Economic evaluation of psychiatric rehabilitation/self-management intervention (PPEP4All) compared with usual care in patients with Persistent Depressive Disorder (PDD) and their partner; a multicenter pragmatic randomized controlled trial.

Published: 20-12-2016
Last updated: 15-04-2024

Objective/research question: What are costs and effects of group-oriented Psychiatric Rehabilitation ("Patient and Partner Education Program for All chronic diseases": PPEP4All) in patients with Persistent Depressive Disorder and their…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON55681

Source
ToetsingOnline

Brief title
Economic evaluation of psychiatric rehabilitation

Condition

- Mood disorders and disturbances NEC

Synonym
chronic depression, persistent depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw Doelmatigheidsprogramma

Intervention

Keyword: Dysthymic Disorder, Group Psychiatric Rehabilitation, Persistent Depressive Disorder Chronic Depressive Disorder

Outcome measures

Primary outcome

Primary is quality of life (QALYs).

Secondary outcome

Secondary are costs, psychopathology, resilience, disease burden

Study description

Background summary

Chronic depression (more than 2 years depressed) is a common psychiatric disorder which is difficult to treat. Usual care is mostly individual, including psychopharmacotherapy and/or psychotherapy and psychiatric nurse guidance. If treatment outcome is insufficient, then psychiatric rehabilitation is indicated according to the guideline: this project concerns psychiatric rehabilitation, in which the partner of the patient (or significant other) is involved in the treatment by means of a partnergroup or individual partner sessions (PPEP4AII: "Patient and Partner Education Program for All chronic diseases"). There is clinical evidence for PPEP4All but its cost-effectiveness has not been investigated yet, which is the aim of the present project. In mental health care is an urgent need for costeffective and easy-to-implement treatment protocols for rehabilitation in chronic depression.

Study objective

Objective/research question: What are costs and effects of group-oriented Psychiatric Rehabilitation ("Patient and Partner Education Program for All

chronic diseases": PPEP4AII) in patients with Persistent Depressive Disorder and their partner (or significant other), compared to Usual care?
Hypothesis is as follows: Compared to Usual care, PPEP4AII will cost less, lead to better quality of life/functioning, fewer psychological symptoms, more resilience, less chronic disease burden.

Study design

Multicenter Pragmatic Randomised Controlled Trial (superiority design).

Intervention

PPEP4AII includes 10 weekly cognitive-behavioral group sessions of Rehabilitation for patients with a separate partner group. PPEP4AII can be given in a group or in individual one-on-one sessions. In accordance with the COVID-19 measures, we will ensure that the PPEP4AII is offered in a safe environment, for example, PPEP4AII online over video-calling.

Study burden and risks

No risks are involved, and the burden for patients is minimal: 6 brief questionnaires during 4 assessments (1 year) by the researcher at the 4 mental health care centres. Assessment time points are as follows: T1/baseline, T2/posttreatment at 3 months, T3/follow-up at 6 months, T4/follow-up at 12 months. There is no somatic assessment involved, and no somatic or psychological discomfort is expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

chronic depression (> 2 years depressed)

Exclusion criteria

no chronic depression, serious somatic comorbidity and/or psychiatric comorbidity (such as psychotic or bipolar disorder)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-04-2017
Enrollment:	179
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-09-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-05-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL59309.058.16