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Short intervention targeting psychosomatic care in elderly patients with complex health care needs

Submission date
04/08/2014

Recruitment status
No longer recruiting

Registration date
15/09/2014

Overall study status
Completed

Last Edited
21/01/2019

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
Psychomatic disorders involve both the mind and the body. Some physical diseases are thought to be particularly affected by mental factors such as stress and anxiety. With increasing age comes the increasing risk of developing multiple health conditions, mental disorders and a number of social challenges (such as isolation, loss of independence, boredom or feeling inadequate) . Here, we want to assess the success of a short patient orientated treatment for elderly patients with complex health care needs. Using an interview method called INTERMED (IM-E), suitable participants will be identified from those that have taken part in ESTHER - a large study about multimorbidity (existence of two or more long-term health conditions) and frailty in old age.

Who can participate?
Elderly people aged 60 years and older with complex health care needs . Participants are recruited from the ESTHER study.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 (the control group) are visited at their home and given some general written information about available psychological or social support facilities. Feedback from the visit can be given to their GP. Those in group 2 (experimental group) are given the same information in an initial home visit. However, they are then also visited by a trained psychosomatic doctor. Depending on the results from the IM-E, tailored information is provided on diagnosed chronic diseases, a (potential) mental disorder, psychological or social support facilities, and possible coordination of care. Supportive counselling regarding being able to manage and cope with chronic conditions are given and appointments with specialists scheduled as needed. Feedback is provided to the GP. Those in the experimental group receive follow-up phone calls one month and then 3 months after the initial visit. All participants (in both groups) take part in a short telephone interview after 6 months.

What are the possible benefits and risks of participating?
All participants will be assessed closely by a professional team at the beginning of the study. Participants of both groups may benefit from the written general information. There are no risks of physical injury or harm.

Where is the study run from?
Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
July 2011 to November 2014

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

Who is the main contact?
Dr Beate Wild
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Study website
http://esther.dkfz.org/esther/esther-net.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
German Ministry of Research and Education (BMBF) 01ET1004B

Study information

Scientific Title
Short intervention targeting psychosomatic care in elderly patients with complex health care needs a randomized controlled trial

Acronym
ASSIST

Study objectives
The aim of the study is to assess the efficacy of a short patient-oriented intervention targeting psychosomatic care in elderly patients with complex health care needs. The primary hypothesis of the randomized controlled trial (RCT) is that compared to the control group, the intervention group shows a better outcome regarding health-related quality of life (HRQOL) at the six-month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Saarland, 30/05/2011, ref. Ha67/00
2. Ethics Committee of the University of Heidelberg, 12/05/2011, ref. Nr. S-126/2011

Study design
Randomized controlled two-armed trial, ratio of intervention to control-group of 1:1

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Patients with complex bio-psycho-social health care needs (according to the INTERMED for the Elderly interview)

Interventions

In the control condition, general written information is provided at the conclusion of a regular home visit (e.g. about psychological or social support facilities, compliance, mental disorders). In addition, feedback of the home visit can be provided to the general practitioner of the patient (GP).

In the experimental condition, general written information is provided at the conclusion of a regular home visit. In addition, in a second home visit is conducted by a trained psychosomatic doctor. Depending on the outcome in the different domains of the IM-E, information will be given about diagnosed chronic diseases, a (potential) mental disorder, psychological or social support facilities, and possible coordination of care. Supportive counselling regarding self-management and coping with chronic conditions can be given. The family can be involved in the counselling meeting. Appointments with specialists can be scheduled if necessary. Feedback can be provided to the GP. In the first and third month after the intervention home visit, follow-up phone calls with the participants will be done to remind them of the consultation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Health-related quality of life (HRQOL) measured by the SF-12, six months after randomization

Secondary outcome measures
1. Depressive symptom severity measured by the PHQ, six months after randomization
2. Somatic symptom severity measured by the PHQ, six months after randomization
3. Hospitalization rate, six months after randomization

Overall study start date
10/07/2011

Completion date
01/11/2014

Eligibility

Key inclusion criteria
1. Participants of the 11-year follow-up of the ESTHER study
2. IM-E interview score ≥ 17
3. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
224

Key exclusion criteria
1. Severe cognitive disturbances
2. Psychotic disorder
3. Terminal illness

Date of first enrolment
10/07/2011

Date of final enrolment
01/11/2014

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Heidelberg
Heidelberg
Germany
69120

Sponsor information

Organisation
German Ministry of Research and Education (BMBF) (Germany)

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Sponsor type
Government

Website
http://www.bmbf.de/

ROR

https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
German Ministry of Research and Education (BMBF) 01ET1004B (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	21/01/2019	Yes	No