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## Mental health specialist video consultations for patients with somatic symptom disorder in primary care: Protocol for a randomised feasibility trial (the VISION-trial)

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**Mental health specialist video consultations for patients with somatic symptom disorder in primary care: Protocol for a randomised feasibility trial (the VISION-trial)**

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## ABSTRACT

**Introduction:** General practitioners (GP) report increasing difficulties in referring patients with somatic symptom disorder (SSD) in specialised psychosocial care. Barriers are structural conditions of the respective health care system and patients' reservations against receiving specialized psychosocial care. As patients with SSD often predominantly assume somatic influencing factors for the development and maintenance of their somatic complaints, close collaboration between the GP and mental health specialist (MHS) seems particularly important. Integrating internet-based video consultations by remotely located MHS and primary care can improve effective treatment of patients with SSD by overcoming structural barriers and provide low-threshold and timely care. The aim of this randomised controlled feasibility trial is to investigate the feasibility of implementing of mental health specialist video consultations in primary care practices.

**Methods and analysis:** Fifty primary care patients with SSD will be individually randomised in two groups receiving either enhanced treatment as usual as provided by their general practitioner (control group) or two vs. five video consultations conducted by an MHS. The video consultations focus on a) diagnostic clarification b) the development of a biopsychosocial disorder model and c) development of a treatment plan against the background of a stepped-care algorithm based on clinical outcomes. We will investigate the following outcomes: effectiveness of the recruitment strategies, patient acceptance of randomisation, practicability of the technical and logistical processes related to implementing video consultations in the practices' workflows, feasibility of the data collection, and clinical parameters.

**Ethics and dissemination:** This trial has undergone ethical scrutiny and has been approved by the Medical Faculty of the University of Heidelberg Ethics Committee (S-620/2021). The findings will be disseminated to the research community through presentations at conferences and publications in scientific journals. This feasibility trial will prepare the ground for a large-scale, fully-powered randomised controlled trial.

**Trial registration number:** DRKS00026075.

**Key words:** primary care, mental health, telemedicine, video consultations, somatic symptom disorder, feasibility, randomised controlled trial

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**ARTICLE SUMMARY**

Strengths and limitations of this study

- This is one of the first feasibility trials investigating mental health specialist video consultations for patients with somatic symptom disorder (SSD) presenting in primary care.
- We will transform and tailor an already tested integrated mental health treatment model, originally developed for depression and anxiety, for patients with SSD, who may benefit particularly due to high barriers in referral to specialised care.
- Given the nature of our feasibility study, we will not be able to determine intervention effectiveness at this point, but our findings will inform the design of a sufficiently powered randomised controlled trial.

## INTRODUCTION

According to the Diagnostic and Statistical Manual of Mental Disorders (DSM–5), catastrophizing cognitions, feelings and behaviours (B-criterion) in response to “one or more somatic symptom(s) that is/are distressing or result(s) in significant disruption of daily life” (A-criterion) are core characteristics of somatic symptom disorder (SSD)[1]. In contrast to the former conceptualization of “somatoform” disorders in DSM-IV[2] and ICD-10[3] the diagnosis SSD does not require no or no sufficient medical explanation for the distressing somatic symptoms. Thus, patients with somatic disorders such as cardiovascular disease or cancer may now be diagnosed with SSD, in case of experiencing the described symptoms for a period of at least 6 months (C-criterion).

While the prevalence of clinically diagnosable SSD in the general population is estimated at 5-7 % [4]; subsyndromal manifestations of SSD are far more common[5]. Further, Haller and colleagues[6] found a prevalence of 26.2 % (DSM-IV) and 34.8 % (ICD-10) for at least one somatoform disorder in general practices, making these symptoms to one of the most common reasons for consultations in primary care[7,8]. Although these symptoms are often associated with a) considerable suffering and psychosocial impairment, b) increased comorbidities with other mental disorders (e. g. depressive and anxiety disorders[9–11]), and c) increased costs for the health care system[12,13], general practitioners (GP) report increasing difficulties in referring patients with mental disorders in specialized mental health care[14–16].

Even when effective treatment options are available – as is the case in many Western healthcare systems[17] – these difficulties often remain due to a) long waiting times with specialists[15,18,19], b) long travel distances, especially in rural and remote locations[20], and c) severe time constraints in primary care, complicating accurate diagnosis by GPs[21,22]. In addition, patients often have reservations against specialized mental health care[23]. Since patients with SSD often find it difficult to accept that they suffer from a mental and not (exclusively) from a somatic disorder[24,25], patients’ reservations are of particular importance here. Further, these disorder-related reservations particularly necessitate a close collaboration between the GP and mental health specialist (MHS) in the effective treatment of patients with SSD[26–28].

To resolve these challenges, one strategy is to define, implement and evaluate innovative care models, that are tailored both to the specific conditions of the respective care system as well as to the specific needs of patients with SSD. For patients with depressive and anxiety disorders, the junior research group PROVIDE (ImPROving cross-sectorial collaboration between primary and psychosocial care: An implementation study on VIDEo consultations) has been defining, tailoring and evaluating an integrated psychosocial care model compatible with small and/or remote general practices [29–35] (<https://www.provide-project.de/vision/>). Specifically, this model features MHS video consultations (MHSVC) in primary care. While the MHS is situated in her/his office, private practice or another suitable, designated room at home, the patient receives the telemedical service in her/his general practice. While the results of the large RCT examining the efficacy of this model are still pending, the intervention in the PROVIDE-B feasibility trial was found to be feasible, acceptable and secure for patients, general practice staff and MHS[34]. In addition, during the COVID-19-pandemic video consultations have been implemented rapidly in many health care systems and providers and patients become more familiar with this mode of care delivery[36–39].

For progressing in this way, our aim is to offer a similar integrated care model to patients with SSD. While the formal conditions of the model (duration and frequency of consultations, location of the patient and MHS etc.) will be retained [31,40], the psychosocial intervention will be adapted to the specific needs of patients with SSD (e. g. development of a shared, multifactorial model of aetiology). In this protocol, we describe a randomised trial to assess the feasibility of MHSVC in patients with SSD in primary care.

**METHODS AND ANALYSIS**

**Study setting**

The main setting are general practices in the southwest (Baden-Wuerttemberg) of Germany. In Germany, general practitioners have no formal gatekeeping function and individuals have free choice among GPs and specialists[41]. Remote video-based treatment is not very common in the German health care system and reimbursement for such treatments is capped at a maximum number per quarter, varying in different specialties. However, during the COVID-19 pandemic the use of remote video-based

treatment has increased as everywhere else. In our study, the patient will be situated in the general practice and MHS in her office or another suitable offsite location. The participating GP practices have experience with MHSVC, already having participated in a large pragmatic effectiveness trial of the PROVIDE Project implementing MHSVC for patients with depression and anxiety disorders.

## Study design

This study is a multicentric, prospective, assessor blinded and individually randomised controlled feasibility trial. After inclusion of patients, the individual intervention period will be three months; the total time of recruitment is planned to be six months. There will be two main measurements including a baseline assessment just prior to randomisation and a post assessment at six months after inclusion. At month four and five after inclusion there will be two additional short measurements focusing on health care services use only. The study will be implemented and reported in line with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Appendix 1)[42].

## Inclusion and exclusion criteria

### *Patients*

Inclusion criteria require patients to 1) exceed cut-offs of a) 9 points on the Somatic Symptom Scale-8 (SSS-8) and b) 21 points for female patients and 18 for male patients, respectively on the Somatic Symptom Disorder–B Criteria Scale (SSD-12), respectively[43,44], 2) currently have no or as yet insufficient treatment (psychotherapy, psychopharmacotherapy, or both) or difficulty with adherence, 3) agree to participate in the study by written informed consent, 4) be capable of giving consent and 5) be 18 years or older. Although any one somatic symptom may not be continuously present, 6) the state of being symptomatic is persistent (typically more than 6 months). Exclusion criteria are as follows: 1) risk of endangerment to others and/or risk of self-endangerment, 2) need for emergency medical treatment, e.g. admission or rehabilitation, 3) acute psychotic symptoms, e.g. persecutory delusions and/or thought insertion, 4) severe cognitive impairment or dementia, 5) significant hearing and/or visual impairment, 6) pregnancy in the  $\geq$  2nd trimester and 7) insufficient German language proficiency. To ensure maximum generalisability, general practitioners as experts for their patients will decide



whether treatment has been insufficient or whether there have been difficulties with adherence so far. All other inclusion and exclusion criteria will be assessed through standardized computer-assisted telephone interviews (CATI) conducted by a study team member. Acute psychotic symptoms will be assessed by using a list of symptoms which originates from the Structured Clinical Interview for DSM-5 (SCID-5)[45].

