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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)

Markus W Haun ,[1] Justus Tönnies ,[1] Leike Graue,[1] Mechthild Hartmann,[1] Michel Wensing ,[2] Joachim Szecsenyi,[2] Beate Wild,[1] Hans-Christoph Friederich[1]

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[1]Department of General Internal Medicine and Psychosomatics, Heidelberg University, Heidelberg, Germany
[2]Department of General Practice and Health Services Research, Heidelberg University, Heidelberg, Germany

Correspondence to
Dr Markus W Haun;
markus.haun@med.uni-heidelberg.de

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 healthcare system and patients' reservations against receiving specialised 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 MHS 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 GP (control group) or two versus 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.

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 Fifth Edition (DSM-5), catastrophising 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 conceptualisation of 'somatoform' disorders in DSM-IV[2] and International Classification of Diseases 10th Revision (ICD-10),[3] the SSD diagnosis 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 as 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 (eg, depressive and anxiety disorders[9–11]), and (c) increased costs for the healthcare system,[12 13] general practitioners (GP) report increasing difficulties in referring patients with mental disorders in specialised mental healthcare.[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 specialised mental healthcare.[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, which are tailored both to the specific conditions of the respective care system and to the specific needs of patients with SSD. For patients with depressive and anxiety disorders, the junior research group ImPROving cross-sectorial collaboration between primary and psychosocial care: An implementation study on VIDEo consultations (PROVIDE) 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 randomised controlled trial (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 healthcare 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 (eg, 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 is the general practices in the southwest (Baden-Wuerttemberg) of Germany. In Germany, GPs 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 healthcare 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 off-site 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 3 months; the total time of recruitment is planned to be 6 months. There will be two main measurements including a baseline assessment just prior to randomisation and a postassessment at 6 months after inclusion. At months 4 and 5 after inclusion, there will be two additional short measurements focusing on healthcare service 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 the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (online supplemental 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 and 12 points for female and male patients, respectively, on the Somatic Symptom Disorder-B Criteria Scale (SSD-12),[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, for example, admission or rehabilitation, (3) acute psychotic symptoms, for example, persecutory delusions and/or thought insertion, (4) severe cognitive impairment or dementia, (5) significant hearing and/or visual impairment, (6) pregnancy in the ≥2nd trimester, and (7) insufficient German language proficiency. To ensure maximum generalisability, GPs 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 standardised 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.[45]

General practices and MHS

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 (ie, at least 1200 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 minimise potential difficulties with handling video consultations and consequently minimise 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 the 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 the GP and the 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 specialised mental healthcare[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 the GP and the 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 (VIdeobasierte psychosoziale Sprechstunde in Hausarztpraxen für PatientInnen mit sOmatoformen BeschwerdeN) intervention targets both patients and their general practice teams (including GPs).

Targeting the general practice teams, we will schedule a videoconferencing 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 conceptualisation of 'somatoform' disorders in DSM-IV[2] and ICD-10,[3] the SSD diagnosis does not require no or no sufficient medical explanation for the distressing somatic symptoms. During the videoconferencing 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 min MHSVCs depending on their level of symptoms and taking place in biweekly intervals. The video consultations will be carried out on a secure (ie, 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 2 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

