[1] F. Wolfe, D.J. Clauw, M.A. Fitzcharles, D.L. Goldenberg, R.S. Katz, P. Mease, A. S. Russell, I.J. Russell, J.B. Winfield, M.B. Yunus, The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity, Arthritis Care Res. 62 (2010) 600–610.
[2] A.J. Zautra, R. Fasman, J.W. Reich, P. Harakas, L.M. Johnson, M.E. Olmsted, M. C. Davis, Fibromyalgia: evidence for deficits in positive affect regulation, Psychosom. Med. 67 (1) (2005) 147–155.
[3] P.H. Finan, A.J. Zautra, M.C. Davis, Daily affect relations in fibromyalgia patients reveal positive affective disturbance, Psychosom. Med. 71 (4) (2009) 474–482.
[4] A.L. Hassett, L.E. Simonelli, D.C. Radvanski, S. Buyske, S.V. Savage, L.H. Sigal, The relationship between affect balance style and clinical outcomes in fibromyalgia, Arthritis Rheum. 59 (2008) 833–840.
[5] E.P. Calandre, F. Rico-Villademoros, M. Slim, An update on pharmacotherapy for the treatment of fibromyalgia, Expert. Opin. Pharmacother. 16 (2015) 1347–1368.
[6] D.J. Clauw, Fibromyalgia: a clinical review, JAMA Intern. Med. 311 (2014) 1547–1555.
[7] S. Morley, C. Eccleston, A. Williams, Systematic review and meta-analysis of randomized controlled trials of cognitive behavior therapy and behavior therapy for chronic pain in adults, excluding headache, Pain 80 (1–2) (1999) 1–13.
[8] P. Grossman, U. Tiefenthaler-Gilmer, A. Raysz, U. Kesper, Mindfulness training as an intervention for fibromyalgia: Evidence of postintervention and 3-year follow-up benefits in well-being, Psychother. Psychosom. 76 (4) (2007) 226–233.
[9] F.J. Keefe, M. Lumley, T. Anderson, T. Lynch, K.L. Carson, Pain and emotion: new research directions, J. Clin. Psychol. 57 (2001) 587–607.
[10] C. Eccleston, S.J. Morley, A.C. Williams, Psychological approaches to chronic pain management: evidence and challenges, Br. J. Anaesth. 111 (2013) 59–63.
[11] M.L. Peters, E. Smeets, M. Feijge, G. van Breukelen, G. Andersson, M. Buhrman, S. J. Linton, Happy despite pain: a randomized controlled trial of an 8-week internet-delivered positive psychology intervention for enhancing well-being in patiens with chronic pain, Clin. J. Pain 33 (2017) 962–975.
[12] R. Muller, K.J. Gertz, I.R. Molton, A.L. Terrill, C.H. Bombardier, D.M. Ehde, M. P. Jensen, Effects of a tailored positive psychology Intervention on well-being and pain in Individuals with chronic pain and a physical disability: a feasibility trial, Clin. J. Pain 32 (2016) 32–44.
[13] A.D. Ong, A.J. Zautra, M.C. Reid, Chronic pain and the adaptive significance of positive emotions, Am. Psychol. 70 (2015) 283–284.
[14] P.H. Finan, E.L. Garland, The role of positive affect in pain and its treatment, Clin. J. Pain 31 (2) (2015) 177–187.
[15] M.H. Hanssen, M.L. Peters, J.J. Boselie, A. Meulders, Can positive affect attenuate (persistent) pain? State of the art and clinical implications, Curr. Rheumatol. Rep. 19 (2017) 1–9.
[16] A.D. Ong, A.J. Zautra, M.C. Reid, Psychological resilience predicts decreases in pain catastrophizing through positive emotions, Psychol. Aging 25 (3) (2010) 516–523.
[17] R. Kalisch, M.B. Müller, O. Tüscher, A conceptual framework for the neurobiological study of resilience, Behav. Brain Sci. (2014) 1–79.
[18] A.D. Ong, F. Thoemmes, K. Ratner, K. Ghezzi-Kopel, M.C. Reid, Positive affect and chronic pain: a preregistered systematic review and meta-analysis, Pain 161 (2020) 1140–1149.
[19] C. Braunwalder, R. Müller, M. Glisic, C. Fekete, Are positive psychology interventions efficacious in chronic pain treatment? A systematic review and meta-analysis of randomized controlled trials, Pain Med. 23 (2021) 122–136.
[20] J. Bender, A. Radhakrishnan, C. Diorio, M. Englesakis, A.R. Jadad, Can pain be managed through the Internet? A systematic review of randomized controlled trials, Pain 152 (2011) 1740–1750.