*General practices and mental health specialists*

Inclusion criteria for practices are as follows: 1) general practice (specialist in general medicine or internal medicine), 2) team members who are able familiarise patients with video consultations, and 3) written informed consent. Exclusion criteria for the practices are 1) lack of a designated room for the video consultations to ensure confidentiality and 2) lack of internet access or low bandwidth (<384 kbps). The participating MHS must be a licensed psychotherapist or advanced trainee in psychotherapy (that is, at least 1,200 hours of treatment experience) and give written informed consent.

**Study procedures**

For enrolling practices, we will visit each participating practice once. During this visit we will deposit the study documents for patients (including questionnaire, information leaflet and written consent form) in the practice and we will obtain informed consent from the practice team. The team member with the most experience in MHSVC, mostly gained during PROVIDE-C, will be responsible for initiating video consultations and will serve as contact person for MHS, patients, and the study team. By assigning the most experienced team member to this task, we are confident that we will minimize potential difficulties with handling video consultations and consequently minimize task-related expenses. In fact, technical competency is regarded as crucial for successfully implementing telepsychiatry services[46]. Additionally, during the enrolment visit we will address remaining questions and equip the teams with a study handbook including comprehensive descriptions of the target patient group and target disorder, the secure videoconferencing platform and contingency plans in case of technical failures including study team’s contact details. GPs will then start recruiting patients by forwarding their contact information to the study team. To screen patients using the SSS-8 and the SSD-12, the study team will

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3 employ CATI. Interested eligible patients will provide written informed consent by mailing the signed  
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5 consent form back to trial coordination centre. They will either send the filled-out baseline questionnaire  
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7 along or fill it out on an online assessment. Patients will be randomly allocated to the intervention or the  
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9 control condition. The study flow is depicted in Figure 1.  
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14 [INSERT Figure 1: Study flowchart HERE  
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18 [INSERT Figure 2: study schedule HERE]  
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**Intervention**

Given that many GPs find it particularly challenging to address patients with SSD, the VISION intervention targets both patients and their general practice teams (including GPs).

Targeting the general practice teams, we will schedule a video conferencing session (if not feasible, a telephone call) with all participating practice teams, in which we will a) inform the team about the concept of SSD as defined in DSM-5 (including diagnostic criteria) and convey current treatment recommendations for patients in primary care, b) introduce the participating MHS, and c) clarify the regular time slots for the consultations.

For targeting patients, we will follow an integrated stepped care PROVIDE approach directly embedded in the general practice[53]. Specifically, patients allocated to the intervention group will receive either two or five 50-minute MHSVC depending on their level of symptoms and taking place in biweekly intervals. The video consultations will be carried out on a secure (i.e. encrypted), web-based videoconferencing platform on a subscription basis (arztkonsultation ak GmbH, <https://arztkonsultation.de>) at fixed time slots the MHS and general practice team have previously agreed on. Appointments for the next video consultation will be mutually scheduled between the patient and the MHS at the end of the previous session, and the MHS will forward the appointments to the general practice. Within two days prior to the first video consultation, there will be a brief hand-off of the patient from the GP to the MHS. At the beginning of each consultation, a practice team member will escort the patient to the room designated for video consultations, set up the computer tablet and the videoconferencing platform, address the patients' questions (if applicable) and then leave the room. Following the last video consultation, the MHS will send a comprehensible case summary to both the patient and the GP. The case summary will be attached to the patients' medical record in her/his general practice and may be an important basis for shared decisions on follow-up procedures.

Only patients requiring further treatment following the intervention will be motivated to seek outpatient/inpatient psychosocial care. If necessary, changes in treatment (e.g. establishment of fixed, regular contacts between the GP and the patient independent of somatic symptoms) are coordinated between the GP and the MHS[54]. The intervention consists of core elements and optional elements. Whereas core elements are elements that must be applied, optional elements may be applied throughout

the intervention as needed, allowing for individualized patient support. Core elements of the intervention are the following: 1) diagnostic clarification (incl. systematic assessment/diagnostics), 2) interventions aimed at rapid stabilisation of the patient (e.g., by means of psychoeducation on psychophysiological interactions arising from cognitive processes such as catastrophizing thinking or symptom focusing) [55]. Provided that the patient is identified as requiring treatment beyond the two minimal MHSVC, the intervention also includes brief psychological therapy aimed at the development of a biopsychosocial disorder model. For this purpose, a somatic complaint diary, body-oriented relaxation techniques, and tangential conversational skills will be applied. Behavioural activation leveraging the patient's strengths and resources will be applied throughout the intervention as optional elements [56].

### **Control condition**

Patients allocated to the control group will receive enhanced treatment as usual provided by the GP who will have undergone the above-mentioned initial training on the diagnosis of SSD and current treatment recommendations. This may or may not include a referral to an MHS. We expect that most people with SSD are currently treated by their GP due to the patients' fixation on a somatic explanation for their symptoms and persistent barriers to specialist mental health services [57]. There will not be any restrictions to the usual treatment by the GP.

### **Sample size**

We project a target sample size of 50 participants. Since the aim of this study is to establish feasibility of a full trial, but no detection of statistically significant difference in efficacy between the arms a formal sample size calculation was not carried out[58]. A sample size of 50 patients offers a reasonable test of the intervention to assess the feasibility objectives. This sample size is also recommended for pilot and feasibility trials by The National Institute for Health Research[59].

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**Recruitment**

*General practitioners*

We plan to recruit five general practices for this feasibility trial. An additional practice will serve as a back-up practice and will be enrolled in case a practice drops out or the recruitment process lags. Consequently, for a sample size of 50 participants each practice will recruit approximately ten patients. General practices will be recruited during their participation in the PROVIDE-C trial, as they meet the inclusion criteria and were committed to the video-based, integrated care model in the first place. During the initial preparation call and the on-site visit, we will inform the practice teams about the study including the concomitant process evaluation and the assessments involved. The participation requires the signed informed consent.

*Mental health specialists*

The MHS (LG) is a psychotherapist trainee in the advanced training period (e. g. > 200 hours of theoretical and > 1200 hours of clinical training) at the Institute for Psychotherapy, Heidelberg (HIP), which is a state-approved psychotherapeutic training facility at Heidelberg University Hospital. The MHS has experience in treating patients with SSD and has also been involved in developing the VISION intervention. She will receive biweekly supervision by a senior consultant in psychosomatic medicine. For the MHS, the expected weekly time expenditure of the MHS for the realisation of the intervention will be approximately 11 hours (ten hours of consultations, one hour of supervision).

*Patients*

General practitioners will recruit patients during their regular clinic hours. Based on their clinical judgement, GPs will prospectively select individuals suspected to suffer from a somatoform disorder or an SSD and present the study to them. If the patient agrees to receive more information, she or he will be handed the study documents including questionnaires, information leaflet and informed consent form and subsequently will be contacted by the study team who will screen her or him with respect to the eligibility criteria during a standardised Computer-Assisted Telephone Interview (CATI). Eligible

patients will then be able to raise questions with the principal investigator who will answer them. Patients who are interested to participate will mail the filled-out questionnaire and the signed informed consent which is required for study participation to the study centre. Whenever inclusion is not possible, we will record the reason, the recruiting general practice along with patient age and gender.

