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PSY-CARE: Psychological counselling and therapy for treating depression in homebound older adults

Submission date
01/02/2019

Recruitment status
No longer recruiting

Registration date
14/02/2019

Overall study status
Completed

Last Edited
22/05/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Older homebound people represent a significant and rapidly growing group of patients in which depression is a common health problem. However, the reality of care for this population is currently deficient. Therefore, PSY-CARE is testing the feasibility and effectiveness of outpatient short-term psychological counselling and therapy.

Who can participate?
Older home care patients (men and women) with depression aged 60 years and older.

What does the study involve?
Patients included in the study will be randomized to one of two treatment arms. One half will receive short-term psychotherapy (intervention condition), the other half will receive a self-help intervention for the patient as well as a training session for the caregiver (active control condition). The effectiveness of both conditions will be compared.

What are the possible benefits and risks of participating?
The project sheds more light on the potential and limitations of providing care for older adults receiving home care with depression, within the regular health care system. Participants benefit from treatment (short-term psychotherapy or psychoeducation training) of their depression. During the treatment, there can be a temporal deterioration in mood, which is a part of the therapeutic process and can be averted by the psychotherapist or the psychoeducation training.

Where is the study run from?
MSB Medical School Berlin, Calandrellistraße 1-9, Berlin, Germany, 12247 (lead centre); Charité – Universitätsmedizin Berlin, Charitéplatz 1, Berlin, Germany, 10117

When is the study starting and how long is it expected to run for?
June 2018 – May 2021

Who is funding the study?
German Innovation Fund of the German Federal Joint Committee (G-BA)

Who is the main contact?
Prof. Dr. Eva-Marie Kessler, eva-marie.kessler@medicalschool-berlin.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
01VSF17048

Study information

Scientific Title
PSY-CARE: Depression in homebound older adults – Short-term psychotherapy in healthcare teams

Acronym
PSY-CARE

Study objectives

Primary Hypothesis: Short-term psychotherapy leads to a greater reduction of depressive symptoms, compared to the alternative psychosocial offer.

Secondary Hypothesis: Short-term psychotherapy leads to a greater increase of quality of life, activities of daily living, functioning and subjective health, compared to the alternative psychosocial offer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/09/2018, ethics committee of the Medical School Hamburg (Geschäftsstelle der Ethikkommission, Medical School Hamburg, Am Kaiserkai 1, 20457, Hamburg; +4940 3612264-77; Ethikkommission@medicalschool-hamburg.de), ref: MSB-2018/20

Study design
Single-centre interventional study, using a pragmatic randomized controlled design. Participants will be blinded to their group allocation for the duration of the study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Patients included in the PSY-CARE study will be randomised to one of the two treatment arms. The first arm comprises short-term psychotherapy (population-appropriate augmented behavioural therapy; intervention condition) comprising of up to 24 therapy sessions and will be conducted by gerontologically qualified psychotherapists. The second arm is a short psychoeducation training for the patient as well as the caregiver (control condition), which includes self-help literature and a short individual training for recognizing and dealing with depression under the condition of home care.

Intervention Type
Behavioural

Primary outcome measure

Reduction of depressive symptoms measured by self-report, including the Geriatric Depression Scale at baseline (T1), directly after the intervention (T2), as well as at follow-up after 3 months (T3).

Secondary outcome measures
1. Quality of life measured by a single item from the WHOQOL-OLD
2. Activities of daily living and functioning measured using the Barthel-Index and the IADL-Scale
3. Subjective health measured by a single question.
All will be assessed at baseline (T1), directly after the intervention (T2), as well as at follow-up after 3 months (T3).

Overall study start date
01/06/2018

Completion date
31/05/2022

Eligibility

Key inclusion criteria
1. 60 years of age and older (male/female)
2. Living at home and near the catchment area of the participating psychotherapists (Berlin and neighbouring areas in Brandenburg)
3. Have a long-term care grade (Pflegegrad) (1-5)
4. Presence of clinically relevant depressive symptoms (major depression; adjustment disorder with depressive symptoms; dysthymia)
5. Are willing to participate in one of the two treatments

Participant type(s)
Patient

Age group
Senior

Lower age limit
60 Years

Sex
Both

Target number of participants
130

Total final enrolment
197

Key exclusion criteria
1. Moderate to severe dementia
2. Delirium, an acute psychosis or other cognitive disorders
3. Mania or hypomania

4. In the terminal stage of a disease
5. Currently receiving psychotherapy
6. Have communication difficulties or visual or hearing impairments that would severely impact on their capacity to take part in the intervention

Date of first enrolment
25/02/2019

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
Germany

Study participating centre
MSB Medical School Berlin
Calandrellistraße 1-9
Berlin
Germany
12247

Study participating centre
Charité – Universitätsmedizin Berlin
Charitéplatz 1
Berlin
Germany
10117

Sponsor information

Organisation
German Innovation Fund of the German Federal Joint Committee (G-BA)

Sponsor details
Gutenbergstraße 13
Berlin
Germany
10587

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
German Innovation Fund of the German Federal Joint Committee (G-BA)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (https://osf.io)

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	outcome results	17/01/2023	18/01/2023	Yes	No
Protocol article		05/08/2020	06/03/2024	Yes	No
Results article		23/11/2022	06/03/2024	Yes	No
Results article		21/05/2024	22/05/2024	Yes	No