[21] M. Gandy, S.T. Pang, A.J. Scott, A.I. Heriseanu, M.A. Bisby, J. Dudeney, E. Karin, N. Titov, B.F. Dear, Internet-delivered cognitive and behavioral based interventions for adults with chronic pain: a systematic review and meta-analysis of randomized controlled trials, Pain (2022), https://doi.org/10.1097/j.pain.0000000000002606. In press.
[22] L.N. Friesen, H.D. Hadjistavropoulos, L.H. Schneider, N.M. Alberts, N. Titov, B. F. Dear, Examination of an internet-delivered cognitive behavioral pain management course for adults with fibromyalgia: a randomized controlled trial, Pain 158 (2017) 593–604.
[23] C. Eccleston, F.M. Blyth, B.F. Dear, E.A. Fisher, F.J. Keefe, M.E. Lynch, T. M. Palermo, M.C. Reid, W.A. C, Managing patients with chronic pain during the COVID-19 outbreak: considerations for the rapid introduction of remotely supported (eHealth) pain management services, Pain 161 (2020) 889–893.
[24] B. Walitt, R.L. Nahin, R.S. Katz, M.J. Bergman, F. Wolfe, The prevalence and characteristics of fibromyalgia in the 2012 National Health Interview Survey, PLoS One 10 (9) (2015), e0138024.
[25] J.T. Moskowitz, E.L. Addington, E.O. Cheung, Positive psychology and health: Well-being interventions in the context of illness, Gen. Hosp. Psychiatry 61 (2019) 136–138.
[26] B.L. Fredrickson, The role of positive emotions in positive psychology - the broaden-and-build theory of positive emotions, Am. Psychol. 56 (3) (2001) 218–226.
[27] S. Folkman, Positive psychological states and coping with severe stress, Soc. Sci. Med. 45 (8) (1997) 1207–1221.
[28] S. Lyubomirsky, K. Layous, How do simple positive activities increase well-being, Curr. Dir. Psychol. Sci. 22 (2013) 57–62.
[29] M.M. Tugade, B.L. Fredrickson, L.F. Barrett, Psychological resilience and positive emotional granularity: examining the benefits of positive emotions on coping and health, J. Pers. 72 (6) (2004) 1161–1190.

[30] A.D. Ong, C.S. Bergeman, T.L. Bisconti, K.A. Wallace, Psychological resilience, positive emotions, and successful adaptation to stress in later life, J. Pers. Soc. Psychol. 91 (4) (2006) 730–749.
[31] B.E. Kok, B.L. Fredrickson, Upward spirals of the heart: autonomic flexibility, as indexed by vagal tone, reciprocally and prospectively predicts positive emotions and social connectedness, Biol. Psychol. 85 (3) (2010) 432–436.
[32] B.L. Fredrickson, R.W. Levenson, Positive emotions speed recovery from the cardiovascular sequelae of negative emotions, Cognit. Emot. 12 (1998) 191–220.
[33] S.M. Bassett, S.A. Schuette, L.C. O'Dwyer, J.T. Moskowitz, Positive affect and medication adherence in chronic conditions: a systematic review, Health Psychol. 38 (11) (2019) 960.
[34] F. Wolfe, D.J. Clauw, M.A. Fitzcharles, D.L. Goldenberg, W. Häuser, R.S. Katz, P. Mease, A.S. Russell, I.J. Russel, J.B. Winfield, Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR preliminary diagnostic criteria for fibromyalgia, J. Rheumatol. 38 (2011) 1113–1122.
[35] C.M. Callahan, F.W. Unverzagt, S.L. Hui, A.J. Perkins, H.C. Hendrie, Six-item screener to identify cognitive impairment among potential subjects for clinical research, Med. Care 40 (2002) 771–781.
[36] J.T. Moskowitz, A.W. Carrico, L.G. Duncan, M.A. Cohn, C.E. O, A. Batchelder, L. Martinez, E. Segawa, M. Acree, S. Folkman, Randomized controlled trial of a positive affect intervention for people newly diagnosed with HIV, J. Consult. Clin. Psychol. 85 (2017) 409–423.
[37] J.T. Moskowitz, A.W. Carrico, M.A. Cohn, L.G. Duncan, C. Bussolari, K. Layous, J. R. Hult, A. Brousset, P. Cotten, S. Maurer, M.E. Pietrucha, M. Acree, J. Wrubel, M. O. Johnson, F.M. Hecht, S. Folkman, Randomized controlled trial of a positive affect intervention to reduce stress in people newly diagnosed with HIV; protocol and design for the IRISS study, Open Access J. Clin. Trials 6 (2014).