## Randomisation

Patients will be randomly allocated to one of the two study conditions (video consultation model vs. treatment-as-usual, TAU) in a 1:1 ratio. After having obtained the informed consent, we will conduct the randomisation centrally at the study centre. The web-based application Randomizer Version 2.0.3 of the Institute for Medical Informatics, Statistics and Documentation of the Medical University of Graz, Austria (<https://www.randomizer.at>) will be used. It ensures the concealment of the treatment sequence up to the allocation by central randomisation. The treatment sequence is generated through a computer-generated sequence of random numbers. Randomisation of participants will be stratified by general practice and balanced for symptom severity at the screening measured with the SSD-12 (two levels with  $SSD-12 < 28$  for female patients and  $< 25$  for male patients, respectively for low to medium symptom severity and  $\geq 28$  for female patients and  $\geq 25$  for male patients, respectively for high symptom severity) using minimisation. A member of the Institute of Medical Biometry and Informatics, Heidelberg University, not involved in the patient recruitment will randomise. We will ensure that the assessors who will collect the data will be blinded to the allocated treatment.

## Measurements

### *Patients' health status*

For patients, the baseline assessment will take place before randomisation and include a set of validated questionnaires: SSD-12 and SSS-8[44], Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS)[47], Recovery Assessment Scale (RAS-G)[48], 12-Item Short-Form Health Survey (SF-12)[49], and the patient satisfaction evaluation instrument EUROPEP[50]. Since in the specific patient group with SSD it is common to have a high use of medical services, we will assess health services use at baseline and follow-up and additionally after the fourth and fifth month after inclusion using the

Questionnaire for the Assessment of Medical and non-Medical Resource Utilisation in Mental Disorders(FIMPsy)[51]. Post measurements will be conducted six months after enrolment in the study and will include the same instruments plus, in the intervention group, the Inventory to Negative Effects of Psychotherapy (INEP) to measure potential adverse effects[52]. As part of the blind outcome assessment, a research assistant who will be blinded to participant allocation, will conduct the post measurement in CATIs with the participants. According to current recommendations, we specifically will make sure that the outcome assessor will not be present when discussing individual patients and avoid mentioning any names or assigned treatments[60]. In addition, we will instruct patients before the interview not to mention which group, control or intervention, they belonged to. In the case of unintentional unblinding during the assessment the assessor will document how, and at which point the unblinding unfolded. Hence, we will be able to subsequently determine the extent to which blinded assessment was successful. The study schedule is depicted in Figure 2 in line with the SPIRIT guidelines.

*Feasibility*

To assess process feasibility from the patients’ perspective, we will conduct semi-guided qualitative interviews with patients from the intervention group stratified by practice site and symptom severity (SSD-12; two levels: low to medium symptom severity and high symptom severity). By applying this criterion, we aim for maximizing the transferability of our feasibility findings, e.g., with respect to compatibility with existing clinical workflows. To evaluate the acceptability of both study and intervention procedures, we will analyse patients’ perceptions whether the intervention and study procedures have been agreeable as well as logistically and technically practical [61]. To evaluate the feasibility, adequacy and acceptance of the proposed model in greater detail from the providers’ perspective, we will conduct individual qualitative semi-guided interviews with all GPs, all team members responsible for initiating video consultations, and the MHS.

**Outcomes**

To determine the feasibility of a subsequent large-scale RCT for patients with SSD, we will assess the following outcomes and aspects[58]:

- sufficiency and efficiency of recruitment strategies for intervention and control group
- adherence for intervention group
- feasibility of study procedures (e.g., patient and provider acceptance of randomisation and outcome measurements)
- feasibility of intervention procedures (manual fidelity, patient acceptance of MHSVC, patient safety)

We will operationalise the sufficiency of recruiting strategies and the acceptance of randomisation by measuring recruitment and retention rates. We will record reasons for non-participation or dropping-out. Adherence will be assessed by the ratio of scheduled and actually conducted MHSVC. Regarding manual fidelity, after every MHSVC, the MHS will systematically document which elements of the intervention was used in the respective session. With respect to process outcomes on the overall practicability of the intervention and the related study procedures, we will draw on qualitative data generated by in-depth interviewing of patients, practice staff, and MHS.

### Data analysis

To promote data quality, we will use the password protected online survey tool (Enterprise Feedback Suite (EFS) Survey, Questback GmbH) during the CATIs and enter data from the mail survey there. To minimise implausible data entry, we will enforce data integrity using forced or multiple-choice items wherever possible. Two members of the study team will have access to the data and will prepare it prior to data analysis. Quantitative data regarding the feasibility of a following large-scale RCT, e.g., overall recruitment yield (number randomised per number screened), the recruitment rate (number recruited and randomised per general practice per month), consent rate (number randomised per number eligible), and attrition at study completion, along with information on health services use from questionnaires will be analysed applying descriptive statistics (absolute and relative frequencies, measures of central tendency, and measures of variability). To illustrate participant flow, we will report results in a CONSORT diagram. We will describe patients' reasons for non-participation and will conduct a non-responder analysis. We will also analyse questionnaire outcome data descriptively. Qualitative data generated in the process evaluation will be subjected to thematic analysis which we will conduct in the qualitative



data analysis software MAXQDA 2020 or higher. Specifically, we will derive key theme bottom-up. We will align all study publications with recommendations from statements for observational and feasibility studies.

**Patient and public involvement**

We involved three patient partners (two females, one male) during the planning phase of the study. The patient partners were currently being treated in a mental health inpatient clinic for SSD (among other diagnoses). Specifically, the patient partners were involved in the conceptualisation of the trial procedures and materials. They revised the draft version of the intervention and all trial materials including information leaflet, consent form and the questionnaire sets with extra regard to clarity and understanding from the service user perspective. We will continue to involve the patient partners during the trial accounting for guidance for public involvement in research[62].

**ETHICS AND DISSEMINATION**

Participants will be asked to provide informed consent prior to baseline assessment. In advance, they will receive detailed information about the study and their right to withdraw it without the obligation to give reasons. Subsequently they will have the opportunity to raise questions with the principal investigator who will answer them. To adequately prepare the MHS for the intervention, the study manual will be based on experiences from prior projects and existing recommendations for telepsychiatry[63–66]. Moreover, MHS will be supported by a biweekly supervision which will be led by a senior consultant both in general and psychosomatic medicine from the Department of General Internal Medicine and Psychosomatics, Heidelberg University. We do not expect major relevant risks for participants irrespective of phases of emotional arousal which frequently occur during psychotherapy. Findings from our own prior works support this expectation. Any potential adverse effects originate from the intervention will be systematically captured by using the INEP as part of the post measurement. The time burden for the participants arising from the assessments will be of a reasonable amount. The data collection and storage will be conducted in accordance with the General Data Protection Regulation (GDPR) which ensures a high level of data safety and a conscientious

handling of all the patient, practice, and therapist data. Ethical approval for the study has been granted from the Medical Faculty of the University of Heidelberg Ethics Committee, Reference S-620/2021. Additionally, considering that the study will take place in routine general practice, we obtained the ethical approval of the State Chamber of Physicians Baden-Wuerttemberg. As part of a wider dissemination, the results of this feasibility trial will inform the setup of a large-scale randomised trial which is supposed to evaluate broad regional implementation of MHSVC for patients with SSD in primary care. Moreover, we will publish and present key findings on conferences and in internationally recognised peer reviewed journals.

## DISCUSSION

To the best of our knowledge, we conduct one of the first feasibility trials on MHSVC for patients with SSD in European routine primary care. As a low-threshold model embedded in a familiar environment, MHSVC in general practices may be of particular value for affected patients, as close collaboration between GPs and MHSs in their effective treatment is of particular importance. This trial will deliver results on the feasibility of this model and prepare the ground for a fully powered RCT on its broader rollout.

## AUTHOR STATEMENT

Markus W. Haun: Conceptualization, methodology, investigation, writing – review & editing, project administration, and funding acquisition. Justus Tönnies: Conceptualization, methodology, investigation, writing – original draft, writing – review & editing. Leike Graue: Methodology, investigation, writing – original draft, writing – review & editing. Mechthild Hartmann: Conceptualization, methodology, writing–original draft, writing – review & editing, and supervision. Michel Wensing: Methodology, writing–original draft, writing – review & editing, and supervision. Joachim Szecsenyi: Conceptualization, writing – review & editing, and supervision. Hans-Christoph Friederich: Conceptualization, resources, writing – review & editing, and funding acquisition. All authors approved the version of the manuscript to be published and have agreed to be accountable for all aspects of the work.

