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Complete List of Authors:	Meinlschmidt, Gunther; University of Basel, Department of Digital and Blended Psychosomatics and Psychotherapy, Psychosomatic Medicine; International Psychoanalytic University Berlin gGmbH, Clinical Psychology and Psychotherapy (focus CBT) Frick, Alexander; University of Basel, Department of Psychosomatic Medicine; University Hospital Basel, Department of Psychosomatic Medicine Baenteli, Iris; University of Basel, Department of Psychosomatic Medicine; University Hospital Basel, Department of Psychosomatic Medicine Karpf, Christina; Department of Health Canton Basel-Stadt, Division of Prevention Studer, Anja; Department of Health Canton Basel-Stadt, Division of Prevention Bachmann, Marco; Klinik Barmelweid AG, Department of Psychosomatic Medicine and Psychotherapy Dörner, Andreas; Sankt Claraspital, Medical Clinic Tschudin, Sibil ; University Hospital Basel, Department of Obstetrics and Gynecology; University of Basel, Department of Obstetrics and Gynecology Wyss, Kaspar; Swiss Tropical and Public Health Institute; University of Basel Fink, Günther; Swiss Tropical and Public Health Institute; University of Basel Schwenkglenks, Matthias; University of Basel, Health Economics Facility, Department of Public Health Caviezel, Seraina; University of Basel, Department of Psychosomatic Medicine; University Hospital Basel, Department of Psychosomatic Medicine Rocco, Tabea; University of Basel, Department of Psychosomatic Medicine; University Hospital Basel, Department of Psychosomatic Medicine Schaefert, Rainer; University Hospital Basel, Department of Psychosomatic Medicine; Bethesda Hospital Basel, Department of Psychosomatics and Psychiatry SomPsyNet, consortium; University Hospital Basel, Department of Psychosomatic Medicine

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Prevention of Psychosocial Distress Consequences in Somatic Hospital Inpatients via a Stepped and Collaborative Care Model: Protocol of SomPsyNet, a Stepped-Wedge Cluster Randomized Trial

Gunther Meinlschmidt[1,2,3,4], Alexander Frick[2], Iris Baenteli[2], Christina Karpf[5], Anja Studer[5], Marco Bachmann[6], Andreas Dörner[7], Sibil Tschudin[8], Sarah Trost[9], Kaspar Wyss[10,11], Günther Fink[10,11], Matthias Schwenkglenks[12,13], Seraina Caviezel[2], Tabea Rocco[2], Rainer Schaefert[2,14], and the SomPsyNet consortium

1) Department of Digital and Blended Psychosomatics and Psychotherapy, Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
2) Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
3) Division of Clinical Psychology and Cognitive Behavioural Therapy, International Psychoanalytic University (IPU) Berlin, Berlin, Germany
4) Division of Clinical Psychology and Epidemiology, Department of Psychology, University of Basel, Basel, Switzerland
5) Division of Prevention, Department of Health Canton Basel-Stadt, Basel, Switzerland
6) Department of Psychosomatic Medicine and Psychotherapy, Klinik Barmelweid AG, Barmelweid, Switzerland
7) St. Claraspital, Medical Clinic, Basel, Switzerland
8) Department of Obstetrics and Gynecology, University Hospital and University of Basel, Basel, Switzerland
9) Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland
10) Swiss Tropical and Public Health Institute, Basel, Switzerland
11) University of Basel, Basel, Switzerland
12) Institute of Pharmaceutical Medicine (ECPM), University of Basel, Basel, Switzerland
13) Health Economics Facility, Department of Public Health, University of Basel, Basel, Switzerland
14) Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland

Corresponding author (contact for public and scientific queries):
Prof. Dr. Gunther Meinlschmidt, Department of Digital and Blended Psychosomatics and Psychotherapy, Psychosomatic Medicine, University Hospital and University of Basel, Hebelstrasse 2, CH-4031 Basel, Switzerland;
Email: gunther.meinlschmidt@unibas.ch

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GLOSSARY OF ABBREVIATIONS

BASEC	*Business Administration System for Ethical Committees*
BESP	*Bethesda Spital, Basel*
CDMA	*Clinical Data Management Application*
CDMS	*Clinical Data Management System*
COVID-19	*Coronavirus disease 2019, SARS-CoV-2*
CLARA	*St. Claraspital, Basel*
CL service	*Psychosomatic-psychiatric consultation and liaison service*
CRF	*Case Report Form*
CTU	*Clinical Trial Unit*
DT	*Distress Thermometer*
UAFP	*Universitäre Altersmedizin Felix Platter, Basel*
eCRF	*Electronic Case Report Form*
EQ-5D	*European Quality of Life-5 Dimensions questionnaire*
EKNZ	*Ethikkommission Nordwest- und Zentralschweiz*
GAD-7	*Generalized Anxiety Disorder, questionnaire with 7 items*
GCP	*Good Clinical Practice*
GD	*Gesundheitsdepartement Basel-Stadt*
GFCH	*Health Promotion Switzerland (in German: Gesundheitsförderung Schweiz)*
HRA	*Human Research Act (in German: HFG, in French: LRH, in Italian: LRUm)*
ICH	*International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*
ICTRP	*International Clinical Trials Registry Platform*
IPU	*International Psychoanalytic University*
MCS	*Mental Component Summary of the SF-36*
NCD	*Non-Communicable Diseases*
ClinO	*Ordinance on Clinical Trials in Human Research (in German: KlinV, in French: OClin, in Italian: OSRUm)*
PCS	*Physical Component Summary of the SF-36*
PHQ	*Patient Health Questionnaire*
PHQ-8	*Depressive Symptom Scale with 8 items from the PHQ*
RCT	*Randomized Controlled Trial*
SAE	*Serious Adverse Event*
SAMW	Swiss Academy of Medical Sciences
SCCM	*Stepped and collaborative care model*

SERI	*Swiss State Secretariat for Education, Research and Innovation*
SF-36	*Short Form (36) Health Survey*
SNCTP	*Swiss National Clinical Trials Portal*
SNSF	*Swiss National Science Foundation*
SSD-12	*Somatic Symptom Disorder, questionnaire with 12 items*
SSS-8	*Somatic Symptom Scale, questionnaire with 8 items*
SW-CRT	*Stepped-wedge cluster randomized trial*
TLS	*Transport Layer Security*
Swiss TPH	*Swiss Tropical and Public Health Institute, Basel*
UHB	*University Hospital Basel*

ABSTRACT

Introduction

Approximately 30% of patients in somatic hospitals experience psychosocial distress, contributing to extended hospitalization, higher rehospitalization rates, decreased treatment response, increased morbidity, and escalated direct and indirect costs. However, mental disorders often remain unrecognized and untreated. We developed and established 'SomPsyNet', a 'Stepped and Collaborative Care Model' (SCCM) for somatic hospital inpatients, aiming at addressing this issue through systematic early identification of psychosocial distress and provision of appropriate care during hospitalization, supplemented with post-discharge interventions, providing problem-focused pathways and strengthening a collaborative care network. We here report on the protocol of the 'SomPsyNet' study, evaluating implementation process, screening procedure, burdened population, intervention efficacy, improvement of mental health-related quality of life, and related costs.

Methods and analysis

SomPsyNet is a stepped-wedge cluster randomized trial, comprising three phases: treatment as usual (TAU) without screening for psychosocial distress (phase 0), TAU with screening but without consequences (phase 1), and TAU with screening and consequential psychosomatic-psychiatric consultations for those screening positive (phase 2). The time-of-transition between phases 1 and 2 was randomized across seven study cluster triplets. The study is conducted across three tertiary somatic hospitals in Switzerland, targeting a sample size of N = 2200–2500 participants, with a 6-month follow-up for distressed (anticipated n = 640–700) and a subset of non-distressed (anticipated n = 200) patients. Additionally collecting health insurance claims will facilitate an evaluation of SCCM's impact on direct and indirect household costs.

Ethics and dissemination

The study adheres to the Helsinki Declaration and is approved by the 'Ethikkommission Nordwest- und Zentralschweiz' (EKNZ; No. 2019–01724). Findings will be published in international peer-reviewed journals and communicated to participants, healthcare professionals, and the public.

Study Registration

SomPsyNet is registered in the Swiss National Clinical Trials Portal (SNCTP) and ClinicalTrials.gov (No. NCT04269005, updated 16.06.2023).

Strengths and limitations of this study

- The interdisciplinary SomPsyNet study is one of the largest of its kind to assess stepped and collaborative care for patients with mental-somatic multimorbidity, including a psychosomatic-psychiatric consultation and liaison service as well as post-hospital intervention supported by a collaborative network structure.
- We conduct the SomPsyNet study as a stepped-wedge cluster randomized trial. Additionally, we collect health insurance claims data for a substantial proportion of participating patients to evaluate the impact of our presented model on medical resource use and healthcare costs.
- The SomPsyNet study focuses on inpatients with mental-somatic multimorbidity, representing a clinically highly relevant population, given longer hospitalization, more frequent rehospitalization, less treatment response, increased morbidity, and higher direct and indirect costs as compared to inpatients with somatic diseases only.
- We do not assess ICD diagnoses using clinical interviews.
- No surgical wards are involved in the study.

INTRODUCTION

Mental health contributes significantly to the global disease burden and is a pressing global health concern[1]. The non-communicable disease (NCD) report identified it as a key factor, alongside cancer, diabetes, cardiovascular, and chronic respiratory disease, also escalating NCD prevalence in Switzerland[2]. Mental disorders not only increase the risk of other diseases[3] but also exacerbate health adversities, escalating the psychosocial burden[3,4]. Two primary global disabilities, major depressive and anxiety disorders, are mental health-related[1]. Mental-somatic multimorbidity affects the development and the course of somatic diseases and is associated with lower quality of life, as well as unfavorable disease progression leading to increased morbidity, and all-cause mortality[3,4].

Mental disorders affect approximately 38% of Europeans annually[5], with an emphasis on the Swiss, where 4% and 11% are severely and moderately affected, respectively[6]. The incidence rises in the working class, impacting 18% of women and 12% of men[6].

The economic implications of mental health are far-reaching, influencing individuals' personal, social, and work spheres while imposing considerable societal and economic costs[7]. Mental illnesses are the foremost cause of disability-induced early retirement[8], emphasizing the importance of preventing mental disorders to prolong employment and mitigate disability insurance costs. Thus, mental health issues bear significant individual and economic relevance[8,9].

Despite this, mental disorders' impact might be underestimated as they often go undetected in domains like economics, social, or somatic health[4]. Hence, it's crucial to integrate mental health awareness in research, healthcare systems, and health policies to optimize care for patients with mental-somatic multimorbidity[3,4].

Psychosocial distress and mental-somatic multimorbidity in somatic hospitals

In somatic hospitals, roughly 30% of patients grapple with psychosocial distress and mental-somatic multimorbidity, yet many cases remain undetected and untreated[10]. A Swiss Health Observatory (Obsan) report revealed a meager 13% detection rate[11], with such patients typically being a decade older than those with only somatic illnesses[11]. Mental-somatic multimorbidity presents numerous challenges:

- Extended hospital stays, averaging 2.6 days longer.
- Higher rehospitalization rates within 18 days post-discharge (3.2% versus 2.5% for those with only somatic diseases).

- Greater complexity level and secondary diagnosis count, yielding poorer health outcomes, reduced quality of life, diminished life expectancy, and heightened mortality risk.
- A significant 28% rise in economic resource utilization in hospitals based on SwissDRG system net cost weights, resulting in substantial direct and indirect costs posing a major societal healthcare challenge.

These findings corroborate established evidence on mental-somatic multimorbidity[3,4,10,12–14], underscoring the need for hospitals to tackle this issue to uphold quality standards and deliver optimal care for these patients.

Public health relevance

Global professional bodies underscore the need to integrate psychosocial health at all healthcare and health policy levels. The demand for action in somatic medicine, including hospitals, is highlighted by a Swiss Federal Office of Public Health report on mental comorbidity care coordination at the intersection of somatic and psychiatric hospitals[14].

The National Strategy on the Prevention of Non-Communicable Diseases (NCD strategy) 2017—2024 adheres to these principles. It aligns the efforts of the federal government, cantons, and Health Promotion Switzerland to enhance prevention and health promotion efficiency[2], incorporating mental health in its scope[15]. The strategy's aim is to fortify prevention across the healthcare continuum, projecting that health promotion and prevention could lower individual and societal healthcare costs[15]. This approach may not only benefit public health but also potentially streamline health resource usage, contributing to cost containment.

Current standard intervention options for mental comorbidity in healthcare

The National Institute for Clinical Excellence (NICE) outlined guidelines in 2011 for identifying and creating care pathways for common mental health disorders[16]. These guidelines, built on solid research, aim to enhance care quality by overcoming barriers to treatment identification and access[16].

NICE endorsed a combined approach, the stepped-care model, to address mental health disorders. It requires a multi-professional healthcare team or collaborative care to mitigate barriers stemming from individual, practitioner, system-service, or resource-based factors[16].

Archer et al.'s recent Cochrane review[17] on collaborative care's effectiveness indicated its potential to significantly improve short- and medium-term depression and

anxiety outcomes compared to standard primary care, based on 79 randomized controlled trials (RCT) with 24,308 participants. Other systematic reviews and meta-analyses corroborated these findings, including long-term outcomes[18–21].

A collaborative care network of interdisciplinary professionals is key to managing mental-somatic multimorbidity in primary care[22], with specialist contacts often represented by the CL service[23]. Integrating the stepped-care model with collaborative care, post-hospital intervention, and CL services establishes a robust framework to address psychosocial distress in somatic patients and pre-empt its consequences.

Prevention strategies focus on health risk reduction, with secondary prevention standing out as cost-effective due to its focus on vulnerable individuals[24,25]. Hospitals serve as potentially relevant venues for such interventions, given patients' increased receptivity to behaviour modification support. Despite this, the reported prevalence of mental-somatic multimorbidities in hospitals, based on doctor diagnoses, appears significantly lower than in the general population[11]. This discrepancy underscores the potential for improved mental disorder detection in somatic hospitals.

Rationale of the research project

Given the considerable impact of psychosocial distress and the pressing need for improved healthcare standards, we have established SomPsyNet. The **SomPsyNet project** aims at patients from **SOM**atic hospitals and promotes the prevention of **PSY**chosocial distress by establishing a stepped and collaborative care **NET**work in Basel-Stadt, Switzerland, potentially addressing the prevailing care gap[26].

The cornerstone of SomPsyNet is a “stepped and collaborative care model” (SCCM), integrating a consultation and liaison (CL) service and post-discharge interventions within a collaborative network structure. It seeks to promptly identify patients with psychosocial distress during their hospital stay, provide appropriate care through a psychosomatic-psychiatric CL service, and facilitate problem-focused follow-up treatment within the network.

We anticipate that SomPsyNet will benefit patients, staff, and stakeholders, potentially leading to decreased healthcare resource utilization in the mid- and long-term, impacting healthcare budgets positively.

SomPsyNet affords an efficient avenue to reach patients with mental-somatic multimorbidity, comprehensively evaluate intervention effects, and assess the project's feasibility and framework conditions. This could yield valuable insights into psychosocial distress and mental-somatic multimorbidity prevalence in hospitals, crucial for long-term implementation and project replication in other regions.

Risk Category and Rationale

SomPsyNet, under Art. 61 of the ClinO regulations governing clinical trials in Switzerland[27], falls under Category A. It constitutes a "remaining clinical trial" in Psychosomatic Medicine, presenting minimal risk and burden as it involves questionnaire-based data collection and interventions partly implemented at the University Hospital of Basel. Thus, the project's primary innovation lies in standardizing pathways using existing tools and strengthening interprofessional collaboration, potentially serving as a reference model for other hospitals.

Objectives and Hypotheses

The project's overarching goal is to enhance somatic patients' management with psychosocial distress by implementing an SCCM, assessing its effects on patients and costs. The primary objective is to evaluate SCCM's impact on health-related quality of life in somatic hospital patients with psychosocial distress. The related hypothesis is that mental health-related quality of life improves more robustly with psychosocial distress screening and follow-up consultation than with screening without consequences. Secondary objectives include evaluating SCCM's effect on other health outcomes, costs, and screening procedures' efficacy in identifying patients with psychosocial distress.

The health economic objectives involve assessing SCCM's effect on medical resource use, healthcare and indirect costs, labour market participation, and income. We anticipate SCCM to reduce costs in the long term through improved general health despite an expected short-term direct cost increase.

METHODS AND ANALYSIS

Overview of SomPsyNet as SCCM and research project

The SomPsyNet evaluation study is a key component of the larger SomPsyNet project, overseen by the Department of Psychosomatic Medicine at the University Hospital Basel (UHB) and the Medical Services of the Department of Health Basel-Stadt (GD). Collaborating closely with Bethesda Spital (BESP), Universitäre Altersmedizin Felix Platter (UAFP), St. Claraspital (CLARA) – the latter participating in the SomPsyNet project, but not the study – and numerous health sector partners, we aimed to implement a comprehensive, evidence-based approach to managing psychosocial distress in patients with mental-somatic multimorbidity.

The implementation of the Stepped and Collaborative Care Model (SCCM) within our study, utilizing a Stepped Wedge Cluster Randomized Trial (SW-CRT) design, is carried out in several phases:

- SomPsyNet phase 0: (non-randomized, additional) control condition with treatment as usual (TAU) without any screening procedures in combination with the baseline and follow-up survey in a distressed focus sample.
- SomPsyNet phase 1: (randomized and main) control condition with TAU in combination with the baseline survey, implementation of screening questions stage 1 ('baseline distress information from professionals', without consequence) in hospital routine and a follow-up survey in a distressed focus sample.
- SomPsyNet phase 2 refers to the implementation of the SCCM: baseline survey, assessment of screening questions stage 1 (with consequence), screening questions stage 2 (with consequence), and if necessary psychosomatic-psychiatric consultation and liaison service including if applicable post-hospital intervention and a follow-up survey in a distressed and non-distressed focus sample.

Transition periods were defined as times at which implementation of the next phase started. These periods contributed to data collection, but their circumstances were specifically assessed to ensure correct allocation to study phases. Details of the study design and the implementation at the different study sites are presented in the section study design.

Inclusion and exclusion criteria

The study population were patients from selected wards in three somatic hospitals in Basel-Stadt: UHB, BESP, and UAFP. Somatic patients who were hospitalized in a ward/cluster that participated in the study at the time of hospitalization were assessed for eligibility according to the criteria below. Patients were enrolled on a daily basis unless at least one of the following exclusion criteria applied:

- Aged below 18 years;
- Inability to understand and speak German or any other language at which study is tailored at that point in time;
- Inability to give informed consent by himself/herself;
- Inability to follow the procedures of the study, e.g., due to severe medical/clinical limitations;
- Need for immediate support as indicated by the risk of current suicidality or attempted suicide;

- Oncological condition (as a psycho-oncological CL service is already implemented in many Swiss hospitals);
- Hospitalization for a gender transition intervention (as psychosocial assessment and support are already implemented in regular care for these patients);
- Already participated in the SomPsyNet project on the occasion of a previous hospitalization;
- Confirmed current COVID-19 disease at the time of screening for exclusion criteria (as COVID-19 patients were included in other disease-specific studies);
- Being hospitalized under the medical supervision of services of a ward ('original ward') that is not part of one of the SomPsyNet study clusters, but physically located in rooms of a ward contributing to one of the study clusters only because of lack of space in the original ward.

Study design

The SomPsyNet study used a stepped-wedge cluster randomized controlled trial design (SW-CRT), conducted as a multicenter study across three hospitals (UHB, BESP, UAFP) in Basel-Stadt, Switzerland. This study involved a baseline assessment, an intervention phase (phase 2) implementing a stepped and collaborative care model (SCCM), and a follow-up assessment for a distressed and a non-distressed focus group. A flow diagram of participant progression through the study is depicted in Figure 1.

– Insert Figure 1 around here –

The intervention was systematically deployed across pre-designated wards/sections at all three study sites using the SW-CRT design (please see the 'Definitions of SW-CRT design' section for terminology clarification). While this study design carries certain bias risks such as "within cluster contamination", "time-varying treatment effects", and "changes in correlation structures over time"[28], it was deemed the most practical study design to both evaluate the intervention and ensure its implementation into ongoing clinical care and practice. This design facilitated the examination of our primary research questions, therefore enabling the study of the effects of the SCCM, as well as the investigation of secondary and health economic outcomes.

We aimed to enroll a substantial patient sample (*n* = 200–500 in phase 0; *n* = 1000 in phase 1; *n* = 1000 in phase 2), from which we aimed to collect clinical and health insurance claim data. From this larger sample, a distressed focus sample (anticipated *n* = approx. 40–100 in phase 0; *n* = 300 in phase 1; anticipated *n* = 300 in phase 2), consisting of patients with identified psychosocial distress, was tracked for a detailed post-assessment. The effects of the SCCM on primary and secondary outcomes were evaluated within this distressed focus sample, i.e., among patients targeted by the SCCM-related CL service intervention. Health insurance data was extracted from the total sample.

An additional non-distressed comparison sub-group of study patients (planned *n* = approx. 200), who were not part of this focus sample, were assessed as an additional comparison group for follow-up.

Due to the need to account for high variability in healthcare costs and related parameters, we aimed to collect health insurance claim data from all patients enrolled in the full sample during phases 0 – 2 (approx. *N* = 2200–2500) if they were enrolled with a participating health insurance provider.

Justification of the study design

The step-by-step implementation of the study phases was essential to ensure the continuity of clinical practice/care, considering the various unique challenges across different hospital wards (different patient groups/diseases/severity, technical challenges like differing hospital software, various departmental processes and procedures, shift-working employees, and changing staff). The step-by-step implementation (compared to case-by-case randomization) was also appreciated by the staff and stakeholders.

Definitions of SW-CRT design

According to the extension of the CONSORT 2010 statement[28]: “The SW-CRT involves randomization of clusters to different sequences that dictate the order (or timing) at which each cluster will switch to the intervention condition.”

Clusters

In the SW-CRT design, according to the extension of the CONSORT 2010 statement[28], ‘clusters’ refer to the hospital wards, which were divided into up to three parts (as outlined in Supplementary material 1, one cluster equalled one part, except if the hospital wards were not divided, then one ward was one cluster), depending on the expected number of subjects recruited per ward. Because of the high heterogeneity between the wards, clusters were pre-grouped into triplets based on patient age, sex, and expected primary outcome as indicated by data from phase 0,

and then randomized to different sequences. Detailed information on clusters predefined for our study, time-periods, sequences, sequence generation, allocation of sequences, concealment mechanism, and implementation is shown in a table provided as Supplementary material 1 and methodological detail provided as Supplementary material 2 with the respective schedule shown as figure in Supplementary material 3.

Intervention

The SomPsyNet intervention, offered to phase 2 patients who screened positively and whose lead physicians approved, centered on psychosomatic-psychiatric consultations. Conducted by trained medical and psychological personnel, these consultations were a mix of in-person and telephone interactions, tailored to patients' needs, and oriented towards identifying individual psychosocial stressors and corresponding support options. Essential elements included pre/post consultation discussions, generation of support recommendations using a custom-built tool ('BAK-list') (see Supplementary material 6), coordinating support implementation, and providing a follow-up consultation after hospital discharge. Concurrent care was permitted, and the intervention protocol was adhered to via regular supervision and documented consultations. More detailed information on the intervention is provided in Supplementary material 4.

Ancillary and post-trial care

We did not provide systematic ancillary and post-trial care, yet in case of need patients could direct themselves to the psychosomatic outpatient clinic at the University Hospital of Basel, or to the hospital where they had been treated.

Primary and secondary outcomes and healthcare cost evaluation

Our outcomes/endpoints were divided into primary, secondary, health economic, and other endpoints. We provide a full list of assessment instruments in Table 1 and more detailed information on the endpoints in Supplementary material 5. Whenever possible, we selected assessment instruments that are regularly used in clinical trials and internationally accepted, with good psychometric properties. The primary endpoint of our study is the change from the baseline of the 'Mental Health Component Summary score' of the Short Form-36 (SF-36)[29]. The SF-36 was administered at study entry ('baseline' or 'pre-assessment') and at 6 months follow-up ('follow-up' or 'post assessment', conducted in the distressed and non-distressed focus sample).

– Insert Table 1 around here –

Recruitment and informed consent procedure

Recruitment for this study spanned from 09-06-2020 to 16-12-2022 at UHB, BESP, and UAFP sites. Eligibility was verified through medical records and staff-patient interactions. Eligible patients received comprehensive study information and a consent form (see Supplementary material 7), with copies kept as part of the study records.

Data collection methods and management

Upon informed consent, patients completed a baseline questionnaire, predominantly via tablet-assisted software, with alternatives for paper-pencil or staff-guided questionnaires available. Six months post-recruitment marked follow-up, with patients consenting for health insurance data collection for cost analysis. Phases 0 and 1 were similar, but phase 1 included two additional psychosocial distress evaluations by intake physicians and nursing staff. The complete SCCM was implemented only in phase 2 (see Supplementary material 3). Table 2 details all assessments. We transfer collected data to the secure SecuTrial® database, and verify for completeness and discrepancies. Only authorized personnel have access to the data, and routine backups are conducted to ensure safety and confidentiality. Further details on data recording and source data are provided in Supplementary material 8. General study data management such as exclusions, recruitment, dropout, or participant rate, was recorded at all stages in the study. Data collection started on 09-06-2020 and is anticipated to be completed on 30-06-2026 (estimated study completion date)

Statistical methods

Sample size and sample size calculation

Our study relied on specific sampling sizes, with the intention to evaluate a significant number of patients suffering from psychosocial distress. We aimed at including approximately 200-500 patients in phase 0, and 1000 patients in both phases 1 and 2. Sample size calculations were undertaken, focusing on the primary endpoint, which was the change from baseline of the Mental Health Component Summary score, as gauged by the SF-36 questionnaire. We employed conservative assumptions, including specific Hedges' g effects in different study conditions.

Taking into account possible drop-outs, our final estimate required 279 patients per condition for the main analyses, leading to an overall expected pool of 2000 subjects for study phases 1 and 2.

Statistical analyses and handling of missing data

Descriptive statistics and estimation of intervention effects are planned following recognized guidelines, and different regression methods will be used based on the outcome parameters' distributional characteristics.

With respect to the management of missing data, we aim to minimize bias via thorough planning and active data review. We plan to differentiate between missing data due to partial participation and loss to follow-up, and will consider various statistical methods to address these issues. Both intention-to-treat and per-protocol analyses are planned.

A comprehensive description of our statistical methods, including the full power analysis, detailed intervention effects estimation, and our approach to handle missing data can be found in Supplementary material 9.

Dissemination policy

We will publish key results of the study in international peer-reviewed journals followed by additional publications focusing on selected aspects of the study. Furthermore, we intend to communicate key results to the public via an online event following main data analysis. Authorship eligibility guidelines followed the guidelines of the journal as well as of the Swiss Academy of Medical Sciences (SAMW); we did not include professional writers. Public access to the full protocol is provided by this manuscript. Public access to participant-level datasets is not intended (see above). Access to statistical codes is intended to be provided on request.

Patient and public involvement statement

SomPsyNet comprises a patient participation committee that includes patient representatives. Patient representatives within the SomPsyNet consortium have been integral since the onset of grant preparation and study design, providing valuable feedback on various aspects, including study material and informed consent. Additionally, they partake in regular enrollment discussions, contribute to publications, and are anticipated to engage in discourse over study results.

ETHICS AND DISSEMINATION

The SomPsyNet study, following the Declaration of Helsinki[38], the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice (ICH-GCP)[39], and the Human Research Act (HRA)[40], conducts regular monitoring and auditing to ensure participant safety and data accuracy. Source data/documents are accessible to monitors, and the study team is

responsive to any arising queries. While no formal Data Monitoring Committee was established due to the low-risk nature of the intervention, the study can be terminated prematurely under specific circumstances. These include insufficient participant recruitment, significant changes in clinical practice, or early evidence of harm or benefit from the experimental intervention.

Despite minimal anticipated risk, the study thoroughly assesses any potential harm. Any Serious Adverse Events (SAEs) that may occur during the study, including those related to suicide attempts or completed suicide, are examined for causality with the intervention and reported in accordance with set guidelines. Complete details regarding the risk assessment and SAEs can be found in Supplementary material 11.

Regular internal audits are carried out at each study site, verifying all procedures, including recruitment, consent, enrolment, and data collection. The software secuTrial® is used to maintain the final database, ensuring an implemented data audit trail.

Amendments to the protocol, which may affect the study's conduct, patient benefits, or safety, are formally documented. As of 31-05-2023, four such amendments have been submitted and approved.

Voluntary participation is a core principle in this study. Potential participants were provided with comprehensive information and were allowed adequate time for deliberation. Written informed consent, which can be withdrawn at any time, was obtained from those willing to participate. If consent is revoked, the participants' data are anonymized, and they are removed from the study while retaining access to treatment as usual (TAU).

Data confidentiality and secure coding are prioritized. Participants' data are only accessible to authorized personnel and are securely stored on a UHB server with regular backup processes. The complete dataset, once finalized, is transferred to the study statistician and the principal investigator, with limited access granted to other team members for analysis. Specific processes are in place for the collection and integration of health insurance claims data.

In-depth details on the aspects of monitoring, risk of harms, reporting of SAEs, auditing, overall ethical considerations, protocol amendments, consent or assent, and confidentiality and coding are available in Supplementary material 10.

