


BMJ Open Investigation of predictors of interest in a brief mindfulness-based intervention and its effects in patients with psoriasis at a rehabilitation clinic (SkinMind): an observational study and randomised controlled trial

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ABSTRACT

Introduction Psoriasis (PS) is a chronic inflammatory skin disease accompanied by reduced quality of life. Mindfulness is the ability to focus on the present moment without evaluation. Findings on the effects of 8-week mindfulness trainings in patients with PS reveal positive effects on the severity of the disease and quality of life. However, it remained unclear what distinguishes patients with PS interested in psychological interventions from those without interest and whether also a shorter, namely 2-week mindfulness-based intervention is beneficial in this patient group. This will be investigated with this study.

Methods and analyses Data will be collected at a rehabilitation clinic in Germany. The study is divided into two parts: study 1a is an observational study. Its aim is to investigate whether sociodemographic, skin-related and psychological factors are significant predictors of interest in a brief psychological intervention in 127 patients with PS. Study 1b is a randomised controlled trial, in which 60 patients (retrieved from study 1a) will be randomised to an intervention or control group (treatment as usual). The main outcome variables are mindfulness and self-compassion. In addition, mediation analyses will be used in an explorative manner to test whether there is a relationship between mindfulness/self-compassion and the severity of PS and whether it is mediated by itch catastrophising and fear of negative evaluation (first model) or perceived stress (second model).

Ethics and dissemination The study protocol has been approved by the University of Giessen. Study results will be disseminated by publication of the results at (inter) national conferences and in scientific journals.

Trial registration numbers DRKS00017426 and DRKS00017429.

INTRODUCTION

Psoriasis

Psoriasis (PS) is a chronic relapsing skin disease with a prevalence of for instance 3% in the USA and 2.5% in Germany.¹ The

Strengths and limitations of this study

- The design of study 1b (randomised controlled trial) is a strength.
- The determination of medium-term effects of the training in a 3-month follow-up is a strength of the study, however, a follow-up after, for example, 12 or even 24 months would have been better.
- The fact that the severity of the skin disease is only assessed by the patients themselves and not by their doctors in charge is a limitation.
- As the training is delivered at a rehabilitation clinic, the transferability of the study results to other situations outside the clinic is not given and can be considered as a limitation of the study.

probability to have PS is associated with age and differs between geographic regions.³ In patients with PS, quality of life is similarly reduced as in patients with cardiovascular diseases.⁴ The severity of PS cannot completely be explained by genetic and environmental factors.⁵ It is summarized that 37%–78% of patients with PS believe that their disease is exacerbated by stress.⁶ These patients can be referred to as stress responders.⁷ Although psychological interventions have been shown to be beneficial in the treatment of PS, it is necessary to identify patient characteristics, which explain the differential effectiveness of psychological procedures in patients with PS.⁸

Mindfulness

Mindfulness is defined as paying attention to experiences occurring in the present moment without judging them.⁹ Mindfulness and the effects of mindfulness-based interventions



have been investigated intensively throughout the last years. Especially, the interest in mechanisms that underly its positive effects has grown rapidly. Standardised mindfulness-based interventions typically last 8 weeks, with new topics being tackled once a week in a 2.5-hour group session led by a teacher.¹⁰ Inbetween the sessions, participants are encouraged to practice mindfulness techniques for 45 min each day.¹⁰ Typical mindfulness techniques are breath meditation and the body scan. Hereby, participants are instructed to focus e.g. on the breathing process.⁹ Recent studies, in which brief mindfulness-based interventions were investigated, found significant effects on stress, mood and cognitive performance.^{11 12} Mindfulness can be captured using standardised questionnaires¹³ and increased on purpose through meditation practice, which is the basis for various clinical interventions.^{14 15}

Effects of mindfulness in patients with chronic diseases

The first clinical interventions aiming to increase mindfulness were developed for pain patients.¹⁶ Over time interventions have been adapted, for example, to relapse prevention in depressed patients.¹⁵ Meanwhile, there are several meta-analyses and systematic reviews on the multiple effects of mindfulness.^{14 17–20} Mindfulness-based practices are believed to change patients' cognitive and emotional reactivity, increase awareness, reduce rumination and anxiety, increase self-compassion and psychological flexibility.¹⁷

