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Establishing and evaluating a health network for somatoform and functional disorders (Sofu-Net)

Submission date
07/08/2014

Recruitment status
No longer recruiting

Registration date
22/10/2014

Overall study status
Completed

Last Edited
14/11/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Somatisation is a condition where mental factors, such as stress, causes a person to suffer physical symptoms. These can include headaches, feeling tired and feeling sick. If the symptoms are experienced for a long time, or are particularly severe, the patient can be diagnosed as having a somatoform disorder. This condition is very common and is one of the main reasons why people visit their doctor or primary care physician (PCP). However, it can take a long time, up to 6 years, for patients to be properly diagnosed and treated (e.g. with psychotherapy). This delay causes distress to the patient and leads to high health care costs. The aim of this study is to set up and evaluate a health network (Sofu-Net) to improve the diagnosis and management of somatoform disorder patients.

Who can participate?
Patients aged at least 18 within the recruitment area that, through filling in a short screening questionnaire, show signs of suffering from the disorder.

What does the study involve?
There are two stages to the study. In the first stage (Phase I) the Sofu-Net health network is set up. It involves the recruitment of a number of PCP practices, psychotherapists, specialized outpatient and inpatient clinics. It uses a standardized screening measure for somatic symptoms, a stepped-care treatment approach, and regular meetings of the network partners for the purpose of professional exchange and education. In order to test Sofu-Net, all patients that had been attending the PCP practices involved before the setup of the network are assessed on 2-3 consecutive days. Another group of patients are assessed in the same way 12 months later. The assessment is done using questionnaires, structured clinical telephone interviews, and PCP checklists. Patients are asked about somatic symptoms, and also any symptoms of anxiety or depression. Those that have severe somatic symptoms, or moderate symptoms along with anxiety or depression are categorized as screening positive and are included in the study and the subsequent telephone interview. The telephone interview is completed for purpose of standardized diagnosis. It also reports when patients start treatment. The PCP checklist assesses physical and psychological disorders of the screening positive patients. The performance of the

Sofu-Net health network is tested by looking at the number of patients who admit their psychological distress to their PCPs, the percentage that are referred to/are engaged with/have attempted to initiate an appointment with a psychotherapist, the number that use available health care and the percentage of correct diagnosis of somatoform and functional disorders by PCPs.

What are the possible benefits and risks of participating?
Patients participating in the study can benefit from early detection of somatoform and functional disorders/other psychological disorders. In addition, patients with somatoform and functional disorders can benefit from being referred to adequate treatment within a short time-period. There are no apparent risks from participating in the study.

Where is the study run from?
The study is part of the Hamburg Network for Mental Health Psychenet, a large health services research study to evaluate and improve mental health care service in the Hamburg metropolitan area. The study is conducted by the department of Psychosomatic Medicine and Psychotherapy, University Medical Centre Hamburg-Eppendorf (UKE).

When is the study starting and how long is it expected to run for?
Phase I: September 2011 to April 2013
Phase II: September 2013 to September 2014

Who is funding the study?
Federal Ministry of Education and Research (BMBF) (Germany)

Who is the main contact?
Prof. Bernd Löwe
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title
Health network somatoform and functional disorders: SOFU-NET (Subproject VIII)

Acronym
Sofu-Net

Study objectives
Phase I (Implementation of the network):
The health network for somatoform and functional disorders (Sofu-Net) will improve the diagnostic process and treatment recommendations for this patient population. In particular, the implementation of Sofu-Net will lead to:
1. An improvement in the diagnostic process
1.1. An increase in the number of patients who are discussing psychological distress with their PCPs
1.2. An increase in the percentage of correct detection of somatoform and functional disorders by PCPs
2. An increase in adequate treatment recommendations
2.1. An increase in the percentage of patients who are referred to a psychotherapist
3. A decrease in health care utilization
3.1. A decrease in the amount of appointments with PCPs and specialized psychiatric and psychological services
3.2. An increase in attempts to initiate psychotherapy

Phase II (Controlled study):
Sofu-Net will improve the diagnostic process and treatment recommendations for patients attending a PCP practice within the network, when compared to patients who are attending a regular PCP practice. In particular, the implementation Sofu-Net will lead to:
1. An increase in the percentage of patients having commenced with appropriate treatment since the implementation of Sofu-Net/since the initial screening (i.e. 6 months post recruitment)
2. A decrease in severity of somatic symptoms as measured with the Patient Health Questionnaire 15 (PHQ-15)
3. A decrease in the amount of health care utilization and costs
4. A decrease in overall disability and comorbidity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Chamber Hamburg (Germany), 28/09/2011, ref. PV3728

Study design
Phase I: Pre-post intervention study evaluating the implementation of Sofu-Net
Phase II: Non-randomized controlled observer-blinded intervention study evaluating the effectiveness of Sofu-Net

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Somatoform and functional disorders; Comorbid symptoms of anxiety and depression

