E-health treatment in dialysis

No registrations found.

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

Summary

ID

NL-OMON20743

Source
Nationaal Trial Register

Brief title
E-health treatment in dialysis

Health condition

End-stage renal disease (ESRD), dialysis, health-related quality of life (HRQOL), E-health, Online CBT, tailored care

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: Dutch Kidney Foundation

Intervention

Outcome measures

Primary outcome

The primary study outcome is distress, as measured by a combination of anxiety (GAD-7) and depression (PHQ-9).

Secondary outcome

1. change in disease-specific self-efficacy and self-management.

2. meaningful improvements on the areas of interest to the patients (using a personalized outcome measure).

Study description

Background summary

End-stage renal disease (ESRD) and renal replacement therapy (e.g. dialysis) have a large impact on all areas of daily life of the patient. Many patients can adjust well to these circumstances, but approximately 30 percent shows adjustment problems. Because of the wide variety of problems that patients with ESRD face, healthcare professionals are also confronted with the difficulty to acknowledge the most prominent problems of individual patients. Moreover, there are currently hardly any psychosocial treatments available for this group, particularly no treatments that are tailored to the individual problems and needs of the patients. E-health strategies offer a great opportunity to optimize detection of adjustment problems and to tailor psychosocial care specifically to these problems. The current project proposes a randomized controlled trial to evaluate for the first time the effectiveness of guided E-health self-management treatment for ESRD patients on dialysis that is tailored to the individual patient needs. It is expected that the E-health self-management treatment results in a lower impact of the disease on daily life in comparison to care as usual and meaningful improvements on the areas of interest to the patients.

Study objective

It is hypothesized that the E-health self-management treatment results in lower impact of the disease on daily life, primarily a lower level of distress, in comparison to care as usual.

As secondary objectives the effectiveness of the treatment on 4 domains will be examined. It is hypothesized that the E-health self-management treatment will:

1.increase disease-specific self-efficacy and self-management.

2.result in meaningful improvements on the areas of interest to the patient.

Study design

All patients will be screened on various aspects of quality of life, after which those patients with adjustment problems will be randomly assigned to one of the two conditions. Participants in the intervention condition will receive a 3- to 4-month intervention. Patients in the control condition will receive care as usual. Assessments will be performed at baseline and 6 (post-treatment) and 12 months (6 months post-treatment) after baseline.

Intervention

The E-health self-management treatment is based on evidence-based cognitive-behavioral principles and aims to reduce the impact of the disease on daily life, by optimizing how a patient copes with the condition and improving physical and mental functioning (e.g., decreasing fatigue and depressed mood). The most important goals to work on during the treatment will be determined during the intake with the psychologist (the E-coach). The treatment consists of an online self-management tool that is guided by the E-coach. The E-coach provides online assignments, feedback and support tailored to the individual patient. The treatment incorporates modules on the most relevant areas of daily life in ESRD patients, aimed at coping with the impact of the disease on daily life, including fatigue, disabilities, dependence upon other people, and depressed mood. Patients will have an end-of-treatment consultation with their E-coach at the end of the study.

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Eligibility criteria

Inclusion criteria

1. end-stage renal disease (GFR <15 ml/min/1.73 m2)

2. treated for at least 3 months by means of dialysis (hemodialysis or peritoneal dialysis)

3. > 18 years of age

4. sufficient command of the Dutch language

Exclusion criteria

1. serious medical conditions that are likely to interfere with completion of the study (such as progressive malignancy or other debilitating illness) at the discretion of the nephrologist

2. a life expectancy < 12 months after the start of the study

3. serious psychological comorbidity interfering with the study protocol (i.e., diagnosis according to the Diagnostic and Statistical Manual of Mental Disorders (DSM)

4. recent serious stressful life event unrelated to the ESRD

5. serious cognitive problems disabling participation in the self-management treatment

6. current psychological treatment

7. no access to a computer and internet

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion
Date: 16-07-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50543
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7160
NTR-old	NTR7359
CCMO	NL63422.058.17
OMON	NL-OMON50543

Study results

Summary results
n/a