Effects of mindfulness-based interventions in patients with PS

In patients with PS, a few minutes mindfulness-based stress reduction (MBSR) three times per week over 13 weeks had effects on physiological PS parameters, but not on psychological outcome variables when compared with treatment as usual (TAU).²¹ Another study²² explored the effects of a 12-week meditation-intervention and found significant improvements in PS outcomes when the intervention group was compared with the control groups. Effects on psychological measures were not assessed in this study. More recent studies reported incongruent results^{8 23 24}: A pilot study using mindfulness-based cognitive therapy (MBCT) showed that this mindfulness training of 8 weeks had positive effects on the severity of PS and quality of life.²³ In contrast, a similar study⁸ found no significant differences, neither on psychological nor on physical outcomes, when comparing the effects of various mindfulness-based interventions to TAU. According to the authors, floor effects might have led to these results as the PS severity in this sample was mild to moderate at the beginning. A recent randomised trial²⁴ compared the effects of MBCT to TAU. Here, participation in an 8-week MBCT programme led to significant improvements in both, skin-related and psychological outcomes, which did not occur in the control group.

A recent review²⁵ concludes that the effects of psychological interventions need to be studied further as studies often only included small samples, follow-ups were missing and/or patients were not blinded. Previous

studies on mindfulness-based interventions in patients with PS were also criticised for not having asked patients with PS whether they regarded psychological interventions as useful and would like to attend, even though interventions adapted to patients' interests could lead to greater effects.²⁵

Proposed effects of mindfulness in patients with PS

The biopsychosocial model of chronic itch²⁶ assumes that patients' internal factors (eg, personality factors) lead to certain cognitions, social reactions and behaviours, which can trigger physiological reactions (eg, the secretion of PS-related cytokines) that in turn trigger a worsening of symptoms of the skin disease. Referring to this model, we postulate that increased mindfulness as internal factor will lead to a reduction of itch catastrophising and fear of negative evaluation and hence to an improvement of PS severity. This assumption is supported by studies in which a negative association between mindfulness and fear of negative evaluation was found.²⁷ We propose that increased mindfulness and self-compassion due to participation in a mindfulness-based training will lead to lower itch catastrophising and lower fear of negative evaluation and subsequently also to a better skin status (emotional-cognitive pathway). Moreover, it is known that stress plays a role in the exacerbation of PS.²⁸ The relationship between stress and PS is thought to be mediated by release of the stress hormone cortisol which has an impact on mast cell degranulation²⁹ and the activity of cytokines,³⁰ which play an important role in the pathogenesis of PS. As mindfulness-based interventions are known to effectively reduce stress²⁰ an increase in mindfulness due to participation in the training should thus also lead to an improvement of the skin through the just described physiological pathway (also see figure 1).

Objectives

Study 1a aims to investigate whether sociodemographic factors, psychological variables or the severity of the disease are significant predictors of interest in participation in a short psychological intervention.

Study 1b aims to investigate the short-term and medium-term effects of a short mindfulness-based intervention on mindfulness and self-compassion as main outcome parameters. In addition, it is tested whether mindfulness is related to the severity of PS and in case this relationship exists it is mediated by itch catastrophising, fear of negative evaluation and/or stress (see above).

METHODS AND ANALYSIS

Setting

Data collection takes place at a German rehabilitation clinic and started August 2019 (also see table 1).

Trial design and procedure

Study 1a is an observational study. Study 1b is a randomised controlled trial. In order to take part in study

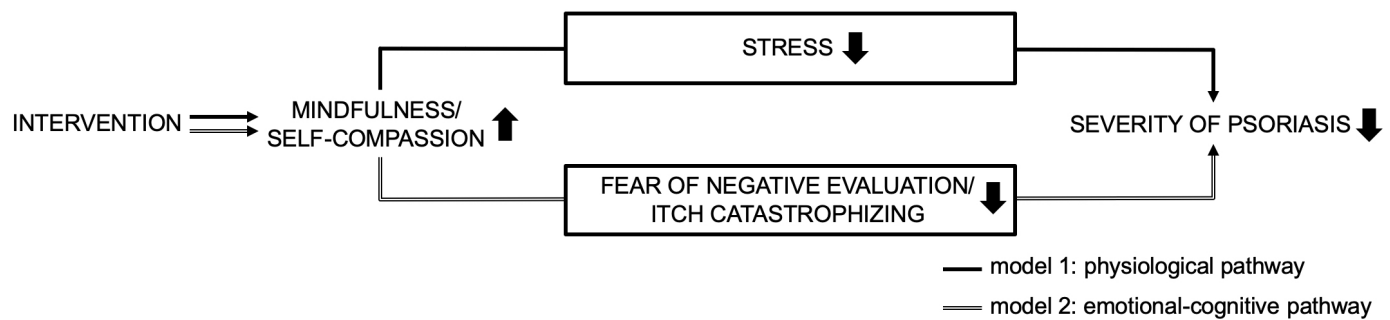


Figure 1 Proposed relationships between the assessed variables.