[38] J.T. Moskowitz, J.R. Hult, L.G. Duncan, M.A. Cohn, S. Maurer, C. Bussolari, M. Acree, A positive affect intervention for people experiencing health-related stress: development and non-randomized pilot test, J. Health Psychol. 17 (5) (2012) 676–692.
[39] M.A. Cohn, M.E. Pietrucha, L.R. Saslow, J.R. Hult, J.T. Moskowitz, An online positive affect skills intervention reduces depression in adults with type 2 diabetes, J. Posit. Psychol. 9 (6) (2014) 523–534.
[40] E. Addington, E.O. Cheung, S. Bassett, I. Kwok, S. Schuette, E. Shiu, D. Yang, M. A. Cohn, Y. Leykin, L.R. Saslow, J.T. Moskowitz, The MARIGOLD study: Feasibility and enhancement of an online intervention to improve emotion regulation in people with elevated depressive symptoms, J. Affect. Disord. 257 (2019) 352–364.
[41] E.O. Cheung, E.L. Addington, S.M. Bassett, S.A. Schuette, E.W. Shiu, M.A. Cohn, Y. Leykin, L.R. Saslow, J.T. Moskowitz, Study protocol and design for the MARIGOLD study: a self-paced online positive emotion skills intervention for people with elevated symptoms of depression, JMIR Res. Protoc. 7 (6) (2018).
[42] J.T. Moskowitz, E.L. Addington, E. Shiu, S.M. Bassett, S. Schuette, I. Kwok, V. Grote, M.E. Freedman, Y. Leykin, L.R. Saslow, M.A. Cohn, E.O. Cheung, Facilitator contact, discussion boards, and virtual badges as adherence enhancements to a web-based, self-guided, positive psychological intervention for depression: randomized controlled trial, J. Med. Internet Res. 23 (9) (2021), e25922.
[43] S. Bassett, M. Cohn, P. Cotten, I. Kwok, J. Moskowitz, Feasibility and acceptability of an online positive affect intervention for those living with comorbid HIV depression, AIDS Behav. 23 (3) (2019) 753–764.
[44] J.M. Salsman, L.E. McLouth, M. Cohn, J.A. Tooze, M. Sorkin, J.T. Moskowitz, A. Web-Based, Positive emotion skills intervention for enhancing posttreatment psychological well-being in young adult cancer survivors (EMPOWER): protocol for a single-arm feasibility trial, JMIR Res. Protoc. 9 (5) (2020), e17078.
[45] E.O. Cheung, M.A. Cohn, L.B. Dunn, M.E. Melisko, S. Morgan, F.J. Penedo, J. M. Salsman, D.M. Shumay, J.T. Moskowitz, A randomized pilot trial of a positive affect skill intervention (lessons in linking affect and coping) for women with metastatic breast cancer, Psycho-Oncology 26 (12) (2016) 2101–2108. In this issue.
[46] E.L. Addington, P. Cummings, K. Jackson, D. Yang, J.T. Moskowitz, Exploring retention, usage, and efficacy of web-based delivery of positive emotion regulation skills during the COVID-19 pandemic, Affect. Sci. (2022). In press.
[47] P.M. Lewinsohn, C.S. Amenson, Some relations between pleasant and unpleasant mood-related events and depression, J. Abnorm. Psychol. 87 (1978) 644–654.
[48] N. Krause, Positive Life evEnts and Depressive Symptoms in Older Adults, 1988.
[49] F.B. Bryant, A four-factor model of perceived control: avoiding, coping, obtaining, and savoring, J. Pers. 57 (4) (1989) 773–797.
[50] C.A. Langston, Capitalizing on and coping with daily-life events: expressive responses to positive events, J. Pers. Soc. Psychol. 67 (1994) 1112–1125.
[51] S.E. Taylor, M. Lobel, Social comparison activity under threat: downward evaluation and upward contacts, Psychol. Rev. 96 (4) (1989) 569–575.
[52] S.E. Taylor, M.E. Kemeny, L.G. Aspinwall, S.G. Schneider, et al., Optimism, coping, psychological distress, and high-risk sexual behavior among men at risk for acquired immunodeficiency syndrome (AIDS), J. Pers. Soc. Psychol. 63 (3) (1992) 460–473.
[53] R.C. Manos, J.W. Kanter, A.M. Busch, A critical review of assessment strategies to measure the behavioral activation model of depression, Clin. Psychol. Rev. 30 (2010) 547–561.