PROJECT FUNDING

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COMPETING INTERESTS & FUNDING INDEPENDENT OF THE PROJECT

GM & RS received funding from the Stanley Thomas Johnson Stiftung & Gottfried und Julia Bangerter-Rhyner-Stiftung under projects no. PC 28/17 and PC 05/18, from the Swiss Cancer League (Krebsliga Schweiz) under project no. KLS-4304-08-2017, and in the context of a Horizon Europe project from the Swiss State Secretariat for Education, Research and Innovation (SERI) under contract number 22.00094. Further, GM & RS received funding from Wings Health Inc. in the context of a proof-of-concept study. GM received funding from the Swiss Heart Foundation under project no. FF21101, from the Research Foundation of the International Psychoanalytic University (IPU) Berlin under projects no. 5087 and 5217, from the Swiss National Science Foundation (SNSF) under project no. 100014_135328, from the German Federal Ministry of Education and Research under budget item 68606, and from the Hasler Foundation under project no. 23004. GM is co-founder, member of the board, and holds stock in Therayou AG, which is active in the field of digital and blended mental healthcare. RS received a speaker honorarium from Novartis. The authors declare no other potential conflict of interests. The research activities were fully independent and there were no intellectual or financial proprietary claims.

AUTHORS' CONTRIBUTIONS

The coordinating center at UHB had the role of overseeing all activities at all sites. The steering committee of SomPsyNet consisted of the project head and responsible of operations of the Department of Health Canton Basel-Stadt, Division of Prevention, the study sponsor, principal investigators, and project responsible of operations at the coordinating center, as well as a representative of CLARA that took part in the SomPsyNet project but not the SomPsyNet study. The steering committee had the role of deciding upon all major aspects of the study. The endpoint was discussed among the investigators of the steering committee, with input from other members of the co-author group. An advisory board provides guidance and feedback related to the project and the study. An patient advisory group consisting of several patient

representatives worked together to oversee and give feedback on study material and protocol. The SomPsyNet consortium met at least on a yearly basis, discussing the development of the study and giving critical feedback on the study conduction and necessary adaptations.

CK, RS, AF, and GM first identified the question leading to the formation of this research. GM, AF, CK, AS, MB, AD, STs, KW, GF, MS, SC, RS contributed to the development of the main trial protocol. RS contributes significantly also as the sponsor of this study. GM serves as lead principal investigator and AF, MB, RS, STs, and STs serve as principal investigators at the different study sites, contributing significantly to data collection and protocol adherence. IB, AS, and SC are the study operative leads, overseeing and managing the execution of the trial protocol. GM drafted the first version of the manuscript. All authors made significant revisions to the manuscript for important intellectual content and all authors reviewed and approved the final version of the manuscript for submission, reflecting their agreement with the work in its current form and their acceptance of accountability for all aspects of the work. This protocol was written following the SPIRIT protocol guidance.

ACCESS TO DATA

The datasets being held by the SomPsyNet project are not readily available. In the case of inquiries by third parties that wish to reuse data SomPsyNet data after an embargo period, the following procedure is planned. Researchers interested in the data may submit a project synopsis addressed to the publications committee of the SomPsyNet project and will have to obtain authorization from the responsible ethics committee as ordained in the Ordinance of 20 September 2013 on Human Research with the exception of Clinical Trials[27] (Human Research Ordinance, HRO). The publication committee will review the project synopsis and will answer the formal requests of applicants. Only upon collection of all important consents and upon approval of the responsible ethics committee(s), the requested data will be transferred to the applicants. Third parties have to confirm and provide evidence to comply with all relevant Swiss and cantonal laws and regulations (especially regarding data protection and Human Research), as well as all obligations and regulations set out in the documents and contracts related to SomPsyNet. Fees may apply to cover expenses related to data reuse. Requests to access the datasets should be directed to Gunther Meinlschmidt, gunther.meinlschmidt@unibas.ch.

MEMBERS OF THE SOMPSYNET CONSORTIUM

- Aebi, NJ., Swiss Tropical and Public Health Institute, Basel, Switzerland, University of Basel, Basel, Switzerland
- Bachmann, M., Department of Psychosomatic Medicine and Psychotherapy, Klinik Barmelweid AG, Barmelweid, Switzerland
- Caviezel, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Baenteli, I., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Bahmané, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Bales, G., University Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland
- Bally, K., Centre for Primary Health Care, University of Basel, Switzerland
- Bassetti, S., Division of Internal Medicine, University Hospital and University of Basel, Basel, Switzerland, Department of Clinical Research, University Hospital and University of Basel, Basel, Switzerland
- Baumgartner, R., Social Insurance Institution Basel-Landschaft, Binningen, Switzerland
- Beck, J., Clinic Sonnenhalde AG, Riehen, Switzerland
- Bosman, S., Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland
- Buechel, D., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Dörner, A., St. Claraspital, Medical clinic, Basel, Switzerland
- Eberle, C., Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland
- Ebner, L., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Erb, J., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Ettlin, P., Foundation Rheinleben, Basel, Switzerland
- Fink, G., Swiss Tropical and Public Health Institute, Basel, Switzerland,

University of Basel, Basel, Switzerland

- Flückiger, L., Department of Health Canton Basel-Stadt, Division of Addictions, Basel, Switzerland
- Frick, A., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Fuchs, S., Department of Health Canton Basel-Stadt, Medical Services, Basel, Switzerland
- Grossmann, F., Department of Medicine, Division of Nursing, University Hospital Basel, Basel, Switzerland
- Hermann, A., Direktion Pflege/MTT, University Hospital and University of Basel, Basel, Switzerland
- Hotopf, M., Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom
- Huber, C., University Psychiatric Clinics (UPK), Department of Psychiatry and Psychotherapy, Basel, Switzerland
- Isler-Christ, L., Sevogel-Apotheke, Basel, Switzerland, Baselstädtischer Apotheker-Verband, Basel, Switzerland
- Kadoic, M., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Karpf, C., Department of Health Canton Basel-Stadt, Division of Prevention, Basel, Switzerland
- Katapodi, MC., Department of Clinical Research, University of Basel, Basel, Switzerland, University of Michigan School of Nursing, Ann Arbor, MI USA
- Keller, RC., Swiss Heart Foundation, Bern, Switzerland
- Klimmeck, S., University Hospital Basel, Basel, Switzerland
- Lang, UE., University Psychiatric Clinics (UPK), Department of Psychiatry and Psychotherapy, Basel, Switzerland
- Liechti, Y., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Mazander, S., IV-Stelle Basel-Stadt, Basel, Switzerland
- Meinlschmidt, G., Department of Digital and Blended Psychosomatics and Psychotherapy, Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland; Division of Clinical Psychology and Cognitive

Behavioural Therapy, International Psychoanalytic University, Berlin, Germany; Division of Clinical Psychology and Epidemiologie, Department of Psychology, University of Basel, Basel, Switzerland

- Minzer, A., Swiss Academy for Psychosomatic and Psychosocial Medicine (SAPPM), Reiden, Switzerland
- Ochs, V., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Schaefert, R., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland; Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland
- Schiess, F., Centre of Self-Help Basel, Basel, Switzerland
- Schirmer, F., Vereinigung der psychosomatisch tätigen Aerztinnen und Aerzte der Region Basel, Basel, Switzerland
- Schur, N., Institute of Pharmaceutical Medicine (ECPM), University of Basel, Basel, Switzerland
- Schwenkglenks, M., Institute of Pharmaceutical Medicine (ECPM), University of Basel, Basel, Switzerland; Health Economics Facility, Department of Public Health, University of Basel, Basel, Switzerland
- Schwob, P., Psychotherapists Association of Basel VPB, Basel, Switzerland
- Seelmann, SF., Department of Internal Medicine, University Hospital Basel, Basel, Switzerland
- Steffen, T., Department of Health Canton Basel-Stadt, Medical Services, Basel, Switzerland
- Stiefel, F., Liaisonpsychiatrischer Dienst, University Hospital Lausanne, Lausanne, Switzerland
- Studer, A., Department of Health Canton Basel-Stadt, Division of Prevention, Basel, Switzerland
- Tegethoff, M., Institute of Psychology, RWTH Aachen University, Aachen, Germany
- Timoney, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Trost, S., Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland
- Tschudin, S., Department of Obstetrics and Gynecology, University Hospital and University of Basel, Switzerland

- Urech, C., Gyn. Social Medicine and Psychosomatics, University Hospital and University of Basel, Basel, Switzerland
- von Allmen, T., Department of Health Canton Basel-Stadt, Health Care, Basel, Switzerland
- Weber, M., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Werner, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Wetz, A., Rheumaliga beider Basel, Basel, Switzerland
- Weyermann, D., Patientenstelle Basel, Basel, Switzerland
- Wyss, K., Swiss Tropical and Public Health Institute, Basel, Switzerland, University of Basel, Basel, Switzerland
- Yarkova, V., St. Claraspital, Medical clinic, Basel, Switzerland
- Zäh, C., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Zarifoglu, L., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland

TABLES

Table 1

Overview of assessment instruments and assessment points

Construct	Instruments	Baseline (T0)	Follow-up (T1)	3-year follow-up
Health/primary outcome: quality of life, 'Mental Health Component Summary score'*	SF-36 [29]	x	x	
Health: quality of life, 'Physical Health Component Summary score'	SF-36 [29]	x	x	
Health: psychosocial distress (patient)	DT [30]	x	x	
Health: psychosomatic burden (intaking physician, nursing staff)	DT routine [30]			
Health: anxiety symptoms	GAD-7 [31]	x	x	
Health: depressive symptom	PHQ-8 [32]	x	x	
Health: somatic symptom disorder	SSD-12 [33]	x	x	
Health: somatic symptom burden	SSS-8 [34]	x	x	
Health: quality of life	EQ-5D [35,36]	x	x	
Health: general resilience	Oslo-Scale Resilience Scale [37]		x	
Health: COVID-19 information	questionnaire	x	x	
Socio-demography: age, sex, and socioeconomic status, work-status and days out of work	questionnaire	x	x	
General information: participation rate, inclusion, exclusion, loss-to-follow up	Study management	x	x	

General information: resources for recruitment (time)	Study management	x		
General information: hospital, hospital ward, length of hospital stay, ICD-10 diagnoses, COVID-19 information, treatments, morbidity, disease history, severity of disease, main diagnosis, secondary diagnosis, type of health insurance, rehospitalization	hospital	x		
General information: treatment as usual – status (including documentation use of intervention for comparison)	hospital	x		
Health economic: total costs of hospital treatment including additional medical, psychiatric or physiotherapeutic treatment during patient's hospital stay; follow-up costs at treating hospitals; healthcare costs, relevant sub-categories of costs and medical resource use based on health insurance claims data; patients' out-of-pocket expenses; indirect costs due to reduced productivity	hospital, health insurance claims data, questionnaire	x	x	x

Note. *primary outcome; DT (Distress Thermometer), EQ-5D (European Quality of Life-5 Dimensions questionnaire), GAD-7 (Generalized Anxiety Disorder, questionnaire with 7 items), PHQ-8 (Depressive symptom scale with 8 items from the Patient Health Questionnaire), SF-36 (Short Form (36) Health Survey), SSD-12 (Somatic Symptom Disorder, questionnaire with 12 items), SSS-8 (Somatic Symptom Scale, questionnaire with 8 items).

FIGURE CAPTIONS

Figure 1

Participant flow chart for study phase 0–2.

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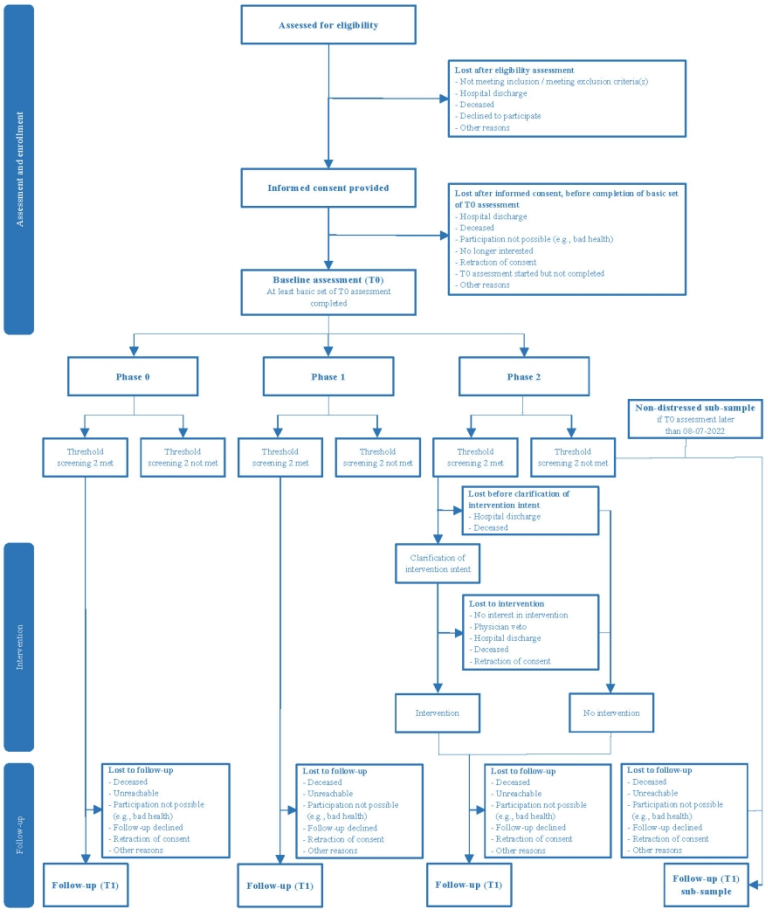


Figure 1. Participant flow chart for study phases 0-2.

Figure 1
Participant flow chart for study phase 0–2.

210x297mm (200 x 200 DPI)

SUPPLEMENTARY MATERIAL

- Supplementary material 1: Table – SomPsyNet study clusters
- Supplementary material 2: Methodological details 1 – Time periods, sequences, sequence generation, allocation of sequences, concealment mechanism, implementation, and blinding
- Supplementary material 3: Figure – Schedule of SomPsyNet stepped-wedge cluster randomized trial
- Supplementary material 4: Methodological details 2 – Intervention
- Supplementary material 5: Methodological details 3 – Primary, secondary, and other endpoints, including healthcare economic endpoints
- Supplementary material 6: BAK-list (provided in German)
- Supplementary material 7: Informed consent materials (provided in German)
- Supplementary material 8: Methodological details 4 – Data recording and source data
- Supplementary material 9: Methodological details 5 – Statistics
- Supplementary material 10: Methodological details 6 – Ethics and dissemination
- Supplementary material 11: Table – Causality assessment of SAEs based on ICH E2A guidelines
- Supplementary material 12: References of the supplementary material

Supplementary material 1: Table – SomPsyNet study clusters

SomPsyNet SCCM cluster	Cluster number
UHB: Department of Obstetrics and Gynecology 1.1	**1**
UHB: Department of Obstetrics and Gynecology 1.2	**2**
UHB: Department of Internal Medicine 5.1-1	**3**
UHB: Department of Internal Medicine 5.1-2	**4**
UHB: Department of Internal Medicine 5.1-3	**5**
UHB: Department of Internal Medicine 6.2-1	**6**
UHB: Department of Internal Medicine 6.2-2	**7**
UHB: Department of Internal Medicine 6.2-3	**8**
UHB: Department of Internal Medicine 7.1-1	**9**
UHB: Department of Internal Medicine 7.1-2	**10**
UHB: Department of Internal Medicine 7.1-3	**11**
UAFP: Department of Acute Geriatrics 1 / Rehabilitation Geriatrics 1 – .1	**12**
UAFP: Department of Acute Geriatrics 2 / Rehabilitation Geriatrics 2	**13**
BESP: Department of Rheumatology.1	**14**
BESP: Department of Rheumatology.2	**15**

BESP: Department of Musculoskeletal Rehabilitation.1	**16**
BESP: Department of Musculoskeletal Rehabilitation.2	**17**
BESP: Department of Musculoskeletal Rehabilitation.3	**18**
BESP: Department of Gynecology (excl. Breast Center and Obstetrics) 1.1	**19**
BESP: Department of Gynecology (excl. Breast Center and Obstetrics) 1.2	**20**
UHB: Department of Internal Medicine 8.1	**21**

Note. BESP (Bethesda Spital), UAFP (Universitäre Altersmedizin Felix Platter), University Hospital Basel (UHB).

Supplementary material 2: Methodological details 1 – Time periods, sequences, sequence generation, allocation of sequences, concealment mechanism, implementation, and blinding

Time periods

Time periods referred to time since implementing the SW-CRT (from; to) (the schedule of the SW-CRT is displayed in Figure 1):

- T0 (start to month 4)
- T1 (month 5 to month 9)
- T2 (month 10 to month 14)
- T3 (month 15 to month 19)
- T4 (month 20 to month 31)

Changing the time period was called SW-CRT steps. The steps were important to point out the time at which some clusters switched from one phase to another phase.

- SW-CRT step 0 was the first switch to initiate piloting
- SW-CRT step 1 (T0 to T1)
- SW-CRT step 2 (T1 to T2)
- SW-CRT step 3 (T2 to T3)
- SW-CRT step 4 (T3 to T4)

Sequences

- The number of time periods of a specific cluster in a certain phase defined the "sequence code"
- The sequence code defined the number of periods with the control condition (in our case phase 1) and the number of periods with the intervention condition (phase 2); the periods from step 0 until step 1 represented phase 0.
- Several clusters could have the same sequence code
- Examples: These were sequence codes with 5 time periods, for clusters starting the intervention condition (phase 2) with T2/step 2, T3/step 3, and T4/step 4, respectively: "00100", "00010", "00001".

Sequence generation, allocation of sequences, concealment mechanism, and implementation

To balance the stepped-wedge design across the different study phases, participating wards were split up into one, two, or three clusters and grouped into Xtriplets of clusters of roughly the same size (in terms of numbers of patients) and with similar patient populations. Within each triplet, the order in which the clusters went on to the

implementation stage was randomly selected from all possible allocation sequences. The allocation sequence was computer-generated by an independent party (clinical trial unit, CTU) by using R software, based on the provision of involved clusters and cluster triplets. The independent party (CTU) stored the sequence allocations and split them into packs of information, each provided via HIN-secured email to the study coordinator.

Blinding

Hospital employees who assigned patients to the wards and clusters were blinded to randomization.

Physicians and study nurses on the respective wards and clusters were trained before implementing phase 1, since they had to implement three questions in their routine process. Yet, they were not informed about switching between phase 1 and phase 2. Blinding of staff involved in the recruitment process was limited as phase 1 and phase 2 consisted of different study information and consent sheets. Trained staff performed the follow-up assessment, offering several assessment options, and repeatedly trying to reach out to the participants aiming at completing follow-up as far as possible, and we intended to blind them regarding the study phase allocation of the patients (if procedural aspects allowed it).

Unblinding was not planned as we did not expect the blinding to affect patients' health or treatment. Blinding only affected the recruitment process. Unblinding was only important for the study team itself and was needed due to procedural aspects.

Supplementary material 3: Figure – *Schedule of SomPsyNet stepped-wedge cluster randomized trial*

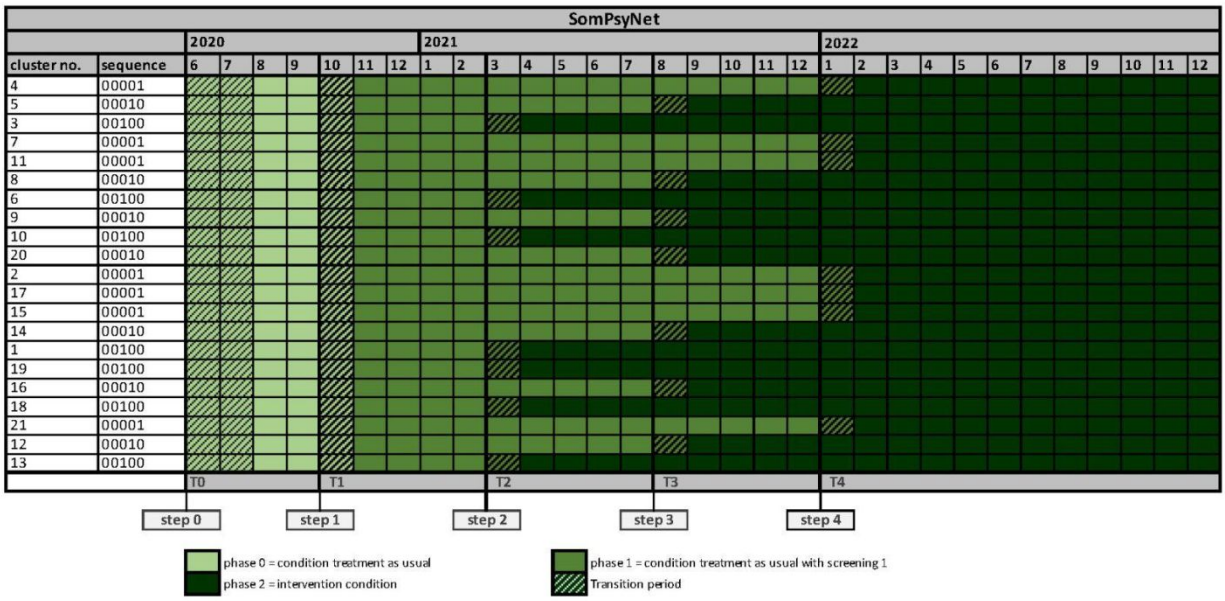


Figure – Schedule of SomPsyNet stepped-wedge cluster randomised trial
Note. No. (number)

Supplementary material 4: Methodological details 2 – Intervention

In phase 2, every patient with a positive result of "screening 2" (i.e., scoring above one of the pre-defined cut-off values) – if the physician in charge agreed – was offered the SomPsyNet intervention. This intervention was a stepped and collaborative care model (SCCM) centering around psychosomatic-psychiatric consultations.

These consultations were conducted by the well-established hospital psychosomatic-psychiatric consultation and liaison (CL) services. The CL services consisted of trained medical and psychological staff. In the Universitäre Altersmedizin Felix Platter (UAFP), an advanced nursing practitioner was working in the psychiatric and social consultation team.

Typically, two facto-to-face consultations of approximately 40 minutes duration, and one telephone consultation of approximately 20 minutes duration about 4 to 6 weeks after hospital discharge took place; this could be reduced if not all three consultations were able to be implemented.

The basic structure of the consultations conducted within this study was the same as in the clinical routine and varied between the participating hospitals. The content of the consultations was customized to the patients' needs. There were some obligatory elements, which were implemented in the SomPsyNet phase 2 consultations at all hospitals. Typically, these elements consisted of an in-hospital part and an interface-related part to pave the way for further outpatient support:

In-hospital part:

- **Telefone contact between the CL-staff and the ward physician** to discuss the consultation before and after.
- **Face-to-face consultations with the patient:** Typically, two face-to-face consultations with usually approximately 40 minutes duration took place during the hospital in-patient stay, usually in the patient's room. In case that consultations could not take place during the inpatient stay period, due to a rather short stay, outpatient consultations were offered, when possible and where feasible. These outpatient consultation offers did not incur any costs for the patient. Objectives of the consultations were to establish a working alliance with the patient, to build an understanding of the psychosocial burden, and - if possible - to provide a first experience of relief, as well as to active patient's resources and competencies. Besides a diagnostic assessment, the consultations aimed to jointly identify problem areas in which the patient needed and wanted support. Therefore, the involved CL staff asked the patients about current psychosocial stress factors.
- **"Support options catalog" to link problem areas and service offers:** To support this process, we developed a Microsoft Excel-based clinical tool called the "BAK-list" (Behandlungs-Angebots-Katalog / support options catalog) in the version

for the UHB. The BAK-list (Supplementary material 1) consisted of two main tables: One table contained a collection of relevant psychosocial issues often met in everyday clinical practice. The other table contained in-house and out-of-hospital services offering support for the different issues. These offers of support were individually linked to the psychosocial issues, so that by selecting a psychosocial issue, relevant offers of support were suggested. Thereby, the BAK-list facilitated generating suggestions for severity-stepped, need-based offers of support that the CL-service, in interaction with the patient, could then select, verify, and recommend. Further, the BAK-list was used as a documentation tool, facilitating reporting by providing standardized text-block templates adapted to the psychosocial issues and support offers. Every hospital adjusted the content of the BAK-list to their patients' needs and to their in-house offers of support. The following procedure applied: During a consultation, the CL-staff opened a new BAK-list file. The CL-staff then selected psychosocial stressors that currently affected the patient and for which the patient sought support. As an output, the BAK-list tool generated need-based support suggestions. The CL-staff was free to recommend these or other appropriate support options, tailored to the severity grade and the patient's needs.

Interface-related part to pave the way for further outpatient support:

- **Coordination person for implementing the recommendations:** If a patient consented to a support option, the CL-staff clarified and documented who initiated contact with the chosen support provider and coordinated the care. As far as possible this was the patient herself/himself, prioritizing self-management and self-responsibility. If she/he was not capable of performing that, another person such as the patient's general practitioner or a relative of the patient should be identified to coordinate the care. This process aimed to reduce the gap between in-hospital and out-hospital support and to improve interface management.
- **Consultation report:** For each patient seen by the CL-staff in phase 2, a consultation report with the recommendations was provided, either directly to the patient or to the attending physician initiating the CL-service consultation, who was encouraged to integrate relevant parts of or the whole consultation report into the discharge letter - as far as the patient agreed with that. The patient could specify to whom the consultation or discharge report was sent after discharge from the hospital (e.g., general practitioner or another reference person). The consultation report was accompanied by a letter explaining the project context.
- **Online platform compiling support options:** Additionally, within SomPsyNet, we developed a platform in the form of a website that contained public offers of support services in the Basel region and partly also across cantons, facilitating identification and access to available services. Every patient in phase 2 was

informed about this website. A leaflet in the form of a postcard helped to promote the platform.

- **Telephone consultation about 4 to 6 weeks after hospital discharge:** It is a well-known challenge that a substantial proportion of patients do not follow treatment recommendations after hospital discharge. To counteract this phenomenon, patients were offered a post-hospital intervention in form of a telephone consultation of approximately 20 minutes duration around 4 to 6 weeks after hospital discharge to support the take-up of the agreed on recommendations, to identify potential barriers for addressing them, and to find viable solutions for establishing contact with the support agency if use was still intended.

We did not prohibit any concomitant care and intervention during the trial. Notably, treatment as usual in the form of pre-SomPsyNet psychosomatic-psychiatric consultations was allowed.

We trained all psychosomatic-psychiatric consultation specialists involved in the study. Adherence to the intervention protocol was shown by regular supervision and/or meetings to discuss any questions and upcoming issues regarding the intervention protocol. Further the documentation of each psychosomatic-psychiatric consultation aimed at increasing adherence to intervention protocols and facilitated monitoring of the respective adherence based on the written documentation.

Supplementary material 5: Methodological details 3 – Primary, secondary, and other endpoints, including healthcare economic endpoints

Primary, secondary, and other endpoints

The primary endpoint of our study is the change from the baseline of the 'Mental Health Component Summary score' of the Short Form 36 Health Survey (SF-36). The SF-36 was administered at study entry ('baseline' or 'pre-assessment') and at 6 months follow-up ('follow-up' or 'post assessment', conducted in the distressed and non-distressed focus sample).

The SF-36 is a widely used patient-reported outcome assessment tool to measure health-related quality of life and has high acceptability. The SF-36 is a standardized questionnaire with good psychometric properties (internal consistency reliability of 0.83-0.94)[1] and translated and validated in various languages, among them German[2]. It consists of 36-Items to assess health-related quality of life using eight dimensions grouped into a physical and a mental component summary scale: The physical component summary (PCS) is calculated based on the four subdimensions physical functioning (PF, 10 items), physical role functioning (RP, 4 items), bodily pain (BP, 2 items), general health perception (GH, 5 items). The mental component summary (MCS) is calculated based on the four subdimensions vitality (VT, 4 items), social role functioning (SF, 2 items), emotional role functioning (RE, 3 items) and mental health (MH, 5 items)[3,4]. Written instructions for the translational process, distribution, and evaluation are available and were clearly defined[2,5,6].

The SF-36 exists in two versions: version 1 and version 2, with the German version 2 being provided by Hogrefe[7,8]. Negotiations between the company 'heartbeat medical' and Hogrefe publisher regarding license regulation issues were ongoing. Yet, based on the state of negotiations at that time, electronic integration of the SF-36 questionnaire version 2 within the heartbeat one system was not feasible in near future. Therefore, since electronic data collection was essential for continuous monitoring, quality control, and plausibility check of collected data, the available SF-36 version 1 is used for this study, which had been developed as a part of the Medical Outcomes Study (MOS) to report patient outcomes[3,5]. The secondary and other endpoints are provided in Table 2. Notably, the SF-36 physical component summary (PCS) is part of the secondary endpoints.

We collect a range of sociodemographic variables, including age, sex, and socioeconomic status, work status and days out of work, length of hospital stay, ICD-10 diagnoses, COVID-19 information, treatments, morbidity, disease history and severity of disease, as well as unintended effects of interventions, by questionnaire/interview and as part of the hospital routine data. These will be used

amongst others to describe the study sample and as potential covariates for statistical analyses.

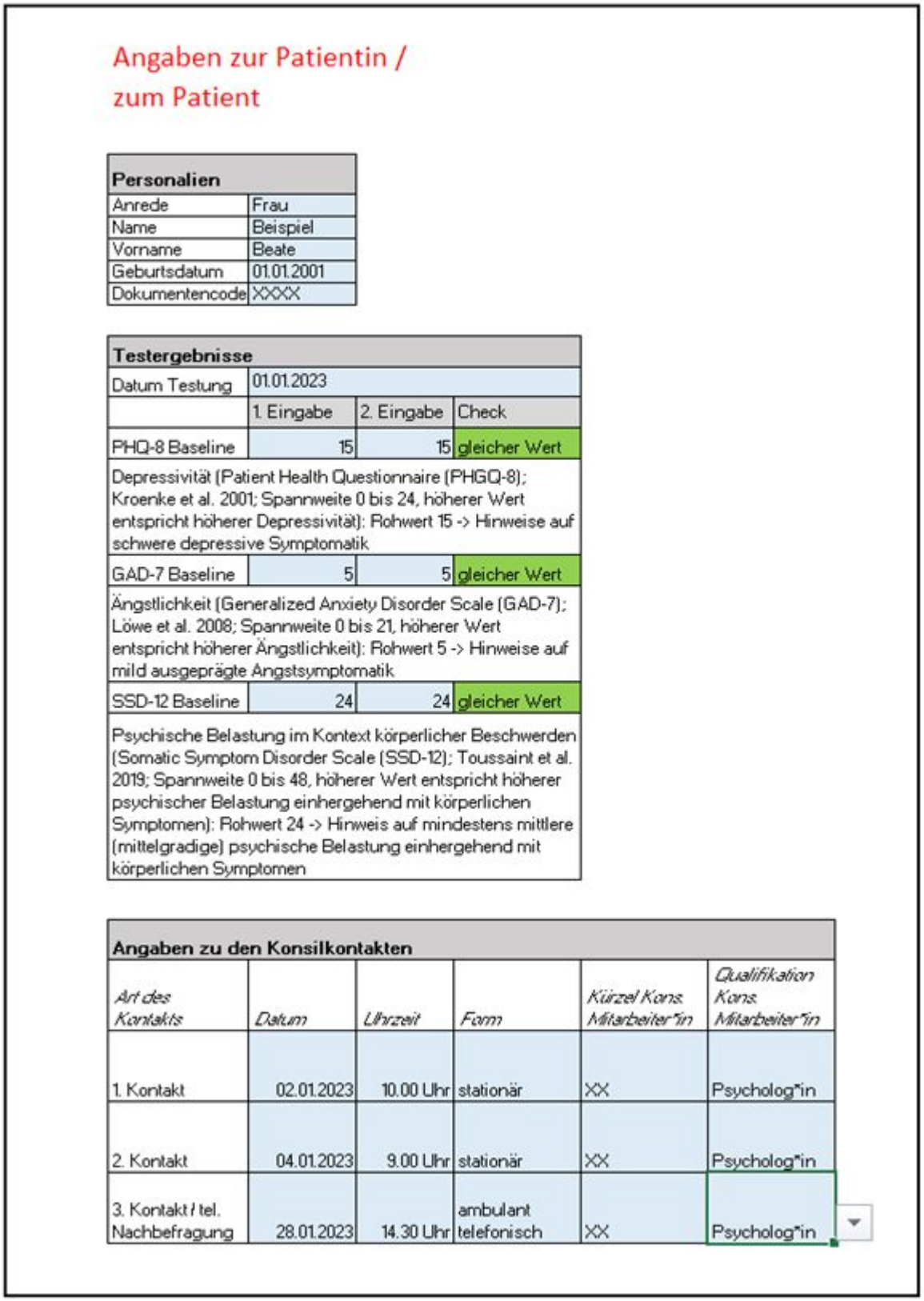
Healthcare economic endpoints

Effects on costs were planned to be assessed from the perspectives of the Swiss statutory health insurance system, the patient, and society. Towards this end, medical resource use, direct and indirect costs will be examined. Specific endpoints include total costs of hospital treatment including additional medical, psychiatric or physiotherapeutic treatment during the patient's hospital stay, follow-up costs at treating hospitals, healthcare costs, patients' out-of-pocket expenses, and indirect costs due to reduced productivity. Relevant sub-categories of costs and key medical resource use are also included.

Health economic assessments will be based on hospital data, information provided by patients at the study visits, and health insurance claims data. The latter will be collected from a set of large health insurance providers with efficient electronic databases that are able to provide data in a standardized format. The claims data will be requested to cover the time period from 1 year before T0 to T0, from T0 until T1, and from T0 until T0+3 years. Pre-baseline information from 1 year before T0 to T0 will be requested to serve as additional control variables. The data includes claims made to the Swiss statutory health insurance. They will be collected from the health insurance providers retrospectively after a reasonable waiting period ensuring sufficient completeness of the data, as patients and healthcare providers may submit reimbursement claims with delay.

Supplementary material 6: BAK-list (provided in German)

Page 1 (Angaben zum Patient)



Angaben zur Patientin / zum Patient

Personalien	
Anrede	Frau
Name	Beispiel
Vorname	Beate
Geburtsdatum	01.01.2001
Dokumentencode	XXXX

Testergebnisse			
Datum Testung	01.01.2023		
	1. Eingabe	2. Eingabe	Check
PHQ-8 Baseline	15	15	gleicher Wert
Depressivität (Patient Health Questionnaire (PHGQ-8); Kroenke et al. 2001; Spannweite 0 bis 24, höherer Wert entspricht höherer Depressivität): Rohwert 15 -> Hinweise auf schwere depressive Symptomatik			
GAD-7 Baseline	5	5	gleicher Wert
Ängstlichkeit (Generalized Anxiety Disorder Scale (GAD-7); Löwe et al. 2008; Spannweite 0 bis 21, höherer Wert entspricht höherer Ängstlichkeit): Rohwert 5 -> Hinweise auf mild ausgeprägte Angstsymptomatik			
SSD-12 Baseline	24	24	gleicher Wert
Psychische Belastung im Kontext körperlicher Beschwerden (Somatic Symptom Disorder Scale (SSD-12); Toussaint et al. 2019; Spannweite 0 bis 48, höherer Wert entspricht höherer psychischer Belastung einhergehend mit körperlichen Symptomen): Rohwert 24 -> Hinweis auf mindestens mittlere (mittelgradige) psychische Belastung einhergehend mit körperlichen Symptomen			

Angaben zu den Konsilkontakten					
Art des Kontakts	*Datum*	*Uhrzeit*	*Form*	*Kürzel Kons. Mitarbeiter*in*	*Qualifikation Kons. Mitarbeiter*in*
1. Kontakt	02.01.2023	10.00 Uhr	stationär	XX	Psycholog*in
2. Kontakt	04.01.2023	9.00 Uhr	stationär	XX	Psycholog*in
3. Kontakt / tel. Nachbefragung	28.01.2023	14.30 Uhr	ambulant telefonisch	XX	Psycholog*in

Page 2a (Eingabemaske Problembereiche)

Eingabemaske Problembereiche & spezifischer Angebotsbedarf

Zu welchen Themen wünschen Sie Angebotsvorschläge?

A. Problembereiche

Nr.	kognitive, psychische & psychosomatische Probleme	Antworten JA = 1 / Nein = 0
1	Symptome einer depressiven Störung	1
2	Symptome einer Angststörung	0
3	Symptome einer traumaassoziierten Störung	0
4	Somatoforme Belastung	0
5	Chronische Schmerzsymptomatik	0
6	Substanzkonsum, Substanzmissbrauch und Abhängigkeit	0
7	Problematisches Essverhalten	0
8	Kognitive Beeinträchtigung	0
9	Delir	0
10	Schwindel	0
11	Tinnitus	0
12	Sonstige Symptome einer psychischen Störung	0
13	Akute psychiatrische Belastung (inkl. Psychotische Symptome, Fremd- oder Selbstgefährdung)	0
14	Symptome einer Zwangsstörung	0

Nr.	Ambulante & stationäre Angebote für Patienten mit somatischen Erkrankungen	Antworten JA = 1 / Nein = 0
15	Lungenerkrankung	0
16	Herzerkrankung	0
17	Multiple Sklerose	0
18	Muskuloskelettale Erkrankungen	0
19	Rheumatische Erkrankung	0
20	Parkinson	0
21	Endokrinologische Erkrankung	0
22	Hauterkrankung	0
23	Onkologische Erkrankung	0

Page 2b (Eingabemaske Problembereiche)

Nr.	Soziale Probleme	Antworten JA = 1 / Nein = 0
24	Fehlende Kinderbetreuung	0
25	Erziehungsfragen bei minderjährigen Kindern	0
26	Partnerschaftskonflikte / Trennung / Scheidung	1
27	Psychisch erkrankte Angehörige	0
28	Einsamkeit / Wunsch nach Begleitung	0
29	Eingeschränkte Mobilität	0
30	Gewalt	0
31	Migration	1
32	Obdachlosigkeit	0
33	Wunsch nach Wohnbegleitung	0
34	Streitigkeiten mit Vermieter / Nachbaren	0
35	Geldsorgen	0
36	Arbeitslosigkeit	0
37	Wunsch nach beruflicher Beratung	0
38	Konflikte am Arbeitsplatz	0
39	Körperliche Einschränkungen am Arbeitsplatz	0

B. Spezifischer Angebotsbedarf

Nr.	Besondere Behandlungssituation	Antworten JA = 1 / Nein = 0
40	Palliative Behandlungssituation	0
41	Angebote für ältere Patienten	0
42	Behinderung / Handicap	0
43	Besondere Bedürfnisse im Akutspital	0

Nr.	Stationäre Behandlungsangebote	Antworten JA = 1 / Nein = 0
44	Stationäre psychosomatische Weiterbehandlung	0
45	Stationäre psychiatrische/psychotherapeutische Weiterbehandlung	0

Page 2c (Eingabemaske Problembereiche)

Nr.	Problembereich-übergreifende Angebote	Antworten JA = 1 / Nein = 0
46	Entspannung	0
47	Komplementärmedizin	0
48	Physiotherapie	0
49	Ernährungsberatung	0
50	Bewegungs-, Tanz-, Körpertherapie	0
51	Musiktherapie	0
52	Kunsttherapie	0
53	Vernetzungswunsch mit anderen Betroffenen	0
54	Tagesstruktur	0
55	Seelsorge	0
56	Ambulante Psychotherapie	0
57	Ergotherapie	0
58	Spitex	0

Page 3a (Ausgabe Empfehlungen)

Ausgabemaske Anschlussinterventionen

Mögliche Anschlussintervention - sortierte Reihenfolge					
Rang	Art der Anschlussintervention	Anzahl Nennungen	Verlinkung	Mit der/dem Patienten/in besprochen?	Möchte der/die Patient*in das aufgleisen?
1	Schweizerisches Rotes Kreuz - Besuchs- &Begleitdienst für MigrantInnen im Seniorenalter	1	Link	Nein	Nein
2	Beratungsstelle für Binationale Paare und Familien	1	Link	Ja	Ja
3	GGG Migration - Übersetzungen, Information, Beratung	1	Link	Nein	Nein
4	MUSUB- Transkulturelle Suchtberatungsstelle beider Basel	1	Link	Nein	Nein
5	UPK Transkulturelle Ambulanz	1	Link	Nein	Nein
6	Juristische Fakultät der Universität Basel - kostenlose Rechtsberatung für Familien	1	Link	Nein	Nein
7	Pro Mente Sana - telefonische oder E-Mail Beratung für betroffene Menschen, deren Angehörige und nahestehende Bezugspersonen	1	Link	Nein	Nein
8	Stiftung Rheinleben - Beratung für Betroffene oder Angehörige von Betroffenen mit psychischen Erkrankungen	1	Link	Nein	Nein
9	Fabe (Familien-, Paar- und Erziehungsberatung) - Erziehungs- und Familienberatung & Beratungsangebot zu Finanzen	1	Link	Nein	Nein
10	Sozialhilfe BS	1	Link	Nein	Nein

Page 3b (Ausgabe Empfehlungen)

11	Zentrum Selbsthilfe Region Basel	1	Link	Nein	Nein
12	Ambulante/r Psychiater/in	1	Link	Nein	Nein
13	Ambulante/r Psychotherapeut/in	1	Link	Ja	Ja
14	Psychosomatische Ambulanz (USB)	1	Link	Ja	Nein
15	Entspannung (Angebot der Psychosomatik) (USB)	1	Link	Nein	Nein
16	Sozialdienst (USB)	1	Link	Nein	Nein
17			Link	Nein	Nein
18			Link	Nein	Nein
19			Link	Nein	Nein
20			Link	Nein	Nein
21			Link	Nein	Nein

Page 4 (Koordination Aufgleisung)

Koordination Aufgleisung

Wer koordiniert die Aufgleisung?	
Patient*in selber	

Wer koordiniert ausserdem die Aufgleisung (falls vorhanden)?	
Koordinationsunterstützung:	https://www.sompsynet.bs.ch/koordinationsunterstützung

Hat der/die Patient*in Einverständnis für eine telefonische Nachbesprechung in zwei bis vier Wochen (je nach Krankheitsverlauf) mit ihm/ihr gegeben?
Ja

Soll der Konsilbericht an einen Arzt oder andere Fachperson des Vertrauens versendet werden?	
Ja	
Name und (falls vorhanden) Adresse?	Dr. Muster

Kommentare

Übersicht Koordinationsunterstützungsangebote

Arbeitgeber: Baloise Bank SoBa, Basler Kantonalbank inkl. Bank Cler, Böhringer Ingelheim GmbH, CABB-Chemical AG, Kanton BS, Roche, Straumann AG, SUVA Basel, Weleda AG

Stiftungen/Gesundheitsligen/Fachstellen: Stiftung Rheinleben, Abteilung Sucht Kanton Basel-Stadt

Versicherungen: SWICA, Baloise Versicherung

Page 5 (Intervention Konsilgespräch)

Interventionen im Konsilgespräch

Welche Interventionen haben Sie im Konsilgespräch angewendet?	
Psychoedukation	Nein
Stützende und sicherheitsvermittelnde Gesprächsführung	Ja
Ressourcenaktivierung	Nein
Motivierende Gesprächsführung	Nein
Vermittlung von Bewältigungsstrategien	Nein
Entspannungsübung	Nein
Atemübung	Nein
Sonstiges	

Page 6 (Telefonische Nachbesprechung)

Telefonische Nachbesprechung

Telefonisches Konsil (3. Termin: telefonische Nachbesprechung)	
Datum	28.01.2023
Uhrzeit	14.30 Uhr
Hat eine telefonische Nachbesprechung stattgefunden?	Ja
Dauer des Gesprächs (in min)	12.00

Wurden die folgenden besprochenen Angebote		
Rang	Art des Angebots	Antworten
1	Beratungsstelle für Binationale Paare und Familien	Ja
2	Ambulante*r Psychotherapeut*in => Wenn nein: Warum?	Nein Zweifel am Nutzen
3		

Wurden weitere Angebote genutzt?	Nein
Einschätzung der/des Konsildienstmitarbeitende*n: Denken Sie, dass die telefonische Nachfrage für die/den den Patient*in hilfreich war?	Ja
Kommentare	

Supplementary material 7: Informed consent materials (provided in German)

Page 1

Phase 2

28710

Universitätsspital Basel

Patienteninformation zur Studie SomPsyNet

SomPsyNet
Prävention psychosozialer Belastungsfolgen in der Somatik: ein Modellprojekt zur kollaborativen Versorgung

Studienorganisator: Prof. Dr. med. Rainer Schäfert

Gesundheitsdepartement des Kantons Basel-Stadt

Page 2

Sehr geehrte Patientin, sehr geehrter Patient
Wir fragen Sie hier an, ob Sie bereit wären, an unserem Forschungsvorhaben mitzuwirken.

Ihre Teilnahme ist freiwillig. Alle Daten, die in diesem Projekt erhoben werden, unterliegen strengen Datenschutzvorschriften. Das Forschungsvorhaben wird durchgeführt von Prof. Dr. Rainer Schäfert. Bei Interesse informieren wir Sie gerne über die Ergebnisse aus dem Forschungsvorhaben.

In einem Gespräch erklären wir Ihnen die wichtigsten Punkte und beantworten Ihre Fragen. Damit Sie sich bereits jetzt ein Bild machen können, hier das Wichtigste vorweg. Im Anschluss folgen dann weitere, detaillierte Informationen.

Warum führen wir dieses Forschungsvorhaben durch?

- Wir wollen untersuchen, ob und wie stark sich Patientinnen und Patienten mit körperlichen Erkrankungen belastet fühlen, d. h. ob Sie gestresst, in Sorge oder unter Druck sind. Zudem wollen wir herausfinden, wie sich die Belastung, die Krankheitsverläufe und die Kosten 6 Monate und 3 Jahre nach Spitaleintritt entwickeln.
- Ergänzend bieten wir Patienten, bei denen wir eine bedeutsame psychosoziale Belastung feststellen, die Möglichkeit, ihre Belastungen in einem Gespräch mit einer Fachperson zu besprechen. Im entlastenden Gespräch werden gegebenenfalls Unterstützungsmöglichkeiten besprochen und wie diese genutzt werden können. Wir wollen untersuchen, ob die Gespräche und Unterstützungsmöglichkeiten den belasteten Patienten helfen.

Was muss ich bei einer Teilnahme tun?

- Wenn Sie sich entscheiden mitzumachen, dann erklären Sie sich einverstanden Fragen zur psychosozialen Belastung und oft damit verbundenen Lebensbereichen zu beantworten. Das Ausfüllen des Fragebogens dauert zirka 30 Minuten.
- Zeigt sich im Fragebogen eine bedeutsame psychosoziale Belastung, so wird Ihnen ein Gespräch mit einer entsprechenden Fachperson angeboten. Es können insgesamt bis zu zwei solcher Gespräche à je 40 Minuten in Anspruch genommen werden. Bei Bedarf kann zusätzlich eine telefonische Nachbesprechung à 20 Minuten geplant.
- Ein basierend auf den Angaben zur Belastung ausgewählter Teil der Studienteilnehmenden wird zudem 6 Monate danach erneut befragt, um den Verlauf zu untersuchen. Diese Nachbefragung dauert zwischen 30 und 60 Minuten.

Welcher Nutzen und welches Risiko sind damit verbunden?

Nutzen:

- Mit Ihrer Teilnahme an dieser Studie helfen Sie den beteiligten Spitälern, deren Forschung zum Wohle der Patienten zu fördern.
- Sie können einen persönlichen Nutzen von der Teilnahme haben, falls ein Gespräch zur psychosozialen Belastung stattfindet.

Risiko und Belastung

- Die Studienteilnahme ist mit keinerlei Risiken verbunden. Je nachdem werden Problembereiche angesprochen, was kurzfristig als unangenehm empfunden werden kann. Durch die professionelle Betreuung erwarten wir dadurch keine negativen Effekte oder Schäden.

Mit Ihrer Unterschrift am Ende des Dokuments bezeugen Sie, dass Sie freiwillig teilnehmen und dass Sie die Inhalte des gesamten Dokuments verstanden haben.

Detaillierte Information

1. Ziel und Auswahl

Körper und Seele hängen oft eng zusammen. Anhand dieser Studie wollen wir untersuchen, wie Patientinnen und Patienten während des Spitalaufenthaltes ihren Gesundheitszustand einschätzen. Zudem wollen wir herausfinden, wie sich die Belastung, die Krankheitsverläufe und die Kosten 6 Monate und 3 Jahre nach Spitaleintritt entwickeln.

Wir fragen Sie an, da alle Personen teilnehmen können, die ab einem bestimmten Datum auf einer Station aufgenommen wurden, welche sich an der Studie beteiligt. Ausserdem müssen sie mindestens 18 Jahre alt sein und ausreichend Deutsch verstehen. Nicht teilnehmen dürfen Personen, die onkologisch betreut werden.

2. Allgemeine Informationen

- Bei **SomPsyNet** soll für Patientinnen und Patienten aus **SOM**atischen Spitälern (Spitäler, in denen Patientinnen und Patienten wegen körperlichen Erkrankungen behandelt werden) zur Prävention **PSY**chosozialer Belastungsfolgen ein Versorgungs-**NET**zwerk aufgebaut und nachhaltig etabliert werden.
- Die Prävention hat zum Ziel, Krankheiten vorzubeugen, so dass man gar nicht erst krank wird; oder falls jemand bereits krank ist, möglichst schnell zu behandeln und negative Folgen der Krankheit zu verhindern.
- Psychosoziale Belastungsfolgen bedeutet bei SomPsyNet, dass jemand mit einer körperlichen Erkrankung auch psychisch oder sozial belastet ist. D.h. dass eine Person gestresst, in Sorge oder unter Druck ist. Häufig sind es Schwierigkeiten im Umgang mit folgenden Bereichen: körperliche Beschwerden oder Einschränkungen, emotionale Probleme (z.B. Traurigkeit, Depression, Ängste), Familie/Kinder/Freunde, Arbeit/Schule, Geld oder Lebenssinn/Spiritualität/Glaube. Patientinnen und Patienten mit psychosozialen Belastungen sollen bei SomPsyNet während des Spitalaufenthaltes systematisch erkannt und entsprechend behandelt werden.
- Informationen zu psychosozialen Belastungen werden der zuständigen Stationsärztin oder dem zuständigen Stationsarzt und dem weiteren Behandlungsteam weitergeleitet, um eine optimale und ganzheitliche Behandlung zu gewährleisten. Ausserdem werden Sie im Gespräch mit der Fachperson gefragt, ob wir den Konsilbericht, welcher unter anderem Informationen zu den aktuellen Belastungsfaktoren und den besprochenen Unterstützungsangeboten enthält, an den Hausarzt oder andere Nachbehandler weiterleiten dürfen.
- Die Datenerhebung der Studie dauert von Januar 2020 bis Dezember 2022. Wir erwarten ca. 3000 Teilnehmende im Gesamten.
- Um die gesundheitsbezogenen Kosten und die Kosten im Gesundheitssystem zu untersuchen, arbeiten wir mit ausgewählten Krankenversicherern zusammen. Es ist daher möglich, dass wir mit Ihrem Einverständnis Ihre Krankenversicherer kontaktieren, um Informationen über die Art Ihrer Versicherungen und die von Ihnen beanspruchte Leistungen und deren Kosten zu bekommen. Wir werden den Krankenversicherern ausser Ihren Kontaktdaten und Ihrer Einverständniserklärung keine persönlichen Informationen zukommen lassen.
- Diese Studie ist nach Schweizer Recht konzipiert. Zudem werden alle international anerkannten Richtlinien beachtet. Die zuständige kantonale Ethikkommission hat die Studie geprüft und bewilligt.
- Eine Beschreibung dieser Studie finden Sie auch auf der Internetseite des Bundesamtes für Gesundheit unter www.kofam.ch

3. Ablauf

- Um die Belastung der Patientinnen und Patienten abzuklären, werden Sie während des Spitalaufenthaltes befragt. Dabei werden Ihnen Fragen zu Ihrem Gesundheitszustand, zu Ihrer Befindlichkeit, zu medizinischen Behandlungen, zu Ihrem Lebensumfeld und zur Lebensqualität gestellt. Falls im Fragebogen eine bedeutsame psychosoziale Belastung festgestellt wird, werden die Ergebnisse an die zuständige Stationsärztin oder den zuständigen Stationsarzt

weitergeleitet. Die zuständige Stationsärztin oder der zuständige Stationsarzt kann auf Ihren Wunsch ein Gespräch mit einer entsprechenden Fachperson anfordern. Im Gespräch werden aktuelle Problembereiche und mögliche Unterstützungsangebote besprochen. Je nach Bedarf können zwei solcher Gespräche à 40 Minuten stattfinden. Zusätzlich kann eine telefonische Nachbesprechung à 20 Minuten geplant werden.

- Ein Teil der Studienteilnehmenden wird zudem 6 Monate nach der ersten Befragung erneut befragt, um den Verlauf zu untersuchen. Sie erhalten die Fragebogen in Papierform, auf einem Tablet/Computer oder die Fragen werden Ihnen mündlich in einem Gespräch gestellt. Wenn Sie es wünschen, können wir Sie bei der Beantwortung der Fragen unterstützen. Dazu werden Sie von einem Studienmitarbeitenden kontaktiert.
- Im Rahmen Ihres Spitalaufenthaltes werden im Routineprozess Patientendaten zu Ihrer Gesundheit, aber auch zu administrativen Zwecken erfasst. Zu diesen Daten gehören Informationen zu Ihrer Person (wie z.B. Geschlecht, Geburtsdatum, Kontaktangaben, Nationalität), zu Ihrer Krankheitsgeschichte (wie z.B. Anamnese, Symptome und Diagnosen) und zu den Spitalstatistiken (wie z.B. Eintrittsdatum, Austrittsdatum, Liegezeit, Kosten, ökonomischer Schweregrad der Erkrankung). Wir dürfen diese Daten jedoch nur analysieren, wenn Sie hiermit Ihr Einverständnis dazu gegeben haben.
- Zeitlicher Aufwand durch die Studienteilnahme für die Patientin/den Patienten (immer Ihr Einverständnis vorausgesetzt) während des dreijährigen Prüfzeitraums:

	Befragung im Spital	**6 Monate nach Studieneinschluss**	**3 Jahre nach Studienschluss**
Basisbefragung (Selbstauskunft auf Papier / Tablet oder per Interview)	20-30 Minuten		
Optional: **Gespräch mit Fachperson**	1 bis 2 Gespräche à 40 Minuten; bei Bedarf zudem ein Telefongespräch à 20 Minuten		
Nachbefragung (Üblicherweise per Telefon)		30-60 Minuten	
Daten der Krankenversicherer (werden durch Studienpersonal angefragt und eingeholt)	Kein Zeitaufwand	Kein Zeitaufwand	Kein Zeitaufwand

4. Nutzen

Mit Ihrer Teilnahme an dieser Studie helfen Sie den beteiligten Spitälern, deren Forschung zum Wohle der Patienten zu fördern.
Sie können einen persönlichen Nutzen von der Teilnahme haben, falls ein Gespräch zur psychosozialen Belastung stattfindet.

5. Freiwilligkeit und Pflichten

Sie nehmen freiwillig teil. Wenn Sie nicht an dieser Studie teilnehmen oder später Ihre Teilnahme zurückziehen wollen, müssen Sie dies nicht begründen. Ihre medizinische Behandlung/Betreuung ist unabhängig von Ihrem Entscheid gewährleistet. Sie dürfen jederzeit Fragen zur Studienteilnahme stellen. Kontaktdaten finden Sie am Ende dieser Studieninformation.
Als Teilnehmerin / als Teilnehmer ist es notwendig, dass Sie die Fragebogen jeweils wahrheitsgemäss nach Ihrem Befinden ausfüllen.

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6. Risiken und Belastungen

Die Studienteilnahme ist mit keinerlei Risiken verbunden. Je nachdem werden Problembereiche angesprochen, was kurzfristig als unangenehm empfunden werden kann. Durch die professionelle Betreuung erwarten wir dadurch keine negativen Effekte oder Schäden.

7. Alternativen

Die Teilnahme an dieser Studie ist freiwillig. Wenn Sie nicht teilnehmen, hat dies keinen Einfluss auf Ihre medizinische Behandlung. Falls Sie sich Unterstützung im psychosozialen Bereich wünschen und nicht an der Studie teilnehmen wollen, wenden Sie sich bitte an die zuständige Stationsärztin oder den zuständigen Stationsarzt. Ihre Prüfperson kann Sie hierzu beraten.

8. Ergebnisse

Es gibt:

1. Individuelle Ergebnisse der Studie, die Sie direkt betreffen: Die Prüfperson wird Sie nach der Befragung über allfällige Anzeichen einer psychosozialen Belastung informieren. Sie können danach selbst entscheiden, ob Sie sich auf ein Gespräch mit einer entsprechenden Fachperson einlassen möchten oder nicht. Sie werden bei Bedarf über alle neuen Erkenntnisse informiert, welche den Nutzen der Studie oder Ihre Sicherheit beeinflussen können.
2. Objektive End-Ergebnisse der gesamten Studie: Am Ende der Studie können wir Ihnen eine Zusammenfassung der Gesamtergebnisse zukommen lassen.

9. Vertraulichkeit der Daten und Proben

Für diese Studie werden persönliche medizinische Daten und Versicherungsdaten erfasst. Bei der Datenerhebung zu Studienzwecken werden die Daten verschlüsselt. Verschlüsselung bedeutet, dass alle Bezugsdaten, die Sie identifizieren könnten (Name, Geburtsdatum), gelöscht und durch einen Schlüssel ersetzt werden.

Die Schlüssel-Liste bleibt immer bei den Studienverantwortlichen. Personen, die den Schlüssel nicht kennen, können daher keine Rückschlüsse auf Ihre Person ziehen. Ihr Name taucht niemals im Internet oder einer Publikation auf. Sämtliche Forschungsprojekte mit Ihren Daten unterliegen den in der Schweiz geltenden gesetzlichen Bestimmungen und müssen vorher von einer Ethikkommission bewilligt werden. Ihre Daten sind gemäss dem Schweizer Datenschutz nur berechtigten Personen des Projektes zugänglich. Alle Personen, die im Rahmen der Studie Einsicht in Ihre Daten haben, unterliegen der Schweigepflicht. Die Vorgaben des Datenschutzes werden eingehalten. Sie als teilnehmende Person haben jederzeit das Recht auf Einsicht in Ihre Daten.

Es ist möglich, dass Ihre Daten für andere Untersuchungen zu einem späteren Zeitpunkt weiterverwendet werden oder später an eine andere Datenbank in der Schweiz oder ins Ausland für noch nicht näher definierte Untersuchungen versandt und verwendet werden. Diese andere Datenbank muss die gleichen Standards einhalten wie die Datenbank zu dieser Studie. Für diese Weiterverwendung bitten wir Sie, ganz am Ende dieses Dokuments eine weitere Einwilligungserklärung zu unterzeichnen.