In participants need to answer several questionnaires during their first week at the clinic. Subjects of study 1a, who are interested in taking part in a short psychological intervention are considered for study 1b. During study 1b, data are collected at three times: before (t1), after the intervention (t2; short-term effects) and 3 months after the intervention (t3; medium-term effects, also see figure 2).

Inclusion and exclusion criteria

Persons aged between 18 and 65 years, who have been diagnosed with PS according to International Classification of Diseases (ICD)-10 criteria³¹ and had symptoms during the last 6 months will be included. The main reason to exclude elderly patients from participation in the study is that rehabilitation programmes are mainly offered to employed people in Germany. The aim of their stay at a rehabilitation clinic is that they learn to cope with their chronic disease in order to be able to return to work. In addition, cognitively impaired patients or patients with another itchy skin disease, patients with epilepsy or serious mental illnesses were excluded from the study, partly because the mindfulness training might have negative effects in some of these patients.³² Patients with meditation experience and/or experience in mindfulness practice will be included. In case the intervention and control group differ regarding this variable it will be considered as covariate.

Table 1 Study dates	
Action	Study dates
Ethical approval	March 2019
Submission of the study protocol	September 2019
Data collection	August 2019–July 2021
Data input	October 2019–August 2021
Data analysis	February 2020–December 2021
Manuscript preparation and presentation of study results at (inter) national conferences	January 2022–December 2022

Patient and public involvement

Patients and the public were not involved in planning the study.

Assignment

After taking part in study 1a and being included in study 1b, participants are randomly assigned to either the intervention or control group by a person not involved in data collection (staff at the Institute of Medical Psychology, Gießen, Germany). In order to randomise male and female subjects separately, two lists of codes (one for females and one for males) are provided. Randomisation is conducted by drawing cards including the subject-codes out of a closed box. Intervention allocations cannot be foreseen before enrollment. The personnel involved in the intervention as well as the patients are not blinded.

Mindfulness-based intervention

The intervention group will receive a 2-week mindfulness-based intervention in addition to TAU at the clinic. The training includes the essential components of a traditional mindfulness-based intervention, but has been adapted to the time available during a rehabilitation stay. All classes include meditation exercises (mindful perception of breathing sensations, walking or moving), a body scan and theoretical input (background information on practical and theoretical aspects of mindfulness as well as its application in patients with chronic itchy skin diseases like psoriasis). Two classes differ from this scheme: In class 1, patients will be introduced to the concept of mindfulness step-by-step and class 6 includes a longer meditation phase without reflection between the different exercises. Patients are encouraged to reflect their experiences and to share them with the group after each mindfulness exercise. At the end of each session, patients receive a handout summarising the respective class content. The scope of the training is equivalent to the minimum of 8 hours given in the literature over a period of 2 weeks (8×1 hours group exercises and 4×15 min of homework), and is on par with earlier studies that used brief mindfulness-based interventions.^{12 24} Groups meet four times per week for two consecutive weeks. For a detailed description of the intervention, see table 2.

The intervention will be conducted by a psychologist (BSc) with profound expertise in meditation (more