CONFLICT OF INTERESTS STATEMENT

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

DATA STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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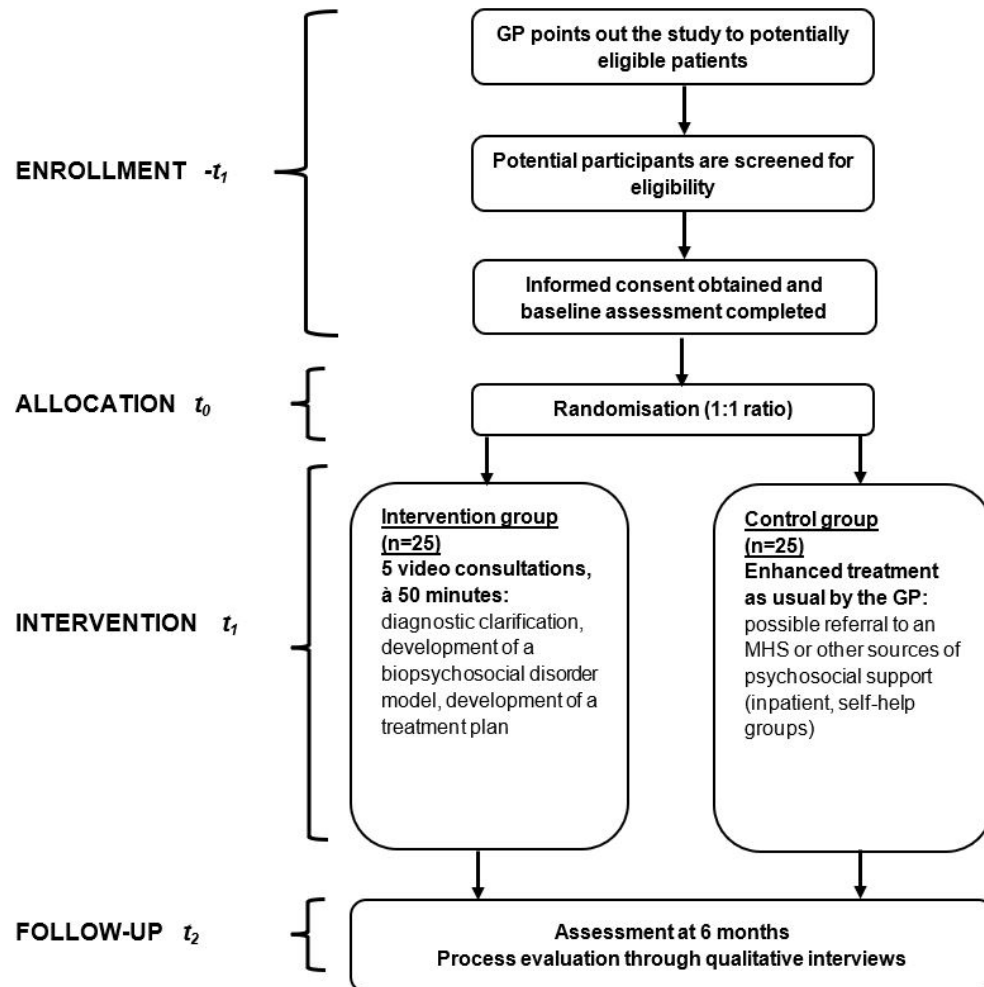




Figure 1. Study flowchart

209x210mm (96 x 96 DPI)



			STUDY PERIOD							
	Enrolment	Allocation	Post-allocation						Close-out	
TIMEPOINT	$-t_1$	$t_0$	$t_1$	$t_{1a}$	$t_{1b}$	$t_{1c}$	$t_{1d}$	$t_2$ $t_{1+6}$ $months$	$t_x$	
Enrolment:										
<i>Screening assessment on inclusion and exclusion criteria</i>	X									
<i>informed consent</i>	X									
<i>baseline assessment</i>	X									
<i>randomisation</i>		X								
<i>allocation</i>		X								
INTERVENTIONS:										
<i>video consultations with MHS</i>										
<i>treatment as usual by the GP</i>										
ASSESSMENTS:										
<i>sociodemographic data</i>	X									
<i>SSD-12<sup>1</sup>, SSS-8<sup>2</sup>, PHQ-ADS<sup>3</sup>, RAS-G<sup>4</sup>, SF-12<sup>5</sup>, EUROPEP<sup>6</sup>, FIMPsy<sup>7</sup></i>	X							X		
<i>INEP<sup>8</sup></i>								X		
<i>interviews (patients, GPs, medical assistants, MHS)</i>								X		

<sup>1</sup> Somatic Symptom Disorder-B Criteria Scale (SSD-12)[44], <sup>2</sup> Somatic Symptom Scale-8 (SSS-8)[44], <sup>3</sup> Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS)[47], <sup>4</sup> Recovery Assessment Scale (RAS-G)[48], <sup>5</sup> 12-Item Short-Form Health Survey (SF-12)[49], <sup>6</sup> patient satisfaction evaluation instrument EUROPEP[50], <sup>7</sup> Questionnaire for the Assessment of Medical and non-Medical Resource Utilisation in Mental Disorders (FIMPsy)[51], <sup>8</sup> Inventory for the Assessment of Negative Effects of Psychotherapy (INEP)[52]

Figure 2. Study schedule

162x223mm (96 x 96 DPI)



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

Section/item	Item No	Description	p.
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	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	1
	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)	n/a
<b>Introduction</b>			
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	4-5
	6b	Explanation for choice of comparators	4-6
Objectives	7	Specific objectives or hypotheses	4-6
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)	6

**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	5-6
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)	6-7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-12
	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)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
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	15
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)	Fig. 1, 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	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13

**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	13-14
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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	13-14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13-14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a

### 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	14-15
	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	14-15
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	16
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	16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16
	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)	n/a

### 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	n/a
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	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	n/a
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	17-18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	17-18
<b>Ethics and dissemination</b>			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
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)	n/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7-8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
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	16
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	n/a
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	17-18
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18

## Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
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	n/a

\*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

# BMJ Open

## Mental health specialist video consultations for patients with somatic symptom disorder in primary care: Protocol for a randomised feasibility trial (the VISION-trial)

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Manuscripts

**Mental health specialist video consultations for patients with somatic symptom disorder in primary care: Protocol for a randomised feasibility trial (the VISION-trial)**

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## ABSTRACT

**Introduction:** General practitioners (GP) report increasing difficulties in referring patients with somatic symptom disorder (SSD) in specialised psychosocial care. Barriers are structural conditions of the respective health care system and patients' reservations against receiving specialized psychosocial care. As patients with SSD often predominantly assume somatic influencing factors for the development and maintenance of their somatic complaints, close collaboration between the GP and mental health specialist (MHS) seems particularly important. Integrating internet-based video consultations by remotely located MHS and primary care can improve effective treatment of patients with SSD by overcoming structural barriers and provide low-threshold and timely care. The aim of this randomised controlled feasibility trial is to investigate the feasibility of implementing of mental health specialist video consultations in primary care practices.

**Methods and analysis:** Fifty primary care patients with SSD will be individually randomised in two groups receiving either enhanced treatment as usual as provided by their general practitioner (control group) or two vs. five video consultations conducted by an MHS additionally to enhanced treatment as usual. The video consultations focus on a) diagnostic clarification b) the development of a biopsychosocial disorder model and c) development of a treatment plan against the background of a stepped-care algorithm based on clinical outcomes. We will investigate the following outcomes: effectiveness of the recruitment strategies, patient acceptance of randomisation, practicability of the technical and logistical processes related to implementing video consultations in the practices' workflows, feasibility of the data collection, and clinical parameters.

**Ethics and dissemination:** This trial has undergone ethical scrutiny and has been approved by the Medical Faculty of the University of Heidelberg Ethics Committee (S-620/2021). The findings will be disseminated to the research community through presentations at conferences and publications in scientific journals. This feasibility trial will prepare the ground for a large-scale, fully-powered randomised controlled trial.

