E-health Guidance in identifying and Overcoming psychological barriers for Adopting a healthy Life style among patients with chronic kidney disease

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

Summary

ID

NL-OMON48539

Source
ToetsingOnline

Brief title
E-GOAL

Condition

- Renal disorders (excl nephropathies)

Synonym
Chronic Kidney Disease (CKD), Kidney Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden

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

Intervention

Keyword: chronic kidney disease, E -health, health behavior change, psychological distress

Outcome measures

Primary outcome

The main outcome parameter is the difference in self-reported change from baseline on psychological distress between patients in the intervention and control condition at post-intervention and 3-month follow up.

Secondary outcome

Secondary outcomes comprise personal goal achievement, self-management, self-efficacy, and mental and physical health-related quality of life.

Study description

Background summary

For patients with chronic kidney disease (CKD), the adoption and maintenance of self-care and a healthy life style is crucial, as it can postpone disease progress and prevent cardiovascular complications. Unfortunately, most patients with CKD experience problems in changing life style habits. Barriers and facilitators to adopt and maintain a healthy life style are often psychological factors, which form risk and resilience factors that influence quality of life and determine how patients cope with CKD and the extent to which they are able to change their life style habits. Therefore, it is essential to identify those barriers and facilitators and treat psychological distress. As patients vary regarding psychological distress levels and related difficulties in changing life style habits, a personalized approach is needed that identifies patients* personal risk profiles for (non)adaptation to CKD and the life style changes it requires. The current project proposes an open randomized controlled trial with (1) the development of a web-based screening tool and an accompanying patient profile chart to identify psychological distress and barriers and facilitators for behavior change among patients with CKD, and (2) a randomized multicenter study to evaluate the effectiveness of an e-care path to treat psychological distress, overcome psychological barriers, and promote psychological

facilitators for behavior change among patients with CKD. The findings will be translated into practical recommendations about implementing a new e-care path.

Study objective

The overall objective is to assess efficacy of an e-care path with screening and treating psychological distress, to overcome psychological barriers and promote psychological facilitators for life style behavior change among patients with CKD. A secondary objective is to detect barriers and facilitating factors among patients and health care professionals for successful nation-wide implementation of the e-care path, resulting in a proposal for implementation strategies.

Study design

The present study is an open randomized controlled trial, in which 120 CKD patients are randomly assigned to either the control condition or intervention condition. After the intervention two follow-up measurements (at 3 and 6 months after the start of the intervention groups) will take place.

Intervention

All patients will fill out a web-based screening questionnaire. Patients who fulfill the criteria of heightened psychological distress and related life style problems will be randomized to either the control or the intervention condition. Patients in the control group will receive a feedback form about the results of the screening, and further receive regular care. Patients in the intervention condition receive tailored online cognitive behavioral therapy aimed to treat psychological distress, overcome psychological barriers, and promote psychological facilitators for behavior change among patients with CKD, with feedback from a psychologist, in a period of maximally 3 months.

Study burden and risks

There are no risks attached to the study and the participating CKD patients are at least 18 years old and mentally competent. The only burden for participants is a time investment. The total involvement in the study for each individual participant will be 6 months*approximately 1-1.25 hour per measurement moment (self-report and clinical measurements) for controls and several additional hours per week during the 3-month intervention period for participants receiving the intervention, tailored to their personal needs and wishes. All participants will receive insight into a range of domains of their psychological functioning. Based on former studies in different populations, the effects on health and quality of life of participants in the intervention condition*the condition with the greatest required time investment*are expected

to be high, in proportion to the time investment burden.

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

* Under medical treatment by an internist-nephrologist
* Chronic kidney disease with an eGFR 20-89 ml/min/1.73m2
* * 18 years of age
* Sufficient command of the Dutch language
* Able to give informed consent
* Access to a computer or tablet with internet

Exclusion criteria

* Rapidly progressive renal function loss (> 10% renal function loss over the last year)
* An anticipated need for dialysis work-up within the time frame of the study
* Blood pressure < 95 mmHg systolic not responding to withdrawal of antihypertensives
* Medical conditions which are likely to interfere with completion of the study (such as progressive malignancy or other debilitating illness) at the discretion of the nephrologist
* Renal transplantation <1 year ago
* Difficulties in (written) communication (e.g., due to analphabetism)
* Severe psychiatric comorbidity that interferes with the study protocol
* Ongoing psychological treatment elsewhere
* Pregnancy

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):	23-04-2018
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2017

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-01-2020
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: 23595
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62540.058.17
Other	NL7338 (NTR7555)

Study results

Date completed:	31-10-2020
Results posted:	27-10-2021
Actual enrolment:	66

First publication
27-10-2021