E-health cognitive behavioral therapy for living kidney donors - a pilot study

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The primary objective is the evaluation of the newly developed ehealth intervention, as regards to the feasibility and satisfaction of donors.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41051

Source
ToetsingOnline

Brief title
E-health cognitive behavioral therapy - pilot study

Condition

- Other condition

Synonym
kidney donors, living kidney donors

Health condition

nierdonoren

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Nierstichting Nederland

Intervention

Keyword: cognitive behavioral therapy, E-health, living kidney donors

Outcome measures

Primary outcome

The primary parameters are the feasibility and satisfaction about the newly

developed eheatlh intervention.

Secondary outcome

Not applicable

Study description

Background summary

Living donor kidney transplantation is the preferred treatment for patients with end-stage renal disease because of better long-term recipient and graft survival than after transplantation with deceased donor kidneys. Furthermore, the availability of a living donor kidney allows planning the transplantation before dialysis treatment becomes necessary. Combined with the shortage of organs from deceased donors, these advantages have led to a strong increase in the number of living donor kidney transplantations in recent years. For example, in the Netherlands, 51% of all kidney transplantations in 2012 was performed with kidneys from living donors compared with 27% in 1996. Donors have been found to have a high quality of life before donation, even better than that of the general population, which is probably due to the stringent medical screening for kidney donor eligibility. However, after donation about 5-25% of donors experience problems in physical or psychosocial functioning, such as depressed mood, fatigue, or pain. For example, by feeling more depressed after donation, or perceiving the surgery and recovery period as stressful, or worrying about surgical complications, recipients* health, their own health, or their work situation after donation. Currently, no evidence-based interventions for living kidney donors at risk are available.

Preliminary research indicates that ehealth cognitive-behavioral interventions are about as effective as face-to-face contact for a broad range of psychological problems, such as anxiety and depression. The applicability of ehealth interventions for patients with chronic somatic conditions have also been examined, and a recent meta-analytic review found that guided ehealth

cognitive-behavioral interventions appears to be an effective treatment for chronic somatic conditions to improve psychological and physical functioning and disease-related impact. Based on evidence-based interventions for patients with chronic somatic conditions, a ehealth intervention for (potential) donors at risk was developed. Focus group interviews with living kidney donors and healthcare professionals were conducted to explore donation-related themes which could be implemented in the intervention.

In the present study, the ehealth intervention will be evaluated by a small group of donors. This intervention is applicable during various stages of the living kidney donation procedure, before donation as well as after donation.

Study objective

The primary objective is the evaluation of the newly developed ehealth intervention, as regards to the feasibility and satisfaction of donors.

Study design

The present study is a pilot intervention study of a small group of (potential) living kidney donors.

Procedure:
Inform
All potential donors who have contacted the hospital for a possible kidney donation and have found to be suitable as kidney donors will be invited to participate in the pilot study, by an information letter.

Screening
Patients who are willing to participate will receive specific information about the screening and a questionnaire to assess potential risk factors for longer-term adaptational problems. Patients will be informed about the results of the questionnaire assessment by mail. Donors who can possibly take advantage of the ehealth treatment receive further information about the cognitive-behavioral intervention, together with an application form.

The intervention: ehealth treatment
Every patient who possibly could take advantage of the ehealth treatment, and who is willing to participate will receive ehealth care with tailored cognitive-behavioral therapy during several weeks.

Evaluation:
After finishing the ehealth treatment, donors will be asked to fill in the evaluation questionnaire.

Intervention

First, one face-to-face consult with the therapist takes place, for acquaintance and to explore treatment goals of the donor. Then tailored cognitive-behavioral therapy will be offered through ehealth, consisting of about eight sessions. One or two out of four possible treatment modules will be offered during the treatment, depending on the risk profile of the donors. The treatment modules are: coping with problems in social relationships, negative mood, fatigue, (temporary) physical disability and pain, and consists about patient education and practical assignments. At least once a week donors will receive feedback from their therapist about the assignments, by means of a mail box. Treatment will be conducted by a therapist who is specifically trained in the tailored cognitive-behavioral protocol.

Study burden and risks

For the participating donors, there are no risks connected to the study. We only ask donors to invest some of their time.

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

medically and psychosocially suitable potential donors or living donors who recently donated, above 18 years old, fluent in Dutch language.

Exclusion criteria

severe psychiatric comorbidity that interferes with the treatment protocol, ongoing psychological treatment elsewhere, pregnancy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2014
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL50145.091.14