**Trial registration number:** DRKS00026075.

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**Key words:** primary care, mental health, telemedicine, video consultations, somatic symptom disorder, feasibility, randomised controlled trial

**ARTICLE SUMMARY**

Strengths and limitations of this study

- This is one of the first feasibility trials investigating mental health specialist video consultations for patients with somatic symptom disorder (SSD) presenting in primary care.
- We will transform and tailor an already tested integrated mental health treatment model, originally developed for depression and anxiety, for patients with SSD, who may benefit particularly due to high barriers in referral to specialised care.
- Given the nature of our feasibility study, we will not be able to determine intervention effectiveness at this point, but our findings will inform the design of a sufficiently powered randomised controlled trial.

## INTRODUCTION

According to the Diagnostic and Statistical Manual of Mental Disorders (DSM–5), catastrophizing cognitions, feelings and behaviours (B-criterion) in response to “one or more somatic symptom(s) that is/are distressing or result(s) in significant disruption of daily life” (A-criterion) are core characteristics of somatic symptom disorder (SSD)[1]. In contrast to the former conceptualization of “somatoform” disorders in DSM-IV[2] and ICD-10[3] the diagnosis SSD does not require no or no sufficient medical explanation for the distressing somatic symptoms. Thus, patients with somatic disorders such as cardiovascular disease or cancer may now be diagnosed with SSD, in case of experiencing the described symptoms for a period of at least 6 months (C-criterion).

While the prevalence of clinically diagnosable SSD in the general population is estimated at 5-7 % [4]; subsyndromal manifestations of SSD are far more common[5]. Further, Haller and colleagues[6] found a prevalence of 26.2 % (DSM-IV) and 34.8 % (ICD-10) for at least one somatoform disorder in general practices, making these symptoms to one of the most common reasons for consultations in primary care[7,8]. Although these symptoms are often associated with a) considerable suffering and psychosocial impairment, b) increased comorbidities with other mental disorders (e. g. depressive and anxiety disorders[9–11]), and c) increased costs for the health care system[12,13], general practitioners (GP) report increasing difficulties in referring patients with mental disorders in specialized mental health care[14–16].

Even when effective treatment options are available – as is the case in many Western healthcare systems[17] – these difficulties often remain due to a) long waiting times with specialists[15,18,19], b) long travel distances, especially in rural and remote locations[20], and c) severe time constraints in primary care, complicating accurate diagnosis by GPs[21,22]. In addition, patients often have reservations against specialized mental health care[23]. Since patients with SSD often find it difficult to accept that they suffer from a mental and not (exclusively) from a somatic disorder[24,25], patients’ reservations are of particular importance here. Further, these disorder-related reservations particularly necessitate a close collaboration between the GP and mental health specialist (MHS) in the effective treatment of patients with SSD[26–28].

To resolve these challenges, one strategy is to define, implement and evaluate innovative care models, that are tailored both to the specific conditions of the respective care system as well as to the specific needs of patients with SSD. For patients with depressive and anxiety disorders, the junior research group PROVIDE (ImPROving cross-sectorial collaboration between primary and psychosocial care: An implementation study on VIDEo consultations) has been defining, tailoring and evaluating an integrated psychosocial care model compatible with small and/or remote general practices [29–35] (<https://www.provide-project.de/vision/>). Specifically, this model features MHS video consultations (MHSVC) in primary care. While the MHS is situated in her/his office, private practice or another suitable, designated room at home, the patient receives the telemedical service in her/his general practice. While the results of the large RCT examining the efficacy of this model are still pending, the intervention in the PROVIDE-B feasibility trial was found to be feasible, acceptable and secure for patients, general practice staff and MHS[34]. In addition, during the COVID-19-pandemic video consultations have been implemented rapidly in many health care systems and providers and patients become more familiar with this mode of care delivery[36–39].

For progressing in this way, our aim is to offer a similar integrated care model to patients with SSD. While the formal conditions of the model (duration and frequency of consultations, location of the patient and MHS etc.) will be retained [31,40], the psychosocial intervention will be adapted to the specific needs of patients with SSD (e. g. development of a shared, multifactorial model of aetiology). In this protocol, we describe a randomised trial to assess the feasibility of MHSVC in patients with SSD in primary care.

**METHODS AND ANALYSIS**

**Study setting**

The main setting are general practices in the southwest (Baden-Wuerttemberg) of Germany. In Germany, general practitioners have no formal gatekeeping function and individuals have free choice among GPs and specialists[41]. Remote video-based treatment is not very common in the German health care system and reimbursement for such treatments is capped at a maximum number per quarter, varying in different specialties. However, during the COVID-19 pandemic the use of remote video-based

treatment has increased as everywhere else. In our study, the patient will be situated in the general practice and MHS in her office or another suitable offsite location. The participating GP practices have experience with MHSVC, already having participated in a large pragmatic effectiveness trial of the PROVIDE Project implementing MHSVC for patients with depression and anxiety disorders.

## Study design

This study is a multicentric, prospective, assessor blinded and individually randomised controlled feasibility trial. After inclusion of patients, the individual intervention period will be three months; the total time of recruitment is planned to be six months. There will be two main measurements including a baseline assessment just prior to randomisation and a post assessment at six months after inclusion. At month four and five after inclusion there will be two additional short measurements focusing on health care services use only. Patient recruitment started in October 2021 and will be completed in March 2022. Data collection will be completed in August 2022. The study will be implemented and reported in line with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Appendix 1)[42].

## Inclusion and exclusion criteria

### *Patients*

Inclusion criteria require patients to 1) exceed cut-offs of a) 9 points on the Somatic Symptom Scale-8 (SSS-8) and b) 15 points for female patients and 12 for male patients, respectively on the Somatic Symptom Disorder-B Criteria Scale (SSD-12), respectively[43,44], 2) currently have no or as yet insufficient treatment (psychotherapy, psychopharmacotherapy, or both) or difficulty with adherence, 3) agree to participate in the study by written informed consent, 4) be capable of giving consent and 5) be 18 years or older. Although any one somatic symptom may not be continuously present, 6) the state of being symptomatic is persistent (typically more than 6 months). Exclusion criteria are as follows: 1) risk of endangerment to others and/or risk of self-endangerment, 2) need for emergency medical treatment, e.g. admission or rehabilitation, 3) acute psychotic symptoms, e.g. persecutory delusions and/or thought insertion, 4) severe cognitive impairment or dementia, 5) significant hearing and/or

visual impairment, 6) pregnancy in the  $\geq$  2nd trimester and 7) insufficient German language proficiency. To ensure maximum generalisability, general practitioners as experts for their patients will decide whether treatment has been insufficient or whether there have been difficulties with adherence so far. All other inclusion and exclusion criteria will be assessed through standardized computer-assisted telephone interviews (CATI) conducted by a study team member. Acute psychotic symptoms will be assessed by using a list of symptoms which originates from the Structured Clinical Interview for DSM-5 (SCID-5)[45].

*General practices and mental health specialists*

Inclusion criteria for practices are as follows: 1) general practice (specialist in general medicine or internal medicine), 2) team members who are able to familiarise patients with video consultations, and 3) written informed consent. Exclusion criteria for the practices are 1) lack of a designated room for the video consultations to ensure confidentiality and 2) lack of internet access or low bandwidth (<384 kbps). The participating MHS must be a licensed psychotherapist or advanced trainee in psychotherapy (that is, at least 1,200 hours of treatment experience) and give written informed consent.

**Study procedures**

For enrolling practices, we will visit each participating practice once. During this visit we will deposit the study documents for patients (including questionnaire, information leaflet and written consent form) in the practice and we will obtain informed consent from the practice team. The team member with the most experience in MHSVC, mostly gained during PROVIDE-C, will be responsible for initiating video consultations and will serve as contact person for MHS, patients, and the study team. By assigning the most experienced team member to this task, we are confident that we will minimize potential difficulties with handling video consultations and consequently minimize task-related expenses. In fact, technical competency is regarded as crucial for successfully implementing telepsychiatry services[46]. Additionally, during the enrolment visit we will address remaining questions and equip the teams with a study handbook including comprehensive descriptions of the target patient group and target disorder, the secure videoconferencing platform and contingency plans in case of technical failures including

study team's contact details. GPs will then start recruiting patients by forwarding their contact information to the study team. We assume that the therapeutic alliance between GP and patient, which in most cases has already existed for several years, will promote the willingness of patients to participate in the study. Especially for patients with SSD who often have reservations against specialized mental health care[23] because they find it difficult to accept that they suffer from a mental and not (exclusively) from a somatic disorder[24,25], the therapeutic alliance between GP and patient can function as a facilitator for study participation. The fact that our intervention is rather a short-term intervention than it is a long-term psychotherapeutic treatment, may also contribute to a general openness on the patients' side. To screen patients using the SSS-8 and the SSD-12, the study team will employ CATI. Interested eligible patients will provide written informed consent by mailing the signed consent form back to the trial coordination centre. They will either send the filled-out baseline questionnaire along or fill it out on an online assessment. Patients will be randomly allocated to the intervention or the control condition. The study flow is depicted in Figure 1.

