

DIVERS-II: Treating depression in dialysis patients with a tailored eHealth cognitive based treatment: A cluster randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29658

Source

NTR

Brief title

DIVERS-II (Internet Intervention)

Health condition

Depressie / Depression / Depressive disorder

Dialyse / Dialysis / Renal replacement therapy

Nierfalen / Eindstadium nierfalen / Kidney failure / End stage renal disease

Sponsors and support

Primary sponsor: OLVG Amsterdam

Source(s) of monetary or material Support: ZonMw projectnummer 843001804

OLVG WO 17.162

Stichting Zabawas

Intervention

Outcome measures

Primary outcome

Cluster randomized controlled trial of the intervention versus care as usual.

The primary outcome is the depression score, measured using the Beck Depression Inventory (BDI). The difference between T0 and T1 (1-2 weeks after treatment) is the primary outcome for clinical effectiveness. Care as usual will be compared with the intervention group.

Secondary outcome

- BDI scores after 6, 12 and 18 months
- Anxiety score, measured using the Beck Anxiety Inventory
- Quality of life, measured using the SF-12
- Inflammatory markers, cortisol and tryptophan to explore possible pathophysiological mechanisms
- Explore the effect on morbidity (hospital admissions) and mortality

Study description

Background summary

Background:

Depressive symptoms are highly prevalent in dialysis patients and associated with adverse outcomes. However, depression is underdiagnosed and undertreated in this population. There is lack of robust randomized controlled trials relating to the effectiveness of therapeutic interventions. This study aims to investigate the effectiveness of an eHealth self-help intervention for depressive symptoms in dialysis patients. Furthermore, the biochemical changes and associations involved in depression in dialysis patients are examined.

This study can provide an accessible, patient friendly, low-cost intervention for the treatment of depressive symptoms and improving quality of life of dialysis patients.

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.

Study objective

An eHealth CBT intervention reduces depressive symptoms in dialysis patients.

Study design

T0: Baseline (before randomization)

T1: Within 1-2 weeks after the intervention

T2: 6 months

T3: 12 months

T4: 18 months

Intervention

Psychosocial intervention: Self-help cognitive based therapy, tailored for dialysis patients with build-in support from a psychotherapist. This treatment is based on a frequently used problem solving therapy. It is offered through both an e-health portal and on paper, depending on the preference of the patient. The intervention consists of 5 modules with explanatory texts and animations, exercises and weekly feedback from a trained psychotherapist.

Care-as-usual:

Care as usual as provided by nephrologist, social workers and if applicable psychotherapists. This group will receive an online infomodule

about depression in end-stage-renal-disease.

Contacts

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Eligibility criteria

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 depression score of 13 or higher (BDI = Beck Depression Inventory-II)

Exclusion criteria

- Suicidal thoughts (measured using a short screening survey)

- Participation in other psychotherapeutic trials

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2018
Enrollment:	206
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	13-11-2017
Application type:	First submission

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
NTR-new	NL6648
NTR-old	NTR6834
Other	OLVG: WO 17.162 : METC: NL58520.100.17

Study results