Evaluation of a rehabilitation group intervention in patients with persistent depressive disorder and their partner.

Gepubliceerd: 20-07-2016 Laatst bijgewerkt: 13-12-2022

Compared to usual care, PPEP4All will cost less, lead to better quality of life, fewer psychological symptoms, more resilience, and less chronic disease burden for both patient and partner.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20302

Bron
NTR

Aandoening

Persistent Depressive Disorder; Chronic Depressive Disorder; Treatment-Resistent Depression.

Persisterende Depressieve Stoornis; Chronisch Depressieve Stoornis; Therapie-Resistente Depressie.

Ondersteuning

Primaire sponsor: Leiden University Medical Centre (LUMC), Department of Psychiatry
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life (QALYs).

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVES/RESEARCH QUESTION: What are costs and effects of group-oriented Psychiatrie Rehabilitation ("Patient and Partner Education Program for All chronic diseases": PPEP4AII) in patients with Persistent Depressive Disorder (PDD) and their partner (or significant other), compared to Usual care?

HYPOTHESIS: Compared to Usual care, PPEP4AII will cost less, lead to better quality of life, fewer psychological symptoms, more resilience, less chronic disease burden.
STUDY DESIGN: Multicentre Pragmatic Randomised Controlled Trial (superiority design).

STUDY POPULATION: Patiënts with PDD (chronic depressed >2 yr), > 18 yr, with their partner/significant other.

INTERVENTION: PPEP4AII (www.ppep4all.nl) with 9 weekly group sessions Rehabilitation and separate partner group.
USUAL CARE: Pharmaco- and/or psychotherapy and psychiatrie nurse guidance.

OUTCOME MEASURES: Primary is quality of life (QALYs); Secondary are costs, psychopathology, resilience, disease burden.

SAMPLE SIZE CALCULATION & DATA ANALYSIS: Based upon power (.85) and alpha (.05), 514 patients are needed (including 10% attrition): 2x257 (PPEP4AII vs Usual care). Primary data analysis: T-test for quality of life using EQ-5D-5L results and cost-effectiveness analysis (at 1 yr). Secondary data analysis: all secondary parameters (weighted generalized estimating equation analyses) and Budget Impact Analysis. All analyses according to intention-to-treat principle; and subgroup analyses for age, gender, ethnicity.

COST-EFFECTIVENESS ANALYSIS (CEA) & BUDGET IMPACT ANALYSIS (BIA): Economic evaluation (CEA) will consist of cost-utility analysis from societal perspective with time horizon of 1 yr. Health care use, patient cost/expenditure, and absence from work will be assessed. Differences in mean costs and effects between strategies will be compared with two-sided bootstrapping. In a net-benefit analysis, costs will be related to patient reported outcomes. In the BIA, the consequences of different scenarios with regard to the extent of

implementation of PPEP4AII will be assessed from several perspectives (societal, public purse, health insurer, health care provider).

TIME SCHEDULE: total of 48 mths. Start-up 3 mnths (1-3); Inclusion/assessments/data entry 30 mnths (4-33); Analysis/publications 15 mnths (34-48).

Doel van het onderzoek

Compared to usual care, PPEP4All will cost less, lead to better quality of life, fewer psychological symptoms, more resilience, and less chronic disease burden for both patient and partner.

Onderzoeksopzet

T1 baseline; T2 post-treatment at 3 months; T3 follow-up 1 at 6 months; T4 follow-up 2 at 12 months.

Onderzoeksproduct en/of interventie

PPEP4All (Patient and Partner Education program for All chronic diseases) compared with usual care.

Contactpersonen

Publiek

Centrum Onderzoek Routine Outcome Monitoring (COROM)

I.V.E. Carlier
Leids Universitair Medisch Centrum (LUMC), Afdeling Psychiatrie
Leiden
The Netherlands
071-5265237

Wetenschappelijk

Centrum Onderzoek Routine Outcome Monitoring (COROM)

I.V.E. Carlier
Leids Universitair Medisch Centrum (LUMC), Afdeling Psychiatrie
Leiden
The Netherlands

071-5265237

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients > 18 years with primary diagnosis Persistent Depressive Disorder.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Severe psychiatric (co)morbidity (e.g. substance abuse, suicidality, psychotic) and/or severe somatic comorbidty; cognitive problems; insufficient Dutch language proficiency.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	30-12-2016
Aantal proefpersonen:	514
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5818
NTR-old	NTR5973
Ander register	ZonMw : 843002709

Resultaten