Interventions
Phase I:
1. The intervention involves the establishment of a health network (Sofu-Net) of PCPs, psychotherapists, inpatient clinics and an outpatient clinic, offering special consultations for patients with somatoform and functional disorders, to allow adequate diagnosis as well as timely and specialized treatment
2. In addition, awareness with regard to somatoform and functional disorders and its treatment options is fostered in the general public by circulating short films, advertising boards and post cards (part of another simultaneous subproject)
3. Time from pre- to post measurement is 12 months

Phase II:
1. Following the establishment of Sofu-Net, patients in PCP practices who are part of the health network are compared to patients in PCP practices outside the health network
2. Data collection was completed over the course of 12 months (September 2013 to September 2014)

Intervention Type
Other

Phase
Phase I/II

Primary outcome(s)
Phase I:
At this stage of network implementation a hierarchy of primary and secondary outcomes is not defined. The following measures are considered equally important in order to evaluate the network:
1. Outcomes related to diagnostic processes:
1.1. The number of patients who are discussing psychological distress with their PCPs
1.2. The percentage of correct detection of somatoform and functional disorders by PCPs
2. Outcomes related to treatment recommendations:
2.1. The percentage of patients who are referred to a psychotherapist
3. Outcomes related to health care utilization
3.1. The amount of appointments with PCPs and with specialized psychiatric and psychological services
3.2. Attempts to initiate psychotherapy

Phase II:
The effectiveness of Sofu-Net will be assessed with the following outcome measures:
1. Outcomes related to adequate treatment and symptom change:
1.1. The percentage of patients attending a Sofu-Net PCP practice who have commenced with appropriate treatment (i.e. psychotherapy) since implementation of Sofu-Net/since the initial screening 6 months post recruitment, when compared to the number of patients attending a

regular PCP practice who have commenced with appropriate treatment at these points in time
1.2. Severity of somatic symptoms (PHQ-15)
2. Outcomes related to health care utilization:
2.1. The amount of health care utilization and costs (e.g., outpatient appointments, emergency appointments, inpatient appointments) in patients attending a Sofu-Net PCP practice when compared to health care utilization and costs in patients attending a regular PCP practice

Key secondary outcome(s))
Phase I:
See comment above: Primary outcome measures - Phase I

Phase II:
In addition to the primary outcomes, patients in the Sofu-Net PCP practices will be compared to patients in regular PCP practices with regards to their outcomes on the measures below:
1. The amount of sickness-leave and self-reported inability to work (measured in days)
2. Health anxiety (Whiteley Index-7; WI-7)
3. Depression (PHQ-9)
4. Anxiety (GAD-7)
5. Health related quality of life/Health status (European Quality of Life-5 Dimensions; EQ-5D)
6. Patient satisfaction with treatment
7. Comorbidity of somatoform and functional symptoms and other psychopathological symptoms as assessed with the PCP checklist

Completion date
01/09/2014

Eligibility

Key inclusion criteria
Phase I and Phase II:
Inclusion criteria for screening questionnaire:
1. Patients aged 18 years and above
2. Patients that attend one of the PCP practices that collaborate with Sofu-Net
3. Patients that give oral informed consent for screening
Inclusion criteria for further assessment:
4. Patients that screen positive on the initial screening questionnaire for somatoform and functional disorders, i.e. patients with severe somatic symptoms (Patient Health Questionnaire-15; PHQ-15 sum score of ≥ 15 points) or with moderate somatoform/ functional symptoms (PHQ-15 sum score of 10-15 points) in combination with moderate symptoms of anxiety (Generalized Anxiety Disorder Scale-7; GAD-7 sum score of ≥ 10 points) and/or moderate symptoms of depression (Patient Health Questionnaire-9; PHQ-9 sum score of ≥ 10 points)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Phase I and Phase II:
Exclusion criteria for screening questionnaire:
1. Patients under the age of 18 years
2. Patients with insufficient language skills
Exclusion criteria for further assessment:
3. Patients with severe physical impairments or severe psychological disorders that impede study participation
4. Patients with cognitive impairments
5. Patients with acute suicidal ideation

Date of first enrolment
01/09/2011

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Center Hamburg-Eppendorf
Hamburg
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Sponsor information

Organisation
Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung) (BMBF) (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung (AE 46-52)

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study are available upon request from Dr Meike Shedden-Mora (m.shedden-mora@uke.de). All of the individual participant data collected during the trial will be shared, after deidentification. The data file will be available beginning immediately after publication ending 5 years following article publication. The data will be shared with researchers who provide a methodologically sound proposal for the analyses necessary to achieve the aims in the approved proposal. Proposals should be directed to Dr Meike Shedden-Mora (m.shedden-mora@uke.de). To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No
Results article	results	01/01/2016		Yes	No
Results article	results	01/11/2017		Yes	No
Results article	results	12/11/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes