The E-GOAL study: E-health in chronic kidney disease

No registrations found.

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

Summary

ID

NL-OMON23595

Source
NTR

Brief title
E-GOAL

Health condition

Chronic kidney disease (CKD), E-health, health behavior change, psychological distress, life style

Sponsors and support

Primary sponsor: Leiden University; Institute of Psychology; Health, Medical and Neuropsychology unit
Source(s) of monetary or material Support: Dutch Kidney Foundation

Intervention

Outcome measures

Primary outcome

The primary study outcome is psychological distress, assessed with a questionnaire by a combination of the Generalized Anxiety Disorder-7 (GAD-7) and the Patient Health Questionnaire-9 (PHQ-9).

Secondary outcome

1. Personal goal achievement (that is, meaningful improvements on the areas of interest to the patient, e.g., healthy life style behavior, coping with fatigue, pain, negative mood, and social functioning);

2. Changes in disease-specific self-efficacy and self-management;

3. Changes in mental and physical health-related quality of life.

Study description

Background summary

For patients with chronic kidney disease (CKD), a healthy life style (i.e., regular physical activity, a healthy diet and weight, no smoking, and medication adherence) is crucial, as it can slow down disease progress. Unfortunately, many patients experience problems in adopting and maintaining a healthy life style, often due to psychological factors, such as negative emotions or a lack of self-efficacy. We developed an e-care path with a screening tool, including a personal profile chart, and e-health treatment, aimed at identifying and treating psychological distress, overcoming psychological barriers, and promoting psychological facilitators for behavior change. We will carry out an open multicenter randomized controlled trial to evaluate the effectiveness of this e-care path. All potential participants will fill out an online screening questionnaire and receive a personal feedback chart. Patients who fulfill criteria of heightened psychological distress and related life style problems (n=120) will be randomly assigned to either the control or the intervention condition. Patients in the control condition will receive regular care. Patients in the intervention condition receive regular care and tailored guided online cognitive behavioral therapy, during a period of 3 months. We hypothesize that patients in the intervention condition will show a significantly larger decrease in self-reported psychological distress at post-treatment and 3-month follow-up as compared to baseline than controls. Additionally, we expect larger improvements in various secondary outcomes: personal goal achievement, self-management, self-efficacy, and mental and physical health-related quality of life. Findings will be translated into recommendations about implementing the e-care path.

Study objective

The effectiveness of the E-health self-management treatment on different domains will be examined.

Primarily, it is hypothesized that the treatment results in a lower level of psychological distress, and thereby might facilitate life style changes, in comparison to care as usual.

Secondarily, it is hypothesized that the E-health self-management treatment will:

1. result in personal goal achievement (that is, meaningful improvements on the areas of interest to the patient, e.g., healthy life style behavior, coping with fatigue, pain, negative mood, and social functioning);

2. increase disease-specific self-efficacy and self-management;

3. improve mental and physical health-related quality of life.

Study design

All patients will be screened on psychological barriers and related life style problems, after which those patients at risk will be randomly assigned to one of the two conditions. Participants in the intervention condition will receive a 3-month intervention. Patients in the control condition will receive care as usual. Assessments will be performed at baseline and 3 (post-treatment) and 6 months (3 months post-treatment) after baseline.

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 (that is, who insufficiently meet nephrology guidelines for a healthy life style) 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. In the intervention group, patients additionally receive (1) an intake with a psychologist (e-coach) to interpret and discuss results of the screening as displayed in the personal profile chart, make shared decisions on personal treatment goals and how to monitor progress on these goals, (2) a brief and tailored e-coach intervention based on cognitive-behavioral therapy to treat psychological distress, overcome barriers and promote facilitators for healthy life style behaviors for a period of approximately 3 months, and (3) a consultation with the psychologist after completing the e-coach trajectory for evaluation and long-term goals. Treatment will be guided by a psychologist who is specifically trained in the tailored cognitive-behavioral protocol.

Contacts

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Eligibility criteria

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

• Heightened psychological distress as indicated by questionnaires: Mild to moderately severe depression scores and/or mild to moderate anxiety scores

• At least one of the nephrology guidelines for healthy life style behavior is not met

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

• Severe psychological distress as indicated by questionnaires: Severe depression and/or anxiety scores

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

Ethics review

Positive opinion

Date:	11-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48539
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7338
NTR-old	NTR7555
CCMO	NL62540.058.17
OMON	NL-OMON48539

Study results