BMJ Open  Helpful explanatory models for somatoform symptoms (HERMES): study protocol of a randomised mixed-methods pilot trial

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Methods and analysis In a randomised controlled mixed-methods pilot trial, 75 adult psychosomatic outpatients with PSS (duration of symptoms ≥6 months) and accompanying psychological (Somatic Symptom B-Criteria Scale total score ≥18) and somatic symptom burden (Patient Health Questionnaire-15 score >10) and no prior psychosomatic treatment will be eligible. Participants will be presented with either the explanatory model without (intervention group 1, n=25) or with elements of personalisation (intervention group 2, n=25). Participants in the control group (n=25) will receive information on current PSS guidelines. Participants will be blinded to group assignment and interventions will be shown on tablet computers at the outpatient clinic. After 1 month, qualitative follow-up telephone interviews will be conducted. As primary outcomes, mean changes in psychological and somatic symptom burden will be compared between groups, respectively. Behavioural change mechanisms and feasibility of the three interventions will be evaluated using quantitative and qualitative measures.

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The impairments caused by PSS affect individuals in terms of a significantly reduced quality of life and the healthcare system in terms of excessive healthcare costs due to medical consultations and diagnostic procedures. Despite their individual and socioeconomic relevance, the majority of affected patients receive no treatment according to guidelines, thus enabling a chronic course of disease. Additionally, there is a considerable delay between PSS symptom onset and the start of an adequate treatment, that is, psychological interventions. Further, treatment options for PSS are limited and multidisciplinary treatment as well as non-pharmacological interventions show only moderate effect sizes. Thus, there is a great need to improve early treatment in PSS.

Early interventions usually include psychoeducational material. While there is evidence for the general usefulness of psychoeducational interventions for medically unexplained symptoms (MUS) and functional disorders, the lack of evidence-based explanatory models has been identified as one central barrier in the early treatment of PSS. A systematic search of MUS literature identified nine different explanatory models for PSS. These explanatory models were based on somatosensory amplification, sensitisation, sensitivity, immune system sensitisation, endocrine dysregulation, the signal filter model, the illness behaviour model, autonomous nervous system dysfunction and abnormal proprioception, and also included one meta-model, the cognitive–behavioural therapy model. However, most of these models were only partly based on empirical evidence. In primary care, health professionals often feel insecure about the management of patients with PSS. They explain the development and maintenance of symptoms only vaguely, and without any references to current aetiological models, thereby failing patients’ needs for biomedical and tangible explanatory models. When symptom explanations and treatment are not readily available, medical doctors may rely on a defensive biomedical approach in dealing with the symptoms. The patients on the other hand may continue to search for the biomedical diagnosis which explains their symptoms, that is, examinations for short-time reassurance instead of actively engaging in treatment, for example, with the help of knowledge of illness and self-management strategies.

Recently, a new aetiological model on PSS was suggested by Henningsen et al. While historically, aetiological models of symptom persistence emphasised bottom-up processes in a biomedical context and further developed into a biopsychosocial understanding, this new model on PSS focuses on top-down processes and conceptualises symptoms as a perceptual dysregulation. It represents a comprehensive biopsychosocial model of PSS and incorporates evidence-based findings, that is, by enhancing existing vulnerability stress models and emphasising the role of the patients’ perception and expectations regarding their symptoms. The model has not yet been translated into an explanatory model adapted for the use with patients with PSS. As the authors conclude, ‘a major challenge remains to develop metaphors and motivational techniques to convince patients to go along with these strategies and modify the patient’s illness belief’.

In order to make explanatory models more accessible, provided information needs to be clearly formulated, articulated in an understandable way and avoid unnecessary and distracting content. Providing feedback on PSS is a peculiar challenge, as patients might feel disbelieved by their doctors in case a biomedical focus is left. Most patients have distinct preferences for how they would choose to receive health information, including the possible use of media. Visual health information is becoming more widely used to communicate information about health and illness to patients. When used in an intervention, it can improve patients’ illness understanding and may ameliorate health behaviour such as adherence to treatment. As illness understanding requires a certain level of abstract thinking, visual information may make these intangible processes easier to understand. Additionally, visual information is often easier to attend to and to be remembered compared with more traditional forms of information.

