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# Protocol for a randomized controlled intervention study on a brief mindfulness based intervention for patients with psoriasis: Who is interested and is it effective?



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| Complete List of Authors: | Stadtmüller, Laura; Justus Liebig Universitat Giessen, Institute of Medical Psychology<br>Eckardt, Markus; Justus Liebig Universitat Giessen, Institute of Medical Psychology<br>Zick, Christoph; Rehabilitation Clinic Borkum Riff, Borkum, Germany , Department of Dermatology<br>Kupfer, Joerg; Justus Liebig Universitat Giessen, Institute of Medical Psychology<br>Schut, Christina; Justus Liebig Universitat Giessen, Institute of Medical Psychology |
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# Protocol for a randomized controlled intervention study on a brief mindfulness based intervention for patients with psoriasis: Who is interested and is it effective?

Stadtmüller L[1]*, Eckardt M[1]*, Zick C[2], Kupfer J[1], Schut C[1].

* These authors contributed equally to this work and should both be considered first authors

1 Institute of Medical Psychology, Justus-Liebig-University Gießen, Germany

2 Rehabilitation Clinic Borkum Riff, Borkum, Germany

Correspondence to:

Dr. Christina Schut

Institute of Medical Psychology

Justus-Liebig-University Gießen

Klinikstraße 29

35392 Gießen

Tel: +49 641 9945682

Email: Christina.Schut@mp.uni-giessen.de

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Authors' contributions: LS, ME and CS wrote the study protocol. JK and CZ critically reviewed the manuscript and made suggestions how to improve.

Keywords: mindfulness, psoriasis, itch-catastrophizing, RCT, rehabilitation clinic

## ABSTRACT


### Introduction

Psoriasis (PS) is a chronic inflammatory skin disease that in the majority of patients goes along with chronic pruritus and a reduced quality of life. Mindfulness describes the ability to focus on the present moment without evaluating it. Initial findings on the effects of mindfulness training in PS-patients revealed that an eight-week mindfulness training has positive effects on disease symptoms and quality of life. However, previous studies did not investigate what distinguishes PS patients, who are interested in psychological interventions from those who are not and whether a *short* (2 weeks) mindfulness-based intervention has beneficial effects in PS patients. Thus, this study aims to identify predictors for interest in taking part in a short psychological intervention as well as its short and medium-term effects in this patient group.

### Methods and analyses

Data will be collected at the rehabilitation clinic Borkum Riff, Germany. The study includes two parts (study 1a and 1b). Study 1a is an observational cross-sectional study and investigates in 127 PS-patients whether age, gender, level of education, PS-severity, the current stress level, anxiety, depression and illness perception are significant predictors of interest in participation in a brief psychological intervention. Study 1b explores the effects of a brief two-week mindfulness intervention on mindfulness, self- compassion, itch-catastrophizing, anxiety of negative social evaluation, severity of PS and perceived stress. 60 patients will be recruited consecutively from study 1a and randomized to either the intervention or control group. Patients will complete validated questionnaires to assess the different outcome variables.

### Ethics and dissemination

The study protocol has been approved by the University of Giessen. Informed consent will be given by each participant. Study results will be disseminated by publication of the results in international, peer-reviewed journals and by presentation of the results at (inter-)national conferences.

**Trial registration number**: DRKS00017426

## Strengths and limitations of this study

- The randomized, controlled design of the study is a strength.
- The determination of medium-term effects of the trainings (3-month-follow-up) is another strength of the study.
- Having no active control group is a limitation.
- Transferability of the study results to everyday life could be a limitation as the study is conducted at a rehabilitation clinic.

## INTRODUCTION

### Psoriasis

PS is a chronic relapsing skin disease with a prevalence of 3% in western countries.[1] The likelihood to have PS is associated with, among other things age, sex, resident and ethnicity of the patients.[2]

In PS patients, quality of life is similarly reduced as in patients with cardiovascular disease.[3] The severity of PS depends on genetic and environmental factors.[4] In addition, 37-78% of PS patients believe that their disease is exacerbated by stress.[5] These patients can be referred to as stress responders.[6] It is necessary to identify patient characteristics that explain the differential effectiveness of psychological procedures in PS patients.[7]

### Mindfulness

Mindfulness is a process of bringing one's attention to experiences occurring in the present moment without judging.[8] Mindfulness and the effects of mindfulness-based interventions are currently investigated intensively. Especially, interest in the effect mechanisms and in the range of potentially benefiting patient populations has grown rapidly in the last 30 years.

Standardized mindfulness interventions typically last eight weeks, with new topics being tackled once a week in a group session (lasting approximately two hours) led by a teacher.[9] Participants are encouraged to practice the learned techniques for 45 minutes each day until the next session.[9] Techniques usually include breath meditation and the body scan. During the breath meditation, the participants are instructed to focus on the breathing process (e.g., raising and falling of the belly). During the body scan, attention is systematically moved through the body (e.g., first through the foot, over the leg, etc., to the crown).[9] Participants are taught to have a patient and gentle attitude towards themselves, when directing their attention back to the object of meditation.[9] Recent studies in which *brief* mindfulness-based interventions were investigated, found significant effects on stress, mood, and cognitive performance. [10,11] Mindfulness can be captured using standardized questionnaires [e.g.12] and be purposefully increased in meditation practice, which is the basis for various clinical interventions.[13,14]

## Effects of mindfulness in patients with chronic diseases

The first clinical interventions to increase mindfulness were developed for pain patients.[15] Over time there have been adapted, further interventions, e.g. to relapse prevention in relapsing depressed patients.[14]

Meanwhile, there are several meta-analyses and systematic reviews on the multiple effects of mindfulness.[13,16-19] Currently, mindfulness-based practices are believed to have an impact primarily on changing cognitive and emotional reactivity of patients, increasing awareness, reducing rumination and anxiety, increasing self-compassion, and psychological flexibility.[18]

In chronic pain patients, it has been shown that low levels of mindfulness are associated with catastrophic thinking.[20] A significant correlation between certain facets of mindfulness and itch catastrophizing was also found in a study of the own working group in dermatological patients (here: atopic dermatitis patients; Schut et al., in prep.). Another study, including PS-patients, showed that a mindfulness training of eight weeks had positive effects on the severity of psoriasis as well as on quality of life.[21] One point of criticism of previous studies on mindfulness-based interventions in PS patients was that PS patients were not asked about their need for a psychological intervention, even though interventions adapted to patient needs could lead to greater effects.[22] Also, the duration of traditional mindfulness-based programs makes implementation difficult during a hospital stay. Patients in the planned study will therefore be asked whether they are interested in participating in a psychological intervention and the effects of a brief mindfulness-based training will be assessed.

## Objectives

Study 1a aims to investigate in PS patients whether sociodemographic factors, psychological variables or the severity of the diseases are significant predictors of interest to take part in a short psychological intervention during the stay at a rehabilitation clinic.

Study 1b aims to investigate the short- and medium-term effects of a short mindfulness-based intervention on mindfulness.

## METHODS AND ANALYSIS

### Setting

Data collection will take place at the rehabilitation clinic Borkum Riff in Germany inbetween August 2019 and October 2019 (also see Table 1). In case not enough patients can be included during this time, another phase of data collection will be added from February to April 2020.