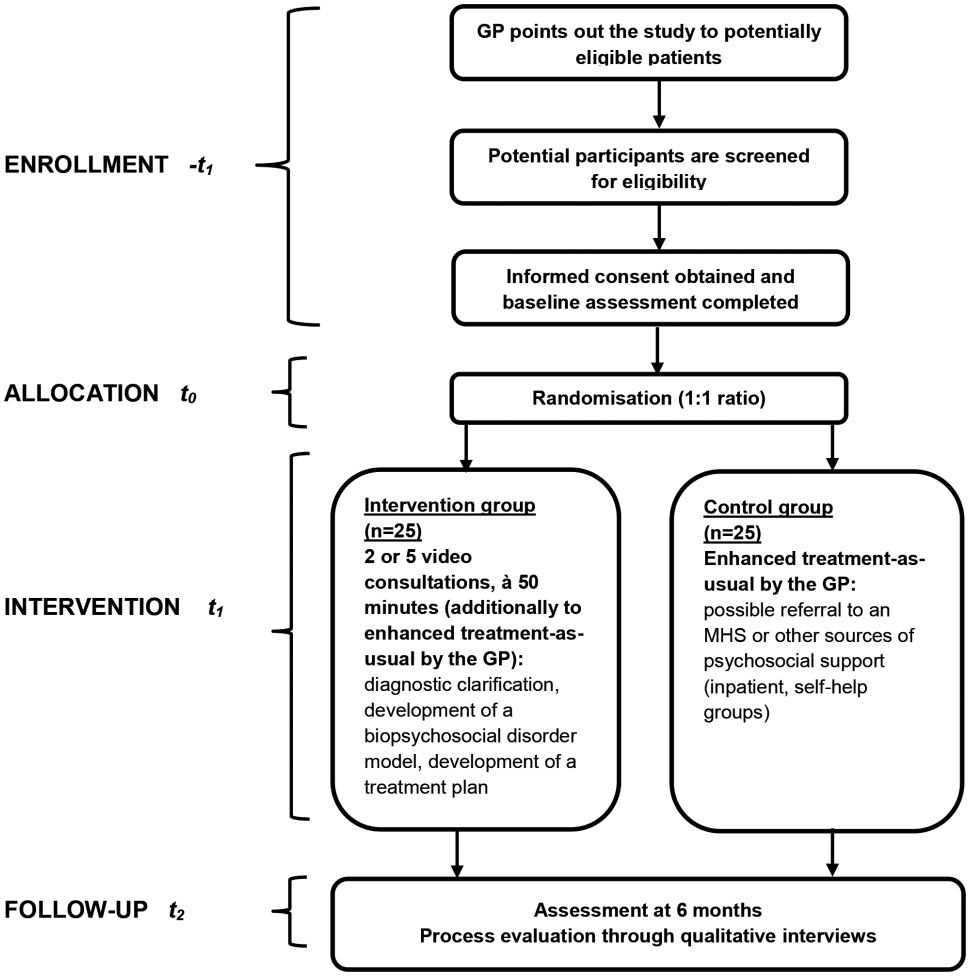

Figure 1 Study flow chart. GP, general practitioner; MHS, mental health specialist.

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 (eg, establishment of fixed, regular contacts between the GP and the patient independent of somatic symptoms) are coordinated between the GP and the MHS.[48] 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 individualised patient support. Core elements of the intervention are the following: (1) diagnostic clarification (including systematic assessment/diagnostics), (2) interventions aimed at rapid stabilisation of the patient (eg, by means of psychoeducation on psychophysiological interactions arising from cognitive processes such as catastrophising thinking or symptom focusing).[49] Provided that the patient is identified as requiring treatment beyond the two minimal MHSVCs, 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.[50] During the individual intervention period, there will be no restrictions on patients receiving treatment from their GP and/or the practice team.

Control condition

Patients allocated to the control group will receive enhanced treatment as usual (TAU) 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 (ie, 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-19 booster vaccination campaign was 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 seamlessly 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 (eg, >200 hours of theoretical and >1200 hours of clinical training) at the Institute for Psychotherapy, Heidelberg, 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 a biweekly supervision from a senior consultant in psychosomatic medicine. The expected weekly time expenditure of the MHS for the realisation of the intervention will be approximately 11 hours (10 hours of consultations, 1 hour of supervision).

Patients

GPs 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 CATI. Eligible patients will then be able to raise questions to 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 at 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 (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 V.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 ≥28 for female patients and ≥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 the feasibility and acceptance of the intervention, and 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 the 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,[57] Recovery Assessment Scale-German version,[58] 12-Item Short-Form Health Survey[59] and the patient satisfaction evaluation instrument EUROPEP (European instrument for patients' evaluations of general practice care).[60] Since in the specific patient group with SSD it is common to have a high use of medical services, we will assess health service use at baseline and follow-up and additionally after the fourth and fifth months after inclusion using the Questionnaire for the Assessment of Medical and non-Medical Resource Utilisation in Mental Disorders.[61] Postmeasurements will

be conducted 6 months after enrolment in the study and will include the same instruments plus, in the intervention group, the Inventory for the Assessment of 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 postmeasurement in CATIs with the participants. According to current recommendations, we will specifically 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 the 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 semiguided 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).