Apart from visualisation, the provided information should be considered as relevant by the patient, thus increasing the likelihood of it being used. To increase individual relevance, the information has to address needs or fears of the individual, should be adjusted to the patients’ level of communication and give patients an active choice in the selection of the content. Such a person-centred, or personalised, approach has been shown to be of value for patients with long-term conditions such as PSS.

In conclusion, explanatory models for PSS are thus far based on current aetiological models, existing knowledge is not available in a way understandable for patients and their practitioners and not designed to suit individual patient needs. However, a current state-of-the-art aetiological model combined with the use of active visualisation and personalisation might be a valuable approach for both patients and their practitioners to communicate explanatory models for PSS.

OBJECTIVES
The primary aim of the HERMES pilot study (full title: Helpful explanatory models in somatoform symptoms) is to explore the feasibility and the impact of an intervention formed on an evidence-based explanatory model which can be used as a state-of-the-art early psychoeducational intervention to improve the physical and psychological symptom burden in patients with PSS. We thus translated the aetiological model on PSS suggested by Henningsen et al into an explanatory model that fits both patients’ and practitioners’ needs, and that employs means of visualisation. Development of this explanatory model
was sustained by the use of feedback both by a patient
group and an expert panel, and feasibility of the model
will be tested in patients with PSS and their practitioners.
Therefore, this study will serve as proof-of-concept and
feasibility study to form the basis for a randomised
controlled study, using explanatory models as a starting
point to improve early treatment for patients with PSS.51
Additionally, the present study will allow an estimation
of randomised controlled trial (RCT) eligibility as well
as recruitment and attrition rates. Last, the present study
will examine the effect of this newly developed explan-
atory model both with and without elements of personal-
ised medicine on psychological and physical symptom
burden.

Study hypotheses
The primary hypothesis is that the presentation of
explanatory models for PSS in both experimental condi-
tions results in significantly greater changes in psycholog-
ical and physical symptom burden between baseline and
1-month follow-up compared with the control group. It
is further explored whether the additional provision of
choice regarding patient information leads to significantly
greater changes in psychological and somatic symptom
burden compared with an explanatory model without
choice. Exploratory analyses will shed light on whether
the presentation of explanatory models for PSS in the
experimental conditions leads to a significantly greater
improvements in quality of life between baseline and
1-month follow-up compared with the control condition.

METHODS AND ANALYSIS
Study design
A pilot RCT was designed to evaluate the influence of
evidence-based explanatory models for PSS on somatic
and psychological symptom burden. Data will be
collected at baseline and after 1 month. Independent
variables will be operationalised through the experi-
mental conditions. At baseline, participants will be
randomised into one of three experimental conditions:
explanatory model without personalised choice versus
explanatory model with personalised choice versus
generic PSS information (control group). Primary
dependent variables are psychological and physical
symptom burden (figure 1).

Study procedures
Inclusion and exclusion criteria
Adult patients aged ≥18 years with PSS (duration ≥6
months) and a sum score of ≥18 in the Somatic Symptom
B-Criteria Scale (SSD-12) and ≥10 in the Patient Health
Questionnaire-15 (PHQ-15) and thus at risk for somatic
symptom disorder will be included. Written informed
consent will be collected.
Exclusion criteria are insufficient knowledge of the
German language, current or previous psychothera-
peutic treatment of PSS, an acute need for treatment
due to other comorbid psychological disorders, and
the possibility of acute self-harm or endangerment of
others.

Figure 1 Rationale of the HERMES Study.
Recruitment
Recruitment will take place in the psychosomatic outpatient clinic of the Department of Psychosomatic Medicine and Psychotherapy at the University Medical Center Hamburg-Eppendorf, Germany. The clinic is specialised in patients with depression, anxiety disorders, eating disorders and somatoform complaints. Patients are usually referred to the clinic after examinations by both the general practitioner (GP) and specialists. In the clinic, patients undergo a thorough psychosomatic evaluation (self-report measures and clinical interview) and receive assistance in the choice and finding of adequate treatment, as well as first clinical interventions. Eligible patients for the study will be verbally informed about the study by the attending clinician after consultation. Information on the study and consent will be provided in written form. In case of willingness to participate, a member of the study team will explain the course of the experiment in detail, answer questions and collect the written consent. If the patient declines to participate despite eligibility, the clinician will document age, sex and the reasons for refusal to participate. Follow-up interviews will be conducted via telephone 1 month after baseline.