### Procedure

The study is divided into two substudies: study 1a and 1b, for which patients will receive separate study information and give their informed consent separately. Study 1a investigates predictor variables for interest in a short psychological intervention during the stay at a rehabilitation clinic at one time point (during the first week of the stay at the clinic). Subjects of study 1a, who reported to be interested in taking part in a short psychological intervention during their stay at the clinic, will be considered for study 1b ("Effects of a short mindfulness based intervention"). The design of study 1b envisages collecting data at three time points using questionnaires. The first measurement will take place before (t1) and the second after the intervention (t2; short-term effects). At the third survey date (three months after the intervention, t3), medium-term effects of the intervention will be investigated (also see Fig. 1).

The brief intervention will contain the essential components of a classic mindfulness intervention (mindfulness practice, exchange of experience, homework), but at the same time be adapted to the time available during a rehabilitation stay. As meditation techniques in particular the basics of breathing meditation and body-scan will be taught using standardized instructions. The instructions are formulated to encourage the patient to have a compassionate attitude towards their own practice. The scope of the training is equivalent to the minimum of eight hours given in the literature over a period of two weeks (8 x 1 hour group exercises and 4 x 15 minutes of homework), and is on a par with earlier studies that used brief mindfulness interventions.[11,23] The intervention will be conducted by a bachelor psychologist. While the intervention group will receive the training, the control group will receive treatment as usual during their stay at the clinic. Three months after the end of the training, participants of both groups (intervention and control group) will receive a set of validated questionnaires to fill in

at home. They will be asked to return the data set via mail during the upcoming two weeks. The timeline of the study is illustrated in Fig. 2.

## Inclusion and exclusion criteria

The main criteria for eligibility are an age between 18 and 65 years, being diagnosed with PS according to ICD-10 criteria for more than six months.[24]

The following exclusion criteria are used to ensure that patients are not cognitively impaired or have another itchy skin disease, and to exclude the risk of reactivation of disease-specific symptoms through a mindfulness-based intervention[25]: presence of other skin-related disorders associated with itching, presence of dementia, presence of epilepsy or of serious mental illnesses.

## Assignment

The patients are informed about the study at the beginning of their stay at the rehabilitation clinic on Borkum by a nurse, their physician in charge or a medical student. They receive information about the study and give their informed consent. They will be randomly assigned to either the experimental or control group by a person not involved in data collection. Gender is stratified.

## Outcome measures

Patients and controls will fill in different questionnaires to gather sociodemographic and disease-related information including education, age, gender, employment and disease characteristics such as duration and localization of skin disease. Data on comorbidities, presence of pruritus and its characteristics will also be recorded. The criterion variable of study 1b will be assessed by asking the question “Do you have interest to participate in a brief psychological intervention during your stay at the rehabilitation clinic?”, which needs to be answered with yes or no. To gather information on the other predictor and outcome variables validated German questionnaires were chosen.

### *The severity of PS*

will be measured by the Self-Administered Psoriasis Area and Severity Index (SAPASI). The questionnaire records the severity of PS assessing redness, thickness and scaliness of the skin as well as the extent of affected areas.[26]

*The perceived stress level*

will be measured by the Perceived Stress Scale 10 (PSS-10).[27,28] The instructions will be modified to capture the perceived stress during the last week (instead of the last month). This modification is necessary in order to be able to detect changes due to participation in the training at t2. The questionnaire comprises ten items that need to be answered on a five-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 (IPQ)[29,30], 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. It includes 58 items (21 of them especially created for skin patients).

*Depression and anxiety*

Will be assessed using the Patient Health Questionnaire (PHQ-4)[31].This short questionnaire includes 4 items (two to measure depression and two to measure anxiety) that need to be answered on a four-point-scale that ranges from “completely not” to “almost every day”.

*Mindfulness*

will be measured using the Comprehensive Inventory of Mindfulness Experiences (CHIME) [12]. This questionnaire captures different aspects of mindfulness that can be categorized into eight subscales: inner awareness, outer awareness, acting with awareness, acceptance, decentration, openness, relativity and insight are recorded by answering a total of 37 items that are answered on a six-point-scale which ranges from “almost never” to “almost always”.

*Self-compassion*

is captured by the German short version of the Self-Compassion Scale (SCS-D short form). [32,33] This questionnaire includes 12 items that need to be answered on a five-point- scale from “very seldom” to “very often”.

*Itch-related cognitions*

will be measured by means of the Itch-Cognition Questionnaire (Juckreiz-Kognitions-Fragebogen; JKF).[34] This instrument assesses cognitions that are favorable for the course of the disease (scale coping) or unfavorable (scale catastrophizing/

helplessness). The JKF comprises 20 items that need to be answered on a five-point-scale from “never” to “always”.

*Social anxiety*

As a measure of social anxiety, the fear of negative social evaluation (short scale; FNE-K) will be used.[35] This questionnaire comprises 12 items that need to be answered on a five-point-scale which ranges from “completely does not characterize myself” to “is extremely typical for me”.

All self-report measures as well as the information whether they are included in substudy 1a and/ or 1b are included in Table 2.

## Statistical analysis

The number of patients that need to be included in study 1a and 1b in order to be able to determine medium-sized effects has been calculated beforehand using G-Power.[36] The statistical analysis will be done using SPSS 24.[37] 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 separate analysis of variance (ANOVA) for the various dependent variables. The group (EG or CG) represents the between subject factor, the dependent variables represent the inner subject factors.

## Ethics

The study will be conducted in concordance with the declaration of Helsinki. All eligible patients will be informed about the purpose of the study, the expected duration of filling in the questionnaires and procedure of the study. Subjects participate on a voluntary basis. The data will be pseudonymised in such a way that every participant will create his own test code following the instructions on the first page of the data set. This code will be created by the participants each time they fill in questionnaires. They receive 15 € for participation in study 1a and no monetary compensation for participation in study 1b. For study 1b, their motivation is to contribute to the improvement regarding the therapy of PS. By filling in the questionnaires they are not exposed to any risks. Care is taken that patients for whom mindfulness procedures are not suitable are excluded from participating in the study (see also exclusion criteria).

The local ethics committee of the department of medicine at the Justus-Liebig-University approved the study (date of IRB approval: 03/21/2019; AZ 19/19). In addition, the Deutsche Rentenversicherung Bund (DRV-Bund) approved the conductance of the study before the recruitment of the first study participant.

## Patient and Public Involvement

Patients and the public were not involved in the planning of the study. However, study results will not only be disseminated by publication in international peer-reviewed journals and presentations at national and international meetings, but also the course manual is planned to be made available to the psychologists on Borkum. They will be coached in the implementation of the intervention. In addition, teach the teacher workshops will be offered in other rehabilitation clinics together with the leading psychologist of the DRV- Bund in order to achieve the mindfulness-based effects with dermatological rehabilitation care. Thus, DRV-Bund will be involved in the dissemination of the research.

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## Tables

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

Table 1. Study dates.

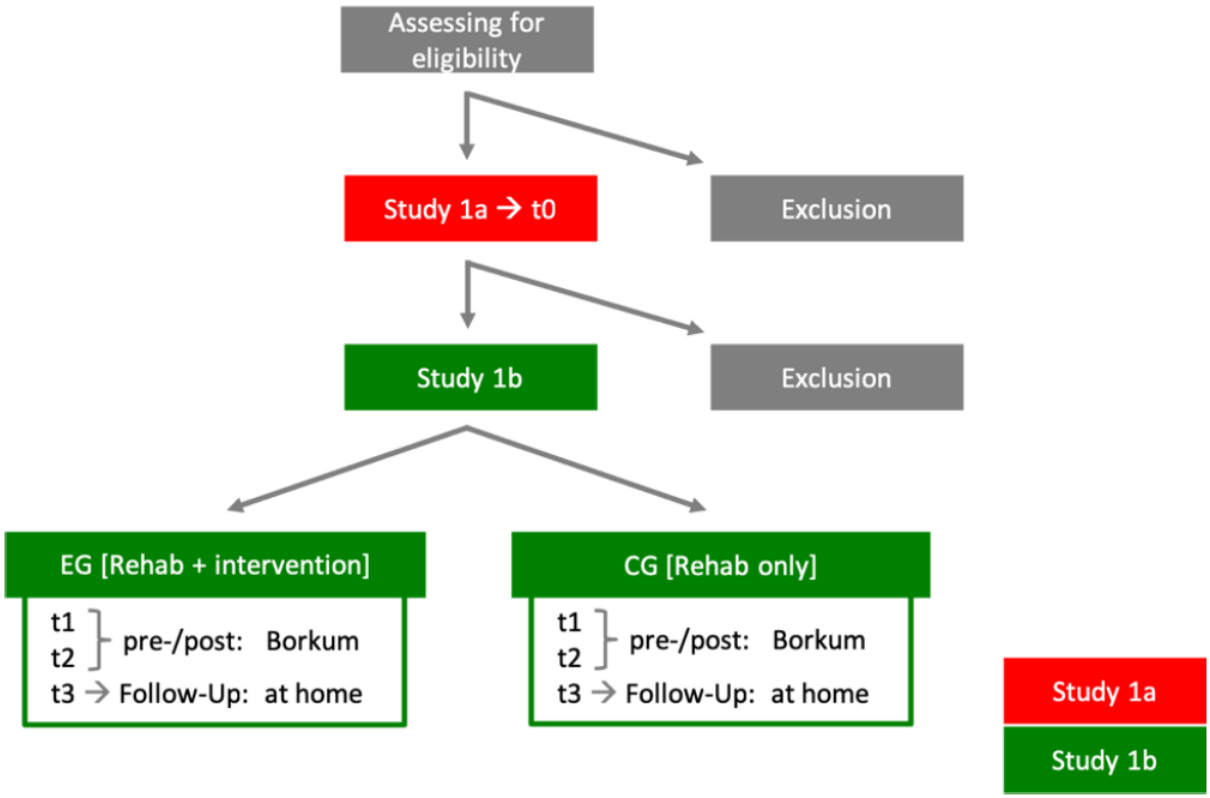
| Questionnaire | Assessed variable(s) | Used in study |
|---|---|---|
| Self-Administered Psoriasis Area and Severity Index (SAPASI) | PS severity | Study 1a and 1b |
| Perceived Stress Scale 10 (PSS-10) | Perceived stress level | Study 1a and 1b |
| Illness Perception Questionnaire (IPQ) | Illness perception | Study 1a |
| Patient Health Questionnaire (PHQ-4) | Anxiety and depression | Study 1a |
| Comprehensive Inventory of Mindfulness Experiences (CHIME). | Mindfulness | Study 1a and 1b |
| Short version of the Self-Compassion Scale (SCS-D short form). | Self-compassion | Study 1b |
| Itch-cognition questionnaire (JKF) | Itch-related cognitions | Study 1b |
| Fear of negative social evaluation - short scale (FNE-K) | Fear of negative social evaluation | Study 1b |

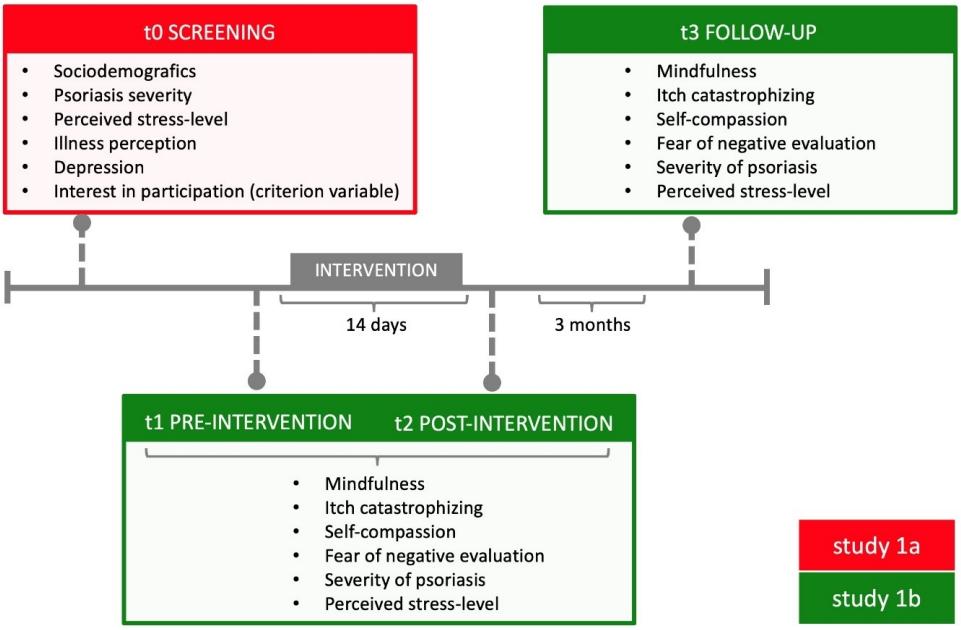
Table 2. Overview of the used questionnaires.

## Figure Legends

**Fig. 1. Study and recruitment procedure.** Rehab: Treatment as usual during the stay at the clinic. t: time point of measurement

**Fig. 2. Time points of the study and used self-report measures at the different times.**


Assessing for eligibility
Study 1a → t0
Exclusion
Study 1b
Exclusion
EG [Rehab + intervention]
t1
t2
pre-/post: Borkum
t3 → Follow-Up: at home
CG [Rehab only]
t1
t2
pre-/post: Borkum
t3 → Follow-Up: at home
Study 1a
Study 1b

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Stadtmüller L[1]*, Eckardt M[1]*, Zick C[2], Kupfer J[1], Schut C[1].