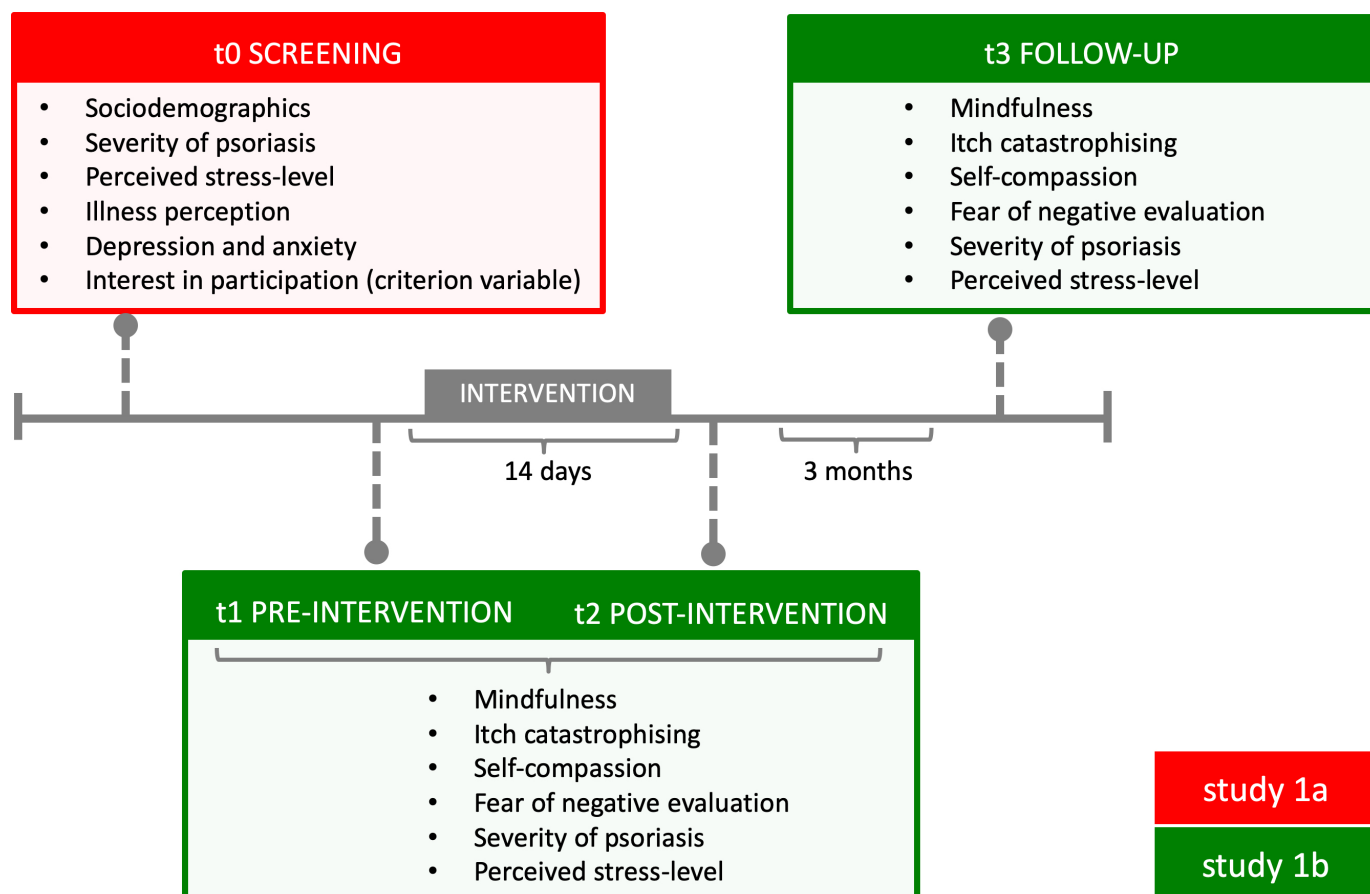


Figure 2 Study procedure.

than 5 years of experience in meditation and meditative body work, participation in several retreats), who was in contact with a clinical psychologist regarding the training or a mindfulness and insight meditation teacher (Vipassana) with 6 years of teaching experience (Dr. Julia Harfensteller). Participants of the control group receive TAU during their stay at the clinic. Three months after the intervention, participants of both groups receive a set of questionnaires to fill in at home. They are asked to return this questionnaire set postally as soon as possible.

Measures study 1A

Patients fill in questionnaires to assess sociodemographic and psychological variables as well as disease-related parameters. Data on comorbidities, presence of pruritus and its characteristics are also recorded. The criterion variable ‘interest in a short psychological intervention’ is assessed by asking the dichotomous question ‘Are you interested in participation in a short psychological intervention during your stay at the rehabilitation clinic?’.