Patient and public involvement
Patients and the public were not involved in the initial design of the study. During development of the intervention, feedback from a patient group will be employed in the design of the interventions.

Randomisation
Randomisation will take place after patients are included, based on a random number system and an urn randomisation. Patients will be blinded regarding their group assignment.

INTERVENTION GROUPS
In order to ensure internal validity, frequency, duration and performance will be kept on an equal level within all three experimental conditions. Demonstration of the respective explanatory model will take place immediately after randomisation. Duration of all three interventions will be approximately 15 min each and the digital content will be presented on a tablet computer.

Development and design of the interventions
The explanatory model was designed around the information contained in the aetiological model by Henningsen et al.38 In a first step, the aetiological model was summarised in a written script with the use of lay language. Then the script was enriched by the application of evidence-based feedback strategies.39 Examples of feedback strategies include the use of examples and metaphors, validation, the opportunity for comparisons with other affected patients and prompting statements. The script was then visualised according to means of active visualisation with two different designs, one containing stock photo images and the other using clip art. Information from the script was set to sound by a semiprofessional synchroniser and implemented in the digital presentation. Both versions were then presented to a feedback group of patients with PSS from a group therapy with focus on psychological distress primarily linked to physical complaints. After receiving feedback, the visual content and the script were adjusted accordingly, forming the first draft of the explanatory model. Based on this draft, all three experimental conditions (explanatory model without personalised choice vs explanatory model with personalised choice vs generic PSS information) were designed. These interventions were then shown to an expert panel consisting of two members (LF and TCOH) from a European network on PSS (Euronet-Soma).11,35 These experienced clinicians and researchers gave their feedback to the initial script and after an elaborated revision of the material approved the final versions of the three digital experimental interventions, which were then rendered and adjusted to the use on tablet computers (for a process summary, see figure 2).

First experimental condition
The first experimental condition includes the aetiological model of PSS by Henningsen et al.38 translated into an explanatory model in a language understandable for both patients and healthcare professionals. Illness perceptions, somatosensory amplification and strategies to avoid symptom-related fears will be addressed within the intervention. In order to further optimise the model, phrases from the vernacular and short summaries will be used.35 Stigma of mental illness is tried to be minimised.39 No personalised information will be implemented in the intervention.

Second experimental condition
In the second experimental condition, an element of personal choice will be added to the initial explanatory model. Though personalisation is generally a highly complex and heterogeneous matter, we tried to implement it by providing the patient with a choice concerning his or her individual need regarding maintaining factors of PSS. The first part of the explanatory model will thus contain information equivalent to the first intervention group. However, after the first part the participant will be asked which psychological mechanism is the most relevant for him or her personally: illness perceptions, somatosensory amplification and strategies to avoid symptom-related anxiety. These three aspects were chosen for individualisation based on their specific relevance for the healthcare sector.56-58 The second part of the intervention will then address the specific information accordingly. If the participant chooses neither of the factors, the information without choice from the first experimental condition will be shown.

Control condition
The control condition will be close to treatment as usual, that is, it will neither contain an explanatory model of
PSS, nor maintaining factors, nor personalised information. Participants will instead receive information based on current guidelines for the treatment of PSS. The information addresses four levels in the treatment of PSS: namely, initial primary care, extended primary care, multimodal treatment and further psychosocial aspects.

VARIABLES AND INSTRUMENTS
Participants of all three experimental conditions will complete questionnaires at baseline and at 1-month follow-up. An overview of all instruments employed at baseline and follow-up is provided in table 1.

Acceptance and feasibility of the interventions
Participation and attrition rates and numerical rating scales on individual acceptance of the intervention and probability to recommend the interventions to family members with PSS will be used to quantitatively estimate acceptance and feasibility of the interventions. Additionally, qualitative aspects of acceptance in terms of applicability of the interventions for individual symptoms and satisfaction of needs will be measured using semi-structured interviews. Expectations with regard to the individual course of treatment, positive and negative aspects of the explanatory model, issues of comprehension and general feedback will also be inquired, respectively. At 1-month follow-up, participants will be asked which aspects of the interventions they remember and whether the explanatory model had any influence on their behaviour (ie, using the explanatory model when interacting with friends or family or practitioners). Interviews will be transcribed verbatim and qualitatively analysed applying thematic analysis as suggested by Braun and Clarke.

Psychological and somatic symptom burden
Primary outcomes of the HERMES pilot study are psychological and somatic symptom burden at 1-month follow-up. Psychological distress due to physical symptoms will be measured using the SSD-12. The SSD-12 was developed to measure the psychological criteria of somatic symptom disorder according to DSM-5. Each of the three psychological subcriteria (cognitive, affective, behavioural) is measured by four items with scores ranging between 0 and 4, resulting in a total of 12 items with a sum score of 0–48. The SSD-12 has good item characteristics, excellent reliability (Cronbach’s $\alpha=0.95$), and its ability to measure change over time has been established.

The PHQ-15 measures somatic symptom burden and has well-established psychometric properties. Using 15 items, the PHQ-15 assesses the presence and severity of common somatic symptoms within the last 4 weeks. A cut-off score of $\geq 10$ points has been established to identify patients at risk for clinically relevant symptom burden. Its convergent and divergent validity have been tested in several patient samples and in the general population.

In addition to the SSD-12 and PHQ-15, we also added two numerical Visual Analogue Scales items on subjective impairment in terms of the intensity of bodily symptoms and their interference with daily life activities over the past 7 days, as recommended by the EURONET-SOMA group.

Psychopathological change mechanisms
Usefulness of the interventions will be measured using an adapted version of the Usefulness Scale for Patient Information Material. The questionnaire comprises nine items measuring cognitive, emotional and behavioural usefulness of patient material. The Brief Illness Perception Questionnaire will indicate changes regarding illness perceptions. Its wide use and good psychometric properties could be demonstrated in a review containing...
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Table 1 Overview of instruments employed in the HERMES Study

<table>
<thead>
<tr>
<th>Construct</th>
<th>Instrument</th>
<th>Baseline (T-0)—before intervention</th>
<th>Baseline (T-0)—after intervention</th>
<th>Follow-up (T-1)—4 weeks after baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatic symptom burden</td>
<td>PHQ-15</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Symptom-related psychological distress</td>
<td>SSD-12</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Quality of life</td>
<td>SF-12</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Depression</td>
<td>PHQ-9</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>GAD-7</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General physical well-being</td>
<td>VAS</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Illness perceptions</td>
<td>IPQ-B</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoidance behaviour</td>
<td>VAS</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control behaviour</td>
<td>VAS</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Attention to symptoms</td>
<td>VAS</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Physical distress last 7 days</td>
<td>VAS</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Symptom influence on daily activities</td>
<td>VAS</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>over the last 7 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catastrophising attribution</td>
<td>FKG</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetative discomfort</td>
<td>FKG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actions related to somatic symptoms</td>
<td>HP</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Usefulness of patient information material</td>
<td>USE</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous knowledge of information in intervention</td>
<td>VAS</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Fit of information to individual symptoms</td>
<td>VAS</td>
<td>X</td>
<td></td>
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<tr>
<td>Credibility of information in intervention</td>
<td>VAS</td>
<td>X</td>
<td></td>
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<tr>
<td>Influence of intervention on perception of physical complaints</td>
<td>VAS</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Influence of intervention on course of treatment with GP</td>
<td>VAS</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional activation due to intervention</td>
<td>Open questions*</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improvement of intervention</td>
<td>Open questions*</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Remembered content of intervention</td>
<td>Open questions*</td>
<td>X</td>
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*Qualitative measure.
FKG, Fragebogen zu Körper und Gesundheit; GAD-7, General Anxiety Disorder Questionnaire-7; GP, general practitioner; HP, actions according to guidelines; IPQ-B, Brief Illness Perception Questionnaire; PHQ-9, Patient Health Questionnaire-9; PHQ-15, Patient Health Questionnaire-15; SF-12, 12-Item Short Form Health Survey; SSD-12, Somatic Symptom B-Criteria Scale; USE, Usefulness Scale for Patient Information Material; VAS, Visual Analogue Scale.