* These authors contributed equally to this work and should both be considered first authors

1 Institute of Medical Psychology, Justus-Liebig-University Gießen, Germany

2 Rehabilitation Clinic Borkum Riff, Borkum, Germany

Correspondence to:

Dr. Christina Schut

Institute of Medical Psychology

Justus-Liebig-University Gießen

Klinikstraße 29

35392 Gießen

Email: Christina.Schut@mp.med.uni-giessen.de

Tel: +49 641 9945682

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## ABSTRACT

### Introduction

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

### Methods and analyses

Data will be collected at the rehabilitation clinic Borkum Riff, Germany. The study includes two parts: Study 1a is a cross-sectional study aiming to identify sociodemografic, skin-related and psychological factors as predictors of interest in a brief psychological intervention in 127 PS-patients. Study 1 b is a RCT, in which 60 patients (from study 1a) will be randomized to an intervention or control group (treatment as usual). Two mediation analyses will test whether participation leads to an increase in mindfulness/ self- compassion followed by lower itch- catastrophizing, anxiety of social evaluation and subsequently lower severity of PS. The second model tests whether the relationship between mindfulness/ self-compassion and the severity of psoriasis is mediated by perceived stress. In case we are able to identify predictors of interest AND the training is effective in these interested patients, the acceptance of psychological interventions in patients who were not interested in participation should be increased (e.g. by motivational interviewing techniques).

#### Ethics and dissemination

The study protocol has been approved by the University of Giessen. Study results will be disseminated by publication of the results and presenting them at (inter-)national conferences.

**Trial registration numbers**: DRKS00017426 (study 1a) and DRKS00017429 (study 1b)

## Strengths and limitations of this study

- The randomized, controlled design of the study is a strength.
- The determination of medium-term effects of the trainings in a 3-months-follow-up is also a strength of the study.
- A second long-term follow-up after e.g. 12 or even 24 months would have been beneficial and can be regarded as a limitation of the study.
- The fact that the severity of the skin disease is only assessed by the patients themselves and not by their doctors in charge could be a limitation.
- Transferability of the study results to everyday life could be a limitation as the study is conducted at a rehabilitation clinic.

## INTRODUCTION

### Psoriasis

PS is a chronic relapsing skin disease with a prevalence of 3% in western countries.[1] The likelihood to have PS is associated with, among other things age, sex and ethnicity of the patients.[2] In PS patients, quality of life is similarly reduced as in patients with cardiovascular disease.[3] The severity of PS not only depends on genetic and environmental factors.[Error! Reference source not found.], 37-78% of PS patients believe that their disease is exacerbated by stress.[5] These patients can be referred to as stress responders.[6] It is necessary to identify patient characteristics that explain the differential effectiveness of psychological procedures in PS patients.[7]

### Mindfulness

Mindfulness is a process of bringing one's attention to experiences occurring in the present moment without judging.[8] Mindfulness and the effects of mindfulness-based interventions are currently investigated intensively. Especially, interest in the effect mechanisms has grown rapidly in the last 30 years. Standardized mindfulness based interventions typically last eight weeks, with new topics being tackled once a week in a group session (lasting approximately two hours) led by a teacher.[9] Participants are encouraged to practice the learned techniques for 45 minutes each day until the next session.[9] Techniques that are usually part of a mindfulness training are breath meditation and the body scan. During the breath meditation, participants are instructed to focus on the breathing process (e.g., raising and falling of the belly). During the body scan, attention is systematically moved through the body (e.g., first through the foot, over the leg, etc., to the crown).[9] Participants are taught to have a patient and gentle attitude towards themselves, when directing their attention back to the object of meditation.[9] Recent studies in which *brief* mindfulness-based interventions were investigated, also found significant effects on stress, mood, and cognitive performance.[10,11] Mindfulness can be captured using standardized questionnaires [e.g.12] and purposefully increased in meditation practice, which is the basis for various clinical interventions.[13,14]

## Effects of mindfulness in patients with chronic diseases

The first clinical interventions to increase mindfulness were developed for pain patients.[15] Over time interventions have been adapted, e.g. to relapse prevention in depressed patients.[14]

Meanwhile, there are several meta-analyses and systematic reviews on the multiple effects of mindfulness. e.g. [13,16-19] Currently, mindfulness-based practices are believed to have an impact primarily on changing patients' cognitive and emotional reactivity, increasing awareness, reducing rumination and anxiety, increasing self-compassion, and psychological flexibility.[18]

## Effects of mindfulness based interventions in patients with psoriasis

One of the first studies on mindfulness in patients with psoriasis compared the effects of a few minutes MBSR three times per week over 13 weeks to treatment as usual (TAU). Significant differences were found with regard to physiological psoriasis outcomes parameters, but not concerning psychological outcome variables [20]. Another very early study [21] explored the effects of a 12-week intervention consisting of meditation vs. meditation + imagery compared to a waiting list control group and an assessment control group (less measuring time points, not on the waiting list). Again, there were significant improvements in psoriasis outcomes in the intervention groups compared to the control groups. However, psychological measures were not assessed in this study. More recent studies brought mixed evidence to light [7, 22,23]: A pilot-study using mindfulness-based cognitive therapy (MBCT) showed that a mindfulness training of eight weeks had positive effects on the severity of psoriasis and quality of life.[22] In contrast, a similar study [7] found no significant differences, neither on psychological nor on physical outcomes, when comparing various mindfulness-based interventions to TAU immediately post-treatment or in a follow-up. According to the authors, floor effects might have been one factor leading to these results as the psoriasis severity in this sample was mild-to-moderate at the beginning. The most recent randomized trial [23] compared the effects of MBCT vs. TAU on psoriasis outcomes and psychological dimensions. Here, participation in an eight-week MBCT program led to significant improvements in both, psoriasis and psychological outcomes, which were not observed in the control group.

Recent reviews [24,25] conclude that the effects of psychological interventions in patients with psoriasis, including mindfulness-based trainings, need to be studied further due

to several reasons: studies e.g. often only included less than 50 patients, follow-ups were missing and/ or patients were not blinded.

In addition, previous studies on mindfulness-based interventions in PS patients were criticized as PS patients were not asked about their subjective wish and need to take part in a psychological intervention, even though interventions adapted to patient needs could lead to greater effects.[24] Also, the duration of traditional mindfulness-based programs makes implementation during a hospital stay difficult. Therefore, the current studies aim to identify predictors of interest in psychological interventions and whether also a two-week mindfulness-based interventions has positive effects in psoriasis.

### Objectives

Study 1a aims to investigate in PS patients whether sociodemographic factors, psychological variables or the severity of the disease are significant predictors of interest to participate in a short psychological intervention during a stay at a rehabilitation clinic.

Study 1b aims to investigate the short- and medium-term effects of a short mindfulness-based intervention. . Hereby, models derived from theoretical considerations and the literature on proposed effects of mindfulness in patients with chronic pain [26] will be tested. In detail, we hypothesize that participation in a mindfulness training will increase mindfulness and self-compassion, which will in turn lower perceived stress and given the physiological consequences of stress, also improve the skin status (physiological pathway). In a second model we propose that increased mindfulness and self-compassion due to participation in a mindfulness-based training will lead to lower itch catastrophizing and lower fear of negative evaluation and subsequently also to a better skin status (emotional-cognitive pathway).

## METHODS AND ANALYSIS

### Setting

Data collection will take place from August 2019 to July 2020 (also see table 1).

### Procedure

Before participation in either study 1a /1bpatients will receive separate study information and give their informed consent separately. When taking part in study 1a participants answer several questionnaires at one time point, namely during the first

week at the clinic. Subjects of study 1a, who reported to be interested in taking part in a short psychological intervention during their stay at the clinic, will be considered for study 1b. During study 1b data will be collected three times: before (t1), after the intervention (t2; short-term effects) and three months after the intervention (t3, also see Fig 1).