Severity of PS is measured by the Self-Administered Psoriasis Area and Severity Index. The questionnaire records the severity of PS assessing redness, thickness and scalliness of the skin as well as the extent of affected areas.³³

The perceived stress level is measured by the Perceived Stress Scale.^{34 35} The instructions are modified to capture

perceived stress during the last week (instead of the last month). This modification is necessary to detect changes due to participation in the training at t2. The questionnaire comprises 10 items that need to be answered on a 5-point scale that ranges from ‘never’ to ‘very often’.

Patients’ illness perceptions will be measured by means of the German version of the Illness Perception Questionnaire,³⁶ which captures five dimensions of illness perception: disease identity, experienced causes, perceived consequences, perceived healing/control and course. The German version also includes specific skin symptoms to measure skin-related illness identity. The questionnaire includes 58 items (21 of them especially created for skin patients).

Depression and anxiety will be assessed using the Patient Health Questionnaire.³⁷ This short questionnaire includes four items (two to measure depression and two to measure anxiety) that need to be answered on a 4-point scale that ranges from ‘completely not’ to ‘almost every day’.

Measures study 1B

In addition to the severity of PS and perceived stress, which are measured by the same instruments as used in study 1a, mindfulness, self-compassion, fear of negative evaluation and itch-related cognitions are measured by validated questionnaires at all three time points:

Table 2 Details regarding the mindfulness-based intervention applied in this study

Class	Content
Class 1	1. Introduction meditation 2. Getting to know each other 3. Raisin exercise 4. Theory: What is the aim of the exercise and the training? 5. Closing
Class 2	1. Announcement of today's programme 2. Exercise: Mindful walking 3. Exercise: Body scan 4. Theory: What does mindfulness (not) mean? Which role does mindfulness play handling diseases? How is it possible to integrate mindfulness in a stay at a rehabilitation clinic? 5. Closing
Class 3	1. Announcement of today's programme 2. Exercise: Mindful moving 3. Exercise: Body scan 4. Theory: How can one cope with difficulties in meditation? Which inner attitude do we adopt? 5. Closing
Class 4	1. Announcement of today's programme 2. Exercise: Mindfulness of the breath 3. Exercise: Body scan 4. Theory: What is stress? How does it arise? Which role does it play in psoriasis? 5. Closing
Class 5	1. Announcement of today's programme 2. Exercise: Mindful walking 3. Exercise: Body scan 4. Theory: How can one cope with stress mindfully? 5. Closing
Class 6	1. Announcement of today's programme 2. Exercise: Mindful walking 3. Exercise: Mindful moving 4. Exercise: Body scan 5. Theory: Reflection 6. Closing
Class 7	1. Announcement of today's programme 2. Exercise: Mindfulness of the breath 3. Exercise: Body scan 4. Theory: How can one integrate mindfulness exercises in everyday life? Why is it necessary to practice mindfulness continuously? 5. Closing
Class 8	1. Announcement of today's programme 2. Exercise: Mindful moving 3. Exercise: Body scan 4. Theory: Discussion on how participants can integrate mindfulness in their everyday life 5. Closing

Mindfulness is measured using the Comprehensive Inventory of Mindfulness Experiences.¹³ This questionnaire captures different aspects of mindfulness that are

categorised into eight subscales: inner awareness, outer awareness, acting with awareness, acceptance, decentration, openness, relativity and insightful understanding. The questionnaire includes 37 items that are answered on a 6-point scale which ranges from 'almost never' to 'almost always'.

Self-compassion is assessed by the German short version of the Self-Compassion Scale (short form).^{38,39} This questionnaire includes 12 items that are answered on a 5-point scale from 'very seldom' to 'very often'.

Itch-related cognitions are measured by means of the Itch-Cognition Questionnaire (Juckreiz-Kognitions-Fragebogen; JKF).⁴⁰ This instrument assesses cognitions that are favourable for the course of the disease (scale coping) or unfavourable (scale catastrophising/helplessness). The JKF comprises 20 items that need to be answered on a 5-point scale from 'never' to 'always'.

Social anxiety is measured by the Fear of Negative Social Evaluation Questionnaire (short scale).⁴¹ This questionnaire comprises 12 items that need to be answered on a 5-point scale which ranges from 'completely does not characterise myself' to 'is extremely typical for me'.

More information regarding the reliability of these self-report instruments can be found in [table 3](#).