Data from 188 studies. In order to operationalise the concept of somatosensory amplification, the subscales ‘catastrophising attribution’ and ‘vegetative discomfort’ of the Questionnaire on Body and Health (Fragebogen zu Körper und Gesundheit) will be used. Strategies to avoid symptom-related anxiety will be assessed with Visual Analogue Scales on ‘physical inactivity’ and ‘request of medical diagnosis’. Additionally, patients will be asked about functional and dysfunctional actions regarding their somatic complaints in the previous 2 weeks according to the recommendations in the German guidelines on functional somatic complaints in dichotomous format (yes vs no).

Quality of life
Using 12 items, the 12-Item Short Form Health Survey measures psychological and physical aspects of generic, health-related quality of life. Multiple studies could demonstrate its good psychometric properties.

Sample characterisation
In order to describe the study sample, sociodemographic information on age, gender, education, cultural
background and data on symptom onset, healthcare util-
isation over the past 4 weeks as well as current capacity
to work and medication will be collected via the basic
service in the outpatient clinic. Data will also include
somatic and mental comorbidities: depression will be
measured using the PHQ-9, anxiety via the General
Anxiety Disorder Questionnaire. Diagnoses from the
spectrum of mental disorders will be extracted from the
clinical consultation referral letters.

SAMPLE SIZE/POWER CALCULATION
To our knowledge, this is the first study examining the
influence of explanatory models on PSS and their influ-
ence on psychological and somatic symptom burden.
Hence, there is no prior knowledge concerning sample
size calculations. We thus used power calculation with an
estimated drop-out rate of 25% based on a previous study
in the same setting, resulting in an estimated amount
of 25 participants per group (75 patients in total). Since
the HERMES Study employs brief interventions, one can
estimate a small effect size of f<0.4. In combination with
three experimental conditions and a double sided α-error
chance of 5%, a power of up to 78% (1−β error chance)
can be reached, according to the respective effect size.
Power calculations were done using the program PASS
(V.15.0.3) and an analysis of covariance (ANCOVA) as
statistical measure.

Handling of missing values
Participants with ≥25% missing baseline scores will not
be included in the study. In case of missing data either at
baseline or follow-up, cases will be analysed according to
intention-to-treat principles if a minimum of 75% of data
are present. Handling of missing data will be adapted to
missing data patterns. If patients are not available for the
interviews at 1-month follow-up, they will be registered as
drop-outs after at least five attempts of being reached via
telephone. Reason for drop-out will be recorded and only
baseline information will be used for analysis. Systematic
differences between participants and drop-outs will be
examined using the provided data.

Statistical analyses
Since normal distribution can be assumed for sum
scores of symptom burden (psychological symptom
burden=SSD-12, somatic symptom burden=PHQ-15),
mean score and SD can be used as descriptive character-
istic. For evaluation of the primary hypothesis, namely the
positive effect of presenting an explanatory model on both
psychological and somatic symptom burden, an ANCOVA
with experimental group (explanatory model without vs
explanatory model with personalised choice vs generic
PSS information) as independent variable and changes in
symptom burden at 1-month follow-up as dependent
variables (psychological=∆SSD-12; somatic=∆PHQ-15)
will be employed, with covariates being age, gender
and symptom burden at baseline. Additionally, post-hoc
analysis will be used for global comparison of the three
experimental conditions. Results will be reported using
adjusted mean differences with corresponding 95% CI
s and p values. Statistical analysis will be performed using
IBM SPSS V.23.0. Mediation analysis will be employed for
answering the exploratory question concerning mecha-
nisms of action (perceived usefulness of the intervention,
ilness perceptions, somatosensory amplification, stra-
tegies to avoid symptom-related anxiety, and functional
and dysfunctional actions regarding somatic complaints)
between explanatory model and changes in psychological
and somatic symptom burden at 1-month follow-up, using
the SPSS macro PROCESS. Qualitative analysis will be
conducted using thematic analysis according to Braun
and Clarke.