Möglicherweise wird diese Studie durch die zuständige Ethikkommission, die die Studie veranlasst hat, überprüft. Der verantwortliche Studienleiter (auch Prüfperson genannt) muss der Ethikkommission allenfalls Ihre persönlichen und medizinischen Daten für solche Kontrollen offenlegen.

10. Rücktritt

Sie können jederzeit von der Studie zurücktreten. Die bis dahin erhobenen Daten und Proben werden noch verschlüsselt ausgewertet, weil das ganze Projekt sonst seinen Wert verliert.
Nach der Auswertung werden Ihre Daten anonymisiert, d.h. Ihre Schlüsselzuordnung wird vernichtet, so dass danach niemand mehr erfahren kann, dass die Daten und Proben ursprünglich von Ihnen stammten. Dies dient vorrangig dem Datenschutz.

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11. Entschädigung für Teilnehmende
Sie erhalten keine Entschädigung für Ihre Studienteilnahme.
Durch die Teilnahme entstehen Ihnen oder Ihren Krankenversicherern keine zusätzlichen Kosten. Falls es angezeigt ist, dass die Nachbefragung nicht per Telefon oder E-Mail, sondern vor Ort in einer unserer Kliniken durchgeführt wird, werden wir eine angemessene Transportkostentschädigung bezahlen. Vergütet werden öffentliche Verkehrsmittel 2. Klasse oder in äquivalenter Höhe Fahrkosten mit dem Auto. Sollte aus gesundheitlichen Gründen ein Taxi benötigt werden, bitten wir darum, die Kosten vorab von der Projektleitung genehmigen zu lassen.
Die Ergebnisse dieser Studie können unter Umständen dazu beitragen, kommerzielle Produkte zu entwickeln. Durch Ihre Studienteilnahme haben Sie kein Anrecht auf Anspruch an kommerziellen Entwicklungen (z. B. Patenten).

12. Haftung
Die jeweilige Institution, die für die Durchführung der Studie verantwortlich ist, haftet für Schäden, welche im Zusammenhang mit den Forschungshandlungen entstehen. Die Voraussetzungen und das Vorgehen dazu sind gesetzlich geregelt. Wenden Sie sich im Schadensfall an die Prüfperson.

13. Finanzierung der Studie
Die Studie wird mehrheitlich von Gesundheitsförderung Schweiz bezahlt.

14. Kontaktperson(en)
Sie dürfen jederzeit Fragen zur Studienteilnahme stellen. Auch bei Unsicherheiten oder Notfällen, die während der Studie oder danach auftreten, wenden Sie sich bitte an:

Kontaktperson Universitätsspital Basel
Prof. Dr. Rainer Schäfert,
Klinik für Psychosomatik, Universitätsspital Basel
Hebelstrasse 2, 4031 Basel
Tel.: +41 61 328 59 79
E-Mail: sompsynet@usb.ch

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SomPsyNet Einwilligungserklärung Studienprojekt

Schriftliche Einwilligungserklärung zur Teilnahme an einem Studienprojekt

Bitte lesen Sie dieses Formular sorgfältig durch. Bitte fragen Sie nach, wenn Sie etwas nicht verstehen. Für die Teilnahme ist Ihre schriftliche Einwilligung notwendig.

BASEC-Nummer:	2019-01724
Titel der Studie:	SomPsyNet – Prävention psychosozialer Belastungsfolgen in der Somatik
Studienorganisator – verantwortliche Person / Institution:	Chefarzt: Prof. Dr. med. Rainer Schäfert Klinik für Psychosomatik Universitätsspital Basel Hebelstr. 2, 4031 Basel
Ort der Durchführung:	Universitätsspital Basel
Verantwortliche Prüfperson am Studienort: Name und Vorname in Druckbuchstaben:	.....

Bitte beantworten Sie die Angaben in Druckbuchstaben und markieren Sie das Kästchen mit einem Kreuz.

☐ männlich ☐ weiblich ☐ anderes

Vorname	.....
Name	.....
Strasse, Nr.	.....
PLZ, Ort	.....
Geburtsdatum (TT/MM/JJJJ):	.....
Telefonnummer:	.....
Mobilenummer:	.....
E-Mail Adresse:	.....

- Ich wurde von der unterzeichnenden Prüfperson mündlich und schriftlich über den Zweck, den Ablauf der Studie und über mögliche Vor- und Nachteile sowie über eventuelle Risiken informiert.
- Ich nehme an dieser Studie freiwillig teil und akzeptiere den Inhalt der abgegebenen schriftlichen Information. Ich hatte genügend Zeit, meine Entscheidung zu treffen.

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- Meine Fragen im Zusammenhang mit der Teilnahme an dieser Studie sind mir beantwortet worden. Ich behalte die schriftliche Information und erhalte eine Kopie meiner schriftlichen Einwilligungserklärung.
- Ich bevollmächtige die Studienleitung (Sponsor), von meinen Krankenversicherern die unmittelbar für den Studienzweck erforderlichen Informationen zur Art meiner Versicherungen, zu meinen Leistungsdaten und deren Kosten einzuholen. Diese Informationen beziehen sich auf die Beobachtungszeit der Studie (ab 1 Jahr vor dem Studieneinschluss bis 6 Monate danach) und auf die längerfristige Kostenentwicklung (bis 3 Jahre nach Studieneinschluss). Ich entbinde hierfür meine Krankenversicherer von ihrer gesetzlichen Schweigepflicht.
- Ich bin einverstanden, dass Fachleute der Studienleitung und der Ethikkommission Einsicht in meine unverschlüsselten Daten nehmen dürfen, unter strikter Einhaltung der Vertraulichkeit.
- Über Studienergebnisse, die direkt meine Gesundheit betreffen, werde ich informiert.
- Ich weiss, dass meine gesundheitsbezogenen und persönlichen Daten in verschlüsselter Form zu Forschungszwecken für diese Studie weitergegeben werden können (auch ins Ausland). Die Studienleitung (Sponsor) gewährleistet, dass der Datenschutz nach Schweizer Standard eingehalten wird.
- Im Fall einer Weiterbehandlung während des Prüfzeitraums ermächtige ich meine nachbehandelnden Ärzte, relevante Nachbehandlungsdaten der Prüfperson zu übermitteln.
- Ich kann jederzeit und ohne Angabe von Gründen von der Studienteilnahme zurücktreten. Meine medizinische Behandlung ist unabhängig von der Studienteilnahme immer gewährleistet. Die bis zum Rücktritt erhobenen Daten und Proben werden für die Auswertung der Studie verwendet.
- Falls Sie durch das Projekt einen Schaden erleiden sollten, haftet die Institution, welche das Projekt veranlasst hat und für die Durchführung verantwortlich ist.
- Ich verpflichte mich, die Fragen wahrheitsgetreu zu beantworten. Im Interesse meiner Gesundheit kann mich die Prüfperson jederzeit von der Studie ausschliessen.

Ort, Datum: **Unterschrift Teilnehmer/in:**

_____ _____

Bestätigung der Prüfperson:
Hiermit bestätige ich, dass ich dieser Teilnehmerin/ diesem Teilnehmer Wesen, Bedeutung und Tragweite der Studie erläutert habe. Ich versichere, alle im Zusammenhang mit dieser Studie stehenden Verpflichtungen gemäss dem geltenden Recht zu erfüllen. Sollte ich zu irgendeinem Zeitpunkt während der Durchführung der Studie von Aspekten erfahren, welche die Bereitschaft der Teilnehmerin/ des Teilnehmers zur Teilnahme an der Studie beeinflussen könnten, werde ich sie/ ihn umgehend darüber informieren.

Ort, Datum: **Name, Vorname der Prüfperson in Druckbuchstaben**

_____

Unterschrift der Prüfperson

_____ _____

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SomPsyNet Einwilligungserklärung für Weiterverwendung von Daten dieser Studie

Einwilligungserklärung für Weiterverwendung von Daten in verschlüsselter Form

Bitte beantworten Sie die Angaben in Druckbuchstaben und markieren Sie das Kästchen mit einem Kreuz.

☐ männlich ☐ weiblich ☐ anderes

Name .....

Vorname .....

- Ich erlaube, dass meine Daten und Proben aus dieser Studie für die medizinische Forschung weiterverwendet werden dürfen. Dies bedeutet, dass meine Daten für zukünftige, noch nicht näher definierte Forschungsprojekte auf unbestimmte Zeitdauer verwendet werden dürfen. Diese Einwilligung gilt unbegrenzt.
- Ich entscheide mich freiwillig für eine Teilnahme und kann diesen Entscheid zu jedem Zeitpunkt wieder zurücknehmen. Wenn ich zurücktrete, werden meine Daten anonymisiert. Ich informiere lediglich meine Prüfperson und muss diesen Entscheid nicht begründen.
- Ich habe verstanden, dass die Daten verschlüsselt sind und der Schüssel sicher aufbewahrt wird. Die Daten können im In- und Ausland an andere Datenbanken zur Analyse gesendet werden, wenn diese dieselben Standards wie in der Schweiz einhalten. Alle rechtlichen Vorgaben zum Datenschutz werden eingehalten.
- Normalerweise werden alle Daten gesamthaft ausgewertet und die Ergebnisse zusammenfassend publiziert. Sollte sich ein für meine Gesundheit wichtiges Ergebnis ergeben, ist es möglich, dass ich über meine Prüfperson kontaktiert werde. Wenn ich das nicht wünsche, teile ich es meiner Prüfperson mit. Wenn Ergebnisse aus den Daten kommerzialisiert werden, habe ich keinen Anspruch auf Anteil an der kommerziellen Nutzung.

Ort, Datum: **Unterschrift Teilnehmer/in:**

_____ _____

Bestätigung der Prüfperson: Hiermit bestätige ich, dass ich dieser Teilnehmerin/ diesem Teilnehmer Wesen, Bedeutung und Tragweite der Weiterverwendung von Daten erläutert habe.

Ort, Datum: **Name, Vorname der Prüfperson in Druckbuchstaben**

_____

Unterschrift der Prüfperson

_____ _____

Supplementary material 8: Methodological details 4 – Data recording and source data

Data were collected by paper-pencil and by an online medical application called 'heartbeat one' from Heartbeat Medical Solutions GmbH. Heartbeat one was already implemented at the UHB and used in clinical practice. The server running heartbeat one for all three study sites was on a UHB server, maintained by the ICT-department of the UHB. All data assessed with heartbeat one as well as hospital information data used for this study purpose was transferred by the UHB ICT team to the project database in secuTrial®. SecuTrial® is an online Clinical Data management Application (CDMA, secuTrial® database) system based at the ICT-Department of the UHB.

All collected paper-pencil data of questionnaires, and hospital information that were not electronically available was entered into the study Electronic Case Report Form (eCRF) of secuTrial®. An audit trail maintained a record of initial entries and any changes made; time and date of entry; and username of the person authorizing entry or change. The eCRF was implemented by the Data management group at the CTU. The Clinical Data Management System (CDMS) ran on a server maintained by the ICT-department of the UHB. Data entry was performed by trained staff. The CDMS was accessible via a standard browser on devices with an internet connection. The data transfer between clients and servers was encrypted using Transport Layer Security (TLS) cryptography protocol. Password protection and user-right management ensured that only authorized study investigators, monitors, data managers, and local authorities (if necessary) had access to the data during and after the study.

For quality assurance, the sponsor, the ethics committee, or an independent trial monitor could visit the research sites. Direct access to the source data and all study related files was granted on such occasions. All involved parties kept the participant data strictly confidential.

Back-up of the heartbeat one and secuTrial® database server are performed regularly according to established processes by the ICT-department of the UHB. The data managers of the CTU Basel implemented validation rules in the CDMS. When data got saved in an eCRF, they were validated for completeness and discrepancies. The data were reviewed by the responsible investigator as well as an independent monitor. The monitor raised queries using the query management system implemented in secuTrial®. Designated investigators had to respond to the query and confirm or correct the corresponding data. Thereafter the monitor could close the query. Health insurance claims data for patients with informed consent available are requested from participating health insurance providers.

Supplementary material 9: Methodological details 5 – Statistics

Sample size

Eligibility for participation in the SomPsyNet study was conditioned on the provided informed consent. Based on a priori power analyses – see below – we aimed at a sample size of *n* = approximately 200–500 in phase 0; *n* = 1000 in phase 1; and *n* = 1000 in phase 2. This was expected to allow for assessing a sufficiently large sample of patients with psychosocial distress (anticipated 30–35% of enrolled patients).

Statistical analysis plan and sample size calculation

Sample size calculations were conducted in close collaboration by Prof. Günther Fink, Head of the Household Economics and Health Systems Research Unit at the Swiss TPH (Swiss Tropical and Public Health Institute, Basel), and the research team. The primary endpoint of our study was the change from baseline of the Mental Health Component Summary score measured by the Short Form health survey questionnaire (SF-36). We made the following conservative assumptions: 1) 80% of those with psychosocial distress in the intervention condition (phase 2, SCCM condition) accepted receiving the SCCM (and none of them receive standard CL) 2) an effect of Hedges' g of 0.5 (based on published and unpublished reports[9] 3) 25% of those with psychosocial distress in the control condition (phase 1, TAU condition) received standard CL-intervention; and 4) a Hedges' g of 0.5 in the control condition (phase 1, TAU) receiving standard CL-intervention; we expected the following Hedges' g between the SCCM condition and TAU condition (delta Hedges' g): delta Hedge's g = 0.8 * 0.5 – 0.25 * 0.5 = 0.275). A priori power analysis based on t-test family tests for calculating differences between two independent means (with *alpha* = 0.05) indicated that a sufficient power of 1-beta = 0.80 would be achieved if 209 participants per condition were included. Notably, the sample size needed to allow for an anticipated drop-out rate to reach sufficient power for both intent-to-treat and per-protocol analyses. Assuming a drop-out rate of 25% (given that follow-up was conducted at baseline + 6 months and a rather morbid study sample), we needed to include 279 patients per condition in the main analyses on the treatment effects of the SCCM (i.e., comparing the outcomes of subjects in the distressed subgroups of phase 2 vs. phase 1). Based on preliminary analyses of data from study phase 0, we expected that approximately 30–35% (more than the 20%, initially anticipated based on the literature[10]) of patients with somatic disease included in the study were psychosocially distressed. Leaving some uncertainty margin, we therefore expected that these 279 patients per condition could be achieved with a total subject pool of *N* = 2000 included in the study phases 1 and 2 (*n* = 1000 in phase 1 and *n* = 1000 in phase 2).

These power calculations were computed under the assumption that a generalized linear model with period and cluster-fixed effects was used to estimate intervention effects. Any deviations from this statistical plan were described and justified in the final trial report.

The statistical power for medical resource use and cost parameters was difficult to establish due to issues such as large background variability and unknown distribution of confounding baseline characteristics. For these analyses, we used the largest achievable sample sizes to be as much as possible on the safe side. This implied to include all enrolled patients in the related analyses based on hospital information data, and all meeting the specific eligibility criteria for the analyses based on health insurance claims data.

Descriptive analyses

Descriptive statistics of study sample characteristics, study condition parameters such as participation rate, and mental health factors for both study phases (T0, T1) by allocated sequence and period will be calculated following the SW-CRT guidelines[11], and appropriate indicators of central tendency and dispersion will be reported, depending on variable scale and distribution.

Estimation of intervention effects on primary, secondary, and other outcomes

- To estimate intervention effects, we intend to primarily conduct generalized linear mixed models of primary, secondary, and other outcome parameters adjusted for the clusters as random effects and for study conditions, calendar time and potential confounders (e. g., socioeconomic status) as fixed effects. The exact choice of regression method will consider the distributional characteristics of the outcome parameters of interest. As dependency of stepped wedge trial results on choice of statistical techniques had been reported, alternative analytical methods may additionally be used for sensitivity checks[12].
- Intervention effects will be estimated, using the distressed focus sample, contrasting Phase 2 vs. Phase 1.

Analysis of outcome parameters representing medical resource use and costs will follow these steps:

- Description of cluster characteristics, contrasting trial-level cluster size etc., and cluster size considering the actual number of observations with health insurance claims data available[13]. This will be accompanied by a CONSORT-type flowchart[11].
- Description of individual-level sociodemographic and disease characteristics per intervention phase[13].

- Naïve comparison of outcome parameter values between intervention phases.
- Generalized linear mixed models of outcome parameters with random effects for the clusters and fixed effects for intervention phases, calendar time, and potential confounders (i.e., patient characteristics etc.)[13,14]. The exact choice of regression method will consider the distributional characteristics of the outcome parameters of interest. (For medical resource use and cost outcomes, left-skewed distributions are expected.) As dependency of stepped wedge trial results on choice of statistical technique had been reported, alternative analytical methods may additionally be used for sensitivity checks[12].
- An additional step will combine the results of the above-described analyses, and especially of the analysis of total healthcare costs over 6 months, with estimates of the per-person cost of the SCCM intervention that will be derived as part of the SomPsyNet project but outside the study addressed here. This will allow us to approximate the net cost of the SCCM intervention. The stability of results will be assessed based on the variation of parameter values, using 95% confidence limits where available. Additional estimates of the proportion of patients with psychosocial distress will enable us to perform a rough estimation of the budget impact of the SCCM, at the level of canton Basel-Stadt and at the national level.

We will conduct additional statistical analyses i) to compare data from phases 2 and 1 vs. phase 0 to estimate the potential effects of introducing parts of screening 1 without consequences ii) to estimate the prevalence of psychosocial distress among somatic hospital patients, iii) to estimate the performance criteria of the screening procedure to identify psychosocially distressed subjects, and iv) to estimate differences in outcome parameter trajectories and costs between distressed and non-distressed subjects, by comparison of subjects in the distressed focus sample with the non-distressed subsample.

To the extent applicable, all reporting follows the rules of the extension of the CONSORT statement to stepped-wedge cluster randomized trials[11].

Minimizing and handling of missing data and drop-outs

First of all, our strategy combines minimizing of missing data bias by careful planning of the questionnaire order (most important outcomes at the beginning); active data management for quality assurance in terms of tight monitoring of planned activities/progress and results and identifying problems as early as possible; and active review of missing data to collect answers when re-contact was planned. Using digital assessment tools should further reduce missing data.

It is essential to distinguish between missing data due to partial participation (drop-outs, withdrawal) and loss to follow-up (death or severe medical health

status/diseases). Inclusion of loss to follow-up reasons for example based on the patient complexity level will be taken into account when conducting statistical methods such as inverse probability weighting and multiple imputation by chained equations. Whenever possible, full complete analyses will be performed including adjustment for proxies of missing data such as age, patient complexity level, and socioeconomic status, and whenever appropriate multiple imputation will be performed. We intend to conduct intention to treat (ITT) as well as per protocol analyses.

Supplementary material 10: Methodological details 6 – Ethics and Dissemination

Monitoring

Source data/documents are accessible to monitors and questions are answered during monitoring. Given the anticipated low risk of the intervention, we did not establish a data monitoring committee (DMC), nor did we implement regular interim analysis or related stopping guidelines. However, the sponsor and investigator could terminate the study prematurely according to certain circumstances, e.g. insufficient participant recruitment, alterations in accepted clinical practice that would have made the continuation of the study unwise, or early evidence of harm or benefit of the experimental intervention.

Risk of harms

Participation in the study was not expected to be associated with relevant risks. In the questionnaires or in the consultation contacts problem areas may be explored for the benefit of the patient that could be perceived as unpleasant for a short time. All applied questionnaires were validated, widely accepted, and routinely applied in research and clinical practice. Consultations were conducted by qualified professionals under appropriate supervision. Hence, the risk-benefit assessment was positive.

Given the large number of hospital inpatients with somatic diseases that were included in this study, we expected that several Serious Adverse Events (SAEs)[15] would occur during the course of the study at the different included study sites (e.g., among the patients hospitalized for cardiac diseases: life-threatening events requiring prolongation of existing hospitalization and resulting in disability). Given the very low probability of a causal relation between study procedures (e.g., collection of self-reported data) and any such events, we do not conduct routine causality assessments of all SAEs, with the exception of SAEs related to suicide attempts or completed suicide. In these cases, both investigator and sponsor conduct a causality assessment of these events to the trial intervention (see table in Supplementary Material 11 for terms given in ICH E2A guidelines[16]). We classify any event assessed as “possibly”, “probably” or “definitely” related to the trial intervention. Further, both investigator and sponsor make a severity assessment of these events as mild, moderate, or severe. “Mild” meant the complication is tolerable, “moderate” meant it interferes with daily activities, and “severe” meant it renders daily activities impossible.

Reporting of SAEs

All SAEs related to suicide attempts or completed suicide are documented and reported immediately (within a maximum of 24 hours after respective information was provided to study staff) to the sponsor of the study.

If it is not possible to exclude that a SAE is attributable to the intervention under investigation, the investigator reports it to the ethics committee via BASEC within 15 days. If a SAE occurs at one of the study sites, the coordinating investigator reports the event to the ethics committee concerned, within 15 days. If a serious SAE related to suicide attempts or completed suicide occurs, we would interrupt the research project and notify the Ethics Committee on the circumstances via BASEC within 7 days according to HRO Art. 21[17].

Auditing

Regular internal audits (usually once a year; with additional visits if needed) were conducted at each study site by trained and experienced staff (i.e., knowledge of Good Clinical Practice) of the principal study site under the supervision of the operative study manager. All study procedures, including participant recruitment, verification of eligibility, consent, enrolment, and allocation to study conditions were reviewed. Before each study phase, the study staff was prepared and trained. All study sites were in regular exchange through monthly meetings. Data managers regularly check completeness, accuracy, and timeliness of data collection and filing. The final database, using the software secuTrial®, provides an implemented data audit trail feature.

Overall ethical considerations

The SomPsyNet study is conducted in compliance with the protocol, the current version of the Declaration of Helsinki[18], the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP)[19], the Human Research Act (HRA)[20], as well as other locally relevant legal and regulatory requirements. Participation of study participants is voluntary and written informed consent prior to participating in the study was obtained and can be withdrawn at any time.

Protocol amendments

Any modifications to the protocol which might impact the conduct of the study, the potential benefit of the patients, or might affect patient safety, including changes in study objectives, study design, patient population, sample sizes, study procedures, or

significant administrative aspects require a formal amendment to the protocol. Until 31-05-2023, four amendments were submitted to and approved by the EKNZ (approval dates: 04-06-2020, 08-01-2021, 11-02-2021, and 27-07-2021). Protocol modifications and administrative changes of the protocol were discussed among the principal investigators. In regular quality management meetings, the operational study management informed the study staff of all study sites in case of relevant protocol modifications.

Consent or assent

Trained Research Nurses and trained master students in psychology, with a completed bachelor degree in psychology introduced the trial to patients. Patients also received information sheets. Patients had the opportunity for questions or queries at any time and sufficient time to form an opinion. Study staff obtained written consent from patients willing to participate in the trial. In addition, patients were asked to agree by signing the informed consent that study investigators collected health insurance claims data directly from the insurer to analyze health resource use and costs. If informed consent for further use of study data was obtained, study data can be further used for other projects.

If consent is revoked, no further data are collected. Already collected data of the person concerned will no longer be transferred to the study database. In case that data were already transferred and fully coded at time of revoking the consent, encoded data will be retained and analyzed. The opportunity to receive TAU remains for any subject who has withdrawn from the study.

Confidentiality and coding

The list of participants with given informed consent is stored on a secure UHB server maintained by the ICT-department and the trial and participant data are handled with uttermost discretion and are only accessible to authorized personnel, who need data access to fulfill their duties within the scope of the study. Back-up of the UHB server is performed regularly according to established processes by the ICT-department of the UHB.

As soon as possible after data collection, the CRFs and other study specific documents are encoded, and the participants are henceforth only identified by a unique participant number. Once all data are entered into the CDMS and monitoring is completed, the secuTrial® database will be locked and closed for further data entry. The complete dataset will then be exported and transferred to the study statistician as well as the principal investigator. Other members of the study team (e.g., health economist) will receive access to the data, as required for analytical tasks.

For the collection of health insurance claims data, the contact details, copies of signed informed consent forms and social insurance number (AHV number) of consenting, eligible patients are sent to the participating health insurance providers, together with a code that can be unequivocally matched with the study's unique participant number. The health insurance providers select and calculate the required variables. Together with the above-mentioned code, they are asked to return these for integration with the main study database.

Supplementary material 11: Table – Causality assessment of SAEs based on ICH E2A guidelines

Causality assessment of SAEs based on ICH E2A guidelines

Relationship	Description
Definitely	Temporal relationship Improvement after dechallenge Recurrence after rechallenge (or other proof of drug cause)
Probably	Temporal relationship Improvement after dechallenge No other cause evident
Possibly	Temporal relationship Other cause possible
Unlikely	Any assessable reaction that does not fulfill the above conditions
Not related	Causal relationship can be ruled out

Note. Source of table: [16]; SAE (Serious Adverse Event), ICH E2A (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Supplementary material 12: References of the supplementary material

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description	Addressed on page number
Administrative information			
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	5
	2b	All items from the World Health Organization Trial Registration Data Set	Several pages
Protocol version	3	Date and version identifier	5
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 19
	5b	Name and contact information for the trial sponsor	1; 19
	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	19
	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)	19; 20
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	7–10
	6b	Explanation for choice of comparators	Not relevant
Objectives	7	Specific objectives or hypotheses	10
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)	12; 13
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	11; 12
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)	11; 12
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	14; Suppl. M. 4
	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)	Not applicable
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14; Suppl. M. 4
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Suppl. M. 4
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; Suppl. M. 5
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)	Suppl. M. 2; Suppl. M. 3 (figure)
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	16; Suppl. M. 9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	15

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	Suppl. M. 2
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	Suppl. M. 2
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Suppl. M. 2
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Suppl. M. 2
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Suppl. M. 2

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	15; 16; Suppl. M. 8
	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	Suppl. M. 2
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	15; 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; Suppl. M. 9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Suppl. M. 9

	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)	16; Suppl. M. 9
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	17
	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	17
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; Suppl. M. 11
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; Suppl. M. 11
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	5; 18; Suppl. M. 11
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)	18; Suppl. M. 11
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15; Suppl. M. 11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Suppl. M. 10
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	15; 16; Suppl. M. 8
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19

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**	20
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	Not applicable
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	16; 17
	31b	Authorship eligibility guidelines and any intended use of professional writers	Not relevant
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Suppl. M. 7
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	Not applicable

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

BMJ Open

Prevention of Psychosocial Distress Consequences in Somatic Hospital Inpatients via a Stepped and Collaborative Care Model: Protocol of SomPsyNet, a Stepped-Wedge Cluster Randomised Trial

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Prevention of Psychosocial Distress Consequences in Somatic Hospital Inpatients via a Stepped and Collaborative Care Model: Protocol of SomPsyNet, a Stepped-Wedge Cluster Randomised Trial

Gunther Meinlschmidt[1,2,3,4], Alexander Frick[2], Iris Baenteli[2], Christina Karpf[5], Anja Studer[5], Marco Bachmann[6], Andreas Dörner[7], Sibil Tschudin[8], Sarah Trost[9], Kaspar Wyss[10,11], Günther Fink[10,11], Matthias Schwenkglenks[12,13], Seraina Caviezel[2], Tabea Rocco[2], Rainer Schaefert[2,14], and the SomPsyNet consortium

1) Department of Digital and Blended Psychosomatics and Psychotherapy, Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
2) Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
3) Division of Clinical Psychology and Cognitive Behavioural Therapy, International Psychoanalytic University (IPU) Berlin, Berlin, Germany
4) Division of Clinical Psychology and Epidemiology, Department of Psychology, University of Basel, Basel, Switzerland
5) Division of Prevention, Department of Health Canton Basel-Stadt, Basel, Switzerland
6) Department of Psychosomatic Medicine and Psychotherapy, Klinik Barmelweid AG, Barmelweid, Switzerland
7) St. Claraspital Medical Clinic, Basel, Switzerland
8) Department of Obstetrics and Gynecology, University Hospital and University of Basel, Basel, Switzerland
9) Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland
10) Swiss Tropical and Public Health Institute, Basel, Switzerland
11) University of Basel, Basel, Switzerland
12) Institute of Pharmaceutical Medicine (ECPM), University of Basel, Basel, Switzerland
13) Health Economics Facility, Department of Public Health, University of Basel, Basel, Switzerland
14) Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland

Corresponding author (contact for public and scientific queries):
Prof. Dr. Gunther Meinlschmidt, Department of Digital and Blended Psychosomatics and Psychotherapy, Psychosomatic Medicine, University Hospital and University of Basel, Hebelstrasse 2, CH-4031 Basel, Switzerland;
Email: gunther.meinlschmidt@unibas.ch

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GLOSSARY OF ABBREVIATIONS

BASEC	*Business Administration System for Ethical Committees*
BESP	*Bethesda Hospital, Basel*
CDMA	*Clinical Data Management Application*
CDMS	*Clinical Data Management System*
COVID-19	*Coronavirus disease 2019, SARS-CoV-2*
CL service	*Consultation and liaison service*
CLARA	*St. Claraspital Medical Clinic, Basel*
ClinO	*Ordinance on Clinical Trials in Human Research (in German: KlinV, in French: OClin, in Italian: OSRUm)*
CRF	*Case Report Form*
CTU	*Clinical Trial Unit*
DT	*Distress Thermometer*
DMC	*Data Monitoring Committee*
UAFP	*Department of Geriatric Medicine FELIX PLATTER (in German: Universitäre Altersmedizin FELIX PLATTER), Basel*
eCRF	*Electronic Case Report Form*
EQ-5D	*European Quality of Life-5 Dimensions questionnaire*
EKNZ	*Ethikkommission Nordwest- und Zentralschweiz*
GAD-7	*Generalised Anxiety Disorder, questionnaire with 7 items*
GCP	*Good Clinical Practice*
GD	*Department of Health Basel-Stadt (in German: Gesundheitsdepartement Basel-Stadt)*
GFCH	*Health Promotion Switzerland (in German: Gesundheitsförderung Schweiz)*
HRA	*Human Research Act (in German: HFG, in French: LRH, in Italian: LRUm)*
ICH	*International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*
IPU	*International Psychoanalytic University*
MCS	*Mental Component Summary of the SF-36*
MICE	*Multiple Imputation by Chained Equations*
NICE	*National Institute for Clinical Excellence*
NCD	*Non-Communicable Diseases*
PCS	*Physical Component Summary of the SF-36*
PHQ-8	*Depressive Symptom Scale with 8 items from the Patient Health Questionnaire*

RCT	*Randomised Controlled Trial*
RSA	*Resilience Scale for Adults*
SAE	*Serious Adverse Event*
SAMW	Swiss Academy of Medical Sciences
SCCM	*Stepped and collaborative care model*
SERI	*Swiss State Secretariat for Education, Research and Innovation*
SF-36	*Short Form (36) Health Survey*
SNCTP	*Swiss National Clinical Trials Portal*
SNSF	*Swiss National Science Foundation*
SSD-12	*Somatic Symptom Disorder, questionnaire with 12 items*
SSS-8	*Somatic Symptom Scale, questionnaire with 8 items*
SW-CRT	*Stepped-wedge cluster randomised trial*
OSSS-3	*Oslo Social Support Scale, questionnaire with 3 items*
TAU	*Treatment As Usual*
TLS	*Transport Layer Security*
UHB	*University Hospital Basel*

ABSTRACT

Introduction

Approximately 30% of somatic hospital inpatients experience psychosocial distress, contributing to increased (re-)hospitalisation rates, treatment resistance, morbidity, and direct and indirect costs. However, such distress often remains unrecognised and unaddressed. We established 'SomPsyNet', a 'Stepped and Collaborative Care Model' (SCCM) for somatic hospital inpatients, aiming at alleviating this issue through early identification of distress and provision of appropriate care, providing problem-focused pathways, and strengthening collaborative care. We report the protocol of the 'SomPsyNet' study, aiming to evaluate implementation and impact of the SCCM on distressed patients' health-related quality of life. Secondary objectives include assessing efficacy of the screening procedures, influence of SCCM on other health outcomes, and associated costs.