## Inclusion and exclusion criteria

Persons aged between 18 and 65 years, who have been being diagnosed PS according to ICD-10 criteria for more than six months[27] will be included. The main reason to not include elderly patients is that rehabilitation programs in Germany are only offered to employed people. The aim of the stays at rehabilitation clinics is that patients learn to cope with their chronic diseases, which at the end should reduce absences from work. In addition, cognitively impaired patients or patients with another itchy skin disease, patients with epilepsy or of serious mental illnesses were excluded from the study, partly because the mindfulness training might have negative effects in some of these patients. [28]

## Assignment

After taking part in study 1a and being included in study 1b, participants are randomly assigned to either the experimental or control group by a person not involved in data collection, the secretary of the Institute of Medical Psychology in Gießen, Germany. In order to conduct the randomization for male and female subjects separately, two lists of codes are sent to him at the end of the recruiting week (Friday morning). He then conducts the randomization by drawing cards including the subject-codes out of a closed box.

## Mindfulness-based intervention

The two-week mindfulness intervention will contain the essential components of a classic mindfulness intervention (mindfulness practice, exchange of experience, homework) adapted to the time available during a rehabilitation stay. As meditation techniques in particular the basics of breathing meditation and body-scan will be taught using standardized instructions. The instructions are formulated to encourage the patient to have a compassionate attitude towards their own practice. The scope of the training is equivalent to the minimum of eight hours given in the literature over a period

of two weeks (8 x 1 group exercises and 4 x 15 minutes of homework), and is on a par with earlier studies that used brief mindfulness interventions.[11,23] Groups meet 4 times per week for two consecutive weeks. For a detailed description of the intervention, please see table 2. The intervention will be conducted by a Psychologist (B. Sc.) with profound expertise in meditation (more than 5-years of experience in meditation and meditative body work, participation in several retreats). While the intervention group will receive the training, the control group will receive treatment as usual during their stay at the clinic. Three months after the end of the training, participants of both groups (intervention and control group) will receive a set of validated questionnaires to fill in at home. They will be asked to return the data set via mail during the upcoming two weeks. The timeline of the study is illustrated in Fig 2.

## Measures – study 1a

Patients will fill in different questionnaires to assess sociodemographic and psychological variables as well as disease-related parameters. Data on comorbidities, presence of pruritus and its characteristics will also be recorded. The criterion variable will be assessed by asking the question "Do you have interest to participate in a short psychological intervention during your stay at the rehabilitation clinic"?, is answered with yes or no. To gather information on the predictor variables the following questionnaires will be used:

*Severity of Psoriasis* will be measured by the Self-Administered Psoriasis Area and Severity Index (SAPASI). The questionnaire records the severity of PS assessing redness, thickness and scaliness of the skin as well as the extent of affected areas.[29]

*The perceived stress level* will be measured by the Perceived Stress Scale 10 (PSS-10).[30,31] The instructions will be modified to capture the perceived stress during the last week (instead of the last month). This modification is necessary in order to be able to detect changes due to participation in the training at t2. The questionnaire comprises ten items that need to be answered on a five-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 (IPQ)[32], 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. It includes 58 items (21 of them especially created for skin patients).

*Depression and anxiety* will be assessed using the Patient Health Questionnaire (PHQ-4)[33].This short questionnaire includes 4 items (two to measure depression and two to measure anxiety) that need to be answered on a four-point-scale that ranges from "completely not" to "almost every day".

## Measures – study 1b

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

*Mindfulness* will be measured using the Comprehensive Inventory of Mindfulness Experiences (CHIME)[12]. This questionnaire captures different aspects of mindfulness that can be categorized into eight subscales: inner awareness, outer awareness, acting with awareness, acceptance, decentration, openness, relativity and insight are recorded by answering a total of 37 items that are answered on a six-point-scale which ranges from "almost never" to "almost always".

*Self-compassion*

is captured by the German short version of the Self-Compassion Scale (SCS-D short form). [34,35] This questionnaire includes 12 items that need to be answered on a five-point- scale from "very seldom" to "very often".

*Itch-related cognitions*

will be measured by means of the Itch-Cognition Questionnaire (Juckreiz-Kognitions-Fragebogen; JKF).[36] This instrument assesses cognitions that are favorable for the course of the disease (scale coping) or unfavorable (scale catastrophizing/ helplessness). The JKF comprises 20 items that need to be answered on a five-point-scale from "never" to "always".

*Social anxiety*

will be measured by the fear of negative social evaluation questionnaire (short scale; FNE-K).[37] This questionnaire comprises 12 items that need to be answered on a five-point-scale which ranges from "completely does not characterize 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

The number of patients that need to be included in study 1a and 1b in order to be able to determine medium-sized effects has been calculated beforehand using G-Power.[38] The statistical analysis will be done using SPSS 24.[39] 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 mindfulness-based intervention". Data of study 1b will be analysed by means of separate analysis of variance (ANOVA) for the various dependent variables. The group (EG or CG) represents the between subject factor, the dependent variables represent the inner subject factors. In addition, two mediation models will be tested by use of the SPSS macro PROCESS. Model 1 investigates whether participation in mindfulness training leads to higher mindfulness and self-compassion and whether the relationship between mindfulness/ self-compassion and the severity of the skin disease is mediated by stress (physiological pathway). The second model will test whether there are direct effects of increased mindfulness on the skin status and whether these effects are mediates by a reduction in itch catastrophizing and fear of negative evaluation.

## Ethics and dissemination

The study will be 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 protocol before the beginning of the study (date of IRB approval: 03/21/2019; 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 will receive 15 € for participation in study 1a and no monetary compensation for participation in study 1b. Care is taken that patients for whom mindfulness procedures are not suitable are excluded from participating in the study (see also exclusion criteria).

Study results will be published in international peer-reviewed journals and presented at (inter-)national conferences. In case of positive effects, the course manual is planned to be made available not only to psychologists working in the rehabilitation

clinic on Borkum, but also to psychologists working in other rehabilitation clinics that treat patients with chronic skin diseases. In case we are able to identify certain predictors of interest in psychological interventions and are able to additionally show that participation in a short mindfulness-based intervention is successful, we plan to conduct a follow-up study in which we would like to also motivate who are not interested in psychological interventions to participate in such a training (e.g. by use of motivational interviewing techniques) in order to see whether it would also be fruitful in these patients.