Methods to reduce bias
Selection bias is minimised by the inclusion of a control
group and an urn randomisation. Presentation of the
interventions will be completely standardised by the use of
videos on tablet computers. The videos have been created
with the attempt to maximise comparability in terms of
length, amount of content and visual representation.
Both participants and interviewers at 1-month follow-up
will be blinded regarding the experimental condition. As
it is not possible to blind the scientific assistant during
intervention, follow-up interviews will be conducted by
an interviewer blinded with regard to the experimental
condition. The rate of participants who refrain from
signing an informed consent (ie, non-response rate)
will be reported. The full recruitment process will be
documented according to Consolidated Standards of
Reporting Trials reporting standards.

Study registration
The study was registered at the German Clinical Trials
Register (Deutsches Register Klinischer Studien), and
thereby automatically submitted to the WHO Interna-
tional Clinical Trials Registry Platform.

Ethics and dissemination
The study procedure was reviewed and approved by the
medical ethics board of the Hamburg Medical Chamber
(approved on 23 October 2017; PV5653). Results from
this study will be published in peer-reviewed journals and
presented at national and international conferences.
Before participation, patients will receive detailed infor-
mation about the nature, purpose and possible conse-
quences of the trial. Participants will be required to give
written informed consent to participate in the study.

DISCUSSION
The HERMES pilot study aims at developing an evidence-
based and visualised explanatory model for PSS, to esti-
mate effect sizes of its influence on both psychological
and somatic symptom burden and to evaluate feasibility
and acceptance of the intervention. It is hypothesised that the
presentation of the explanatory model to patients with PSS will result in significant changes in psychological and somatic symptom burden compared with a control group and further, that an additional personalisation through choice of information will lead to an even greater change. Furthermore, we also will explore whether the explanatory models will foster greater improvements in quality of life between baseline and 1-month follow-up compared with the control condition.

Explanatory models are not only part of psychotherapy/patient-activating treatments, yet form the basis for an individual understanding of complaints. They might thus for example help GPs in their role as gatekeeper within the health system and should easily be employed in early interventions. By ensuring a high scientific standard in the development and the content of the intervention, we want to fill the void of evidence-based explanatory models for PSS. While there is a number of useful clinical tools and verbalisations available, the majority is limited to clinical use and has not been reviewed within research. Additionally, we are to our knowledge the first to systematically evaluate an explanatory model for PSS that has been developed using means of active visualisation and personalisation.

In spite of the numerous advantages of the planned investigation and the high demand for evidence-based explanatory models for PSS, some limitations have to be considered: Visualisation and wording of an intervention are always bound to a subjective nature, and will thus never appeal to all patients. However, by employing a patient feedback group, we will try to minimise this effect during development of the intervention and use qualitative data for further improvement after the trial. By employing an animated intervention and tablet computers, we are arguably also at risk of entering ‘unfamiliar territory’ for the patients when it comes to clinical interventions. However, the technological advancements and user data of the past centuries support this change of therapeutic paradigm rather than restraining from it. From a methodological point of view, we are aware that the employed personalisation will be of limited external value in regard to the extremely heterogeneous group of patients with PSS, and as they considerably differ in terms of patients’ history, complaints and attitudes towards (psycho)therapeutic approaches. These limitations notwithstanding, we hope to ensure a first insight of the added value of this patient-centred approach in order to foster both effectiveness and appeal of the explanatory model.

If proven effective, the planned interventions will make an important contribution to the early treatment of PSS. They might thus form the basis for the much needed additional research within this area. Future trials might increasingly incorporate concepts of blended interventions, combining various psychoeducational delivery methods. Our use of tablet computers might represent one possible delivery method. Analysis of our data will further provide insight into whether our choice of personalisation is valid or if for example more complex algorithms or the use of psychometrical data might be more suitable approaches.

Contributors AW conceived the study, AW, PH and BL were involved in the concept and design of the study. PH wrote the draft of this manuscript. TOH, LF, AW and BL provided valuable revisions. All authors contributed to further writing and approved the final version of the manuscript.

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Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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