Methods and analysis

Our stepped-wedge cluster randomised trial conducted at three tertiary hospitals comprises three conditions: treatment as usual (TAU) without screening for distress (phase 0), TAU with screening but without consequences (phase 1, main comparator), and TAU with screening and psychosomatic-psychiatric consultations for those distressed (phase 2). The time-of-transition between phases 1 and 2 was randomised. Sample size target is *N*=2200-2500 participants, with 6-month follow-up for distressed (anticipated *n*=640-700) and a subsample of non-distressed (anticipated *n*=200) patients. Primary outcome is mental health related quality of life (SF-36 'Mental Health Component Summary score'); secondary outcomes include psychosocial distress, anxiety, depressive, and somatic symptoms, symptom burden and distress, resilience, social support, and qualitative of life, assessed by internationally accepted instruments, with good psychometric properties. Further, health claims data will be used to assess SCCM's impact on direct and indirect costs.

Ethics and dissemination

SomPsyNet adheres to the Helsinki Declaration and is approved by the 'Ethikkommission Nordwest- und Zentralschweiz' (2019–01724). Findings will be published in peer-reviewed journals and communicated to participants, healthcare professionals, and the public.

Study Registration

Swiss National Clinical Trials Portal; ClinicalTrials.gov (NCT04269005, updated 19.09.2023).

Strengths and limitations of this study

- The interdisciplinary SomPsyNet study is one of the largest of its kind to assess stepped and collaborative care for patients with mental-somatic comorbidity, including a psychosomatic-psychiatric consultation and liaison service (CL service) as well as post-hospital intervention supported by a collaborative network structure.
- We conduct the SomPsyNet study as a stepped-wedge cluster randomised trial. Additionally, we collect health claims data for a substantial proportion of participating patients to evaluate the impact of our presented model on medical resource use and healthcare costs.
- The SomPsyNet study focuses on inpatients with mental-somatic comorbidity, representing a clinically highly relevant population, given longer hospitalisation, more frequent rehospitalisation, less treatment response, increased morbidity, and higher direct and indirect costs as compared to inpatients with somatic diseases only.
- We do not assess ICD diagnoses using clinical interviews.
- No surgical wards are involved in the study.

INTRODUCTION

Mental health is a global concern, with its implications contributing significantly to the global disease burden[1]. The non-communicable disease (NCD) report singles out mental health as a crucial factor, aligning it with diseases like cancer, diabetes, cardiovascular, and chronic respiratory illnesses, with an observed rise in NCD prevalence in Switzerland[2]. Two key distinctions must be made at this juncture: I) 'Psychosocial distress': This refers to an individual's emotional and psychological reaction to adverse events, encompassing stress, anxiety, and depression that might not qualify as clinically diagnosable mental disorders. II) 'Mental disorders': These are diagnosable conditions that can significantly interfere with an individual's cognitive, emotional, or social abilities. They include major depressive and anxiety disorders, which are among the leading global disabilities[1]. Our study works with the concept of psychosocial distress, as we did not seek to formally diagnose any mental disorders. Yet, while mental disorders elevate the risk of acquiring other diseases and intensify health adversities, escalating the psychosocial burden[3,4], the literature predominantly addresses the issue of mental-somatic comorbidity in somatic patients within a mental disorder framework, which is explored further in this background section. Overall, mental-somatic comorbidity not only influences the development and trajectory of somatic diseases but also correlates with a reduced quality of life, unfavourable disease progression, heightened morbidity, and increased all-cause mortality[3,4].

In Europe, mental disorders impact approximately 38% of the population yearly, with notable prevalence in Switzerland, where 4% are severely affected and 11% moderately[5,6]. The incidence is even more prominent among the working class, with 18% of women and 12% of men affected[6]. This prevalence has economic repercussions, affecting individuals across personal, social, and professional realms and exerting extensive societal and economic strains[7]. They stand as the leading cause of disability-induced early retirement[8], highlighting the need for preventive measures. Thus, mental health issues bear significant individual and economic relevance[8,9].

However, the ramifications of mental disorders may be underestimated, as their presence often remains undetected in sectors like economics, societal health, and somatic health[4]. Therefore, there's an imperative to embed mental health awareness within research, healthcare protocols, and health policy frameworks to optimise care for somatic patients with psychosocial distress, including and beyond mental-somatic comorbidities[3,4].

Psychosocial distress and mental-somatic comorbidity in somatic hospital inpatients

In somatic hospitals, about 30% of patients struggle with both psychosocial distress and mental-somatic comorbidity, yet a significant portion of these cases remain unnoticed and unaddressed[10]. A Swiss Health Observatory (Obsan) report indicates a detection rate of just 13%, with such patients typically being older compared to those suffering only from somatic illnesses[11]. Mental-somatic comorbidity presents numerous challenges:

- Prolonged hospital stays, with an average extension of 2.6 days.
- Increased rehospitalisation rates within 18 days post-discharge (3.2% versus 2.5% for those with only somatic diseases).
- Greater complexity level and secondary diagnosis count, yielding poorer health outcomes, reduced quality of life, diminished life expectancy, and heightened mortality risk.
- A noteworthy 28% rise in economic resource utilisation in hospitals based on SwissDRG system net cost weights, resulting in substantial direct and indirect costs posing a major societal healthcare challenge.

These findings corroborate established evidence on mental-somatic comorbidity[3,4,10,12–18], accentuating the essentiality for hospitals to address these challenges comprehensively, ensuring superior care for affected patients

Public health relevance

Global professional bodies underscore the need to integrate psychosocial health at all healthcare and health policy levels. The demand for action in somatic medicine, including hospitals, is highlighted by a Swiss Federal Office of Public Health report on mental comorbidity care coordination at the intersection of somatic and psychiatric hospitals[14].

The National Strategy on the Prevention of NCD 2017—2024 adheres to these principles. It aligns the efforts of the federal government, cantons, and Health Promotion Switzerland to enhance prevention and health promotion efficiency[2], incorporating mental health in its scope[19]. The strategy's aim is to fortify prevention across the healthcare continuum, projecting that health promotion and prevention could lower individual and societal healthcare costs[19]. This approach may not only benefit public health but also potentially streamline health resource usage, contributing to cost containment.

Current standard intervention options for mental-somatic comorbidity in healthcare

The National Institute for Clinical Excellence (NICE) outlined guidelines in 2011 for identifying and creating care pathways for common mental health disorders[20]. These guidelines, built on solid research, aim to enhance care quality by overcoming barriers to treatment identification and access[20].

NICE endorsed a combined approach, the stepped-care model, to address mental health disorders. It requires a multi-professional healthcare team or collaborative care to mitigate barriers stemming from individual, practitioner, system-service, or resource-based factors[20].

Archer et al.'s recent Cochrane review[21] on collaborative care's effectiveness indicated its potential to significantly improve short- and medium-term depression and anxiety outcomes compared to standard primary care, based on 79 randomised controlled trials (RCT) with 24,308 participants. Other systematic reviews and meta-analyses corroborated these findings, including long-term outcomes[22-25].

A collaborative care network of interdisciplinary professionals is key to managing mental-somatic comorbidity in primary care[26], with specialist contacts often represented by the consultation and liaison service (CL service) [27]. Integrating the stepped-care model with collaborative care, post-hospital intervention, and CL services establishes a robust framework to address psychosocial distress in somatic patients and pre-empt its consequences.

Prevention strategies focus on health risk reduction, with secondary prevention standing out as cost-effective due to its focus on vulnerable individuals[28,29]. Hospitals serve as potentially relevant venues for such interventions, given patients' increased receptivity to behaviour modification support. Despite this, the reported prevalence of mental-somatic multimorbidities in hospitals, based on doctor diagnoses, appears significantly lower than in the general population[11]. This discrepancy underscores the potential for improved psychosocial distress detection in somatic hospitals.

The treatment as usual (TAU) with regard to psychosomatic-psychiatric CL services for somatic hospital inpatients provided in this study is reflecting current common procedures in Switzerland[30,31]. These CL services bridge the interface between mental and physical care within somatic hospitals. Depending on local needs and circumstances, individual CL services vary widely; organizationally they are assigned to psychiatric, psychosomatic, or psychological departments. Usually, they have multidisciplinary staffing, including medical specialists in psychiatry, psychosomatic medicine, and psychotherapy, trained clinical psychologists, psychological

psychotherapists, or in some instances, specialised Advanced Nurse Practitioners (ANPs). Based on a diagnostic assessment, the integrated psychosomatic-psychiatric interventions emphasise a holistic approach to patient care, combining biological and psychosocial perspectives and treatments. Intervention methodologies encompass psychoeducation, coping strategies, relaxation techniques, psychotherapeutic interventions, resource activation, and psychopharmacotherapy. At the centre are medical/therapeutic dialogues, which are foundational to foster a trustworthy patient-therapist relationship. With regard to the structure of care, a distinction can be made between a consultation (service called upon an as-needed basis), and a liaison model (service fully integrated within a ward): Consultation pertains to direct clinical assessments and advisories provided to the main treatment team, whereas liaison emphasises continuous collaboration with the psychosocial liaison staff being part of the ward team; Of note, TAU in the form of CL services slightly varies across institutions, medical specialities, and wards participating in SomPsyNet, especially with regard to intensity and staffing, depending on the specific settings.

Rationale of the research project

Given the considerable impact of psychosocial distress and the pressing need for improved healthcare standards, we have established SomPsyNet. The **SomPsyNet project** aims at patients from **SOM**atic hospitals and promotes the prevention of **PSY**chosocial distress by establishing a stepped and collaborative care **NET**work in Basel-Stadt, Switzerland, potentially addressing the prevailing care gap[32].

The cornerstone of SomPsyNet is a “stepped and collaborative care model” (SCCM), integrating a consultation and liaison (CL) service and post-discharge interventions within a collaborative network structure. It seeks to promptly identify patients with psychosocial distress during their hospital stay, provide appropriate care through a psychosomatic-psychiatric CL service, and facilitate problem-focused follow-up treatment within the network.

We anticipate that SomPsyNet will benefit patients, staff, and stakeholders, potentially leading to decreased healthcare resource utilisation in the mid- and long-term, impacting healthcare budgets positively. Of note, assessment of benefit for staff and stakeholders is not part of this SomPsyNet study outlined here, but is assessed in the context of a process evaluation that accompanies SomPsyNet. Results of this process evaluation are shared with different stakeholders such as local and national health authorities and key results published in scientific journals[33,34].

SomPsyNet affords an efficient avenue to reach patients with mental-somatic comorbidity, comprehensively evaluate intervention effects, and assess the project's feasibility and framework conditions. This could yield valuable insights into

psychosocial distress and mental-somatic comorbidity prevalence in hospitals, crucial for long-term implementation and project replication in other regions.

Risk Category and Rationale

Per the Ordinance on Clinical Trials in Human Research (ClinO) regulations in Switzerland, clinical trials are stratified based on potential risk profiles[35]. Pursuant to Article 61 of this regulatory framework, the SomPsyNet trial is demarcated as a “Category A” investigation, indicating a minimal risk profile to study participants. Situated within the purview of Psychosomatic Medicine, the trial's objective is not to explore novel therapeutic interventions. Rather, it seeks to optimise and refine extant protocols. Utilising non-invasive methodologies, primarily through structured questionnaire-based data collection, the trial ensures robust safety and methodological credibility. This focus underscores its potential to establish benchmarks for other institutions aiming to refine their clinical practices, ensuring a unified, evidence-based approach to patient care.

Objectives and Hypotheses

The project's overarching goal is to enhance somatic patients' management with psychosocial distress by implementing an SCCM, assessing its effects on patients and costs. The primary objective is to evaluate SCCM's impact on health-related quality of life in somatic hospital patients with psychosocial distress. The related hypothesis is that mental health-related quality of life improves more robustly with psychosocial distress screening and follow-up consultation than with screening without consequences. Secondary objectives include evaluating SCCM's effect on other health outcomes, costs, and screening procedures' efficacy in identifying patients with psychosocial distress.

The health economic objectives involve assessing SCCM's effect on medical resource use, healthcare and indirect costs, labour market participation, and income. We anticipate SCCM to reduce costs in the long term through improved general health despite an expected short-term direct cost increase.

METHODS AND ANALYSIS

Overview of SomPsyNet as SCCM and research project

The SomPsyNet evaluation study is a key component of the larger SomPsyNet project, overseen by the Department of Psychosomatic Medicine at the University Hospital

Basel (UHB) and the Medical Services of the Department of Health Basel-Stadt (GD). Collaborating closely with Bethesda Hospital (BESP), Department of Geriatric Medicine FELIX PLATTER (UAFP), St. Claraspital Medical Clinic (CLARA) – the latter participating in the SomPsyNet project, but not the study – and numerous health sector partners, we aimed to implement a comprehensive, evidence-based approach to managing psychosocial distress in patients with mental-somatic comorbidity.

The implementation of the SCCM within our study, utilising a Stepped Wedge Cluster randomised Trial (SW-CRT) design comprises three conditions that we call “phases” as each ward or part of the ward (cluster) participating in the study is subsequently transitioning through the phases:

- SomPsyNet phase 0: (non-randomised) additional comparator condition with TAU without any screening procedures in combination with the baseline and follow-up survey in the distressed subsample.
- SomPsyNet phase 1: (randomised and) main comparator condition with TAU in combination with the baseline survey, implementation of screening questions stage 1 ('baseline distress information from professionals', without consequence) in hospital routine and a follow-up survey in the distressed subsample.
- SomPsyNet phase 2 refers to the implementation of the SCCM: baseline survey, assessment of screening questions stage 1 (with consequence), screening questions stage 2 (with consequence), and if necessary psychosomatic-psychiatric CL service including if applicable post-hospital intervention and a follow-up survey in a distressed and non-distressed subsample.

As depicted in Supplementary material 1: Figure – Schedule of SomPsyNet stepped-wedge cluster randomised trial, all clusters started at the same time in phase 0 and transitioned at the same time (at step 1) from phase 0 to phase 1. However, the timing of transitioning of a specific cluster from phase 1 to phase 2 could occur at different times (either at step 2, step 3 or step 4) and this timing of transitioning from phase 1 to phase 2 was randomised: Some clusters transitioned from phase 1 to phase 2 at step 2, other clusters transitioned from phase 1 to phase 2 at step 3, and further clusters transitioned from phase 1 to phase 2 at step 4.

Transition periods are defined as times at which implementation of the next phase started. These transition periods contribute to data collection, but their circumstances are specifically assessed to ensure correct allocation to study phases. Details of the study design and the implementation at the different study sites are presented in the section study design and in Supplementary material 2.

Inclusion and exclusion criteria

The study population are patients from selected wards in three somatic hospitals in Basel-Stadt: UHB, BESP, and UAFP. All patients who are hospitalised in a ward/cluster that participates in the study at the time of hospitalisation are assessed for eligibility according to the criteria below. Patients are enrolled on a daily basis at the day of or in the days following admission to a ward participating in the study, unless at least one of the following exclusion criteria applied:

- Aged below 18 years;
- Inability to understand and speak German or any other language at which the study is tailored at that point in time;
- Inability to give informed consent by himself/herself;
- Inability to follow the procedures of the study, e.g., due to severe medical/clinical limitations;
- Need for immediate support as indicated by the risk of current suicidality or attempted suicide;
- Oncological condition (as a psycho-oncological CL service is already implemented in many Swiss hospitals);
- hospitalisation for a gender affirming intervention (as psychosocial assessment and support are already implemented in regular care for subjects seeking respective interventions);
- Already participated in the SomPsyNet project on the occasion of a previous hospitalisation;
- Confirmed current COVID-19 disease (Coronavirus disease 2019) at the time of screening for exclusion criteria (as COVID-19 patients were included in other disease-specific studies);
- Being hospitalised under the medical supervision of services of a ward ('original ward') that is not part of one of the SomPsyNet study clusters, but physically located in rooms of a ward contributing to one of the study clusters only because of lack of space in the original ward.

Please note regarding the exclusion criterion “Inability to understand and speak German or any other language at which the study is tailored at that point in time” that even though originally considered, we did not tailor the study to any other language than German. Hence, regarding this exclusion criterion, we check whether there is any inability to understand and speak German.

Of note, the patient journey until study inclusion varies, with admission to the ward participating in the SomPsyNet study either from home, from other hospitals, from the emergency department, from ICU, or from any other ward of the same hospital.

Study design

The SomPsyNet study uses a SW-CRT, conducted as a multicenter study across three hospitals (UHB, BESP, UAFP) in Basel-Stadt, Switzerland. This study involves a baseline assessment, an intervention phase (phase 2) implementing a SCCM, and a follow-up assessment for the distressed subsample and a non-distressed subsample. A flow diagram of participant progression through the study is depicted in Figure 1.

– Insert Figure 1 around here –

The intervention is systematically deployed across pre-designated wards/sections at all three study sites using the SW-CRT design (please see the 'Definitions of SW-CRT design' section for terminology clarification). While this study design carries certain bias risks such as “within cluster contamination”, “time-varying treatment effects”, and “changes in correlation structures over time”[36], it was deemed the most practical study design to both evaluate the intervention and ensure its implementation into ongoing clinical care and practice. This design facilitates the examination of our primary research questions, therefore enabling the study of the effects of the SCCM, as well as the investigation of secondary and health economic outcomes.

We aimed to enrol a substantial patient sample (*n* = 200–500 in phase 0; *n* = 1000 in phase 1; *n* = 1000 in phase 2), from which we aim to collect clinical and health insurance claim data. From this larger sample, a distressed subsample (anticipated *n* = approx. 40–100 in phase 0; *n* = 300 in phase 1; anticipated *n* = 300 in phase 2), consisting of patients with identified psychosocial distress, is tracked for a detailed post-assessment. The effects of the SCCM on primary and secondary outcomes will be evaluated within in the distressed subsample, i.e., among patients targeted by the SCCM-related CL service intervention. Health insurance data will be extracted from the total sample.

An additional non-distressed comparison sub-sample of study patients (planned *n* = approx. 200), who are not part of the distressed sample, is assessed as an additional comparison group for follow-up.

Due to the need to account for high variability in healthcare costs and related parameters, we hope to collect health insurance claim data from all patients enrolled

in the full sample during phases 0 – 2 (approx. *N* = 2200–2500) if they were enrolled with a collaborating health insurance provider.

Justification of the study design

The step-by-step implementation of the study phases was essential to ensure the continuity of clinical practice/care, considering the various unique challenges across different hospital wards (different patient groups/diseases/severity, technical challenges like differing hospital software, various departmental processes and procedures, shift-working employees, and changing staff).

Definitions of SW-CRT design

According to the extension of the CONSORT 2010 statement[36]: “The SW-CRT involves randomization of clusters to different sequences that dictate the order (or timing) at which each cluster will switch to the intervention condition.” Thereby, 'clusters' refer to the specific sections of hospitals. As outlined in Supplementary material 3, we divided larger wards into 2-3 clusters, while smaller hospital wards were not divided, and thus constitute their own cluster. Because of the high heterogeneity between the wards, clusters were pre-grouped into triplets based on patient age, sex, and expected primary outcome as indicated by data from phase 0 that, with this regard, provided information similar to a pilot phase. Then clusters were randomised to different sequences. Detailed information on clusters predefined for our study, time-periods, sequences, sequence generation, allocation of sequences, concealment mechanism, and implementation is shown in a table provided as Supplementary material 3 and methodological detail provided as Supplementary material 2 with the respective schedule shown as figure in Supplementary material 1.

Intervention

The SomPsyNet intervention, offered to phase 2 patients who screened positively and whose lead physicians approved, centres on psychosomatic-psychiatric consultations. The intervention is conducted by trained medical and psychological personnel, being mainly study personnel and in some rare occasions TAU personnel from the psychosomatic wards, supplemented by the study team for training and support. The intervention consists of consultations being a mix of in-person and telephone interactions, tailored to patients' needs, and oriented towards identifying individual psychosocial stressors and corresponding support options. Essential elements include pre/post consultation discussions, generation of support recommendations using a custom-built tool ('BAK-list') (see Supplementary material 4), coordinating support implementation, and providing a follow-up consultation after hospital discharge.

Utilising a comprehensive framework, the CL service evaluates each patient's distinct support requirements, suggesting appropriate intervention strategies at regional institutions offering respective services. These recommendations derive from a broad spectrum of specialised intervention avenues. For example: Expert institutions may offer tailored care for those with terminal illnesses, emphasising comfort and comprehensive support. Recognized bodies may guide individuals through housing challenges, while other institutions may mediate tenant-landlord disputes, ensuring stable living conditions. Several organisations may cater to the diverse and multicultural populace, offering translation services, guidance, and tailored assistance for migrant families and seniors. There are dedicated centres that may provide transcultural addiction counselling, and specialised professionals who deal with specific mental health issues, including eating disorders. Specialised entities may ensure those with mobility challenges have access to essential transport facilities. Comprehensive care facilities are available for the ageing population, ensuring medical, social, and conflict-resolution needs are addressed. Additionally, there are platforms that specifically disseminate health information pertinent to this age group. For patients with distinct health challenges, there are associations focusing on a variety of conditions, from respiratory issues and allergies to rare diseases and cardiac concerns. Overall, the CL service acts as a bridge, connecting patients to these multifaceted support systems based on individual needs.

Concurrent care is permitted, and the intervention protocol is adhered to via regular supervision and documented consultations. More detailed information on the intervention is provided in Supplementary material 5.

Ancillary and post-trial care

We did not provide systematic ancillary and post-trial care, yet in case of need patients could direct themselves to the psychosomatic outpatient clinic at the University Hospital of Basel, or to the hospital where they had been treated.

Primary and secondary outcomes and healthcare cost evaluation

Our outcomes/endpoints were divided into primary, secondary, health economic, and other endpoints. We provide a full list of assessment instruments in Table 1 that also includes the list of secondary endpoints, and more detailed information on the endpoints in Supplementary material 6. Whenever possible, we selected assessment instruments that are regularly used in clinical trials and internationally accepted, with good psychometric properties. The primary endpoint of our study is the change from the baseline of the 'Mental Health Component Summary score' of the Short Form-36 (SF-36)[37]. The SF-36 was administered at study entry ('baseline' or 'pre-

assessment') and at 6 months follow-up ('follow-up' or 'post assessment', conducted in the distressed and non-distressed subsamples).

Table 1

Overview of assessment instruments and assessment points

Construct	Instruments	Baseline	Follow-up	3-year follow-up
Health/primary outcome: quality of life, 'Mental Health Component Summary score'*	SF-36 [37]	x	x	
Health: quality of life, 'Physical Health Component Summary score'**	SF-36 [37]	x	x	
Health: psychosocial distress (patient)**	DT [38]	x	x	
Health: psychosomatic burden (intaking physician, nursing staff)	DT routine [38]			
Health: anxiety symptoms**	GAD-7 [39]	x	x	
Health: depressive symptom**	PHQ-8 [40]	x	x	
Health: somatic symptom disorder**	SSD-12 [41]	x	x	
Health: somatic symptom burden**	SSS-8 [42]	x	x	
Health: quality of life**	EQ-5D [43,44]	x	x	
Health: social and support**	OSSS-3 [45]	x	x	
Health: general resilience**	RSA [46]		x	
Health: COVID-19 information	questionnaire	x	x	

Socio-demography: age, sex, and socioeconomic status, work-status and days out of work	questionnaire	x	x	
General information: participation rate, inclusion, exclusion, loss-to-follow up	Study management	x	x	
General information: resources for recruitment (time)	Study management	x		
General information: hospital, hospital ward, length of hospital stay, ICD-10 diagnoses, COVID-19 information, treatments, morbidity, disease history, severity of disease, main diagnosis, secondary diagnosis, type of health insurance, rehospitalisation	hospital	x		
General information: treatment as usual – status (including documentation use of intervention for comparison)	hospital	x		
Health economics: total costs of hospital treatment including additional medical, psychiatric or physiotherapeutic treatment during patient's hospital stay; follow-up costs at treating hospitals; healthcare costs, relevant sub-categories of costs and medical resource use based on health claims data; patients' out-of-pocket expenses; indirect costs due to reduced productivity**	hospital, health claims data, questionnaire	x	x	x

Note. *primary outcome; **secondary outcomes; DT (Distress Thermometer), EQ-5D (European Quality of Life-5 Dimensions questionnaire), GAD-7 (Generalised Anxiety Disorder, questionnaire with 7 items), OSSS-3 (Oslo Social Support Scale), PHQ-8 (Depressive symptom scale with 8 items from the Patient Health Questionnaire), RSA (Resilience Scale for Adults), SF-36 (Short Form (36) Health Survey), SSD-12 (Somatic Symptom Disorder, questionnaire with 12 items), SSS-8 (Somatic Symptom Scale, questionnaire with 8 items), Covid-19 (Coronavirus disease 2019).

Recruitment and informed consent procedure

Recruitment for this study spanned from 09-06-2020 to 16-12-2022 at UHB, BESP, and UAFP sites. During the recruitment period, a systematic process was adopted to enrol patients into the study. Study staff maintained a daily routine of accessing electronic patient management systems to identify any new admissions to the participating wards. Alongside this digital tracking, a hands-on approach was also taken, where the study team established regular communication with the ward staff to gather information on potential candidates. Upon identification of prospective participants, a two-step verification process was employed. Firstly, the medical records of the newly admitted patients were scrutinised. This was followed if still relevant by staff-patient interactions which provided deeper insights into the patients' eligibility for the study.

In terms of participation, every new patient was checked or approached unless they met any of the predefined exclusion criteria. Those deemed eligible were presented with comprehensive information about the study's objectives and methodology. Following this orientation, they were provided with a consent form, as detailed in Supplementary material 7. Upon receiving their agreement, signed copies of the consent forms were securely archived. Due to multiple study centres with numerous hospital wards, multiple inclusions cannot always be prevented. In these cases, only the first participation of a patient is included in the analyses. If informed consent is withdrawn, no further data will be collected, and data already collected will not be analysed further.

Data collection methods and management

Upon informed consent, patients completed a baseline questionnaire, predominantly via tablet-assisted software, with alternatives for paper-pencil or staff-guided questionnaires available. Hence, the questionnaires were primarily self-administered, but assistance was provided for patients who requested it. Six months post-recruitment marked follow-up, with patients consenting for health insurance data collection for cost analysis. Phases 0 and 1 were similar, but phase 1 included two additional psychosocial distress evaluations by intake physicians and nursing staff. The complete SCCM was implemented only in phase 2 (see Supplementary material 1). Table 1 details all assessments. We transfer collected data to the secure SecuTrial® database and verify for completeness and discrepancies. Only authorised personnel have access to the data, and routine backups are conducted to ensure safety and confidentiality. Further details on data recording and source data are provided in Supplementary material 8. General study data management such as exclusions, recruitment, dropout, or participant rate, was recorded at all stages in the study. Data collection started on 09-06-2020 and is anticipated to be completed on 30-

06-2026 (estimated study completion date, including completion of collection of health claims data), with completion of the six months follow-up assessments in June 2023.