## Intervention

Given that many GPs find it particularly challenging to address patients with SSD, the VISION intervention targets both patients and their general practice teams (including GPs).

Targeting the general practice teams, we will schedule a video conferencing session (if not feasible, a telephone call) with all participating practice teams, in which we will a) inform the team about the concept of SSD as defined in DSM-5 (including diagnostic criteria) and convey current treatment recommendations for patients in primary care. In this training, we will especially focus on the aspect that in contrast to the former conceptualization of "somatoform" disorders in DSM-IV[2] and ICD-10[3], the diagnosis SSD does not require no or no sufficient medical explanation for the distressing somatic symptoms. During the video conferencing session, we will also b) introduce the participating MHS, and c) clarify the regular time slots for the consultations.

For targeting patients, we will follow an integrated stepped care PROVIDE approach directly embedded in the general practice[47]. Specifically, patients allocated to the intervention group will receive either two or five 50-minute MHSVC depending on their level of symptoms and taking place in biweekly



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3 intervals. The video consultations will be carried out on a secure (i.e. encrypted), web-based  
4 videoconferencing platform on a subscription basis (arztkonsultation ak GmbH,  
5 <https://arztkonsultation.de>) at fixed time slots the MHS and general practice team have previously agreed  
6 on. Appointments for the next video consultation will be mutually scheduled between the patient and  
7 the MHS at the end of the previous session, and the MHS will forward the appointments to the general  
8 practice. Within two days prior to the first video consultation, there will be a brief hand-off of the patient  
9 from the GP to the MHS. At the beginning of each consultation, a practice team member will escort the  
10 patient to the room designated for video consultations, set up the computer tablet and the  
11 videoconferencing platform, address the patients' questions (if applicable) and then leave the room.  
12 Following the last video consultation, the MHS will send a comprehensible case summary to both the  
13 patient and the GP. The case summary will be attached to the patients' medical record in her/his general  
14 practice and may be an important basis for shared decisions on follow-up procedures.

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16 Only patients requiring further treatment following the intervention will be motivated to seek  
17 outpatient/inpatient psychosocial care. If necessary, changes in treatment (e.g. establishment of fixed,  
18 regular contacts between the GP and the patient independent of somatic symptoms) are coordinated  
19 between the GP and the MHS[48]. The intervention consists of core elements and optional elements.  
20 Whereas core elements are elements that must be applied, optional elements may be applied throughout  
21 the intervention as needed, allowing for individualized patient support. Core elements of the intervention  
22 are the following: 1) diagnostic clarification (incl. systematic assessment/diagnostics), 2) interventions  
23 aimed at rapid stabilisation of the patient (e.g., by means of psychoeducation on psychophysiological  
24 interactions arising from cognitive processes such as catastrophizing thinking or symptom focusing)  
25 [49]. Provided that the patient is identified as requiring treatment beyond the two minimal MHSVC, the  
26 intervention also includes brief psychological therapy aimed at the development of a biopsychosocial  
27 disorder model. For this purpose, a somatic complaint diary, body-oriented relaxation techniques, and  
28 tangential conversational skills will be applied. Behavioural activation leveraging the patient's strengths  
29 and resources will be applied throughout the intervention as optional elements [50]. During the  
30 individual intervention period, there will be no restrictions on patients receiving treatment from their  
31 GP and/or the practice team.



### Control condition

Patients allocated to the control group will receive enhanced treatment as usual provided by the GP who will have undergone the above-mentioned initial training on the diagnosis of SSD and current treatment recommendations. This may or may not include a referral to an MHS. We expect that most people with SSD are currently treated by their GP due to the patients' fixation on a somatic explanation for their symptoms and persistent barriers to specialist mental health services [51]. There will not be any restrictions to the usual treatment by the GP.

### Sample size

Since the aim of this study is to establish feasibility of a full trial (i. e. the aim of this study is not to provide evidence of a statistically significant difference between the two treatment conditions), a formal sample size calculation was not carried out [52]. Instead, we project a target sample size of  $N = 50$  participants. In determining the sample size, we followed the recommendations for conducting pilot and feasibility trials as described by the National Institute for Health Research [53]. A sample size of  $N = 50$  patients offers a reasonable test of the intervention to assess the feasibility objectives [52,54–56].

**Recruitment**

*General practitioners*

We planned to recruit five general practices for this feasibility trial. After recruitment had started in these practices, the COVID booster vaccination campaign launched in Germany. As a result, the participating general practices faced an enormous workload as being responsible for a large number of patients. Consequently, the recruitment process lagged, and we decided to enrol four additional practices that had previously been considered as back-up practices. They were informed and prepared for a quick enrolment, which then worked out seamless and they started recruiting patients immediately. General practices were recruited during their participation in the PROVIDE-C trial, as they met the inclusion criteria and were committed to the video-based, integrated care model in the first place. During the initial preparation call and the on-site visit, we informed the practice teams about the study including the concomitant process evaluation and the assessments involved. The participation requires the signed informed consent.

*Mental health specialists*

The MHS (LG) is a psychotherapist trainee in the advanced training period (e. g. > 200 hours of theoretical and > 1200 hours of clinical training) at the Institute for Psychotherapy, Heidelberg (HIP), which is a state-approved psychotherapeutic training facility at Heidelberg University Hospital. The MHS has experience in treating patients with SSD and has also been involved in developing the VISION intervention. She will receive biweekly supervision by a senior consultant in psychosomatic medicine. For the MHS, the expected weekly time expenditure of the MHS for the realisation of the intervention will be approximately 11 hours (ten hours of consultations, one hour of supervision).

*Patients*

General practitioners will recruit patients during their regular clinic hours. Based on their clinical judgement, GPs will prospectively select individuals suspected to suffer from a somatoform disorder or an SSD and present the study to them. If the patient agrees to receive more information, she or he will

be handed the study documents including questionnaires, information leaflet and informed consent form and subsequently will be contacted by the study team who will screen her or him with respect to the eligibility criteria during a standardised Computer-Assisted Telephone Interview (CATI). Eligible patients will then be able to raise questions with the principal investigator who will answer them. Patients who are interested to participate will mail the filled-out questionnaire and the signed informed consent which is required for study participation to the study centre. Whenever inclusion is not possible, we will record the reason, the recruiting general practice along with patient age and gender. By recording this information, we will be able to conduct a comprehensive non-responder analysis which will provide us further insights of the acceptance of the intervention.

### Randomisation

Patients will be randomly allocated to one of the two study conditions (treatment-as-usual, TAU vs. video consultation model (additionally to TAU)) in a 1:1 ratio. After having obtained the informed consent, we will conduct the randomisation centrally at the study centre. The web-based application Randomizer Version 2.0.3 of the Institute for Medical Informatics, Statistics and Documentation of the Medical University of Graz, Austria (<https://www.randomizer.at>) will be used. It ensures the concealment of the treatment sequence up to the allocation by central randomisation. The treatment sequence is generated through a computer-generated sequence of random numbers. Randomisation of participants will be stratified by general practice and balanced for symptom severity at the screening measured with the SSD-12 (two levels with  $\text{SSD-12} < 28$  for female patients and  $< 25$  for male patients, respectively for low to medium symptom severity and  $\geq 28$  for female patients and  $\geq 25$  for male patients, respectively for high symptom severity) using minimisation. A member of the Institute of Medical Biometry and Informatics, Heidelberg University, not involved in the patient recruitment will randomise. We will ensure that the assessors who will collect the data will be blinded to the allocated treatment.

