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Somatic symptom disorder: factors associated with physical complaints

Submission date
27/01/2022

Recruitment status
No longer recruiting

Registration date
15/02/2022

Overall study status
Ongoing

Last Edited
09/09/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Somatic symptom disorder (SSD) is a distressing mental disorder characterised by the presence of at least one persistent physical complaint (somatic symptom) and a heavy psychological burden due to excessive thoughts, feelings, or behaviours related to those complaints or associated health concerns. Current explanatory models construe expectations both as triggering and as maintaining factors for SSD. However, the influences of patients' expectations on somatic symptoms and the interaction between expectations and other relevant factors such as one or more co-occurring physical conditions (somatic comorbidity) have not been studied. Therefore, this study aims to investigate models for the prediction of persistent somatic symptoms in patients with SSD by considering multiple contributing factors. The researchers think that patients' expectations of symptom severity and different levels of somatic comorbidity may be associated with somatic symptom severity. They also think that these two factors independently or together with other factors such as previous treatment experience determine the long-term symptom course over a period of 12 months and that they are predictive of daily changes in somatic symptom severity over a period of 12 days. The researchers will also analyse the impact of different expectation measures as well as possible mediating factors for the impact of somatic comorbidity on somatic symptom severity.

Who can participate?
Adult patients from the outpatient clinics of the Department of Psychosomatic Medicine and Psychotherapy and the Institute of Psychotherapy at the University Medical Center Hamburg-Eppendorf, Germany, who fulfil the diagnostic criteria for SSD and further eligibility criteria

What does the study involve?
Somatic symptom severity is investigated in patients with SSD over a period of 12 months (macro-level). An additional 12-day smartphone-based study (EMA; ecological momentary assessment) will be embedded to investigate daily symptom changes (micro-level). Expectation measures will include repeated assessments using two different frames of reference on the micro-level. Somatic comorbidity will be measured with standardised ratings, medical records, and medical exams that are performed by study physicians. Statistical prediction models

including multiple factors and accounting for the complex interactions between them will be used to examine the influence of expectations and somatic comorbidity on symptom severity (e. g., multivariate latent growth curve models on the micro-level).

What are the possible benefits and risks of participating?
This is an observational study that investigates the natural course of somatic symptoms in patients with SSD without performing study-related interventions on participants. Since the study procedure will not influence patients' regular psychological or medical treatments, there is no, or at most minimal, risk of untoward medical or psychological occurrences (adverse events) in patients expected due to study participation. Adverse events not related to the study, such as severe medical complications or suicidality, will be reported to treating specialists or, in case of an emergency, treated immediately at the University Medical Centre Hamburg-Eppendorf, Germany. There are no disadvantages for participants compared to non-participants and participants will get an expense allowance after completing the study.

Where is the study run from?
1. University Medical Centre Hamburg-Eppendorf (Germany)
2. Helmut-Schmidt University / University of the Federal Armed Forces Hamburg (Germany)

When is the study starting and how long is it expected to run for?
March 2020 to September 2025

Who is funding the study?
German Research Foundation (Deutsche Forschungsgemeinschaft, DFG) (Germany)

Who is the main contact?
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Study website
https://www.uke.de/kliniken-institute/kliniken/psychosomatische-medizin-und-psychotherapie/forschung/studien/for-5211-somacross/projekt-5/index.html

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Grant number (Nestoriuc): NE 1635/3-1; Grant number (Toussaint): TO 908/2-1

Study information

Scientific Title
Modifiable factors for somatic symptom persistence in patients with somatic symptom disorder

Acronym
SOMA.SSD

Study objectives
Hypothesis 1: Expectation of symptom severity and somatic comorbidity, independently or conjointly with biomedical and psychosocial factors, are associated with somatic symptom severity on macro and micro levels, respectively.
Hypothesis 2a: Expectation of symptom severity and somatic comorbidity, independently or conjointly with biomedical and psychosocial factors, determine the long-term course of somatic symptom severity (macro-level) as well as daily fluctuations of somatic symptom severity (micro-level).
Hypothesis 2b: Specifically, expectation of symptom severity, independently or conjointly with biomedical and psychosocial factors, has more predictive value for future symptom severity (macro-level) and for somatic symptom course (micro-level) than prior treatment experience.
Hypothesis 3 (exploratory): Measuring expectation of symptom severity versus expectation of burden-free periods will result in differing influences on temporal changes in perceived somatic symptom severity and courses on the micro-level.
Hypothesis 4 (exploratory): The impact of somatic comorbidity on symptom severity and course is mediated by other psychological and biomedical predictors on the macro and micro levels, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, Ethics Committee of the Hamburg Medical Association (Ethik-Kommission der Ärztekammer Hamburg, Weidestraße 122 b, 22083, Hamburg, Germany; +49 (0) 40 202299-240; ethik@aekhh.de), ref: 2020-10196-BO-ff

Study design
Observational prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Somatic symptom disorder

Interventions
Macro-level:
In the observational cohort study, somatic symptom severity as the primary outcome and a set of relevant predictors will be investigated and assessed at three measurement points during the course of 12 months. After the baseline assessment (T0), two follow-ups will take place at 6 (T2), and 12 months (T3) on the macro level. Depending on the measurement point, patient data will be collected through self-report questionnaires, diagnostical and clinical interviews, physiological exams, medical records, and blood samples.

Micro-level:
An embedded 12-day smartphone-based study (EMA; ecological momentary assessment) with intermediate status assessments at the first day (T1a) and the last day (T1b) of this period will take place between weeks 2 and 4 after the baseline assessment (T0) on the macro level. Following T1a, ambulatory assessments will start with patients being randomised to one of two groups, receiving either a standard or a positive frame of reference for the assessment of expectations of symptoms (i.e., neutral frame: expectation of symptom severity vs. positive frame: expectation of burden-free periods). During ambulatory assessments, patients will be prompted three times a day for 10 consecutive days to rate their somatic symptom severity, symptom expectations (either neutral frame or positive frame) and treatment experiences. Ambulatory assessments will include self-report questionnaires that will be administered as web-based surveys. These surveys will take place with a customized smartphone application that will be applied to personal smartphones or study-provided smartphones, depending on patients' preferences, using the software package movisensXS (Movisens GmbH).

Intervention Type
Other

Primary outcome measure
Macro-level with three measurement points: T0 (baseline), T2 (6 months after T0), T3 (12 months after T0):
1. Patient-reported somatic symptom burden assessed using the sum score of the Patients Health Questionnaire (PHQ-15) at all measurement points on the macro level
2. Patient-reported somatic symptom intensity assessed using the score on an 11-point numeric rating scale (EURONET-SOMA1, NRS) at all measurement points on the macro level

Micro-level with two intermediate measurement points and 30 ambulatory measurement points: intermediate measurement point T1a (2 weeks after T0), ambulatory measurement points (3 times a day on 10 consecutive days after T1a), intermediate measurement point T1b (after ambulatory measurement points)
1. Patient-reported somatic symptom burden assessed using the sum score of the Patients

Health Questionnaire (PHQ-15) at the intermediate measurement points T1a and T1b
2. Patient-reported somatic symptom intensity assessed using the score on an 11-point numeric rating scale (EURONET-SOMA1, NRS) at the intermediate measurement points T1a and T1b
3. Patient-reported somatic symptom burden assessed using the sum score of an adapted version of the Patients Health Questionnaire (PHQadapt) at the ambulatory measurement points

Secondary outcome measures
Assessed at all three measurement points on the macro level: T0 (baseline), T2 (6 months after T0), T3 (12 months after T0):
1. Overall somatic symptom interference assessed using the score on an 11-point numeric rating scale (EURONET-SOMA1, NRS)
2. Symptom-related disability assessed using the sum score of the Pain Disability Index – adapted (PDI)
3. Health-related quality of life assessed using the sum score of the Short Form health survey (SF-12)
4. Health care use assessed using the sum score of the Health care Utilization Questionnaire (HCU-Q)
5. Perceived efficacy of health care assessed using the score on an 11-point numeric rating scale (PercE, NRS)
6. Perceived adverse effects of health care assessed using the score on an 11-point numeric rating scale (PercA, NRS)

Overall study start date
30/03/2020

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Clinical diagnosis of SSD
2. Sufficient oral and written German language proficiency
3. Provision of written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
240

Total final enrolment
240

Key exclusion criteria
1. Acute serious somatic and/or psychological illness requiring immediate intervention
2. Florid psychosis
3. Substance abuse disorder
4. Acute suicidality
5. Severe cognitive impairment affecting self-report questionnaires and interviews

Date of first enrolment
01/04/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Germany

Study participating centre
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University/education

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ROR
https://ror.org/04e8jbs38

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
The study protocol will be submitted for publication. According to the WHO Statement on Public Disclosure of Clinical Trials (https://www.who.int/ictrp/results/reporting/en/), the main findings will be submitted for publication in a high-impact peer-reviewed journal within 12 months of study completion.

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (e.g., DRYAD Digital Repository; https://datadryad.org/stash). The study protocol and statistical analysis plan will be available at the ISRCTN registry. Individual participant data that underlie the reported results in a published article will be shared after de-identification beginning 3 months and ending 5 years following article publication. Data will be shared with researchers who provide a methodologically sound proposal to achieve the aims in the approved proposal. Proposals should be directed to Dr Anne Toussaint (a.toussaint@uke.de). To gain access, data requestors will need to sign a data access agreement. Informed consent from participants was obtained.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			15/02/2022	No	Yes
Protocol article		17/11/2024	05/12/2024	Yes	No
Results article		07/02/2025	10/02/2025	Yes	No