			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 t1+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[1], SSS-8[2], PHQ-ADS[3], RAS-G[4], SF-12[5], EUROPEP[6], FIMPsy[7]	X							X	
INEP[8]								X	
interviews (patients, GPs, medical assistants, MHS)								X	

Figure 2 Study schedule. [1]SSD-12, Somatic Symptom Disorder-B Criteria Scale.[44] [2]SSS-8, Somatic Symptom Scale-8.[44] [3]PHQ-ADS, Patient Health Questionnaire Anxiety and Depression Scale.[57] [4]RAS-G, Recovery Assessment Scale-German version.[58] [5]SF-12, 12-Item Short-Form Health Survey.[59] [6]Patient satisfaction evaluation instrument EUROPEP, European instrument for patients' evaluations of general practice care.[60] [7]FIMPsy, Questionnaire for the Assessment of Medical and non-Medical Resource Utilisation in Mental Disorders.[61] [8]INEP, Inventory for the Assessment of Negative Effects of Psychotherapy.[62] GP, general practitioner; MHS, mental health specialist.

By applying this criterion, we aim for maximising the transferability of our feasibility findings, for example, 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 (including study procedures such as recruitment strategy, data collection procedures, randomisation and logistic aspects) is appropriate and (b) that MHSVCs are feasible in this specific population (eg, patients with SSD) and in this specific setting (eg, 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 groups.
- Adherence for intervention group.
- Feasibility of study procedures (eg, 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 the reasons for non-participation or dropping out. Adherence will be assessed by the ratio of scheduled and actually conducted MHSVCs. Regarding manual fidelity, after every MHSVC, the MHS will systematically document which elements of the intervention were 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 Survey, QuestBack) 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, for example, 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 service use from questionnaires, will be analysed by applying descriptive statistics (absolute and relative frequencies, measures of central tendency and measures of variability). To illustrate participant flow, we will report the results in a Consolidated Standards of Reporting Trials 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 minimise the amount of missing values by carrying out most assessments by making use of CATIs (ie, screening, follow-up). With regard to missing values occurring during the collection of baseline data, we will check the completeness of each patient's baseline questionnaire prior to randomisation. These two procedures will reduce the amount of missing values due to carelessness on the part of the patient and research team. The missing values occurring beyond these two procedures will be considered 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 to 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. The findings from our own prior works support this expectation. Any potential adverse effects that originate from the intervention will be systematically captured by using the INEP as part of the postmeasurement. 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 which ensures a high level of data safety and a conscientious handling of all the patients, 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 of Baden-Wuerttemberg. As part of a wider dissemination, the results of this feasibility trial will inform the set-up of a large-scale randomised trial which is supposed to evaluate the 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 MHS 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 roll-out. 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 (eg, contact restrictions, modified working conditions), their related consequences (eg, 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 healthcare system (eg, 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.

Contributors MWH: conceptualisation, methodology, investigation, writing–review and editing, project administration, funding acquisition. JT: conceptualisation, methodology, investigation, writing–original draft, writing–review and editing. LG: methodology, investigation, writing–original draft, writing–review and editing. MH: conceptualisation, methodology, writing–original draft, writing–review and editing, supervision. MW: methodology, writing–original draft, writing–review and editing, supervision. JS: conceptualisation, writing–review and editing, supervision. BW: methodology, investigation, writing–review and editing. H-CF: conceptualisation, resources, writing–review and editing, 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.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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ORCID iDs
Markus W Haun http://orcid.org/0000-0003-1851-3747
Justus Tönnies http://orcid.org/0000-0002-0308-8226
Michel Wensing http://orcid.org/0000-0001-6569-8137

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