### Measurements

In this study, we will assess feasibility and acceptance not only of the intervention, but also of study procedures, such as data collection as it would occur in a sufficiently powered effectiveness trial. Therefore, we will collect data on several clinical endpoints and will assess whether these procedures are appropriate for this specific patient group.

*Patients' health status*

For patients, the baseline assessment will take place before randomisation and include a set of validated questionnaires: SSD-12 and SSS-8[44], Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS)[57], Recovery Assessment Scale (RAS-G)[58], 12-Item Short-Form Health Survey (SF-12)[59], and the patient satisfaction evaluation instrument EUROPEP[60]. Since in the specific patient group with SSD it is common to have a high use of medical services, we will assess health services use at baseline and follow-up and additionally after the fourth and fifth month after inclusion using the Questionnaire for the Assessment of Medical and non-Medical Resource Utilisation in Mental Disorders (FIMPsy)[61]. Post measurements will be conducted six months after enrolment in the study and will include the same instruments plus, in the intervention group, the Inventory to Negative Effects of Psychotherapy (INEP) to measure potential adverse effects[62]. As part of the blind outcome assessment, a research assistant who will be blinded to participant allocation, will conduct the post measurement in CATIs with the participants. According to current recommendations, we specifically will make sure that the outcome assessor will not be present when discussing individual patients and avoid mentioning any names or assigned treatments[63]. In addition, we will instruct patients before the interview not to mention which group, control or intervention, they belonged to. In the case of unintentional unblinding during the assessment the assessor will document how, and at which point the unblinding unfolded. Hence, we will be able to subsequently determine the extent to which blinded assessment was successful. The study schedule is depicted in Figure 2 in line with the SPIRIT guidelines.

*Feasibility*

To assess process feasibility from the patients' perspective, we will conduct semi-guided qualitative interviews with patients from the intervention group stratified by practice site and symptom severity

(SSD-12; two levels: low to medium symptom severity and high symptom severity). By applying this criterion, we aim for maximizing the transferability of our feasibility findings, e.g., with respect to compatibility with existing clinical workflows. To evaluate the acceptability of both study and intervention procedures, we will analyse patients' perceptions whether the intervention and study procedures have been agreeable as well as logistically and technically practical [64]. To evaluate the feasibility, adequacy and acceptance of the proposed model in greater detail from the providers' perspective, we will conduct individual qualitative semi-guided interviews with all GPs, all team members responsible for initiating video consultations, and the MHS.

## Outcomes

Since this is a feasibility trial, we will not test any hypotheses or perform any statistical tests. Thus, we do not expect any effects of the intervention in this small sample. Instead, we expect that a) our trial design (incl. study procedures such as recruitment strategy, data collection procedures, randomization and logistic aspects) is appropriate and b) that MHSVC are feasible in this specific population (e. g. patients with SSD) and in this specific setting (e. g. general practices).

To determine the feasibility of a subsequent large-scale RCT for patients with SSD, we will assess the following outcomes and aspects[52]:

- sufficiency and efficiency of recruitment strategies for intervention and control group
- adherence for intervention group
- feasibility of study procedures (e.g., patient and provider acceptance of randomisation and outcome measurements)
- feasibility of intervention procedures (manual fidelity, patient acceptance of MHSVC, patient safety)

We will operationalise the sufficiency of recruiting strategies and the acceptance of randomisation by measuring recruitment and retention rates. We will record reasons for non-participation or dropping-out. Adherence will be assessed by the ratio of scheduled and actually conducted MHSVC. Regarding manual fidelity, after every MHSVC, the MHS will systematically document which elements of the

intervention was used in the respective session. With respect to process outcomes on the overall practicability of the intervention and the related study procedures, we will draw on qualitative data generated by in-depth interviewing of patients, practice staff, and MHS.

**Data analysis**

To promote data quality, we will use the password protected online survey tool (Enterprise Feedback Suite (EFS) Survey, Questback GmbH) during the CATIs and enter data from the mail survey there. To minimise implausible data entry, we will enforce data integrity using forced or multiple-choice items wherever possible. Two members of the study team will have access to the data and will prepare it prior to data analysis. Quantitative data regarding the feasibility of a following large-scale RCT, e.g., overall recruitment yield (number randomised per number screened), the recruitment rate (number recruited and randomised per general practice per month), consent rate (number randomised per number eligible), and attrition at study completion, along with information on health services use from questionnaires will be analysed applying descriptive statistics (absolute and relative frequencies, measures of central tendency, and measures of variability). To illustrate participant flow, we will report results in a CONSORT diagram. We will describe patients' reasons for non-participation and will conduct a non-responder analysis. We will also analyse questionnaire outcome data descriptively. Qualitative data generated in the process evaluation will be subjected to thematic analysis which we will conduct in the qualitative data analysis software MAXQDA 2020 or higher. Specifically, we will derive key theme bottom-up. We will align all study publications with recommendations from statements for observational and feasibility studies.

**Missing values**

Throughout the whole process of data collection, we will try to minimize the amount of missing values by carrying out most assessments by making use of CATIs (i. e. screening, follow-up). With regard to missing values occurring during the collection of baseline-data, we will check the completeness of each patients' baseline questionnaire prior to randomization. These two procedures will reduce the amount of missing values due to carelessness on the part of the patient and research team. Missing values

occurring beyond these two procedures, we will consider as important findings in the context of this feasibility trial: For example, a possible scenario is, that several patients do not want to answer one or more specific questions in the questionnaires. By respecting this, we will gain important information on the acceptance and appropriateness of the questionnaires used.

### **Patient and public involvement**

We involved three patient partners (two females, one male) during the planning phase of the study. The patient partners were currently being treated in a mental health inpatient clinic for SSD (among other diagnoses). Specifically, the patient partners were involved in the conceptualisation of the trial procedures and materials. They revised the draft version of the intervention and all trial materials including information leaflet, consent form and the questionnaire sets with extra regard to clarity and understanding from the service user perspective. We will continue to involve the patient partners during the trial accounting for guidance for public involvement in research[65].

### **ETHICS AND DISSEMINATION**

Participants will be asked to provide informed consent prior to baseline assessment. In advance, they will receive detailed information about the study and their right to withdraw it without the obligation to give reasons. Subsequently they will have the opportunity to raise questions with the principal investigator who will answer them. To adequately prepare the MHS for the intervention, the study manual will be based on experiences from prior projects and existing recommendations for telepsychiatry[66–69]. Moreover, MHS will be supported by a biweekly supervision which will be led by a senior consultant both in general and psychosomatic medicine from the Department of General Internal Medicine and Psychosomatics, Heidelberg University. We do not expect major relevant risks for participants irrespective of phases of emotional arousal which frequently occur during psychotherapy. Findings from our own prior works support this expectation. Any potential adverse effects originate from the intervention will be systematically captured by using the INEP as part of the post measurement. The time burden for the participants arising from the assessments will be of a



reasonable amount. The data collection and storage will be conducted in accordance with the General Data Protection Regulation (GDPR) which ensures a high level of data safety and a conscientious handling of all the patient, practice, and therapist data. Ethical approval for the study has been granted from the Medical Faculty of the University of Heidelberg Ethics Committee, Reference S-620/2021. Additionally, considering that the study will take place in routine general practice, we obtained the ethical approval of the State Chamber of Physicians Baden-Wuerttemberg. As part of a wider dissemination, the results of this feasibility trial will inform the setup of a large-scale randomised trial which is supposed to evaluate broad regional implementation of MHSVC for patients with SSD in primary care. Moreover, we will publish and present key findings on conferences and in internationally recognised peer reviewed journals.

