Psycho-education in depression - an important step in treatment!

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In addition to the above mentioned background of this research, it is important to investigate the effectiveness of psycho-education in depressed patients within specialized mental health care. In this study, the focus is on self-efficacy, because...

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

Summary

ID

NL-OMON48242

Source
ToetsingOnline

Brief title
PE study

Condition

- Mood disorders and disturbances NEC

Synonym
depression, sombre

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: PsyQ Depressie Den Haag

Intervention

Keyword: Depression, Psycho-education, Self-efficacy

Outcome measures

Primary outcome

Self-efficacy measured by the GSE-scale.

The difference in course of self-efficacy at the three moments of measurement between the groups is analyzed by an analysis of variance for repeated measurements (RM-ANOVA). The group assignment is used for the between-subjects factor. The repeated measurements are the within-subjects factor time. By the group assignment * time interaction it is examined if psycho-education leads to higher self-afficacy.

Secondary outcome

Depression (severity) measured by the IDS-SR.

The difference in course of depression at the three moments of measurement between the groups is analyzed by an analysis of variance for repeated measurements (RM-ANOVA). The group assignment is used for the between-subjects factor. The repeated measurements are the within-subjects factor time. By the group assignment * time interaction it is examined if psycho-education leads to a decrease of the severity of depression.

Study description

Background summary

In the patient-practitioner relationship psycho-education is legally required according to the WGBO (law of medical treatment agreement). A patient has the

right to be informed about his disease or disorder and must be able to value the diagnostic and treatment options. The multidisciplinary guideline for depression says 'always start with psycho-education and individual advices in order to activate the patient and to promote a healthy lifestyle '.

Psycho-education is a didactic intervention: on cognitive and emotional level experiences will be shared with the patient and his relatives, which leads to more knowledge and understanding of the disease or disorder the patient suffers from. The premise is that patients can make their own important decisions about their treatment instead of depending on the opinion of the practitioner. This principle also applies to the current development in mental health care in which patients stay in control as much as possible and in which autonomy and self-efficacy will be pursued as much as possible.

Research of psycho-education in depression only focused on the prevention of depression. A meta-analysis of thirteen studies examined the effectiveness of the course 'coping with depression' (in different variants) on reducing depression, measured with the BDI (Cuijpers, 1996). Of the participants in these studies the average BDI score was 21, which means a moderate depression (range 20-28). The average BDI score after following this course was 9.4. This comes close to the average BDI score in the general population (7.0), which means that the participants no longer met the criteria of a depression (mild depression 14-19). The average effect size was 0.62 (95% confidence interval), which can be considered as a big effect. In these studies the participants were recruited by mass media, which can lead to a different population in comparison to depressive patients following treatment in the specialized mental healthcare. Most of these studies focused on a course of ten sessions of psycho-education in combination with cognitive behavioral therapy, which is more extended than what is generally meant by psycho-education. A meta-analysis of studies focusing on the prevention of depression showed that participants of the course 'coping with depression' had 38% less chance of developing a depressive disorder (Cuijpers et al., 2009).

Valli et al., 2010, showed by means of a literature review (nine Rcts) to the prevention of depression that post measurements an immediate positive effect of psycho-education on depression was to see and that this effect at a follow-up after two years retain remained.

These are promising results, however this may not be without more generalized to depressive patients within the specialist mental healthcare (or 2nd line). In these patients, there is often a serious depression that is often associated with comorbid mental disorders, such as post-traumatic stress disorder and (cluster C) personality problems, and comorbid physical symptoms such as headaches and intestinal problems. In addition, patients with major depression often lead to concentration problems, what the record and retain information more difficult. It is very unlikely that the course ' coping with depression ' at this serious and complex depressive patients will lead to remission of

depression. This shows once again that the patients within the specialist mental healthcare not to be compared with the depressed people who participated in the above studies. That psycho-education in depressive patients within the specialist mental healthcare important is found, it is clear from the directive and WGBO multidisciplinary and also seems to general thoughts well with practitioners, however, is the effect of psycho-education at this Group depressive patients never examined.

Study objective

In addition to the above mentioned background of this research, it is important to investigate the effectiveness of psycho-education in depressed patients within specialized mental health care. In this study, the focus is on self-efficacy, because it is expected that psycho-education will increase the self-efficacy of the patient. It is expected that patients who are well informed about their disorder and its treatment are better able to make their own choices. Explorative the study will examine the effect of psycho-education on the severity of the depression, because this ultimately is the purpose of treatment for depression.

