The effectiveness of tailored E-health self-management treatment for patients with end-stage renal disease: A randomized controlled trial

Published: 14-06-2018
Last updated: 19-03-2025

The overall aim is to assess the effectiveness of guided E-health self-management treatment that is tailored to the individual patient in patients with end-stage renal disease treated by dialysis.

Ethical review	Approved WMO
Status	Completed
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON50543

Source
ToetsingOnline

Brief title
E-HELD

Condition

- Renal disorders (excl nephropathies)

Synonym
End-stage renal disease (ESRD), Kidney Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: Nierstichting Nederland

Intervention

Keyword: Adjustment problems, E-health, End-stage renal disease, Self-management

Outcome measures

Primary outcome

As primary outcome measure, the effects of the treatment on distress will be examined.

Secondary outcome

As secondary outcome measures, the effectiveness of the treatment on 4 domains will be examined:

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

2. changes in relevant aspects of functioning related to the treatment modules (e.g., coping with fatigue, pain, itch, negative mood and social functioning)

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

4. cost-effectiveness of the treatment (the profits of the intervention in terms of health care use and societal participation as compared to the extra costs of the treatment in addition to care as usual

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, meaningful improvements on the areas of interest to the patients, and lower costs.

Study objective

The overall aim is to assess the effectiveness of guided E-health self-management treatment that is tailored to the individual patient in patients with end-stage renal disease treated by dialysis.

Study design

A randomized controlled trial consisting of two conditions: the intervention condition and the control condition. 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 (e.g., problem-focused coping skills) and improving physical and mental functioning (e.g., decreasing fatigue and depressed mood). Patients will have a face-to-face intake session with a therapist (the E-coach). The most important goals to work on during the treatment will be determined during the intake session(s). The treatment consists of an online self-management tool that is guided by the E-coach, which is based on an effective face-to-face treatment and has previously shown to be effective in improving quality of life in patients with other chronic somatic conditions. 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 by phone at the end of the study.

Study burden and risks

There are no risks attached to the study and the participating ESRD patients are at least 18 years old and mentally competent. The only burden for participants is a time investment. The total duration of the study for each individual participant will be 12 months, but the extent of the burden will be different for the two conditions. Patients in the control condition will only have to fill out questionnaires at three time points (baseline and 6 and 12 months later), whereas patients in the intervention condition in addition to filing out questionnaires will participate in a 3- to 4-month intervention. Patients in the intervention condition will, depending on the effectiveness of the treatment, potentially experience positive results regarding the impact of the disease on their daily life. Based on former studies, these effects are expected to be in proportion to the time investment burden.

Contacts

Public
Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL
Scientific
Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• End-stage renal disease (GFR <15 ml/min/1.73 m2)
• Treated for at least 3 months by means of dialysis (hemodialysis or peritoneal dialysis)
• >= 18 years of age
• Sufficient command of the Dutch language

Exclusion criteria

• 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
• A life expectancy < 12 months at the start of the study
• A planned kidney transplant within 12 months
• Serious psychological comorbidity interfering with the study protocol (i.e., diagnosis according to the Diagnostic and Statistical Manual of Mental Disorders (DSM))
• Recent serious stressful life event unrelated to the ESRD
• Serious cognitive problems disabling participation in the self-management treatment
• Current psychological treatment
• 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-02-2019
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	11-09-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	04-09-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	11-02-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	04-12-2020

Application type:	Amendment
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

ID: 20743
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63422.058.17
Other	Trial NL7160 (NTR7359)
OMON	NL-OMON20743

Study results

Date completed:	24-07-2022
Results posted:	12-12-2024
Actual enrolment:	34

Summary results
Trial ended prematurely

First publication
01-01-1900