Trial Description

Title

eHealth supported case management for patients with mental disorders in primary care

Trial Acronym

PREMA

URL of the trial

https://innovationsfonds.g-ba.de/projekte/neue-versorgungsformen/capri-ehealth-gestuetztes-case-management-fuer-psychisch-erkrankte-in-der-hausaerztlichen-primaerversorgung.182

Brief Summary in Lay Language

Depression and panic/ anxiety disorder are some of the most mental disorders which are treated by the general practitioner. An early identification and effective treatment are of great importance. Despite quality-assured standards for diagnostic and treatment, there is a significant proportion of patients who are still not adequately treated. That is the reason why general practitioners should get a training which is based on PREMA. It includes handling with patients who suffer from depression or panic/anxiety disorder. Through this structured care program the health status of the patients should improve.

Brief Summary in Scientific Language

On the basis of cluster randomized study, the intervention and control group will be compared by the impact of symptoms, quality of life and care costs.
In the control group, patients will be treated by current national guidelines, while the patients of the intervention group will be treated by a special program which will take 12 months.
The qualitative survey of the study will investigate, whether the new form of care in primary care is feasible and will significantly improve the care for patients and GP surgeries.
If the treatment is successful, it can be assumed, that the new form of care can also be expanded to further regions and mental illnesses.

Organizational Data

- DRKS-ID: **DRKS00016622**
- Date of Registration in DRKS: **2019/02/22**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **432/18 , Ethikkommission des Fachbereichs**

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Ethics Approval/Approval of the Ethics Committee: **Approved**
Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main

Secondary IDs

Health condition or Problem studied

- ICD10: **F41.0 - Panic disorder [episodic paroxysmal anxiety]**
- ICD10: **F40.01 - [generalization F40.0: Agoraphobia]**
- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F34 - Persistent mood [affective] disorders**

Interventions/Observational Groups

- Arm 1: **The patients from the intervention group will be treated by a new treatment program which is especially developed for PREMA. On 4 treatment appointments, the general practitioner will apply a customized treatment to the patient's complaints. The treatment includes specially for the general practitioners practice developed elements of behavioural therapy and 17 telephone conversations with the medical assistant of the doctor's practice. Participants will get an eHealth-supported intervention with structured exercise training as well. The program takes 12 months.**
- Arm 2: **The usual of care group will get an intensive standard treatment by current guidelines for depression and panic disorder. There will be a special training for general practitioners and medical assistants to refresh the current guidelines which will be performed by TelePsy. The training includes information like diagnostics, therapy and care.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

- Blinding: **[---]***
- Who is blinded: **data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The Mental Health Index-5 (MHI-5) score is used for cross-illness measurement of mental health (depression and anxiety disorder) at the survey time T0, T1 and T2. The MHI-5 is a five question subscale of the Short Form (36) Health Survey (SF 36) and consists of a six-step response scale (1-6 points), in which the scores are added (total range: 5-30 points). A higher score on the scale indicates a better mental health status. After that the points of the scale are transformed by standard linear transformation so that the value range is 0-100. The internal consistency (Cronbach's alpha) is between 0.67 and 0.95.

The main aim of the study is to strengthening the task of general practitioners in the care of patient with depression or anxiety/panic disorders through a therapy combination of case management, GP-guided exercises and blended care (eHealth) tools. The GP should quickly and competently develop an adequate treatment strategy and decide whether the patient must be referred to a specialist immediately or he can treat the patient himself.

T0= Beginning
T1= 6 month
T2= 12 month

Secondary Outcome

screening and final diagnosis; T-1
mental health (depression and anxiety disorder); T0-T2
depression level (PHQ-9); T1-T2
anxiety level (OASIS); T1-T2
number and subjective severity of panic attack; T0-T2
anxiety related avoidance behavior (MIA); T0-T2
quality of supply from chronic disease patients (PACIC); T0-T2
adherence for medical intake; T0-T2
quality of life; T0-T2
comorbidity; T0-T2
use of health care service; T0-T2
work absences; T0-T2
costs of health services; T0-T2

acceptance, attitude, expectation, feasibility, training, communication, job satisfaction, implementation of the intervention; T0-T2

T0= Beginning
T1= 6 month
T2= 12 month

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Hessen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/09/01**
- Target Sample Size: **1844**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

depression (ICD-10 F.32-34), panic disorder with or without agoraphobia (ICD-10: F41.0 or F40.01), positive screening questionnaires,
sufficient German language skills, private telephone, insured by Techniker Krankenkasse

Exclusion criteria

acute or chronic psychosis,
acute suicidality,
current psychotherapeutic treatment of anxiety,
general practitioner does not recommend PREMA

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*