## Patient and Public involvement

No patient involved

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## Tables

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

Table 1. Study dates.

| Class | Content |
|---|---|
| Class 1 | 1. Introduction meditation<br>2. Getting to know each other and the group framework<br>3. Practice: raisin exercise<br>4. Theory: What is the aim of the exercise and the training? |
| Class 2 | 1. Announcing of today's program<br>2. Practice: mindful walking<br>3. Practice: body-scan<br>4. Theory: What does mindfulness (not) mean? Which role does mindfulness play in the handling of diseases? How is it possible to integrate mindfulness in a rehab stay?<br>5. Closing |
| Class 3 | 1. Announcing of today's program<br>2. Practice: mindful moving<br>3. Practice: body-scan<br>4. Theory: How can one cope with difficulties in meditation? Which inner attitude do we adopt?<br>5. Closing |
| Class 4 | 1. Announcing of today's program<br>2. Practice: mindfulness of the breath<br>3. Practice: body-scan<br>4. Theory: What is stress? How does it arise? Which role does it play in psoriasis?<br>5. Closing |
| Class 5 | 1. Announcing of today's program<br>2. Practice: mindful walking<br>3. Practice: body-scan<br>4. Theory: How can one cope with stress mindfully?<br>5. Closing |
| Class 6 | 1. Announcing of today's program<br>2. Practice: mindful walking<br>3. Practice: mindful moving<br>4. Practice: body-scan<br>5. Theory: Reflection<br>6. Closing |
| Class 7 | 1. Announcing of today's program<br>2. Practice: mindfulness of the breath<br>3. Practice: body-scan<br>4. Theory: How can one integrate mindfulness exercises in everyday life? Why does mindfulness need a continuous practice?<br>5. Closing |
| Class 8 | 1. Announcing of today's program<br>2. Practice: mindful moving<br>3. Practice: body-scan<br>4. Theory: Discussion on how participants can integrate mindfulness in their everyday life<br>5. Closing |

Table 2. Intervention details. All classes include a focus meditation practice (mindful perception of the 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 on 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 will focus on the practice of mindfulness (longer meditation time without reflection between the different exercises). Patients will be encouraged to reflect their experiences and to share them with the group after the each mindfulness exercise. At the end of each session, patients receive a handout summarizing the respective class content.

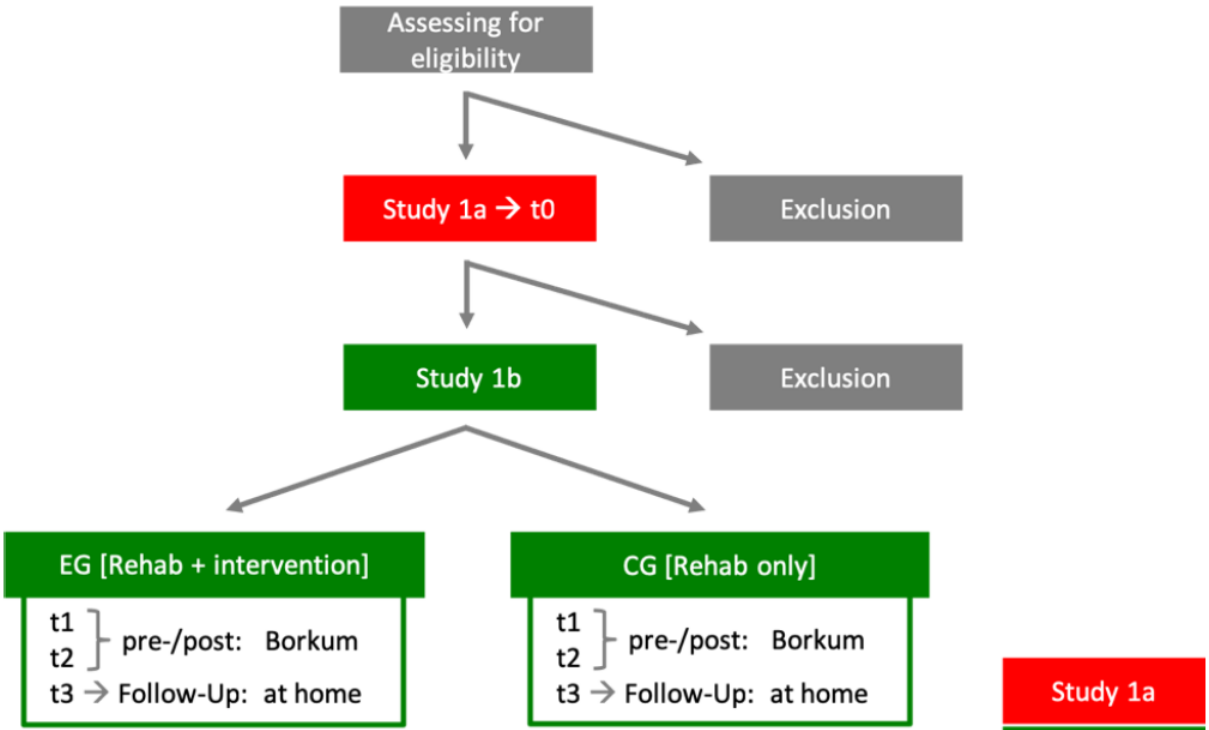
| Questionnaire | Assessed variable(s) | Reliability measures |
|---|---|---|
| Self-Administered Psoriasis Area and Severity Index (SAPASI)[29] | PS severity | $r_{tt}$ = .82 |
| Perceived Stress Scale 10 (PSS-10)[31] | Perceived stress level | α = .84 |
| Illness Perception Questionnaire (IPQ)[40] | Illness perception | α = .73 - .82 |
| Patient Health Questionnaire (PHQ-4)[33] | Anxiety and depression | α = .82 |
| Comprehensive Inventory of Mindfulness Experiences (CHIME)[41] | Mindfulness | $r_{tt}$ ≥ .70<br>α ≥ .70 (except for one scale) |
| Short version of the Self-Compassion Scale (SCS-D short form) [35] | Self-compassion | α = .84<br>$r_{tt}$ = .83 |
| Itch-cognition questionnaire (JKF)[42] | Itch-related cognitions | α = .78-.90 |
| Fear of negative social evaluation - short scale (FNE-K)[37] | Fear of negative social evaluation | α = .94<br>$r_{tt}$ = .90 |

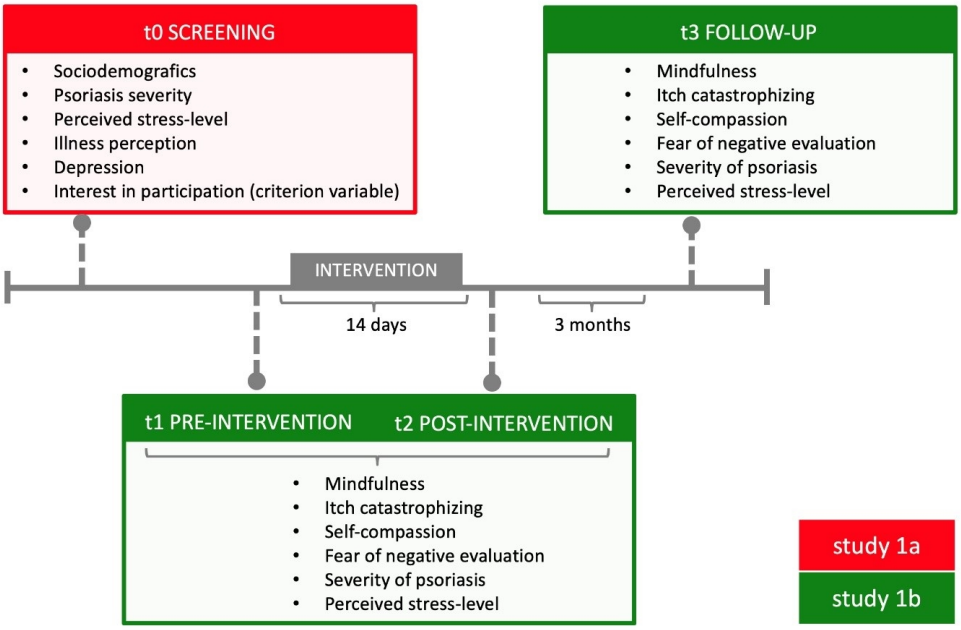
Table 3. Information on the used questionnaires.

Figure Legends

Fig. 1. Study and recruitment procedure.

Fig. 2. Self-report measures used in studies 1a and/ or study 1b.


Assessing for eligibility
Study 1a → t0
Exclusion
Study 1b
Exclusion
EG [Rehab + intervention]
t1
t2
pre-/post: Borkum
t3 → Follow-Up: at home
CG [Rehab only]
t1
t2
pre-/post: Borkum
t3 → Follow-Up: at home
Study 1a
Study 1b




159x105mm (220 x 220 DPI)

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 randomized controlled trial

| | |
|---|---|
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| Primary Subject Heading: | Dermatology |
| Secondary Subject Heading: | Rehabilitation medicine |
| Keywords: | mindfulness, itch catastrophizing, RCT, Psoriasis < DERMATOLOGY, rehabilitation clinic |
| | |

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# 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 randomized controlled trial

Stadtmüller L[1]*, Eckardt M[1]*, Zick C[2], Kupfer J[1], Schut C[1,3]

* These authors contributed equally to this work and should both be considered first authors

1 Institute of Medical Psychology, Justus-Liebig-University Gießen, Germany
2 Rehabilitation Clinic Borkum Riff, Borkum, Germany
3 Institute of Psychology, University of Wuppertal, Germany

Correspondence to:
Dr. Christina Schut
Institute of Medical Psychology
Justus-Liebig-University Gießen
Klinikstraße 29
35392 Gießen
Email: Christina.Schut@mp.med.uni-giessen.de
Tel: +49 641 9945682

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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 eight-week-mindfulness trainings in PS-patients reveal positive effects on the severity of the disease and quality of life. However, it remained unclear what distinguishes PS patients interested in psychological interventions from those without interest and whether also a shorter, namely 2-week mindfulness-based intervention is beneficial to 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 PS-patients. Study 1b is a RCT, in which 60 patients (retrieved from study 1a) will be randomized to an intervention or control group (treatment as usual). The main outcome variable 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 psoriasis and whether it is mediated by itch catastrophizing and fear of negative evaluation (first model) or perceived stress (2nd 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 (study 1a) and DRKS00017429 (study 1b)

## Strengths and limitations of this study

- The design of study 1b (RCT) is a strength.
- The determination of medium-term effects of the training in a 3-months-follow- is a strength of the study, however a follow-up after e.g. 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.

## INTRODUCTION

### Psoriasis

Psoriasis (PS) is a chronic relapsing skin disease with a prevalence of for instance 3% in the United States and 2.5% in Germany.[1,2] The probability to have PS is associated with age, sex and ethnicity of the patients.[3] For PS patients, 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] 37-78% of PS patients 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, that explain the differential effectiveness of psychological procedures in PS patients.[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. Standardized mindfulness-based interventions typically last eight weeks, with new topics being tackled once a week in a 2.5 hours group session led by a teacher.[10] In between the sessions, participants are encouraged to practice mindfulness techniques for 45 minutes each day.[10] Typical mindfulness techniques are breath meditation and the body scan. Hereby, participants are instructed to focus on the breathing process and attention is systematically moved through the body.[10] Participants are taught to have a patient and gentle attitude towards themselves.[10] 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 standardized questionnaires [e.g. 13] 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, e.g. to relapse prevention in depressed patients.[15] Meanwhile, there are several meta-analyses and systematic reviews on the multiple effects of mindfulness.[e.g. 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 psoriasis**

In PS patients 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 to treatment as usual.[21] Another study[22] explored the effects of a 12-week meditation-intervention and found significant improvements in PS outcomes when the intervention group was compared to the control groups. 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 eight weeks had positive effects on the severity of PS and quality of life.[23] In contrast, a similar study[8] 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 randomized trial[24] compared the effects of MBCT to TAU. Here, participation in an 8-week MBCT program led to significant improvements in both, skin-related and psychological outcomes, which did not occur in the control group.

Recent reviews[25,26] conclude that the effects of psychological interventions in patients with PS, including mindfulness-based trainings, need to be studied further as studies often only included less than 50 patients, follow-ups were missing and/ or patients were not blinded. Previous studies on mindfulness-based interventions in PS patients were also criticized for not having asked PS patients whether they regarded psychological interventions as useful and would like to attend, even though interventions adapted to patient's interests could lead to greater effects.[25]

**Proposed effects of mindfulness in patients with psoriasis**

The biopsychosocial model of chronic itch[26] assumes that patients' internal factors (e.g. personality factors) lead to certain cognitions, social reactions and behaviors, which can trigger physiological reactions (e.g. 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 catastrophizing 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] Against this background, we propose that increased mindfulness and self-compassion due to participation in a mindfulness-based training will lead to lower itch catastrophizing 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 psoriasis is thought to be mediated by release of the stress hormone cortisol which has an impact on mast cell degranulation[29] and the activity of cytokines[30], which play an important role in the pathogenesis of psoriasis. As mindfulness-based interventions are known to effectively reduce stress[20] an increase in mindfulness, due to participation should thus also lead to an improvement of the skin through the just described physiological pathway (also see Fig. 1).

*[Please insert Fig. 1 here.]*

**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- 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 catastrophizing, fear of negative evaluation and/ or stress (see above).

## METHODS AND ANALYSIS

### Setting

Data collection will take place at a German rehabilitation clinic from August 2019 to July 2021 (also see table 1).

| Action | Study dates |
|---|---|
| **Ethical approval** | March 2019 |
| **Submission of the study protocol** | July 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 |

Table 1. Study dates.

## Trial design and Procedure

Study 1a is an observational study. Study 1b is a randomized controlled trial. In order to take part in study 1a 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 three months after the intervention (t3; medium-term effects, also see Fig. 2).

*(Please insert Fig. 2 here]*

## Inclusion and exclusion criteria

Persons aged between 18 and 65 years, who have been being diagnosed with PS according to ICD-10 criteria[31] and had symptoms during the last six months will be included. The main reason to exclude elderly patients from participation in the study is that rehabilitation programs are only offered to employed people in Germany. The aim of the stay at a rehabilitation clinic is that patients learn to cope with their chronic disease in order to reduce absence from 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.

## 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 (secretary at the Institute of Medical Psychology, Gießen, Germany). In order to randomize male and female subjects separately, two lists of codes (one for females and one for males) are provided. Randomization 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 (mindfulness practice, exchange of experience, homework), but has been adapted to the time available during a rehabilitation stay. In particular, breathing meditation and body-scan are taught using standardized instructions. The instructions are formulated to encourage patients to have a compassionate attitude towards their own practice. The scope of the training is equivalent to the minimum of eight hours given in the literature over a period of two weeks (8 x 1h group exercises and 4 x 15 minutes of homework), and is on par with earlier studies that used brief mindfulness-based interventions.[12,24] Groups meet 4 times per week for two consecutive weeks. For a detailed description of the intervention, see table 2.

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

Table 2. Details regarding the mindfulness-based intervention applied in this study. 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 summarizing the respective class content.

The intervention will be conducted by a psychologist (B. Sc.) with profound expertise in meditation (more 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. 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 Psoriasis* is measured by the Self-Administered Psoriasis Area and Severity Index (SAPASI). The questionnaire records the severity of PS assessing redness, thickness and scaliness of the skin as well as the extent of affected areas.[33]

*The perceived stress level* is measured by the Perceived Stress Scale 10 (PSS-10).[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 ten 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 (IPQ)[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 (PHQ-4).[37] This short questionnaire includes 4 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:

*Mindfulness* is measured using the Comprehensive Inventory of Mindfulness Experiences (CHIME)[13]. This questionnaire captures different aspects of mindfulness that are categorized 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 (SCS-D 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 favorable for the course of the disease (scale coping) or unfavorable (scale catastrophizing/ 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; FNE-K).[41] This questionnaire comprises 12 items that need to be answered on a 5-point scale which ranges from “completely does not characterize myself” to “is extremely typical for me”.

More information regarding the reliability of these self-report instruments can be found in table 3.

| Questionnaire | Assessed variable(s) | Reliability measures |
|---|---|---|
| Self-Administered Psoriasis Area and Severity Index (SAPASI)[33] | PS severity | $r_{tt}$ = .82 |
| Perceived Stress Scale 10 (PSS-10)[35] | Perceived stress level | α = .84 |
| Illness Perception Questionnaire (IPQ)[42] | Illness perception | α = .73 - .82 |
| Patient Health Questionnaire (PHQ-4)[37] | Anxiety and depression | α = .82 |
| Comprehensive Inventory of Mindfulness Experiences (CHIME)[13] | Mindfulness | $r_{tt}$ ≥ .70<br>α ≥ .70 (except for one scale) |
| Short version of the Self-Compassion Scale (SCS-D short form)[39] | Self-compassion | α = .84<br>$r_{tt}$ = .83 |
| Itch-cognition questionnaire (JKF)[43] | Itch-related cognitions | α = .78 - .90 |
| Fear of negative social evaluation - short scale (FNE-K)[41] | Fear of negative social evaluation | α = .94<br>$r_{tt}$ = .90 |

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

## Statistical analysis

A G*Power-analysis[44] 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 (α = 0.05, 1-β = 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 ANOVA with repeated measures (α = 0.05, 1-β = 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 24.[45] 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 analyses of variance (ANOVA) with repeated measures. The group (intervention or control) represents the between subject factor, the other

assessed variables represent the inner-subject 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 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 itch catastrophizing and fear of negative evaluation, model 2 tests whether this relationship is mediated by perceived stress.

## 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: 03/21/2019; 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 (EHPS) 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 (e.g. by use of motivational interviewing techniques). In case protocol amendments will be conducted, the trial registry (DRKS) will be informed.

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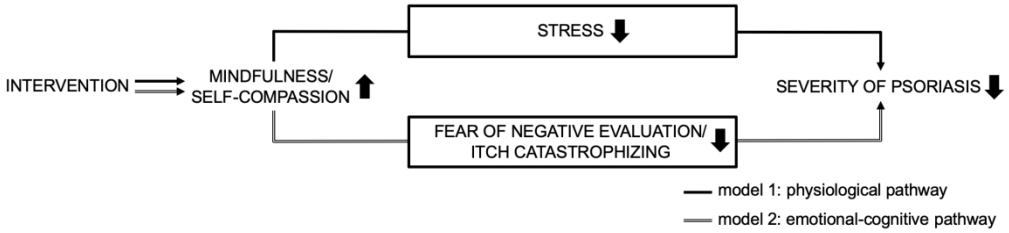
45. IBM Corp. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp 2016.

## Figure Legends

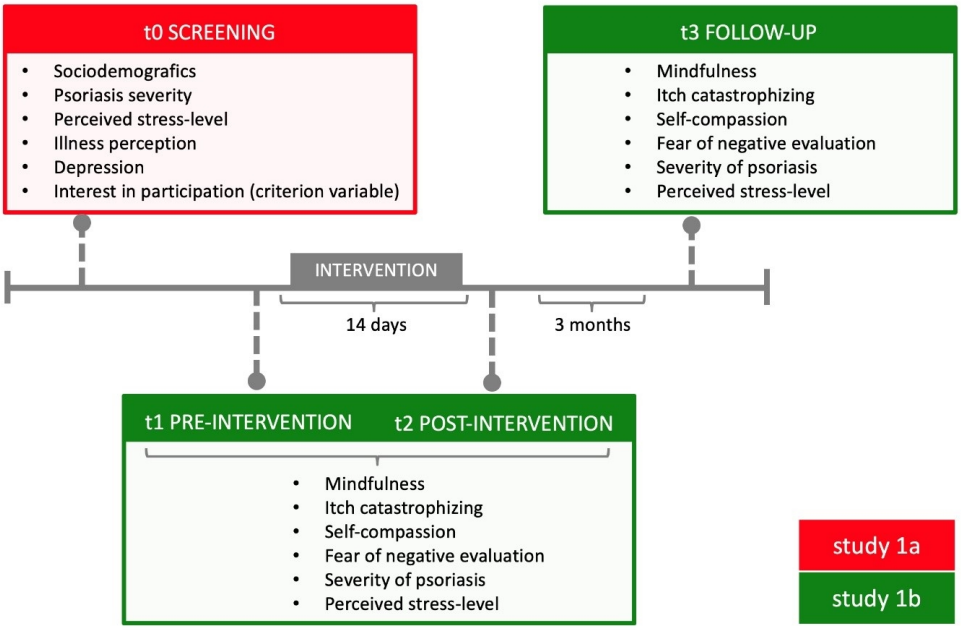
Fig. 1. Proposed relationships between the assessed variables.

Fig. 2. Study procedure.




Proposed relationships between the assessed variables

376x91mm (144 x 144 DPI)




Study procedure

159x105mm (220 x 220 DPI)


SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page/line in clean manuscript |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1/1-3 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2/55-56 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | / |
| Protocol version | 3 | Date and version identifier | / |
| Funding | 4 | Sources and types of financial, material, and other support | 1/24-25 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1/ 4-5<br>1/28-30 |
| | 5b | Name and contact information for the trial sponsor | / |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | / |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | / |
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 4/69-6/151 |
| | 6b | Explanation for choice of comparators | / |
| Objectives | 7 | Specific objectives or hypotheses | 6/155-163 |

| | | | |
|---|---|---|---|
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 7/171-199 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 6/167 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 7/178-189 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 7/201-223 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | / |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | / |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 7/201-8/223 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 8/227-11/306 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Figure 2 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 10/282-290 |

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|---|---|---|---|
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 6/167-168 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 7/191-199 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 7/191-199 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 7/191-199 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 7/198-199 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | / |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 8/227-10/280 Table 3 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | / |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 10/290-294 |

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|---|---|---|---|
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 11/294-12/306 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 11/294-12/306 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | / |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | / |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 11/321-324<br>11/318-319 |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | / |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | / |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 11/309-315 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 12/332-333 |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 11/309-315 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | / |

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|---|---|---|---|
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | / |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 1/26-27 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 1/29-30 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | / |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 11/309-333 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 1/30 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | / |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | / |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | / |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.