Statistical analysis

A G*Power-analysis⁴² revealed that n=127 patients have to be included in study 1a in order to detect medium effects assuming that all 12 potential predictors have an impact on the interest in the intervention ($\alpha=0.05$, $1-\beta=0.8$). In addition, the power analysis revealed that n=54 patients have to be included in study 1b in order to detect small to medium-sized effects on mindfulness/self-compassion using an analysis of variance (ANOVA) with repeated measures ($\alpha=0.05$, $1-\beta=0.8$; 2 groups, 3 measurement time points). We proposed that small to medium effects would occur due to a 2-week mindfulness-based training referring to a study,¹² in which also such a short mindfulness-based intervention had small to medium effects on cognitive variables. Data will be entered into SPSS by ME and LS. The data will be double checked by at least two persons working at the Institute of Medical Psychology of whom one was not involved in study planning or data collection. Data will be stored for at least ten years at the Institute of Medical Psychology, Gießen. The statistical analysis will be done using SPSS.⁴³ For study 1a, a binary multiple logistic regression will be performed to investigate whether the assessed variables are significant predictors of the dichotomous criterion variable 'interest in participation in a brief psychological intervention'. Data of study 1b will be analysed by means of ANOVA with repeated measures. The group (intervention or control) represents the between subject factor, the other assessed variables represent the innersubject factors. Main outcome parameters are mindfulness/self-compassion. The effects on the other outcome parameters are investigated exploratively. In addition, two mediation models will be tested in an explorative manner by

**Table 3** Information on the questionnaires used in the current study

Questionnaire	Assessed variable(s)	Reliability measures
Self-Administered Psoriasis Area and Severity Index ³³	PS severity	$r_{tt}=0.82$
Perceived Stress Scale 10 ³⁵	Perceived stress level	$\alpha=0.84$
Illness Perception Questionnaire ⁴⁴	Illness perception	$\alpha=0.73-0.82$
Patient Health Questionnaire ³⁷	Anxiety and depression	$\alpha=0.82$
Comprehensive Inventory of Mindfulness Experiences ¹³	Mindfulness	$r_{tt} \geq 0.70$ $\alpha \geq 0.70$ (except for one scale)
Short version of the Self-Compassion Scale (short form) ³⁹	Self-compassion	$\alpha=0.84$ $r_{tt}=0.83$
Itch-cognition questionnaire (JKF) ⁴⁵	Itch-related cognitions	$\alpha=0.78-0.90$
Fear of Negative Social Evaluation - Short Scale ⁴¹	Fear of negative social evaluation	$\alpha=0.94$ $r_{tt}=0.90$

JKF, Juckreiz-Kognitions-Fragebogen; PS, Psoriasis.

use of the SPSS macro PROCESS. Model 1 investigates whether mindfulness is related to the severity of PS and whether this relationship is mediated by perceived stress, model 2 tests whether this relationship is mediated by itch catastrophising and fear of negative evaluation.

ETHICS AND DISSEMINATION

The study is conducted in concordance with the declaration of Helsinki. The local ethics committee of the department of Medicine at the Justus-Liebig-University has approved the study before the beginning of the study (date of IRB approval: 21 March 2019; AZ 19/19). In addition, the Deutsche Rentenversicherung Bund (DRV-Bund) approved the conductance of the study before recruiting the first study participant. All eligible patients are informed about the purpose and procedure of the study. Subjects participate in the study on a voluntary basis. They receive €15 for participation in study 1a and no monetary compensation for participation in study 1b. It is taken care of that patients for whom mindfulness procedures are not suitable are excluded from participation in the study (also see exclusion criteria). Data collection will be stopped as soon as the sample size is reached. No harm outcomes are expected.

Study results will be published in international peer-reviewed journals and presented at (inter)national conferences. Interim analyses have been conducted for study 1b in order to present preliminary findings of the study at the conference of the European Health Psychology Society in 2020. This conference has been cancelled due to the Corona Virus recently.

In case of positive effects, the course manual is planned to be made available not only to psychologists working at the rehabilitation clinic Borkum, but also to psychologists working at other rehabilitation clinics in Germany. In case we identify certain predictors of interest in psychological interventions and additionally show that participation in a short mindfulness-based intervention is successful,

we plan to conduct a follow-up study in which we aim to motivate patients not interested in psychological interventions to participate in such a training (eg, by use of motivational interviewing techniques). In case protocol amendments will be conducted, the trial registry (DRKS) will be informed.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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