DIVERS-II: Internet Intervention Self-help Cognitive Behavioural Therapy for depressive symptoms in dialysis patients: a randomized controlled trial.

Published: 10-11-2017
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Primary objective:To deliver an easy accessible, patient friendly and low-cost self-help intervention for the treatment of depressive symptoms in dialysis patients.Main hypothesis: An eHealth CBT intervention reduces depressive symptoms in dialysis...

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

Summary

ID

NL-OMON55601

Source
ToetsingOnline

Brief title
DIVERS-II: Internet Intervention

Condition

- Mood disorders and disturbances NEC
- Renal disorders (excl nephropathies)

Synonym
Depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: ZonMw Doelmatigheidssubsidie;Stichting Zabawas;Stichting wetenschap OLVG

Intervention

Keyword: Cognitive Behavioural Therapy, Depression, Dialysis, eHealth

Outcome measures

Primary outcome

Primary Objective:

To investigate the clinical and cost-effectiveness of a self-help cognitive

behavioural therapy in lowering depressive symptoms.

Hypothesis:

Our eHealth intervention reduces depressive symptoms more than in the

care-as-usual group.

Secondary outcome

Secondary Objectives:

- To examine the changes in inflammatory and stress parameters before

and after the intervention.

- To investigate the effectiveness in improving Quality of Life scores.

- To explore the effect on morbidity and mortality.

Psychosocial: Depressive symptoms scale (BDI-II, HADS-D, MINI-plus)

Symptoms, severity and subtyping depression (IDS-SR)

Quality of Life (SF-12)

Anxiety symptoms (BAI, HADS-A, MINI-plus)

COVID-19 stress (PSQ-10)

Clinical: Baseline data from patient file including laboratory measurements

Hospitalization

Mortality

Biochemical: Inflammatory markers (IL-1*, IL-6, IL-10, TNF-*, hs-CRP)

Cortisol (sample hair cortisol which displays mean cortisol for the

past 3 months)

Tryptophan (serum tryptophan, KYN and 3-hydroxykynrenin)

Study description

Background summary

Depressive symptoms are highly prevalent in chronic dialysis patients, with a prevalence of 43% in the Netherlands. Individuals with depressive symptoms have an impaired quality of life, increased treatment non-adherence, increased hospitalization and a considerably higher mortality risk. Despite the major health problem of depression, it is often under-recognized and under-treated in the dialysis population. To effectively treat depressive symptoms and improve quality of life, more evidence is needed. A promising new development to overcome several problems with intensive psychotherapy is the use of self-help internet based Cognitive Behavioural Therapy (CBT). A widely used eHealth CBT module has been tailored to the needs of dialysis patients. A robust randomised trial with sufficient power could result in an easy accessible patient-friendly treatment.

Study objective

Primary objective:
To deliver an easy accessible, patient friendly and low-cost self-help intervention for the treatment of depressive symptoms in dialysis patients.

Main hypothesis:
An eHealth CBT intervention reduces depressive symptoms in dialysis patients.

Objective:
1. To investigate the effectiveness of a self-help CBT in lowering depressive symptoms and the associated adverse outcomes.
2. To examine the biochemical mechanisms involved in treating depression.

Relevance for renal patients and the scientific field:
This study is relevant for the renal scientific field for multiple reasons.
1. First, this study may deliver a nationwide accessible self-help intervention which reduces depressive symptoms in chronic dialysis patients.
2. Second, this study can provide insight in the biochemical background and interplay between the mind and the body. Associations from previous research has only been investigated without treatment. This study provides an opportunity to examine the effect of treatment on the associations found between biochemical parameters and depressive symptoms. These results can be relevant beyond the renal scientific field.
3. Third, this study examines the long term effects of an intervention measured in psychosocial and clinical parameters such as hospitalization. Most studies examining treatment of depressive symptoms in the chronically ill have a much shorter follow-up period.
4. Lastly, This study combines data from the large DIVERS-cohort and a new intervention study. This may lead to new insights in the development of depression, subtyping different types of depression and in psychosocial and pathophysiological reaction to treatment.
This study extends our knowledge of depressive symptoms in dialysis patients and can serve as a base for future projects and research.

Study design

Study design:
This study is a parallel two-arm randomized trial comparing care as usual versus an eHealth cognitive based therapy. Patients will be selected from 10 dialysis centres in Amsterdam and the Hague.

Intervention:
E-Health Problem Solving Therapy, duration of 5 weeks

Care-as-usual:
Care as usual as provided by nephrologist, social workers and if applicable psychotherapists. This group will receive an online info-module about depression in end-stage-renal-disease.

Duration:
The study will start in January 2017. Inclusion will end in 2018. Maximum follow-up of an individual patient will be 18 months.
T0: Baseline (before randomization)
T1: Within 1-2 weeks after the intervention
T2: 6 months

T3: 12 months
T4: 18 months

Intervention

The intervention consists of five modules with explanatory text, figures and exercises. Patients are asked to examine 1 module per week and work on their assignments for at least 2 hours per week. Patients will be asked to finish the module within 6 weeks. However, there will be a possibility of extending this period. This extension beyond 6 weeks will be documented. Patients can access their intervention from several digital devices such as mobile phones, tablets and personal computers. It works in every main browser available to date.

Supported care:
Within the module patients can ask questions to trained psychologist. They will receive feedback from the same psychologists concerning their assignments. Furthermore, they will receive a weekly e-mail to announce a new module.

Nurses & social workers:
Per center nurses and social workers will be trained in aiding the patients using the intervention. They can explain the goals of the intervention, give patients reminders to fill in their assignments and provide practical support.

Study burden and risks

Risks:
Patients will not be exposed to additional risks due to the treatment. Patients and treating physicians are free to treat depressive symptoms to their best intentions. No restrictions are given to the patients participating in this trial. Suicidal thoughts will be screened in all participating patients. Participants who indicate that they either intend to harm themselves or want to attempt suicide will be excluded from this trial and referred to their nephrologist. Patients who do not want to participate in this trial will receive care-as-usual from their nephrologist.

Burden:
Personal: Completing the module and filling in questionnaires about depressive symptoms could be confronting for some of the patients.
Time: Filling in questionnaires (5 x 30 min), completing the module (5 sessions of 2 hours).
Blood samples: Will be taken prior to the dialysis session, no additional puncture is needed for these samples.

Benefits:
An easy to use, patient friendly low intensive treatment to develop coping skils to face their problems. Possibly improve depressive symptoms and quality

of life.

Relevance for renal patients and scientific field
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This study extends our knowledge of depressive symptoms in dialysis patients and can serve as a base for future projects and research.

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

* *18 years of age
* undergoing dialysis treatment for at least 90 days
* being able to complete a questionnaire in Dutch
* have a BDI score of 10 or higher

Exclusion criteria

* Suicidal thoughts
* Participation in other psychotherapeutic trials

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2018
Enrollment:	206
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-12-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-04-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	01-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-04-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-02-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL58520.100.17
Other	Trial NL6648 (NTR6834)