[54] J.T. Moskowitz, J.R. Hult, C. Bussolari, M. Acree, What works in coping with HIV? A meta-analysis with implications for coping with serious illness, Psychol. Bull. 135 (2009) 121–141.
[55] J. Kabat-Zinn, Mindfulness-based interventions in context: past, present, and future, Clin. Psychol. 10 (2003) 144–156.
[56] J.T. Moskowitz, S. Folkman, L. Collette, E. Vittinghoff, Coping and mood during AIDS-related caregiving and bereavement, Ann. Behav. Med. 18 (1) (1996) 49–57.
[57] R.A. Emmons, C.A. Crumpler, Gratitude as a human strength: appraising the evidence, J. Soc. Clin. Psychol. 19 (1) (2000) 56–69.
[58] B.L. Fredrickson, Gratitude, like other positive emotions, broadens and builds, in: R.A. Emmons, M.E. McCullough (Eds.), The Psychology of Gratitude, Oxford University Press, New York, 2022 in press.
[59] L.A. Penner, J.F. Dovidio, J.A. Piliavin, D.A. Schroeder, Prosocial behavior: multilevel perspectives, Annu. Rev. Psychol. 56 (2005) 365–392.
[60] S.L. Brown, R.M. Nesse, A.D. Vinokur, D.M. Smith, Providing social support may be more beneficial than receiving it: results from a prospective study of mortality, Psychol. Sci. 14 (2003) 320–327.
[61] N.L. Sin, A.D. Ong, R.S. Stawski, D.M. Almeida, Daily positive events and diurnal cortisol rhythms: examination of between-person differences and within-person variation, Psychoneuroendocrinology 83 (2017) 91–100.
[62] N.L. Sin, J.E. Graham-Engeland, D.M. Almeida, Daily positive events and inflammation: Findings from the National Study of Daily Experiences, Brain Behav. Immun. 43 (2015) 130–138.
[63] V. Panaite, A.R. Devendorf, T.B. Kashdan, J. Rottenberg, Daily life positive events predict well-being among depressed adults 10 years later, Clinical, Clinical Psychological Science 9 (2) (2021) 222–235. In this issue.
[64] S.L. Gable, H.T. Reis, E.A. Impett, E.R. Asher, What do you do when things go right? The intrapersonal and interpersonal benefits of sharing positive events, J. Pers. Soc. Psychol. 87 (2) (2004) 228–245.
[65] S.L. Gable, H.T. Reis, Good news! Capitalizing on positive events in an interpersonal context, Adv. Exp. Soc. Psychol. 42 (2010) 195–257.
[66] F.B. Bryant, C.M. Smart, S.P. King, Using the past to enhance the present: boosting happiness through positive reminiscence, J. Happiness Stud. 6 (2005) 227–260.
[67] C.S. Carver, M.F. Scheier, Origins and functions of positive and negative affect: a control-process view, in: Arie W. Kruglanski, Etory Higgins (Eds.), Motivational Science: Social and Personality Perspectives, Psychology Press, Philadelphia, PA, US, 2000, p. 256272, xii, 454 pp.
[68] M. Graziosi, D.B. Yaden, J.D.W. Clifton, N. Mikanik, R.M. Niemiec, A strength-based approach to chronic pain, J. Positive Psychol. 17 (3) (2020) 400–408.
[69] H. Flor, D.C. Turk, Chronic Pain: An Integrated Biobehavioral Approach, IASP Press, Seattle, WA, 2011.
[70] L. Hausmann, A. Youk, C. Kwoh, S. Ibrahim, M. Hannon, D. Weiner, R. Gallagher, A. Parks, Testing a positive psychological intervention for osteoarthritis, Pain Med. 18 (2017) 1908–1920.
[71] J.D. Creswell, E.K. Lindsay, D.K. Villaba, B. Chin, Mindfulness training and physical health: mechanisms and outcomes, Psychosom. Med. 81 (2019) 224–232.
[72] J.D. Creswell, Mindfulness interventions, Annu. Rev. Psychol. 68 (2017) 491–516.
[73] M.C. Davis, A.J. Zautra, B.W. Smith, Chronic pain, stress, and the dynamics of affective differentiation, J. Pers. 72 (6) (2004) 1133–1159.
[74] E.L. Garland, A.W. Hanley, A.K. Baker, M.O. Howard, Biobehavioral mechanisms of mindfulness as a treatment for chronic stress: an RDoC perspective, Chron. Stress 1 (2017) 1–14.
[75] A.M. Wood, J.J. Froh, A.W.A. Geraghty, Gratitude and well-being: a review and theoretical integration, Clin. Psychol. Rev. 30 (2010) 890–905.