The ultimate goal of this study is more attention to psycho-education and a better implementation within settings for treatment of depressive patients. In practice, the way psycho-education is given (and its quality) differs between institutions, but also within institutions. It is important that all depressed patients recieve good psycho-education, regardless of the setting in which they are treated.

Study design

Hypotheses:
Psycho-education given to depressive patients increase their self-efficacy.
Explorative: Psycho-education given to depressive patients decrease the severity of depression.
Explorative: At 5 weeks follow up the effect on self-efficacy and depression is retained.

Design:
Randomized Controlled Trial (RCT)
Subjects will be randomly assigned to the intervention or control condition by a randomization program.
Intervention condition: Subjects participate in a psycho-education group for depression.
Control condition: Subjects do not participate in a psycho-education group for depression.

Instruments:

1. Dutch General Self-efficacy Scale (GSE-scale)
This questionnaire is used to determine the degree of self-efficicy. The psychometric properties of the Dutch GSE-scale are good (review Dijcks en Joeris, 2012).
2. Inventory of Depressive Symptomotology (IDS-SR).
This questionnaire is used to determine the severity of the depression. The psychometric properties of the IDS-SR are good (Rush et al. 1996, Trivedi et al, 2004). Fried (2017) compared seven in research and practice frequently used questionnaires of depression and it appeared that the IDS-SR measures the most symptoms of depression. In outpatients the self report version can be used (Nolen en Dingemans, 2004).

Questionnaires per moment:
GSE-scale IDS-SR
0 weeks x x
5 weeks x x
10 weeks x x

Power analysis:
F tests-ANOVA: Repeated measures, within-between interaction
Analysis: A priori: Compute required sample size
Input: Effect size f (f) = 0.6 (clinical relevance)
* err prob = 0.05
Power (1-* err prob) = 0.95
Number of groups = 2
Number of measurements = 3
Nonsphericity correction * = 1
Output: Noncentrality parameter * = 16.5600000
Critical F = 3.1000686
Numerator, df = 2.0000000
Denominator df = 88.0000000
Total sample size = 46
Actual power = 0.9566890

N = 46, 23 in the intervention condition and 23 in the control condition.

N=46, waarvan 23 in de interventieconditie en 23 in de controleconditie.
Subjects with missing data will be replaced by more subjects. For this reasen, more subjects will be recruited. With an estimated drop-out of 20% approximately 58 (2*29) subjects will be recruited.

Feasibility:
Inclusion criteria: all patients with a depressive disorder and/or dysthymic disorder, according to the DSM5, who are indicated for treatment at PsyQ Depression after the intake.
Exclusion criteria: insufficient knowledge of the Dutch language.
Estimated number of participants in a year and 8 months: 58 subjects.

In practice: in a year and 8 months 266 patients participate in the psycho-education group (2 groups, each consists of 8 patients, 10 times a year).

Intervention

Subjects in the intervention condition participate in a psycho-education groups during five sessions of 1.5 hours. Subjects will be adviced to participate together with a partner, parent or other close relative. This can increase the understanding and support of the patient, and attention is also given to their role and burden. During these meetings the subjects will be informed about and will share experiences with the diagnosis (symptoms, course, causes, effects), dealing with a depressed person, sleep and rhythm, exercise and positive activities, social network and the options for treatment. Two therapists of PsyQ Depression lead the group and at one of the sessions someone who had a depression for herself is present.

Subjects in the control condition get no intervention.

Study burden and risks

Subjects are not at risk and the burden is limited.
Subjects will be assigned to the intervention condition or control condition by a randomization program.
Subjects in the intervention participate in a psycho-education group for depression, consisting of five weekly sessions of 1.5 hours.
All subjects (in the intervention and the control condition) fill in two questionnaires at three different moments. The questionnaires are easy to fill in and the it takes 10-15 minutes per moment.
(E9 contains a detailed description)

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

All patients diagnosed with a depressive disorder and/or dysthymic disorder, according to the DSM5, who are indicated for treatment at PsyQ Depression.

Exclusion criteria

Insufficient knowledge of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2019
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2019
Application type:	First submission
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	NL67447.058.18

Study results

Date completed:	11-06-2020
Actual enrolment:	19