**DISCUSSION**

To the best of our knowledge, we conduct one of the first feasibility trials on MHSVC for patients with SSD in European routine primary care. As a low-threshold model embedded in a familiar environment, MHSVC in general practices may be of particular value for affected patients, as close collaboration between GPs and MHSs in their effective treatment is of particular importance. Given that the acceptance and satisfaction of video-based mental health treatment facilitated by the COVID-19 pandemic has already been demonstrated[34,70–72], this study will primarily provide results on the feasibility of the specific (core) elements of this model and prepare the ground for a fully powered RCT on its broader rollout. Accordingly, an important limitation of the study is that no conclusions on the effectiveness of the intervention can be made. Another important aspect is that this feasibility trial will be conducted under the conditions of the COVID-19 pandemic. Since we cannot yet estimate for how long we will have to cope with the pandemic-related restrictions (e. g. contact restrictions, modified working conditions), their related consequences (e. g. increase in psychosocial distress for many people which may lead to an increased need for mental health consultations in primary care practices) and related increased demands on our health care system (e. g. increased workload for GPs and thus little capacity to engage in “additional” tasks such as recruiting patients for an effectiveness trial), this aspect may represent either a strength or limitation with regard to a possible subsequent effectiveness trial.

## AUTHOR STATEMENT

Markus W. Haun: Conceptualization, methodology, investigation, writing – review & editing, project administration, and funding acquisition. Justus Tönnies: Conceptualization, methodology, investigation, writing – original draft, writing – review & editing. Leike Graue: Methodology, investigation, writing – original draft, writing – review & editing. Mechthild Hartmann: Conceptualization, methodology, writing–original draft, writing – review & editing, and supervision. Michel Wensing: Methodology, writing–original draft, writing – review & editing, and supervision. Joachim Szecsenyi: Conceptualization, writing – review & editing, and supervision. Beate Wild: Methodology, investigation, writing – review & editing. Hans-Christoph Friederich: Conceptualization, resources, writing – review & editing, and funding acquisition. All authors approved the version of the manuscript to be published and have agreed to be accountable for all aspects of the work.

## CONFLICT OF INTERESTS STATEMENT

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## DATA STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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## FIGURE LEGENDS

Figure 1: Study flowchart

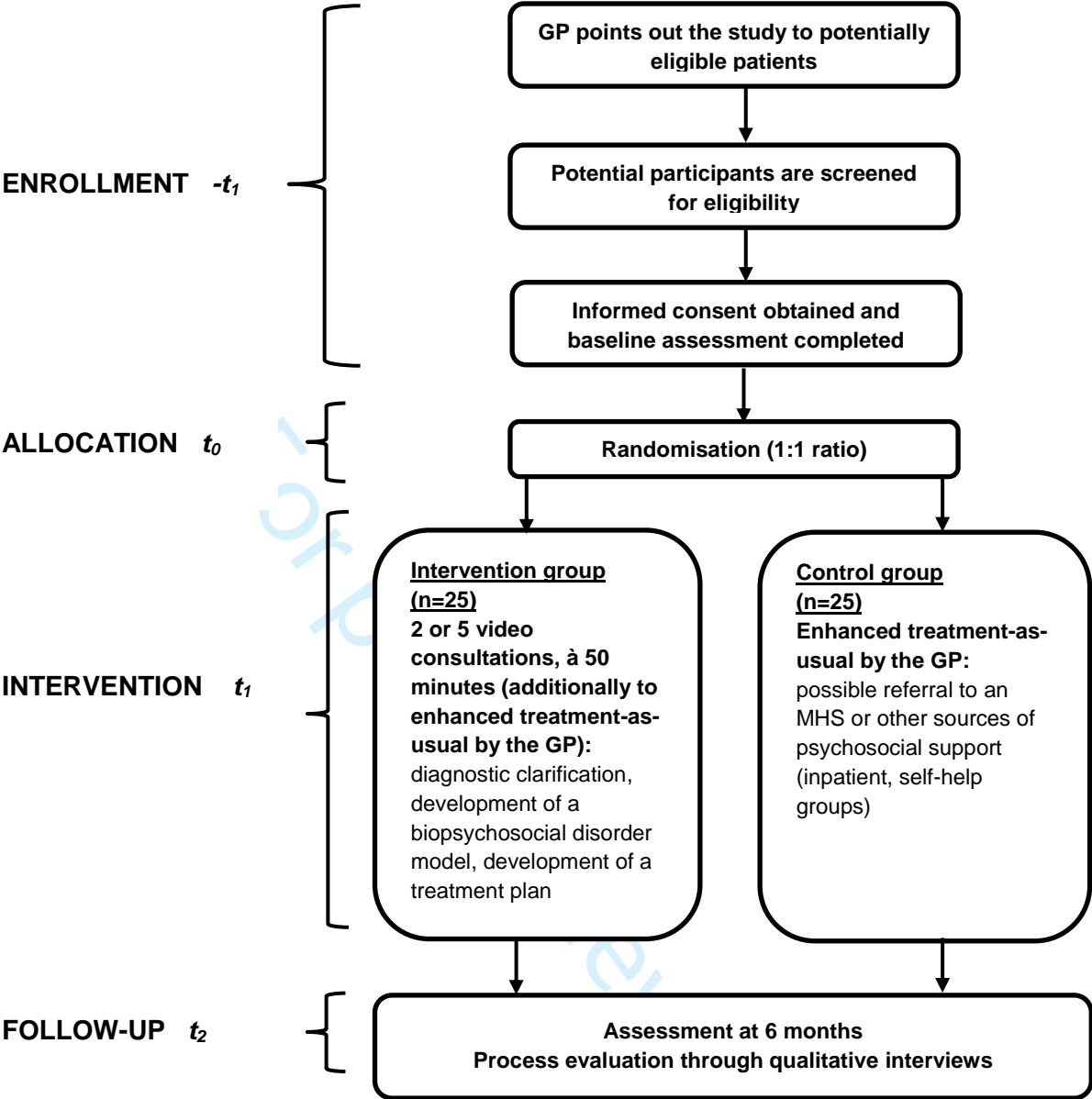
<sup>1</sup> Somatic Symptom Disorder–B Criteria Scale (SSD-12)[44], <sup>2</sup> Somatic Symptom Scale-8 (SSS-8)[44], <sup>3</sup> Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS)[57], <sup>4</sup> Recovery Assessment Scale (RAS-G)[58], <sup>5</sup> 12-Item Short-Form Health Survey (SF-12)[59], <sup>6</sup> patient satisfaction evaluation instrument EUROPEP[60], <sup>7</sup> Questionnaire for the Assessment of Medical and non-Medical Resource Utilisation in Mental Disorders (FIMPsy)[61], <sup>8</sup> Inventory for the Assessment of Negative Effects of Psychotherapy (INEP)[62]

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Figure 2: study schedule

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			STUDY PERIOD						
	Enrolment	Allocation	Post-allocation						Close-out
TIMEPOINT	$-t_1$	$t_0$	$t_1$	$t_{1a}$	$t_{1b}$	$t_{1c}$	$t_{1d}$	$t_2$ $t_1+6$ months	$t_x$
Enrolment:									
Screening assessment on inclusion and exclusion criteria	X								
informed consent	X								
baseline assessment	X								
randomisation		X							
allocation		X							
INTERVENTIONS:									
video consultations with MHS									
treatment as usual by the GP									
ASSESSMENTS:									
sociodemographic data	X								
SSD-12 <sup>1</sup> , SSS-8 <sup>2</sup> , PHQ-ADS <sup>3</sup> , RAS-G <sup>4</sup> , SF-12 <sup>5</sup> , EUROPEP <sup>6</sup> , FIMPSy <sup>7</sup>	X							X	
INEP <sup>8</sup>								X	
interviews (patients, GPs, medical assistants, MHS)								X	



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

Section/item	Item No	Description	p.
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	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	1
	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)	n/a
<b>Introduction</b>			
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	4-5
	6b	Explanation for choice of comparators	4-6
Objectives	7	Specific objectives or hypotheses	4-6
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)	6

## 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	5-6
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)	6-7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-12
	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)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
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	15
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)	Fig. 1, 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	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13

## 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	13-14
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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	13-14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13-14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
<b>Methods: Data collection, management, and analysis</b>			
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	14-15
	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	14-15
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	16
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	16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16
	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)	n/a
<b>Methods: Monitoring</b>			
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	n/a

	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	n/a
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	17-18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	17-18
<b>Ethics and dissemination</b>			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
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)	n/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7-8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
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	16
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	n/a
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	17-18
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18



Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
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	n/a

\*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.

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