[76] R.J. Eaton, G. Bradley, S. Morrissey, Positive predispositions, quality of life and chronic illness, Psychol. Health Med. 19 (2014) 473–489.
[77] L. Toussaint, F. Sirois, J. Hirsch, A. Weber, C. Vajda, J. Schelling, N. Kohls, M. Offenbacher, Gratitude mediates quality of life differences between fibromyalgia patients and healthy controls, Qual. Life Res. 26 (2017) 2449–2457.
[78] S. Lyubomirsky, K. Sheldon, D. Schkade, Pursuing happiness: the architecture of sustainable change, Rev. Gen. Psychol. 9 (2005) 111–131.
[79] R.A. Deyo, K. Ramsey, D.I. Buckley, L. Michaels, A. Kobus, E. Eckstrom, V. Forro, C. Morris, Performance of a patient reported outcomes measurement information system (PROMIS) short form in older adults with chronic musculoskeletal pain, Pain Med. 17 (2016) 314–324.
[80] D.A. Amtmann, K.F. Cook, M.P. Jensen, W.H. Chen, S.W. Choi, D. Revicki, D. Cella, N. Rothrock, F. Keefe, I. Callahan, J.S. Lai, Development of a PROMIS item bank to measure pain interference, Pain 150 (2010) 173–182.
[81] D. Watson, L.A. Clark, A. Tellegen, Development and validation of brief measures of positive and negative affect: the PANAS scales, J. Pers. Soc. Psychol. 54 (6) (1988) 1063–1070.
[82] T. Björgvinsson, S.J. Kertz, J.S. Bigda-Peyton, K.L. McCoy, I.M. Aderka, Psychometric properties of the CES-D-10 in a psychiatric sample, Assessment 20 (2013) 429–436.
[83] M. Rose, J.B. Bjorner, J. Becker, J.F. Fries, J.E. Ware, Evaluation of a preliminary physical function item bank supported the expected advantages of the Patient-Reported Outcomes Measurement Information System (PROMIS), J. Clin. Epidemiol. 61 (2008) 17–33.
[84] C. Bingham, A. Gutierrez, A. Butanis, V. Bykerk, J. Curtis, A. Leong, A. Lyddiatt, W. Nowell, A. Orbai, S. Bartlett, PROMIS fatigue short forms are reliable and valid in adults with rheumatoid arthritis, J. Patient Rep. Outcomes 21 (2019) 1–9.
[85] S. Cohen, T. Kamarck, R. Mermelstein, A global measure of perceived stress, J. Health Soc. Behav. 24 (4) (1983) 385–396.
[86] B.L. Fredrickson, M.M. Tugade, C.E. Waugh, G.R. Larkin, What good are positive emotions in crisis? A prospective study of resilience and emotions following the terrorist attacks on the United States on September 11th, 2001, J. Pers. Soc. Psychol. 84 (2003) 365–376.
[87] D.M. Almeida, E. Wethington, R.C. Kessler, The Daily Inventory of Stressful Events: an interview-based approach for measuring daily stressors, Assessment 9 (2002) 41–55.

[88] M.E. Charlson, P. Pompei, K.L. Ales, C.R. MacKenzie, A new method of classifying prognostic comorbidity in longitudinal studies: development and validation, J. Chronic Dis. 40 (5) (1987) 373–383.
[89] P. Li, E.A. Stuart, D.B. Allison, Multiple imputation: a flexible tool for handling missing data, JAMA 314 (2015) 1966–1967.
[90] J.A. Teresi, X. Yu, A.L. Stewart, R.D. Hays, Guideliness for designing and evaluating feasibility pilot studies, Med. Care 60 (2022) 95–103.
[91] A.L. Whitehead, S.A. Julious, C.L. Cooper, M.J. Campbell, Estimating the sample size for a pilot randomized trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable, Stat. Methods Med. Res. 25 (2016) 1057–1073.
[92] R.A. Parker, C.J. Weir, Non-adjustment for multiple testing in multi-arm trials of distinct treatments: rationale and justification, Clin. Trials 17 (2020) 562–566.
[93] S. Folkman, J.T. Moskowitz, Stress, positive emotion, and coping, Curr. Dir. Psychol. Sci. 9 (4) (2000) 115–118.
[94] S. Folkman, The case for positive emotions in the stress process, Anxiety Stress Coping 21 (1) (2008) 3–14.
[95] B.L. Fredrickson, The role of positive emotions in positive psychology: the broaden-and-build theory of positive emotions, Am. Psychol. 56 (2001) 218–226.