Statistical methods

Sample size and sample size calculation

Our study relies on specific sampling sizes, with the intention to evaluate a significant number of patients suffering from psychosocial distress. We aimed at including approximately 200-500 patients in phase 0, and 1000 patients in both phases 1 and 2, yielding a total sample of approximately 600 distressed patients across phases 1 and 2. Sample size calculations were undertaken, focusing on the primary endpoint, which was the change from baseline of the Mental Health Component Summary score, as gauged by the SF-36 questionnaire. Assuming an effect size of 0.5 SD and an additional 55% of patients received mental health support in the intervention arm, 208 patients were needed in each treatment condition. To allow for attrition as well as clustering of outcomes, we aimed for a sample of 300 distressed patients in each arm. Power calculations were originally made using basic two-arm clustered comparisons and verified using power simulations implemented in Stata[47-49].

Statistical analyses and handling of missing data

Descriptive statistics and estimation of intervention effects are planned following recognised guidelines, and different regression methods will be used based on the outcome parameters' distributional characteristics.

To estimate intervention effects, we will primarily conduct generalised linear mixed models of primary, secondary, and other outcome parameters adjusted for the clusters as random effects and for study conditions, calendar time, and potential confounders (e. g., gender, age categories, socioeconomic status) as fixed effects. The exact choice of regression method will consider the distributional characteristics of the outcome parameters of interest. As dependency of stepped wedge trial results on choice of statistical technique has been reported, alternative analytical methods will additionally be used for sensitivity checks[50,51].

A comprehensive description of our statistical methods, including the full power analysis, detailed intervention effects estimation, and our approach to handle missing data can be found in Supplementary material 9.

With respect to the management of missing data, we aim to minimise bias via thorough planning and active data review. We plan to differentiate between missing data due to partial participation and loss to follow-up, and will consider various statistical methods to address these issues.

Patient and public involvement statement

SomPsyNet comprises a patient participation committee that includes patient representatives. Patient representatives within the SomPsyNet consortium have been integral since the onset of grant preparation and study design, providing valuable feedback on various aspects, including study material and informed consent. Additionally, they partake in regular enrolment discussions, contribute to publications, and are anticipated to engage in discourse over study results.

ETHICS AND DISSEMINATION

The SomPsyNet study, following the Declaration of Helsinki[52], the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice (ICH-GCP)[53], and the Human Research Act (HRA)[54], conducts regular monitoring and auditing to ensure participant safety and data accuracy. Source data/documents are accessible to monitors, and the study team is responsive to any arising queries. While no formal Data Monitoring Committee was established due to the low-risk nature of the intervention, the study can be terminated prematurely under specific circumstances. These include insufficient participant recruitment, significant changes in clinical practice, or early evidence of harm or benefit from the experimental intervention.

Despite minimal anticipated risk, the study thoroughly assesses any potential harm. Any Serious Adverse Events (SAEs) that may occur during the study, including those related to suicide attempts or completed suicide, are examined for causality with the intervention and reported in accordance with set guidelines. Complete details regarding the risk assessment and SAEs can be found in Supplementary material 10.

Regular internal audits are carried out at each study site, verifying all procedures, including recruitment, consent, enrolment, and data collection. The software secuTrial® is used to maintain the final database, ensuring an implemented data audit trail.

The study is approved by the 'Ethikkommission Nordwest- und Zentralschweiz' (EKNZ; No. 2019–01724). Amendments to the protocol, which may affect the study's conduct, patient benefits, or safety, are formally documented. As of 31-05-2023, four such amendments have been submitted and approved.

Voluntary participation is a core principle in this study. Potential participants were provided with comprehensive information and were allowed adequate time for deliberation. Written informed consent, which can be withdrawn at any time, was obtained from those willing to participate. If consent is revoked, the participants' data are anonymised, and they are removed from the study while retaining access to TAU.

Data confidentiality and secure coding are prioritised. Participants' data are only accessible to authorised personnel and are securely stored on a UHB server with regular backup processes. The complete dataset, once finalised, is transferred to the study statistician and the principal investigator, with limited access granted to other team members for analysis. Specific processes are in place for the collection and integration of health claims data.

In-depth details on the aspects of monitoring, risk of harms, reporting of SAEs, auditing, overall ethical considerations, protocol amendments, consent or assent, and confidentiality and coding are available in Supplementary material 11.

Dissemination policy

We will publish key results of the study in international peer-reviewed journals followed by additional publications focusing on selected aspects of the study. Furthermore, we intend to communicate key results to the public via an online event following main data analysis. Authorship eligibility guidelines thereby follow the guidelines of the journal as well as of the Swiss Academy of Medical Sciences (SAMW); further we mention professional writers whenever involved. Public access to the full protocol is provided by this manuscript. Public access to participant-level datasets is not intended (see section 'access to data'). Access to statistical codes is intended to be provided on request.

PROJECT FUNDING

The project SomPsyNet received funding from Health Promotion Switzerland (GFCH) under project no. PGV01_087 and was supported by intramural funds from the Department of Health, Canton of Basel-Stadt, and from the Department of Psychosomatic Medicine, University Hospital and University of Basel. GFCH had no impact on the design of this study and did not influence the collection, execution, analyses, interpretation of the data, or the decision to submit the article/contribution for publication.

COMPETING INTERESTS & FUNDING INDEPENDENT OF THE PROJECT

GM & RS received funding from the Stanley Thomas Johnson Stiftung & Gottfried und Julia Bangerter-Rhyner-Stiftung under projects no. PC 28/17 and PC 05/18, from the Swiss Cancer League under project no. KLS-4304-08-2017, and in the context of a Horizon Europe project from the Swiss State Secretariat for Education, Research and Innovation (SERI) under contract number 22.00094. Further, GM & RS received funding from Wings Health Inc. in the context of a proof-of-concept study. GM received funding from the Swiss Heart Foundation under project no. FF21101, from the Research Foundation of the International Psychoanalytic University (IPU) Berlin under projects no. 5087 and 5217, from the Swiss National Science Foundation (SNSF) under project no. 100014_135328, from the German Federal Ministry of Education and Research under budget item 68606, and from the Hasler Foundation under project no. 23004. GM is co-founder, member of the board, and holds stock in Therayou AG, which is active in the field of digital and blended mental healthcare. GM receives royalties from publishing companies as author, including a book published by Springer, and an honorarium from Lundbeck for speaking at a symposium. Furthermore, GM is compensated for providing psychotherapy to patients, acting as a supervisor, serving as a self-experience facilitator (‘Selbsterfahrungsleiter’), and for postgraduate training of psychotherapists and supervisors. RS received a speaker honorarium from Novartis. The authors declare no other potential conflict of interests. The research activities were fully independent and there were no intellectual or financial proprietary claims.

AUTHORS' CONTRIBUTIONS

The coordinating centre at UHB had the role of overseeing all activities at all sites. The steering committee of SomPsyNet consisted of the project head and responsible of operations of the Department of Health Canton Basel-Stadt, Division of Prevention, the study sponsor, principal investigators, and project responsible of operations at the coordinating centre, as well as a representative of CLARA that took part in the SomPsyNet project but not the SomPsyNet study. The steering committee had the

role of deciding upon all major aspects of the study. The endpoint was discussed among the investigators of the steering committee, with input from other members of the co-author group. An advisory board provides guidance and feedback related to the project and the study. A patient advisory group consisting of several patient representatives worked together to oversee and give feedback on study material and protocol. The SomPsyNet consortium met at least on a yearly basis, discussing the development of the study, and giving critical feedback on the study conduction and necessary adaptations.

CK, RS, AF, and GM first identified the question leading to the formation of this research. GM, AF, CK, AS, MB, AD, STs, KW, GF, MS, SC, RS contributed to the development of the main trial protocol. RS contributes significantly also as the sponsor of this study. GM serves as lead principal investigator and AF, MB, RS, STs, and STs serve as principal investigators at the different study sites, contributing significantly to data collection and protocol adherence. IB, AS, and SC are the study operative leads, overseeing and managing the execution of the trial protocol. GM drafted the first version of the manuscript. All authors made significant revisions to the manuscript for important intellectual content and all authors reviewed and approved the final version of the manuscript for submission, reflecting their agreement with the work in its current form and their acceptance of accountability for all aspects of the work. This protocol was written following the SPIRIT protocol guidance.

ACCESS TO DATA

The datasets being held by the SomPsyNet project are not readily available. In the case of inquiries by third parties that wish to reuse data SomPsyNet data after an embargo period, the following procedure is planned. Researchers interested in the data may submit a project synopsis addressed to the publications committee of the SomPsyNet project and will have to obtain authorization from the responsible ethics committee as ordained in the Ordinance of 20 September 2013 on Human Research with the exception of Clinical Trials[35] (Human Research Ordinance, HRO). The publication committee will review the project synopsis and will answer the formal requests of applicants. Only upon collection of all important consents and upon approval of the responsible ethics committee(s), the requested data will be transferred to the applicants. Third parties have to confirm and provide evidence to comply with all relevant Swiss and cantonal laws and regulations (especially regarding data protection and Human Research), as well as all obligations and regulations set out in the documents and contracts related to SomPsyNet. Fees may apply to cover expenses related to data reuse. Requests to access the datasets should be directed to Gunther Meinlschmidt, gunther.meinlschmidt@unibas.ch. Any future changes to the data sharing plan will be noted in Data Availability Statements and updated in the registry record.

MEMBERS OF THE SOMPSYNET CONSORTIUM

- Aebi, NJ., Swiss Tropical and Public Health Institute, Basel, Switzerland, University of Basel, Basel, Switzerland
- Bachmann, M., Department of Psychosomatic Medicine and Psychotherapy, Klinik Barmelweid AG, Barmelweid, Switzerland
- Caviezel, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Baenteli, I., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Bahmané, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Bales, G., Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland
- Bally, K., Centre for Primary Health Care, University of Basel, Switzerland
- Bassetti, S., Division of Internal Medicine, University Hospital and University of Basel, Basel, Switzerland, Department of Clinical Research, University Hospital and University of Basel, Basel, Switzerland
- Baumgartner, R., Social Insurance Institution Basel-Landschaft, Binningen, Switzerland
- Beck, J., Clinic Sonnenhalde AG, Riehen, Switzerland
- Bosman, S., Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland
- Buechel, D., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Dietsche, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Dörner, A., St. Claraspital Medical clinic, Basel, Switzerland
- Eberle, C., Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland
- Ebner, L., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Erb, J., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland

- Ettlin, P., Foundation Rheinleben, Basel, Switzerland
- Fink, G., Swiss Tropical and Public Health Institute, Basel, Switzerland, University of Basel, Basel, Switzerland
- Flückiger, L., Department of Health Canton Basel-Stadt, Division of Addictions, Basel, Switzerland
- Frick, A., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Fuchs, S., Department of Health Canton Basel-Stadt, Medical Services, Basel, Switzerland
- Grossmann, F., Department of Medicine, Division of Nursing, University Hospital Basel, Basel, Switzerland
- Hermann, A., Direktion Pflege/MTT, University Hospital and University of Basel, Basel, Switzerland
- Hotopf, M., Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom
- Huber, C., University Psychiatric Clinics (UPK), Department of Psychiatry and Psychotherapy, Basel, Switzerland
- Isler-Christ, L., Sevogel-Apotheke, Basel, Switzerland, Baselstädtischer Apotheker-Verband, Basel, Switzerland
- Kadoic, M., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Karpf, C., Department of Health Canton Basel-Stadt, Division of Prevention, Basel, Switzerland
- Katapodi, MC., Department of Clinical Research, University of Basel, Basel, Switzerland, University of Michigan School of Nursing, Ann Arbor, MI USA
- Keller, RC., Swiss Heart Foundation, Bern, Switzerland
- Klimmeck, S., University Hospital Basel, Basel, Switzerland
- Lang, UE., University Psychiatric Clinics (UPK), Department of Psychiatry and Psychotherapy, Basel, Switzerland
- Liechti, Y., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Mazander, S., IV-Stelle Basel-Stadt, Basel, Switzerland

- Meinlschmidt, G., Department of Digital and Blended Psychosomatics and Psychotherapy, Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland; Division of Clinical Psychology and Cognitive Behavioural Therapy, International Psychoanalytic University, Berlin, Germany; Division of Clinical Psychology and Epidemiologie, Department of Psychology, University of Basel, Basel, Switzerland
- Minzer, A., Swiss Academy for Psychosomatic and Psychosocial Medicine (SAPPM), Reiden, Switzerland
- Ochs, V., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Schaefert, R., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland; Department of Psychosomatics and Psychiatry, Bethesda Hospital, Basel, Switzerland
- Schiess, F., Centre of Self-Help Basel, Basel, Switzerland
- Schirmer, F., Vereinigung der psychosomatisch tätigen Aerztinnen und Aerzte der Region Basel, Basel, Switzerland
- Schur, N., Institute of Pharmaceutical Medicine (ECPM), University of Basel, Basel, Switzerland
- Schwenkglenks, M., Institute of Pharmaceutical Medicine (ECPM), University of Basel, Basel, Switzerland; Health Economics Facility, Department of Public Health, University of Basel, Basel, Switzerland
- Schwob, P., Psychotherapists Association of Basel VPB, Basel, Switzerland
- Seelmann, SF., Department of Internal Medicine, University Hospital Basel, Basel, Switzerland
- Steffen, T., Department of Health Canton Basel-Stadt, Medical Services, Basel, Switzerland
- Stiefel, F., Liaisonpsychiatrischer Dienst, University Hospital Lausanne, Lausanne, Switzerland
- Studer, A., Department of Health Canton Basel-Stadt, Division of Prevention, Basel, Switzerland
- Tegethoff, M., Institute of Psychology, RWTH Aachen University, Aachen, Germany
- Timoney, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland

- Trost, S., Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland
- Tschudin, S., Department of Obstetrics and Gynecology, University Hospital and University of Basel, Switzerland
- Urech, C., Gyn. Social Medicine and Psychosomatics, University Hospital and University of Basel, Basel, Switzerland
- von Allmen, T., Department of Health Canton Basel-Stadt, Health Care, Basel, Switzerland
- Weber, M., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Werner, S., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Wetz, A., Rheumaliga beider Basel, Basel, Switzerland
- Weyermann, D., Patientenstelle Basel, Basel, Switzerland
- Wyss, K., Swiss Tropical and Public Health Institute, Basel, Switzerland, University of Basel, Basel, Switzerland
- Yarkova, V., St. Claraspital, Medical clinic, Basel, Switzerland
- Zäh, C., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland
- Zarifoglu, L., Department of Psychosomatic Medicine, University Hospital and University of Basel, Basel, Switzerland

FIGURE CAPTIONS

Figure 1

Participant flow chart for study phases 0–2.

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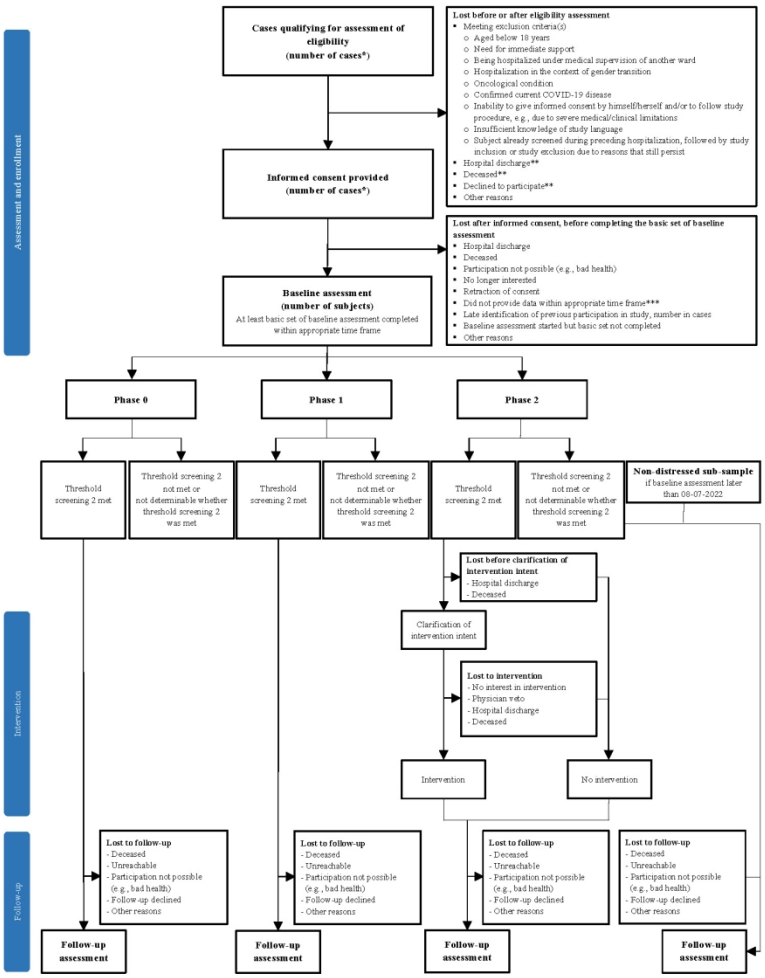

Figure 1. Participant flow chart for study phases 0-2.

*** Due to multiple study centres, repeated recruitment and inclusion of the same patient could not always be prevented. Therefore, numbers are here shown in cases (i.e., the same subject could contribute to several cases).**
**** Not confirmed that we have no exclusion criteria**
***** Completion of baseline assessment > 30 days after hospital discharge**

Figure 1 Participant flow chart for study phases 0–2.

210x297mm (200 x 200 DPI)

SUPPLEMENTARY MATERIAL

- Supplementary material 1: Figure – Schedule of SomPsyNet stepped-wedge cluster randomised trial
- Supplementary material 2: Methodological details 1 – Time periods, sequences, sequence generation, allocation of sequences, concealment mechanism, implementation, and blinding
- Supplementary material 3: Table – SomPsyNet study clusters
- Supplementary material 4: BAK-list (provided in German)
- Supplementary material 5: Methodological details 2 – Intervention
- Supplementary material 6: Methodological details 3 – Primary, secondary, and other outcomes, including healthcare economic outcomes
- Supplementary material 7: Informed consent materials (provided in German)
- Supplementary material 8: Methodological details 4 – Data recording and source data
- Supplementary material 9: Methodological details 5 – Statistics
- Supplementary material 10: Table – Causality assessment of Serious Adverse Events (SAEs) based on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E2A guidelines
- Supplementary material 11: Methodological details 6 – Ethics and dissemination
- Supplementary material 12: References of the Supplementary material

Supplementary material 1: Figure – *Schedule of SomPsyNet stepped-wedge cluster randomised trial*

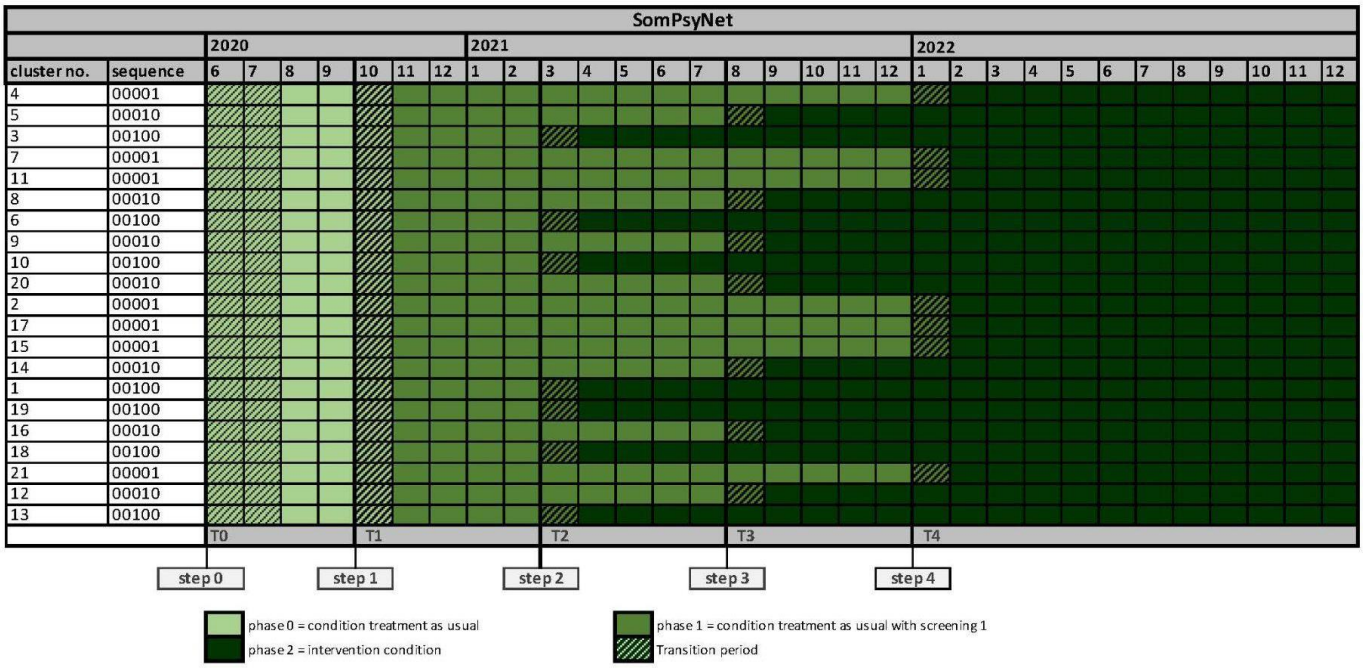

Figure – Schedule of the SomPsyNet stepped-wedge cluster randomised trial

Note. T0 to T4 denotes the time periods (T0, T1, T2, T3, and T4), i.e., the periods between the SW-CRT steps (or between the last step and the end of recruitment for the last period T4); The SW-CRT steps (step 0 to step 4) indicate the time at which some clusters switched from one phase to another phase. No. (number), SW-CRT (stepped-wedge cluster randomised trial).

Supplementary material 2: Methodological details 1 – Time periods, sequences, sequence generation, allocation of sequences, concealment mechanism, implementation, and blinding

As outlined in the "Overview of SomPsyNet as Stepped and collaborative care model (SCCM) and research project" section of the main manuscript, the SomPsyNet study comprises three conditions, denoted "phase 0", "phase 1", and "phase 2". As depicted in Supplementary material 1: Figure – Schedule of SomPsyNet stepped-wedge cluster randomised trial, all clusters started at the same time (at step 0) in phase 0 and transitioned at the same time (at step 1) from phase 0 to phase 1. However, the timing of transitioning of a specific cluster from phase 1 to phase 2 could occur at different times (either at step 2, step 3 or step 4). Of note, this timing of transitioning from phase 1 to phase 2 was randomised: Some clusters transitioned from phase 1 to phase 2 at step 2, other clusters transitioned from phase 1 to phase 2 at step 3, and further clusters transitioned from phase 1 to phase 2 at step 4.

Time periods

Time periods (T0, T1, T2, T3, and T4) are the periods between the Stepped-wedge cluster randomised trial (SW-CRT) steps (or between the last step and the end of recruitment for the last period T4); their time window notation refers to time since implementing the SW-CRT (from; to) (the schedule of the SW-CRT is displayed in the Figure provided as Supplementary material 1):

- T0 (start to month 4)
- T1 (month 5 to month 9)
- T2 (month 10 to month 14)
- T3 (month 15 to month 19)
- T4 (month 20 to month 31)

The SW-CRT steps are important to indicate the time at which some clusters switched from one phase to another phase.

- SW-CRT step 0 was the initiation of the study, i.e., switch to phase 0
- SW-CRT step 1 (switch from T0 to T1)
- SW-CRT step 2 (switch from T1 to T2)
- SW-CRT step 3 (switch from T2 to T3)
- SW-CRT step 4 (switch from T3 to T4)

Sequences

- The number of time periods of a specific cluster in a certain phase define the "sequence code"
- The sequence code defines the number of periods with the main comparator condition (in our case phase 1) and the number of periods with the intervention condition (phase 2); the periods from step 0 until step 1 represent phase 0.

- Several clusters could have the same sequence code.
- Examples: Sequence codes with 5 time periods, for clusters starting the intervention condition (phase 2) with T2 / step 2, T3 / step 3, and T4 / step 4, respectively: “00100”, “00010”, “00001”.

Sequence generation, allocation of sequences, concealment mechanism, and implementation

To balance the stepped-wedge design across the different study phases, participating wards were split up into one, two, or three clusters and grouped into triplets of clusters of roughly the same size (in terms of numbers of patients) and with similar patient populations. Within each triplet, the order in which the clusters went on to the implementation stage was randomly selected from all possible allocation sequences. The allocation sequence was computer-generated by an independent party (clinical trial unit, CTU) by using R software, based on the provision of involved clusters and cluster triplets. The CTU, as an independent party, stored the sequence allocations and split them into packs of information, each provided via HIN-secured email to the study coordinator.

Blinding

Hospital employees who assigned patients to the wards and clusters were blinded to randomization.

Physicians and study nurses on the respective wards and clusters were trained before implementing phase 1, since they had to implement three questions in their routine process. Yet, they were not informed about switching between phase 1 and phase 2. Blinding of staff involved in the recruitment process was limited as phase 1 and phase 2 consisted of different study information and consent sheets. Trained staff performed the follow-up assessment, offering several assessment options, and repeatedly trying to reach out to the participants aiming at completing follow-up as far as possible, and we intended to blind them regarding the study phase allocation of the patients (if procedural aspects allowed it).

Unblinding was not planned as we did not expect the blinding to affect patients’ health or treatment. Blinding only affected the recruitment process. Unblinding was only important for the study team itself and was needed due to procedural aspects.

Supplementary material 3: Table – SomPsyNet study clusters

SomPsyNet SCCM cluster	Cluster number
UHB: Department of Obstetrics and Gynecology 1.1	**1**
UHB: Department of Obstetrics and Gynecology 1.2	**2**
UHB: Department of Internal Medicine 5.1-1	**3**
UHB: Department of Internal Medicine 5.1-2	**4**
UHB: Department of Internal Medicine 5.1-3	**5**
UHB: Department of Internal Medicine 6.2-1	**6**
UHB: Department of Internal Medicine 6.2-2	**7**
UHB: Department of Internal Medicine 6.2-3	**8**
UHB: Department of Internal Medicine 7.1-1	**9**
UHB: Department of Internal Medicine 7.1-2	**10**
UHB: Department of Internal Medicine 7.1-3	**11**
UAFP: Department of Acute Geriatrics 1 / Rehabilitation Geriatrics 1	**12**
UAFP: Department of Acute Geriatrics 2 / Rehabilitation Geriatrics 2	**13**
BESP: Department of Rheumatology.1	**14**
BESP: Department of Rheumatology.2	**15**

BESP: Department of Musculoskeletal Rehabilitation.1	**16**
BESP: Department of Musculoskeletal Rehabilitation.2	**17**
BESP: Department of Musculoskeletal Rehabilitation.3	**18**
BESP: Department of Gynecology (excl. Breast Centre and Obstetrics) 1.1	**19**
BESP: Department of Gynecology (excl. Breast Centre and Obstetrics) 1.2	**20**
UHB: Department of Internal Medicine 8.1	**21**

Note. BESP (Bethesda Hospital), SCCM (Stepped and collaborative care model), UAFP (Department of Geriatric Medicine FELIX PLATTER), University Hospital Basel (UHB).

Supplementary material 4: BAK-list (provided in German)

Page 1 (Angaben zum Patient)

Angaben zur Patientin / zum Patient

Personalien	
Anrede	Frau
Name	Beispiel
Vorname	Beate
Geburtsdatum	01.01.2001
Dokumentencode	XXXX

Testergebnisse			
Datum Testung	01.01.2023		
	1. Eingabe	2. Eingabe	Check
PHQ-8 Baseline	15	15	gleicher Wert
Depressivität (Patient Health Questionnaire (PHGQ-8); Kroenke et al. 2001; Spannweite 0 bis 24, höherer Wert entspricht höherer Depressivität): Rohwert 15 -> Hinweise auf schwere depressive Symptomatik			
GAD-7 Baseline	5	5	gleicher Wert
Ängstlichkeit (Generalized Anxiety Disorder Scale (GAD-7); Löwe et al. 2008; Spannweite 0 bis 21, höherer Wert entspricht höherer Ängstlichkeit): Rohwert 5 -> Hinweise auf mild ausgeprägte Angstsymptomatik			
SSD-12 Baseline	24	24	gleicher Wert
Psychische Belastung im Kontext körperlicher Beschwerden (Somatic Symptom Disorder Scale (SSD-12); Toussaint et al. 2019; Spannweite 0 bis 48, höherer Wert entspricht höherer psychischer Belastung einhergehend mit körperlichen Symptomen): Rohwert 24 -> Hinweis auf mindestens mittlere (mittelgradige) psychische Belastung einhergehend mit körperlichen Symptomen			

Angaben zu den Konsilkontakten					
Art des Kontakts	*Datum*	*Uhrzeit*	*Form*	*Kürzel Kons. Mitarbeiter*in*	*Qualifikation Kons. Mitarbeiter*in*
1. Kontakt	02.01.2023	10.00 Uhr	stationär	XX	Psycholog*in
2. Kontakt	04.01.2023	9.00 Uhr	stationär	XX	Psycholog*in
3. Kontakt / tel. Nachbefragung	28.01.2023	14.30 Uhr	ambulant telefonisch	XX	Psycholog*in

Page 2a (Eingabemaske Problembereiche)

Eingabemaske Problembereiche & spezifischer Angebotsbedarf

Zu welchen Themen wünschen Sie Angebotsvorschläge?

A. Problembereiche

Nr.	kognitive, psychische & psychosomatische Probleme	Antworten JA = 1 / Nein = 0
1	Symptome einer depressiven Störung	1
2	Symptome einer Angststörung	0
3	Symptome einer traumaassoziierten Störung	0
4	Somatoforme Belastung	0
5	Chronische Schmerzsymptomatik	0
6	Substanzkonsum, Substanzmissbrauch und Abhängigkeit	0
7	Problematisches Essverhalten	0
8	Kognitive Beeinträchtigung	0
9	Delir	0
10	Schwindel	0
11	Tinnitus	0
12	Sonstige Symptome einer psychischen Störung	0
13	Akute psychiatrische Belastung (inkl. Psychotische Symptome, Fremd- oder Selbstgefährdung)	0
14	Symptome einer Zwangsstörung	0

Nr.	Ambulante & stationäre Angebote für Patienten mit somatischen Erkrankungen	Antworten JA = 1 / Nein = 0
15	Lungenerkrankung	0
16	Herzerkrankung	0
17	Multiple Sklerose	0
18	Muskuloskelettale Erkrankungen	0
19	Rheumatische Erkrankung	0
20	Parkinson	0
21	Endokrinologische Erkrankung	0
22	Hauterkrankung	0
23	Onkologische Erkrankung	0

Page 2b (Eingabemaske Problembereiche)

Nr.	Soziale Probleme	Antworten JA = 1 / Nein = 0
24	Fehlende Kinderbetreuung	0
25	Erziehungsfragen bei minderjährigen Kindern	0
26	Partnerschaftskonflikte / Trennung / Scheidung	1
27	Psychisch erkrankte Angehörige	0
28	Einsamkeit / Wunsch nach Begleitung	0
29	Eingeschränkte Mobilität	0
30	Gewalt	0
31	Migration	1
32	Obdachlosigkeit	0
33	Wunsch nach Wohnbegleitung	0
34	Streitigkeiten mit Vermieter / Nachbaren	0
35	Geldsorgen	0
36	Arbeitslosigkeit	0
37	Wunsch nach beruflicher Beratung	0
38	Konflikte am Arbeitsplatz	0
39	Körperliche Einschränkungen am Arbeitsplatz	0

B. Spezifischer Angebotsbedarf

Nr.	Besondere Behandlungssituation	Antworten JA = 1 / Nein = 0
40	Palliative Behandlungssituation	0
41	Angebote für ältere Patienten	0
42	Behinderung / Handicap	0
43	Besondere Bedürfnisse im Akutspital	0

Nr.	Stationäre Behandlungsangebote	Antworten JA = 1 / Nein = 0
44	Stationäre psychosomatische Weiterbehandlung	0
45	Stationäre psychiatrische/psychotherapeutische Weiterbehandlung	0

Page 2c (Eingabemaske Problembereiche)

Nr.	Problembereich-übergreifende Angebote	Antworten JA = 1 / Nein = 0
46	Entspannung	0
47	Komplementärmedizin	0
48	Physiotherapie	0
49	Ernährungsberatung	0
50	Bewegungs-, Tanz-, Körpertherapie	0
51	Musiktherapie	0
52	Kunsttherapie	0
53	Vernetzungswunsch mit anderen Betroffenen	0
54	Tagesstruktur	0
55	Seelsorge	0
56	Ambulante Psychotherapie	0
57	Ergotherapie	0
58	Spitex	0

Page 3a (Ausgabe Empfehlungen)

Ausgabemaske Anschlussinterventionen

Mögliche Anschlussintervention - sortierte Reihenfolge					
Rang	Art der Anschlussintervention	Anzahl Nennungen	Verlinkung	Mit der/dem Patienten/in besprochen?	Möchte der/die Patient*in das aufgleisen?
1	Schweizerisches Rotes Kreuz - Besuchs- &Begleitdienst für MigrantInnen im Seniorenalter	1	Link	Nein	Nein
2	Beratungsstelle für Binationale Paare und Familien	1	Link	Ja	Ja
3	GGG Migration - Übersetzungen, Information, Beratung	1	Link	Nein	Nein
4	MUSUB- Transkulturelle Suchtberatungsstelle beider Basel	1	Link	Nein	Nein
5	UPK Transkulturelle Ambulanz	1	Link	Nein	Nein
6	Juristische Fakultät der Universität Basel - kostenlose Rechtsberatung für Familien	1	Link	Nein	Nein
7	Pro Mente Sana - telefonische oder E-Mail Beratung für betroffene Menschen, deren Angehörige und nahestehende Bezugspersonen	1	Link	Nein	Nein
8	Stiftung Rheinleben - Beratung für Betroffene oder Angehörige von Betroffenen mit psychischen Erkrankungen	1	Link	Nein	Nein
9	Fabe (Familien-, Paar- und Erziehungsberatung) - Erziehungs- und Familienberatung & Beratungsangebot zu Finanzen	1	Link	Nein	Nein
10	Sozialhilfe BS	1	Link	Nein	Nein

Page 3b (Ausgabe Empfehlungen)

11	Zentrum Selbsthilfe Region Basel	1	Link	Nein	Nein
12	Ambulante/r Psychiater/in	1	Link	Nein	Nein
13	Ambulante/r Psychotherapeut/in	1	Link	Ja	Ja
14	Psychosomatische Ambulanz (USB)	1	Link	Ja	Nein
15	Entspannung (Angebot der Psychosomatik) (USB)	1	Link	Nein	Nein
16	Sozialdienst (USB)	1	Link	Nein	Nein
17			Link	Nein	Nein
18			Link	Nein	Nein
19			Link	Nein	Nein
20			Link	Nein	Nein
21			Link	Nein	Nein

Page 4 (Koordination Aufgleisung)

Koordination Aufgleisung

Wer koordiniert die Aufgleisung?	
Patient*in selber	

Wer koordiniert ausserdem die Aufgleisung (falls vorhanden)?	
Koordinationsunterstützung:	https://www.sompsynet.bs.ch/koordinationsunterstützung

Hat der/die Patient*in Einverständnis für eine telefonische Nachbesprechung in zwei bis vier Wochen (je nach Krankheitsverlauf) mit ihm/ihr gegeben?
Ja

Soll der Konsilbericht an einen Arzt oder andere Fachperson des Vertrauens versendet werden?	
Ja	
Name und (falls vorhanden) Adresse?	Dr. Muster

Kommentare

Übersicht Koordinationsunterstützungsangebote

Arbeitgeber: Baloise Bank SoBa, Basler Kantonalbank inkl. Bank Cler, Böhringer Ingelheim GmbH, CABB-Chemical AG, Kanton BS, Roche, Straumann AG, SUVA Basel, Weleda AG

Stiftungen/Gesundheitsligen/Fachstellen: Stiftung Rheinleben, Abteilung Sucht Kanton Basel-Stadt

Versicherungen: SWICA, Baloise Versicherung

Page 5 (Intervention Konsilgespräch)

Interventionen im Konsilgespräch

Welche Interventionen haben Sie im Konsilgespräch angewendet?	
Psychoedukation	Nein
Stützende und sicherheitsvermittelnde Gesprächsführung	Ja
Ressourcenaktivierung	Nein
Motivierende Gesprächsführung	Nein
Vermittlung von Bewältigungsstrategien	Nein
Entspannungsübung	Nein
Atemübung	Nein
Sonstiges	

Page 6 (Telefonische Nachbesprechung)

Telefonische Nachbesprechung

Telefonisches Konsil (3. Termin: telefonische Nachbesprechung)		
Datum		28.01.2023
Uhrzeit		14.30 Uhr
Hat eine telefonische Nachbesprechung stattgefunden?		Ja
Dauer des Gesprächs (in min)		12.00
Wurden die folgenden besprochenen Angebote		
Rang	Art des Angebots	Antworten
1	Beratungsstelle für Binationale Paare und Familien	Ja
2	Ambulante/r Psychotherapeut/in => Wenn nein: Warum?	Nein Zweifel am Nutzen
3		
Wurden weitere Angebote genutzt?		Nein
Einschätzung der/des Konsildienstmitarbeitende*n: Denken Sie, dass die telefonische Nachfrage für die/den den Patient/in/en hilfreich war?		Ja
Kommentare		

Supplementary material 5: Methodological details 2 – Intervention

In phase 2, every patient with a positive result of "screening 2" (i.e., scoring above threshold, which was the case if at least one of the three instruments, Depressive Symptom Scale with 8 items from the PHQ (PHQ-8), Generalised Anxiety Disorder, questionnaire with 7 items (GAD-7), and Somatic Symptom Disorder, questionnaire with 12 items (SSD-12) scored equal or above the predefined values that were based on previously validated cut-off scores of the respective instruments: PHQ-8 >= 10; GAD-7 >= 10; SSD-12 >= 23) – if the physician in charge agreed – was offered the SomPsyNet intervention. The agreement of the physician was relevant, as interventions in the hospital need to be agreed upon by the responsible physician. This intervention was a stepped and collaborative care model (SCCM) centring around psychosomatic-psychiatric consultations.

These consultations were conducted by the well-established hospital psychosomatic-psychiatric consultation and liaison services (CL service). The CL services consisted of trained medical and psychological staff. In the Department of Geriatric Medicine FELIX PLATTER (UAFP), an advanced nursing practitioner was working in the psychiatric and social consultation team.

Typically, two facto-to-face consultations of approximately 40 minutes duration, and one telephone consultation of approximately 20 minutes duration about 4 to 6 weeks after hospital discharge took place; this could be reduced if not all three consultations were able to be implemented.

The basic structure of the consultations conducted within this study was the same as in the clinical routine and varied between the participating hospitals. The content of the consultations was customised to the patients' needs. There were some obligatory elements, which were implemented in the SomPsyNet phase 2 consultations at all hospitals. Typically, these elements consisted of an in-hospital part and an interface-related part to pave the way for further outpatient support:

In-hospital part:

- **Telefone contact between the CL-staff and the ward physician** to discuss the consultation before and after.
- **Face-to-face consultations with the patient:** Typically, two face-to-face consultations with usually approximately 40 minutes duration took place during the hospital in-patient stay, usually in the patient's room. In case that consultations could not take place during the inpatient stay period, due to a rather short stay, outpatient consultations were offered, when possible and where feasible. These

outpatient consultation offers did not incur any costs for the patient. Objectives of the consultations were to establish a working alliance with the patient, to build an understanding of the psychosocial burden, and - if possible - to provide a first experience of relief, as well as to active patient's resources and competencies. Besides a diagnostic assessment, the consultations aimed to jointly identify problem areas in which the patient needed and wanted support. Therefore, the involved CL staff asked the patients about current psychosocial stress factors.

- **"Support options catalogue" to link problem areas and service offers:** To support this process, we developed a Microsoft Excel-based clinical tool called the "BAK-list" (Behandlungs-Angebots-Katalog / support options catalogue) in the version for the University Hospital Basel (UHB). The BAK-list (see Supplementary material 4) consists of two main tables: One table contains a collection of relevant psychosocial issues often met in everyday clinical practice. The other table contains in-house and out-of-hospital services offering support for the different issues. These offers of support were individually linked to the psychosocial issues, so that by selecting a psychosocial issue, relevant offers of support were suggested. Thereby, the BAK-list facilitates generating suggestions for severity-stepped, need-based offers of support that the CL-service, in interaction with the patient, could then select, verify, and recommend. Further, the BAK-list is used as a documentation tool, facilitating reporting by providing standardised text-block templates adapted to the psychosocial issues and support offers. Every hospital adjusted the content of the BAK-list to their patients' needs and to their in-house offers of support. The following procedure applied: During a consultation, the CL-staff opens a new BAK-list file. The CL-staff then selects psychosocial stressors that currently affected the patient and for which the patient sought support. As an output, the BAK-list tool generates need-based support suggestions. The CL-staff is free to recommend these or other appropriate support options, tailored to the severity grade and the patient's needs.

Interface-related part to pave the way for further outpatient support:

- **Coordination person for implementing the recommendations:** If a patient consented to a support option, the CL-staff clarifies and documents who initiated contact with the chosen support provider and coordinated the care. As far as possible this is the patient herself/himself, prioritising self-management and self-responsibility. If she/he is not capable of performing that, another person such as the patient's general practitioner or a relative of the patient should be identified to coordinate the care. This process aimes to reduce the gap between in-hospital and out-hospital support and to improve interface management.
- **Consultation report:** For each patient seen by the CL-staff in phase 2, a consultation report with the recommendations is provided, either directly to the

patient or to the attending physician initiating the CL-service consultation, who is encouraged to integrate relevant parts of or the whole consultation report into the discharge letter – as far as the patient agreed with that. The patient can specify to whom the consultation or discharge report is sent after discharge from the hospital (e.g., general practitioner or another reference person). The consultation report is accompanied by a letter explaining the project context.

- **Online platform compiling support options:** Additionally, within SomPsyNet, we developed a platform in the form of a website that contained public offers of support services in the Basel region and partly also across cantons, facilitating identification and access to available services. Every patient in phase 2 is informed about this website. A leaflet in the form of a postcard helps to promote the platform.

- **Telephone consultation about 4 to 6 weeks after hospital discharge:** It is a well-known challenge that a substantial proportion of patients do not follow treatment recommendations after hospital discharge. To counteract this phenomenon, patients are offered a post-hospital intervention in form of a telephone consultation of approximately 20 minutes duration around 4 to 6 weeks after hospital discharge to support the take-up of the agreed on recommendations, to identify potential barriers for addressing them, and to find viable solutions for establishing contact with the support agency if use is still intended.

We do not prohibit any concomitant care and intervention during the trial. Notably, treatment as usual in the form of pre-SomPsyNet psychosomatic-psychiatric consultations is allowed.

We trained all psychosomatic-psychiatric consultation specialists involved in the study. Adherence to the intervention protocol is fostered by regular supervision and/or meetings to discuss any questions and upcoming issues regarding the intervention protocol. Further, the documentation of each psychosomatic-psychiatric consultation aims at increasing adherence to intervention protocols and facilitated monitoring of the respective adherence based on the written documentation.

Supplementary material 6: Methodological details 3 – Primary, secondary, and other outcomes, including healthcare economic outcomes

Primary, secondary, and other outcomes

The primary endpoint of our study is the change from the baseline of the 'Mental Health Component Summary score' of the Short Form 36 Health Survey (SF-36). The SF-36 was administered at study entry ('baseline' or 'pre-assessment') and at 6 months follow-up ('follow-up' or 'post assessment', conducted in the distressed and non-distressed subsamples).

The SF-36 is a widely used patient-reported outcome assessment tool to measure health-related quality of life and has high acceptability. The SF-36 is a standardised questionnaire with good psychometric properties (internal consistency reliability of 0.83-0.94)[1] and translated and validated in various languages, among them German[2]. It consists of 36-Items to assess health-related quality of life using eight dimensions grouped into a physical and a mental component summary scale: The physical component summary (PCS) is calculated based on the four subdimensions physical functioning (PF, 10 items), physical role functioning (RP, 4 items), bodily pain (BP, 2 items), general health perception (GH, 5 items). The mental component summary of the SF-36 (MCS) is calculated based on the four subdimensions vitality (VT, 4 items), social role functioning (SF, 2 items), emotional role functioning (RE, 3 items) and mental health (MH, 5 items)[3,4]. Written instructions for the translational process, distribution, and evaluation are available and were clearly defined[2,5,6].

The SF-36 exists in two versions: version 1 and version 2, with the German version 2 being provided by Hogrefe[7,8]. Negotiations between the company 'heartbeat medical' and Hogrefe publisher regarding licence regulation issues were ongoing. Yet, based on the state of negotiations at that time, electronic integration of the SF-36 questionnaire version 2 within the heartbeat one system was not feasible in near future. Therefore, since electronic data collection was essential for continuous monitoring, quality control, and plausibility check of collected data, the available SF-36 version 1 is used for this study, which had been developed as a part of the Medical Outcomes Study (MOS) to report patient outcomes[3,5]. The secondary and other outcomes are provided in Table 1 of the main manuscript. Notably, the SF-36 PCS is part of the secondary endpoints.

We collect a range of sociodemographic variables, including age, sex, and socioeconomic status, work status and days out of work, length of hospital stay, ICD-10 diagnoses, Coronavirus disease 2019 (COVID-19) information, treatments, morbidity, disease history and severity of disease, as well as unintended effects of interventions, by questionnaire/interview and as part of the hospital routine data. These will be used amongst others to describe the study sample and as potential covariates for statistical analyses.

Healthcare economic outcomes

Effects on costs were planned to be assessed from the perspectives of the Swiss statutory health insurance system, the patient, and society. Towards this end, medical resource use, direct and indirect costs will be examined. Specific endpoints include total costs of hospital treatment including additional medical, psychiatric or physiotherapeutic treatment during the patient's hospital stay, follow-up costs at treating hospitals, healthcare costs, patients' out-of-pocket expenses, and indirect costs due to reduced productivity. Relevant sub-categories of costs and key medical resource use are also included.

Health economic assessments will be based on hospital data, information provided by patients at the study visits, and health insurance claims data. The latter will be collected from a set of large health insurance providers with efficient electronic databases that are able to provide data in a standardised format. The claims data will be requested to cover the time period from 1 year before baseline assessment to baseline assessment, from baseline assessment until follow-up assessment, and from follow-up assessment until baseline assessment plus 3 years. Pre-baseline information from 1 year before baseline assessment to baseline assessment will be requested to serve as additional control variables. The data includes claims made to the Swiss statutory health insurance. They will be collected from the health insurance providers retrospectively after a reasonable waiting period ensuring sufficient completeness of the data, as patients and healthcare providers may submit reimbursement claims with delay.

Supplementary material 7: Informed consent materials (provided in German)

Page 1

Phase 2

28710

Universitätsspital Basel

Patienteninformation zur Studie SomPsyNet

SomPsyNet
Prävention psychosozialer Belastungsfolgen in der Somatik: ein Modellprojekt zur kollaborativen Versorgung

Studienorganisator: Prof. Dr. med. Rainer Schäfert

Gesundheitsdepartement des Kantons Basel-Stadt

Page 2

Sehr geehrte Patientin, sehr geehrter Patient
Wir fragen Sie hier an, ob Sie bereit wären, an unserem Forschungsvorhaben mitzuwirken.

Ihre Teilnahme ist freiwillig. Alle Daten, die in diesem Projekt erhoben werden, unterliegen strengen Datenschutzvorschriften. Das Forschungsvorhaben wird durchgeführt von Prof. Dr. Rainer Schäfert. Bei Interesse informieren wir Sie gerne über die Ergebnisse aus dem Forschungsvorhaben.

In einem Gespräch erklären wir Ihnen die wichtigsten Punkte und beantworten Ihre Fragen. Damit Sie sich bereits jetzt ein Bild machen können, hier das Wichtigste vorweg. Im Anschluss folgen dann weitere, detaillierte Informationen.

Warum führen wir dieses Forschungsvorhaben durch?

- Wir wollen untersuchen, ob und wie stark sich Patientinnen und Patienten mit körperlichen Erkrankungen belastet fühlen, d. h. ob Sie gestresst, in Sorge oder unter Druck sind. Zudem wollen wir herausfinden, wie sich die Belastung, die Krankheitsverläufe und die Kosten 6 Monate und 3 Jahre nach Spitaleintritt entwickeln.
- Ergänzend bieten wir Patienten, bei denen wir eine bedeutsame psychosoziale Belastung feststellen, die Möglichkeit, ihre Belastungen in einem Gespräch mit einer Fachperson zu besprechen. Im entlastenden Gespräch werden gegebenenfalls Unterstützungsmöglichkeiten besprochen und wie diese genutzt werden können. Wir wollen untersuchen, ob die Gespräche und Unterstützungsmöglichkeiten den belasteten Patienten helfen.

Was muss ich bei einer Teilnahme tun?

- Wenn Sie sich entscheiden mitzumachen, dann erklären Sie sich einverstanden Fragen zur psychosozialen Belastung und oft damit verbundenen Lebensbereichen zu beantworten. Das Ausfüllen des Fragebogens dauert zirka 30 Minuten.
- Zeigt sich im Fragebogen eine bedeutsame psychosoziale Belastung, so wird Ihnen ein Gespräch mit einer entsprechenden Fachperson angeboten. Es können insgesamt bis zu zwei solcher Gespräche à je 40 Minuten in Anspruch genommen werden. Bei Bedarf kann zusätzlich eine telefonische Nachbesprechung à 20 Minuten geplant.
- Ein basierend auf den Angaben zur Belastung ausgewählter Teil der Studienteilnehmenden wird zudem 6 Monate danach erneut befragt, um den Verlauf zu untersuchen. Diese Nachbefragung dauert zwischen 30 und 60 Minuten.

Welcher Nutzen und welches Risiko sind damit verbunden?

Nutzen:

- Mit Ihrer Teilnahme an dieser Studie helfen Sie den beteiligten Spitälern, deren Forschung zum Wohle der Patienten zu fördern.
- Sie können einen persönlichen Nutzen von der Teilnahme haben, falls ein Gespräch zur psychosozialen Belastung stattfindet.

Risiko und Belastung

- Die Studienteilnahme ist mit keinerlei Risiken verbunden. Je nachdem werden Problembereiche angesprochen, was kurzfristig als unangenehm empfunden werden kann. Durch die professionelle Betreuung erwarten wir dadurch keine negativen Effekte oder Schäden.

Mit Ihrer Unterschrift am Ende des Dokuments bezeugen Sie, dass Sie freiwillig teilnehmen und dass Sie die Inhalte des gesamten Dokuments verstanden haben.

Page 3

Detaillierte Information

1. Ziel und Auswahl

Körper und Seele hängen oft eng zusammen. Anhand dieser Studie wollen wir untersuchen, wie Patientinnen und Patienten während des Spitalaufenthaltes ihren Gesundheitszustand einschätzen. Zudem wollen wir herausfinden, wie sich die Belastung, die Krankheitsverläufe und die Kosten 6 Monate und 3 Jahre nach Spitaleintritt entwickeln.

Wir fragen Sie an, da alle Personen teilnehmen können, die ab einem bestimmten Datum auf einer Station aufgenommen wurden, welche sich an der Studie beteiligt. Ausserdem müssen sie mindestens 18 Jahre alt sein und ausreichend Deutsch verstehen. Nicht teilnehmen dürfen Personen, die onkologisch betreut werden.

2. Allgemeine Informationen

- Bei **SomPsyNet** soll für Patientinnen und Patienten aus **SOM**atischen Spitälern (Spitäler, in denen Patientinnen und Patienten wegen körperlichen Erkrankungen behandelt werden) zur Prävention **PSY**chosozialer Belastungsfolgen ein Versorgungs-**NET**zwerk aufgebaut und nachhaltig etabliert werden.
- Die Prävention hat zum Ziel, Krankheiten vorzubeugen, so dass man gar nicht erst krank wird; oder falls jemand bereits krank ist, möglichst schnell zu behandeln und negative Folgen der Krankheit zu verhindern.
- Psychosoziale Belastungsfolgen bedeutet bei SomPsyNet, dass jemand mit einer körperlichen Erkrankung auch psychisch oder sozial belastet ist. D.h. dass eine Person gestresst, in Sorge oder unter Druck ist. Häufig sind es Schwierigkeiten im Umgang mit folgenden Bereichen: körperliche Beschwerden oder Einschränkungen, emotionale Probleme (z.B. Traurigkeit, Depression, Ängste), Familie/Kinder/Freunde, Arbeit/Schule, Geld oder Lebenssinn/Spiritualität/Glaube. Patientinnen und Patienten mit psychosozialen Belastungen sollen bei SomPsyNet während des Spitalaufenthaltes systematisch erkannt und entsprechend behandelt werden.
- Informationen zu psychosozialen Belastungen werden der zuständigen Stationsärztin oder dem zuständigen Stationsarzt und dem weiteren Behandlungsteam weitergeleitet, um eine optimale und ganzheitliche Behandlung zu gewährleisten. Ausserdem werden Sie im Gespräch mit der Fachperson gefragt, ob wir den Konsilbericht, welcher unter anderem Informationen zu den aktuellen Belastungsfaktoren und den besprochenen Unterstützungsangeboten enthält, an den Hausarzt oder andere Nachbehandler weiterleiten dürfen.
- Die Datenerhebung der Studie dauert von Januar 2020 bis Dezember 2022. Wir erwarten ca. 3000 Teilnehmende im Gesamten.
- Um die gesundheitsbezogenen Kosten und die Kosten im Gesundheitssystem zu untersuchen, arbeiten wir mit ausgewählten Krankenversicherern zusammen. Es ist daher möglich, dass wir mit Ihrem Einverständnis Ihre Krankenversicherer kontaktieren, um Informationen über die Art Ihrer Versicherungen und die von Ihnen beanspruchte Leistungen und deren Kosten zu bekommen. Wir werden den Krankenversicherern ausser Ihren Kontaktdaten und Ihrer Einverständniserklärung keine persönlichen Informationen zukommen lassen.
- Diese Studie ist nach Schweizer Recht konzipiert. Zudem werden alle international anerkannten Richtlinien beachtet. Die zuständige kantonale Ethikkommission hat die Studie geprüft und bewilligt.
- Eine Beschreibung dieser Studie finden Sie auch auf der Internetseite des Bundesamtes für Gesundheit unter www.kofam.ch

3. Ablauf

- Um die Belastung der Patientinnen und Patienten abzuklären, werden Sie während des Spitalaufenthaltes befragt. Dabei werden Ihnen Fragen zu Ihrem Gesundheitszustand, zu Ihrer Befindlichkeit, zu medizinischen Behandlungen, zu Ihrem Lebensumfeld und zur Lebensqualität gestellt. Falls im Fragebogen eine bedeutsame psychosoziale Belastung festgestellt wird, werden die Ergebnisse an die zuständige Stationsärztin oder den zuständigen Stationsarzt

weitergeleitet. Die zuständige Stationsärztin oder der zuständige Stationsarzt kann auf Ihren Wunsch ein Gespräch mit einer entsprechenden Fachperson anfordern. Im Gespräch werden aktuelle Problembereiche und mögliche Unterstützungsangebote besprochen. Je nach Bedarf können zwei solcher Gespräche à 40 Minuten stattfinden. Zusätzlich kann eine telefonische Nachbesprechung à 20 Minuten geplant werden.

- Ein Teil der Studienteilnehmenden wird zudem 6 Monate nach der ersten Befragung erneut befragt, um den Verlauf zu untersuchen. Sie erhalten die Fragebogen in Papierform, auf einem Tablet/Computer oder die Fragen werden Ihnen mündlich in einem Gespräch gestellt. Wenn Sie es wünschen, können wir Sie bei der Beantwortung der Fragen unterstützen. Dazu werden Sie von einem Studienmitarbeitenden kontaktiert.
- Im Rahmen Ihres Spitalaufenthaltes werden im Routineprozess Patientendaten zu Ihrer Gesundheit, aber auch zu administrativen Zwecken erfasst. Zu diesen Daten gehören Informationen zu Ihrer Person (wie z.B. Geschlecht, Geburtsdatum, Kontaktangaben, Nationalität), zu Ihrer Krankheitsgeschichte (wie z.B. Anamnese, Symptome und Diagnosen) und zu den Spitalstatistiken (wie z.B. Eintrittsdatum, Austrittsdatum, Liegezeit, Kosten, ökonomischer Schweregrad der Erkrankung). Wir dürfen diese Daten jedoch nur analysieren, wenn Sie hiermit Ihr Einverständnis dazu gegeben haben.
- Zeitlicher Aufwand durch die Studienteilnahme für die Patientin/den Patienten (immer Ihr Einverständnis vorausgesetzt) während des dreijährigen Prüfzeitraums:

	Befragung im Spital	**6 Monate nach Studieneinschluss**	**3 Jahre nach Studienschluss**
Basisbefragung (Selbstauskunft auf Papier / Tablet oder per Interview)	20-30 Minuten		
Optional: **Gespräch mit Fachperson**	1 bis 2 Gespräche à 40 Minuten; bei Bedarf zudem ein Telefongespräch à 20 Minuten		
Nachbefragung (Üblicherweise per Telefon)		30-60 Minuten	
Daten der Krankenversicherer (werden durch Studienpersonal angefragt und eingeholt)	Kein Zeitaufwand	Kein Zeitaufwand	Kein Zeitaufwand

4. Nutzen

Mit Ihrer Teilnahme an dieser Studie helfen Sie den beteiligten Spitälern, deren Forschung zum Wohle der Patienten zu fördern.
Sie können einen persönlichen Nutzen von der Teilnahme haben, falls ein Gespräch zur psychosozialen Belastung stattfindet.

5. Freiwilligkeit und Pflichten

Sie nehmen freiwillig teil. Wenn Sie nicht an dieser Studie teilnehmen oder später Ihre Teilnahme zurückziehen wollen, müssen Sie dies nicht begründen. Ihre medizinische Behandlung/Betreuung ist unabhängig von Ihrem Entscheid gewährleistet. Sie dürfen jederzeit Fragen zur Studienteilnahme stellen. Kontaktdaten finden Sie am Ende dieser Studieninformation.
Als Teilnehmerin / als Teilnehmer ist es notwendig, dass Sie die Fragebogen jeweils wahrheitsgemäss nach Ihrem Befinden ausfüllen.

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6. Risiken und Belastungen

Die Studienteilnahme ist mit keinerlei Risiken verbunden. Je nachdem werden Problembereiche angesprochen, was kurzfristig als unangenehm empfunden werden kann. Durch die professionelle Betreuung erwarten wir dadurch keine negativen Effekte oder Schäden.

7. Alternativen

Die Teilnahme an dieser Studie ist freiwillig. Wenn Sie nicht teilnehmen, hat dies keinen Einfluss auf Ihre medizinische Behandlung. Falls Sie sich Unterstützung im psychosozialen Bereich wünschen und nicht an der Studie teilnehmen wollen, wenden Sie sich bitte an die zuständige Stationsärztin oder den zuständigen Stationsarzt. Ihre Prüfperson kann Sie hierzu beraten.

8. Ergebnisse

Es gibt:

1. Individuelle Ergebnisse der Studie, die Sie direkt betreffen: Die Prüfperson wird Sie nach der Befragung über allfällige Anzeichen einer psychosozialen Belastung informieren. Sie können danach selbst entscheiden, ob Sie sich auf ein Gespräch mit einer entsprechenden Fachperson einlassen möchten oder nicht. Sie werden bei Bedarf über alle neuen Erkenntnisse informiert, welche den Nutzen der Studie oder Ihre Sicherheit beeinflussen können.
2. Objektive End-Ergebnisse der gesamten Studie: Am Ende der Studie können wir Ihnen eine Zusammenfassung der Gesamtergebnisse zukommen lassen.

9. Vertraulichkeit der Daten und Proben

Für diese Studie werden persönliche medizinische Daten und Versicherungsdaten erfasst. Bei der Datenerhebung zu Studienzwecken werden die Daten verschlüsselt. Verschlüsselung bedeutet, dass alle Bezugsdaten, die Sie identifizieren könnten (Name, Geburtsdatum), gelöscht und durch einen Schlüssel ersetzt werden.

Die Schlüssel-Liste bleibt immer bei den Studienverantwortlichen. Personen, die den Schlüssel nicht kennen, können daher keine Rückschlüsse auf Ihre Person ziehen. Ihr Name taucht niemals im Internet oder einer Publikation auf. Sämtliche Forschungsprojekte mit Ihren Daten unterliegen den in der Schweiz geltenden gesetzlichen Bestimmungen und müssen vorher von einer Ethikkommission bewilligt werden. Ihre Daten sind gemäss dem Schweizer Datenschutz nur berechtigten Personen des Projektes zugänglich. Alle Personen, die im Rahmen der Studie Einsicht in Ihre Daten haben, unterliegen der Schweigepflicht. Die Vorgaben des Datenschutzes werden eingehalten. Sie als teilnehmende Person haben jederzeit das Recht auf Einsicht in Ihre Daten.

Es ist möglich, dass Ihre Daten für andere Untersuchungen zu einem späteren Zeitpunkt weiterverwendet werden oder später an eine andere Datenbank in der Schweiz oder ins Ausland für noch nicht näher definierte Untersuchungen versandt und verwendet werden. Diese andere Datenbank muss die gleichen Standards einhalten wie die Datenbank zu dieser Studie. Für diese Weiterverwendung bitten wir Sie, ganz am Ende dieses Dokuments eine weitere Einwilligungserklärung zu unterzeichnen.

Möglicherweise wird diese Studie durch die zuständige Ethikkommission, die die Studie veranlasst hat, überprüft. Der verantwortliche Studienleiter (auch Prüfperson genannt) muss der Ethikkommission allenfalls Ihre persönlichen und medizinischen Daten für solche Kontrollen offenlegen.

10. Rücktritt

Sie können jederzeit von der Studie zurücktreten. Die bis dahin erhobenen Daten und Proben werden noch verschlüsselt ausgewertet, weil das ganze Projekt sonst seinen Wert verliert.
Nach der Auswertung werden Ihre Daten anonymisiert, d.h. Ihre Schlüsselzuordnung wird vernichtet, so dass danach niemand mehr erfahren kann, dass die Daten und Proben ursprünglich von Ihnen stammten. Dies dient vorrangig dem Datenschutz.

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11. Entschädigung für Teilnehmende
Sie erhalten keine Entschädigung für Ihre Studienteilnahme.
Durch die Teilnahme entstehen Ihnen oder Ihren Krankenversicherern keine zusätzlichen Kosten. Falls es angezeigt ist, dass die Nachbefragung nicht per Telefon oder E-Mail, sondern vor Ort in einer unserer Kliniken durchgeführt wird, werden wir eine angemessene Transportkostentschädigung bezahlen. Vergütet werden öffentliche Verkehrsmittel 2. Klasse oder in äquivalenter Höhe Fahrkosten mit dem Auto. Sollte aus gesundheitlichen Gründen ein Taxi benötigt werden, bitten wir darum, die Kosten vorab von der Projektleitung genehmigen zu lassen.
Die Ergebnisse dieser Studie können unter Umständen dazu beitragen, kommerzielle Produkte zu entwickeln. Durch Ihre Studienteilnahme haben Sie kein Anrecht auf Anspruch an kommerziellen Entwicklungen (z. B. Patenten).

12. Haftung
Die jeweilige Institution, die für die Durchführung der Studie verantwortlich ist, haftet für Schäden, welche im Zusammenhang mit den Forschungshandlungen entstehen. Die Voraussetzungen und das Vorgehen dazu sind gesetzlich geregelt. Wenden Sie sich im Schadensfall an die Prüfperson.

13. Finanzierung der Studie
Die Studie wird mehrheitlich von Gesundheitsförderung Schweiz bezahlt.

14. Kontaktperson(en)
Sie dürfen jederzeit Fragen zur Studienteilnahme stellen. Auch bei Unsicherheiten oder Notfällen, die während der Studie oder danach auftreten, wenden Sie sich bitte an:

Kontaktperson Universitätsspital Basel
Prof. Dr. Rainer Schäfert,
Klinik für Psychosomatik, Universitätsspital Basel
Hebelstrasse 2, 4031 Basel
Tel.: +41 61 328 59 79
E-Mail: sompsynet@usb.ch

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SomPsyNet Einwilligungserklärung Studienprojekt

Schriftliche Einwilligungserklärung zur Teilnahme an einem Studienprojekt

Bitte lesen Sie dieses Formular sorgfältig durch. Bitte fragen Sie nach, wenn Sie etwas nicht verstehen. Für die Teilnahme ist Ihre schriftliche Einwilligung notwendig.

BASEC-Nummer:	2019-01724
Titel der Studie:	SomPsyNet – Prävention psychosozialer Belastungsfolgen in der Somatik
Studienorganisator – verantwortliche Person / Institution:	Chefarzt: Prof. Dr. med. Rainer Schäfert Klinik für Psychosomatik Universitätsspital Basel Hebelstr. 2, 4031 Basel
Ort der Durchführung:	Universitätsspital Basel
Verantwortliche Prüfperson am Studienort: Name und Vorname in Druckbuchstaben:	.....

Bitte beantworten Sie die Angaben in Druckbuchstaben und markieren Sie das Kästchen mit einem Kreuz.

☐ männlich ☐ weiblich ☐ anderes

Vorname	.....
Name	.....
Strasse, Nr.	.....
PLZ, Ort	.....
Geburtsdatum (TT/MM/JJJJ):	.....
Telefonnummer:	.....
Mobilenummer:	.....
E-Mail Adresse:	.....

- Ich wurde von der unterzeichnenden Prüfperson mündlich und schriftlich über den Zweck, den Ablauf der Studie und über mögliche Vor- und Nachteile sowie über eventuelle Risiken informiert.
- Ich nehme an dieser Studie freiwillig teil und akzeptiere den Inhalt der abgegebenen schriftlichen Information. Ich hatte genügend Zeit, meine Entscheidung zu treffen.

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- Meine Fragen im Zusammenhang mit der Teilnahme an dieser Studie sind mir beantwortet worden. Ich behalte die schriftliche Information und erhalte eine Kopie meiner schriftlichen Einwilligungserklärung.
- Ich bevollmächtige die Studienleitung (Sponsor), von meinen Krankenversicherern die unmittelbar für den Studienzweck erforderlichen Informationen zur Art meiner Versicherungen, zu meinen Leistungsdaten und deren Kosten einzuholen. Diese Informationen beziehen sich auf die Beobachtungszeit der Studie (ab 1 Jahr vor dem Studieneinschluss bis 6 Monate danach) und auf die längerfristige Kostenentwicklung (bis 3 Jahre nach Studieneinschluss). Ich entbinde hierfür meine Krankenversicherer von ihrer gesetzlichen Schweigepflicht.
- Ich bin einverstanden, dass Fachleute der Studienleitung und der Ethikkommission Einsicht in meine unverschlüsselten Daten nehmen dürfen, unter strikter Einhaltung der Vertraulichkeit.
- Über Studienergebnisse, die direkt meine Gesundheit betreffen, werde ich informiert.
- Ich weiss, dass meine gesundheitsbezogenen und persönlichen Daten in verschlüsselter Form zu Forschungszwecken für diese Studie weitergegeben werden können (auch ins Ausland). Die Studienleitung (Sponsor) gewährleistet, dass der Datenschutz nach Schweizer Standard eingehalten wird.
- Im Fall einer Weiterbehandlung während des Prüfzeitraums ermächtige ich meine nachbehandelnden Ärzte, relevante Nachbehandlungsdaten der Prüfperson zu übermitteln.
- Ich kann jederzeit und ohne Angabe von Gründen von der Studienteilnahme zurücktreten. Meine medizinische Behandlung ist unabhängig von der Studienteilnahme immer gewährleistet. Die bis zum Rücktritt erhobenen Daten und Proben werden für die Auswertung der Studie verwendet.
- Falls Sie durch das Projekt einen Schaden erleiden sollten, haftet die Institution, welche das Projekt veranlasst hat und für die Durchführung verantwortlich ist.
- Ich verpflichte mich, die Fragen wahrheitsgetreu zu beantworten. Im Interesse meiner Gesundheit kann mich die Prüfperson jederzeit von der Studie ausschliessen.

Ort, Datum: _____ **Unterschrift Teilnehmer/in:** _____

Bestätigung der Prüfperson:
Hiermit bestätige ich, dass ich dieser Teilnehmerin/ diesem Teilnehmer Wesen, Bedeutung und Tragweite der Studie erläutert habe. Ich versichere, alle im Zusammenhang mit dieser Studie stehenden Verpflichtungen gemäss dem geltenden Recht zu erfüllen. Sollte ich zu irgendeinem Zeitpunkt während der Durchführung der Studie von Aspekten erfahren, welche die Bereitschaft der Teilnehmerin/ des Teilnehmers zur Teilnahme an der Studie beeinflussen könnten, werde ich sie/ ihn umgehend darüber informieren.

Ort, Datum: **Name, Vorname der Prüfperson in Druckbuchstaben**

_____

Unterschrift der Prüfperson

_____ _____

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SomPsyNet Einwilligungserklärung für Weiterverwendung von Daten dieser Studie

Einwilligungserklärung für Weiterverwendung von Daten in verschlüsselter Form

Bitte beantworten Sie die Angaben in Druckbuchstaben und markieren Sie das Kästchen mit einem Kreuz.

☐ männlich ☐ weiblich ☐ anderes

Name .....

Vorname .....

- Ich erlaube, dass meine Daten und Proben aus dieser Studie für die medizinische Forschung weiterverwendet werden dürfen. Dies bedeutet, dass meine Daten für zukünftige, noch nicht näher definierte Forschungsprojekte auf unbestimmte Zeitdauer verwendet werden dürfen. Diese Einwilligung gilt unbegrenzt.
- Ich entscheide mich freiwillig für eine Teilnahme und kann diesen Entscheid zu jedem Zeitpunkt wieder zurücknehmen. Wenn ich zurücktrete, werden meine Daten anonymisiert. Ich informiere lediglich meine Prüfperson und muss diesen Entscheid nicht begründen.
- Ich habe verstanden, dass die Daten verschlüsselt sind und der Schüssel sicher aufbewahrt wird. Die Daten können im In- und Ausland an andere Datenbanken zur Analyse gesendet werden, wenn diese dieselben Standards wie in der Schweiz einhalten. Alle rechtlichen Vorgaben zum Datenschutz werden eingehalten.
- Normalerweise werden alle Daten gesamthaft ausgewertet und die Ergebnisse zusammenfassend publiziert. Sollte sich ein für meine Gesundheit wichtiges Ergebnis ergeben, ist es möglich, dass ich über meine Prüfperson kontaktiert werde. Wenn ich das nicht wünsche, teile ich es meiner Prüfperson mit. Wenn Ergebnisse aus den Daten kommerzialisiert werden, habe ich keinen Anspruch auf Anteil an der kommerziellen Nutzung.

Ort, Datum: **Unterschrift Teilnehmer/in:**

_____ _____

Bestätigung der Prüfperson: Hiermit bestätige ich, dass ich dieser Teilnehmerin/ diesem Teilnehmer Wesen, Bedeutung und Tragweite der Weiterverwendung von Daten erläutert habe.

Ort, Datum: **Name, Vorname der Prüfperson in Druckbuchstaben**

_____

Unterschrift der Prüfperson

_____ _____

Supplementary material 8: Methodological details 4 – Data recording and source data

Data were collected by paper-pencil and by an online medical application called 'heartbeat one' from Heartbeat Medical Solutions GmbH. Heartbeat one was already implemented at the University Hospital Basel (UHB) and used in clinical practice. The server running heartbeat one for all three study sites was on a UHB server, maintained by the ICT-department of the UHB. All data assessed with heartbeat one as well as hospital information data used for this study purpose was transferred by the UHB ICT team to the project database in secuTrial®. SecuTrial® is an online Clinical Data management Application (CDMA, secuTrial® database) system based at the ICT-Department of the UHB.

All collected paper-pencil data of questionnaires, and hospital information that were not electronically available was entered into the study Electronic Case Report Form (eCRF) of secuTrial®. An audit trail maintained a record of initial entries and any changes made; time and date of entry; and username of the person authorising entry or change. The eCRF was implemented by the Data management group at the Clinical Trial Unit (CTU). The Clinical Data Management System (CDMS) ran on a server maintained by the ICT-department of the UHB. Data entry was performed by trained staff. The CDMS was accessible via a standard browser on devices with an internet connection. The data transfer between clients and servers was encrypted using Transport Layer Security (TLS) cryptography protocol. Password protection and user-right management ensured that only authorised study investigators, monitors, data managers, and local authorities (if necessary) had access to the data during and after the study.

For quality assurance, the sponsor, the ethics committee, or an independent trial monitor could visit the research sites. Direct access to the source data and all study related files was granted on such occasions. All involved parties kept the participant data strictly confidential.

Back-up of the heartbeat one and secuTrial® database server are performed regularly according to established processes by the ICT-department of the UHB. The data managers of the CTU Basel implemented validation rules in the CDMS. When data got saved in an eCRF, they were validated for completeness and discrepancies. The data were reviewed by the responsible investigator as well as an independent monitor. The monitor raised queries using the query management system implemented in secuTrial®. Designated investigators had to respond to the query and confirm or correct the corresponding data. Thereafter the monitor could close the query. Health insurance claims data for patients with informed consent available are requested from participating health insurance providers.

Supplementary material 9: Methodological details 5 – Statistics

Sample size

Eligibility for participation in the SomPsyNet study was conditioned on provided informed consent. Based on a priori power analyses – see below – we aimed at an enrolled sample size of *n* = approximately 200–500 in phase 0; *n* = 1000 in phase 1; and *n* = 1000 in phase 2, assuming that at least 30% of enrolled patients would be in psychosocial distress (and followed up)). Of note, the rather large interval of the sample size of phase 0 was due to some uncertainties regarding the length of the initial transition phase and limited information on the number of patients eligible for study inclusion being admitted per month.

Statistical analysis plan and sample size calculation

The primary endpoint of our study is the change from baseline of the Mental Health Component Summary score measured by the Short Form health survey questionnaire (SF-36). We made the following conservative assumptions: 1) 80% of those with psychosocial distress in the intervention condition (phase 2, Stepped and collaborative care model (SCCM) condition) accepted receiving the SCCM (and none of them receive standard CL) 2) an effect of Hedges' g of 0.5 (based on published and unpublished reports[9] 3) 25% of those with psychosocial distress in the control condition (phase 1, treatment as usual (TAU) condition) received standard CL-intervention; and 4) a Hedges' g of 0.5 in the control condition (phase 1, TAU) receiving standard CL-intervention; we expected the following Hedges' g between the SCCM condition and TAU condition (delta Hedges' g): delta Hedges' g = 0.8 * 0.5 – 0.25 * 0.5 = 0.275). A priori power analysis based on t-test family tests for calculating differences between two independent means (with *alpha* = 0.05) indicated that a sufficient power of 1-beta = 0.80 would be achieved if 209 participants per condition were included. Notably, the sample size needed to allow for an anticipated drop-out rate to reach sufficient power for both intent-to-treat and per-protocol analyses. Assuming a rate of drop-out and missing data due to other reasons of 25% (given that follow-up was conducted at baseline and 6 months and a rather morbid study sample), we needed to include 279 patients per condition in the main analyses on the treatment effects of the SCCM (i.e., comparing the outcomes of subjects in the distressed subsamples of phase 2 vs. phase 1). Based on preliminary analyses of data from study phase 0, we expected that approximately 30–35% (more than the 20%, initially anticipated based on the literature[10]) of patients with somatic disease included in the study were psychosocially distressed. Leaving some uncertainty margin, we therefore expected that these 279 patients per condition could be achieved with a total subject pool of *N* = 2000 included in the study phases 1 and 2 (*n* = 1000 (300 distressed) in phase 1 and *n* = 1000 (300 distressed) in phase 2)[11,12].

Given the complex nature of the stepped-wedge design, additional power simulations were conducted in Stata to ensure the proposed sample sizes would be sufficient to achieve 0.8 power under the assumptions stated above.

The statistical power for medical resource use and cost parameters was difficult to establish due to issues such as large background variability and unknown distribution of confounding baseline characteristics[13]. For these analyses, we used the largest achievable sample sizes to be as much as possible on the safe side. This implied to include all enrolled patients in the related analyses based on hospital information data, and all meeting the specific eligibility criteria for the analyses based on health insurance claims data.

Descriptive analyses

Descriptive statistics of study sample characteristics, study condition parameters such as participation rate, and mental health factors by allocated sequence, phase, and period will be calculated following the Stepped-wedge cluster randomised trial (SW-CRT) guidelines[14], and appropriate indicators of central tendency and dispersion will be reported, depending on variable scale and distribution.

Estimation of intervention effects on primary, secondary, and other outcomes

- To estimate intervention effects, we intend to primarily conduct generalised linear mixed models of primary, secondary, and other outcome parameters adjusted for the clusters as random effects and for study conditions, calendar time and potential confounders (e. g., gender, age categories, socioeconomic status) as fixed effects. Of note, as the comparison of phase 2 versus phase 1 was randomised, we did not expect confounding *ex ante* for respective comparisons, as we do not expect that patient characteristics potentially predictive of the outcome are somehow associated with the timing of the rollout. Still, we intend to include covariates to improve fitting the model with greater precision. The exact choice of regression method will consider the distributional characteristics of the outcome parameters of interest. As mediators, we primarily intend to assess uptake of the CL-service offers and recommendations. As dependency of stepped wedge trial results on choice of statistical techniques had been reported, alternative analytical methods may additionally be used for sensitivity checks[15].
- Intervention effects will be estimated, using the distressed subsample only, contrasting program exposures in Phases 1 and 2.

Analysis of outcome parameters representing medical resource use and costs will follow these steps:

- Description of cluster characteristics, contrasting trial-level cluster size etc., and cluster size considering the actual number of observations with health insurance claims data available[16]. This will be accompanied by a CONSORT-type flowchart[14].
- Description of individual-level sociodemographic and disease characteristics per intervention phase[16].
- Naïve comparison of outcome parameter values between intervention phases.
- Generalised linear mixed models of outcome parameters with random effects for the clusters and fixed effects for intervention phases, calendar time, and potential confounders (such as somatic morbidity characteristics, insurance model, etc.)[16,17,18]. The exact choice of regression method will consider the distributional characteristics of the outcome parameters of interest. (For medical resource use and cost outcomes, left-skewed distributions are expected.) As dependency of stepped wedge trial results on choice of statistical technique had been reported, alternative analytical methods may additionally be used for sensitivity checks[15].
- An additional step will combine the results of the above-described analyses, and especially of the analysis of total healthcare costs over 6 months, with estimates of the per-person cost of the SCCM intervention that will be derived as part of the SomPsyNet project but outside the study addressed here. This will allow us to approximate the net cost of the SCCM intervention. The stability of results will be assessed based on the variation of parameter values, using 95% confidence limits where available. Additional estimates of the proportion of patients with psychosocial distress will enable us to perform a rough estimation of the budget impact of the SCCM, at the level of canton Basel-Stadt and at the national level.

We will conduct additional statistical analyses i) to compare data from phases 2 and 1 vs. phase 0 to estimate the potential effects of introducing parts of screening 1 without consequences ii) to estimate the prevalence of psychosocial distress among somatic hospital patients, iii) to estimate the performance criteria of the screening procedure to identify psychosocially distressed subjects, and iv) to estimate differences in outcome parameter trajectories and costs between distressed and non-distressed subjects, by comparison of subjects in the distressed subsample with those of the non-distressed subsample.

To the extent applicable, all reporting follows the rules of the extension of the CONSORT statement to stepped-wedge cluster randomised trials[14].

Minimising and handling of missing data and drop-outs

First, our strategy combines minimising of missing data bias by careful planning of the questionnaire order (most important outcomes at the beginning); active data management for quality assurance in terms of tight monitoring of planned activities/progress and results and identifying problems as early as possible; and active review of missing data to collect answers when re-contact was planned. Using digital assessment tools should further reduce missing data.

It is essential to distinguish between missing data due to partial participation (drop-outs, withdrawal) and loss to follow-up (death or severe medical health status/diseases). Inclusion of loss to follow-up reasons for example based on the patient complexity level will be taken into account when conducting statistical methods such as inverse probability weighting and multiple imputation by chained equations (MICE). Whenever possible, full complete analyses will be performed including adjustment for proxies of missing data such as age, patient complexity level, and socioeconomic status, and whenever appropriate multiple imputation will be performed. We intend to conduct intention to treat (ITT) as well as per protocol analyses.

Supplementary material 10: Table – Causality assessment of Serious Adverse Events (SAEs) based on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E2A guidelines

Causality assessment of SAEs based on ICH E2A guidelines

Relationship	Description
Definitely	Temporal relationship Improvement after dechallenge Recurrence after rechallenge (or other proof of drug cause)
Probably	Temporal relationship Improvement after dechallenge No other cause evident
Possibly	Temporal relationship Other cause possible
Unlikely	Any assessable reaction that does not fulfill the above conditions
Not related	Causal relationship can be ruled out

Note. Source of table: [19]; SAE (Serious Adverse Event), ICH E2A (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Supplementary material 11: Methodological details 6 – Ethics and Dissemination

Monitoring

Source data/documents are accessible to monitors and questions are answered during monitoring. Given the anticipated low risk of the intervention, we did not establish a data monitoring committee (DMC), nor did we implement regular interim analysis or related stopping guidelines. However, the sponsor and investigator could terminate the study prematurely according to certain circumstances, e.g. insufficient participant recruitment, alterations in accepted clinical practice that would have made the continuation of the study unwise, or early evidence of harm or benefit of the experimental intervention.

Risk of harms

Participation in the study was not expected to be associated with relevant risks. In the questionnaires or in the consultation contacts problem areas may be explored for the benefit of the patient that could be perceived as unpleasant for a short time. All applied questionnaires were validated, widely accepted, and routinely applied in research and clinical practice. Consultations were conducted by qualified professionals under appropriate supervision. Hence, the risk-benefit assessment was positive.

Given the large number of hospital inpatients with somatic diseases that were included in this study, we expected that several Serious Adverse Events (SAEs)[20] would occur during the course of the study at the different included study sites (e.g., among the patients hospitalised for cardiac diseases: life-threatening events requiring prolongation of existing hospitalisation and resulting in disability). Given the very low probability of a causal relation between study procedures (e.g., collection of self-reported data) and any such events, we do not conduct routine causality assessments of all SAEs, with the exception of SAEs related to suicide attempts or completed suicide. In these cases, both investigator and sponsor conduct a causality assessment of these events to the trial intervention (see table in Supplementary material 10 for terms given in International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH E2A) guidelines[19]). We classify any event assessed as “possibly”, “probably” or “definitely” related to the trial intervention. Further, both investigator and sponsor make a severity assessment of these events as mild, moderate, or severe. “Mild” meant the complication is tolerable, “moderate” meant it interferes with daily activities, and “severe” meant it renders daily activities impossible.

Reporting of SAEs

All SAEs related to suicide attempts or completed suicide are documented and reported immediately (within a maximum of 24 hours after respective information was provided to study staff) to the sponsor of the study.

If it is not possible to exclude that a SAE is attributable to the intervention under investigation, the investigator reports it to the ethics committee via Business Administration System for Ethical Committees (BASEC) within 15 days. If a SAE occurs at one of the study sites, the coordinating investigator reports the event to the ethics committee concerned, within 15 days. If a SAE related to suicide attempts or completed suicide occurs, we would interrupt the research project and notify the Ethics Committee on the circumstances via BASEC within 7 days according to HRO Art. 21[21].

Auditing

Regular internal audits (usually once a year; with additional visits if needed) were conducted at each study site by trained and experienced staff (i.e., knowledge of Good Clinical Practice) of the principal study site under the supervision of the operative study manager. All study procedures, including participant recruitment, verification of eligibility, consent, enrolment, and allocation to study conditions were reviewed. Before each study phase, the study staff was prepared and trained. All study sites were in regular exchange through monthly meetings. Data managers regularly check completeness, accuracy, and timeliness of data collection and filing. The final database, using the software secuTrial®, provides an implemented data audit trail feature.

Overall ethical considerations

The SomPsyNet study is conducted in compliance with the protocol, the current version of the Declaration of Helsinki[22], the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP)[23], the Human Research Act (HRA)[24], as well as other locally relevant legal and regulatory requirements. Participation of study participants is voluntary and written informed consent prior to participating in the study was obtained and can be withdrawn at any time.

Protocol amendments

Any modifications to the protocol which might impact the conduct of the study, the potential benefit of the patients, or might affect patient safety, including changes in study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects require a formal amendment to the protocol. Until 31-05-2023, four amendments were submitted to and approved by the 'Ethikkommission Nordwest- und Zentralschweiz' (EKNZ; approval dates: 04-06-2020, 08-01-2021, 11-02-2021, and 27-07-2021). Protocol modifications and administrative changes of the protocol were discussed among the principal investigators. In regular quality management meetings, the operational study management informed the study staff of all study sites in case of relevant protocol modifications.

Consent or assent

Trained Research Nurses and trained master students in psychology, with a completed bachelor's degree in psychology introduced the trial to patients. Patients also received information sheets. Patients had the opportunity for questions or queries at any time and sufficient time to form an opinion. Study staff obtained written consent from patients willing to participate in the trial. In addition, patients were asked to agree by signing the informed consent that study investigators collected health insurance claims data directly from the insurer to analyse health resource use and costs. If informed consent for further use of study data was obtained, study data can be further used for other projects.

If consent is revoked, no further data are collected. Already collected data of the person concerned will no longer be transferred to the study database. In case that data were already transferred and fully coded at time of revoking the consent, encoded data will be retained and analysed. The opportunity to receive treatment as usual (TAU) remains for any subject who has withdrawn from the study.

Confidentiality and coding

The list of participants with given informed consent is stored on a secure University Hospital Basel (UHB) server maintained by the ICT-department and the trial and participant data are handled with uttermost discretion and are only accessible to authorised personnel, who need data access to fulfil their duties within the scope of the study. Back-up of the UHB server is performed regularly according to established processes by the ICT-department of the UHB.

As soon as possible after data collection, the Case Report Forms (CRFs) and other study specific documents are encoded, and the participants are henceforth only identified by a unique participant number. Once all data are entered into the CDMS and monitoring is completed, the secuTrial® database will be locked and closed for further data entry. The complete dataset will then be exported and transferred to the study statistician as well as the principal investigator. Other members of the study team (e.g., health economist) will receive access to the data, as required for analytical tasks.

For the collection of health insurance claims data, the contact details, copies of signed informed consent forms and social insurance number of consenting, eligible patients are sent to the participating health insurance providers, together with a code that can be unequivocally matched with the study's unique participant number. The health insurance providers select and calculate the required variables. Together with the above-mentioned code, they are asked to return these for integration with the main study database.

Supplementary material 12: References of the Supplementary material

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description	Addressed on page number
Administrative information			
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	5
	2b	All items from the World Health Organization Trial Registration Data Set	Several pages
Protocol version	3	Date and version identifier	5
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 19
	5b	Name and contact information for the trial sponsor	1; 19
	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	19
	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)	19; 20
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	7–10
	6b	Explanation for choice of comparators	Not relevant
Objectives	7	Specific objectives or hypotheses	10
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)	12; 13
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	11; 12
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)	11; 12
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	14; Suppl. M. 4
	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)	Not applicable
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14; Suppl. M. 4
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Suppl. M. 4
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; Suppl. M. 5
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)	Suppl. M. 2; Suppl. M. 3 (figure)
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	16; Suppl. M. 9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	15

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	Suppl. M. 2
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	Suppl. M. 2
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Suppl. M. 2
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Suppl. M. 2
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Suppl. M. 2

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	15; 16; Suppl. M. 8
	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	Suppl. M. 2
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	15; 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; Suppl. M. 9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Suppl. M. 9

	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)	16; Suppl. M. 9
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	17
	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	17
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; Suppl. M. 11
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; Suppl. M. 11
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	5; 18; Suppl. M. 11
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)	18; Suppl. M. 11
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15; Suppl. M. 11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Suppl. M. 10
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	15; 16; Suppl. M. 8
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19

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**	20
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	Not applicable
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	16; 17
	31b	Authorship eligibility guidelines and any intended use of professional writers	Not relevant
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Suppl. M. 7
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	Not applicable

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