Dyadic coping with renal transplant and renal disease

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON32608

Source
ToetsingOnline

Brief title
DCRT

Condition

- Renal disorders (excl nephropathies)

Synonym
kidney disease, renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adjustment to illness, dyadic coping, renal transplantation, well-being

Outcome measures

Primary outcome

This study aims at gaining insight into psychosocial well-being of partners of patients who have undergone renal transplantation, in terms of affect and marital satisfaction, and at gaining insight into dyadic processes of well-being and medical adjustment over time.

Secondary outcome

N.v.t.

Study description

Background summary

Dealing with the consequences of end-stage renal disease (ESRD) as well as renal transplantation (RT) is a challenging task. Both do not only impact patients, but also their social environment, most notably their partners, and dealing with the disease can be seen as a joint effort of the couple. However, research concerning psychosocial well-being of partners and dyadic coping with ESRD and RT is scarce. This study aims to fill this gap by examining the emotional well-being of partners and the couple during the phase of ESRD, while patients are on a waiting list for RT, and after RT. In addition, we propose to examine the role of interpersonal variables in psychosocial well-being of both patients and partners. Attention will also be paid to the role of these factors in patients* adherence to medical regimen and dietary and exercise recommendations after RT.

Study objective

The objective of the study is threefold:

1) to examine the psychosocial well-being of partners after patients have undergone RT, as a function of gender
of the partner and medical characteristics of the patient.

2) to examine interpersonal factors that are associated with psychosocial well-being in patients as well as
their partners and patients* adherence to medical regimen, dietary and exercise recommendations after RT.

3) to investigate the psychosocial well-being and adjustment of couples during the phase of end-stage renal
disease (ESRD), while patients are on a waiting list, and after RT.

Study design

The proposed study is part of an ongoing project designed to examine the short- and long-term impact of end stage renal disease (ESRD) and renal transplantation (RT) on quality of life of patients. In this ongoing project the goal is to gain insight into factors that predict adherence to medical regimen, as well as compliance with dietary and exercise recommendations of patients during the first year after transplantation. The current study is aimed at the partners of patients that have undergone transplantation and consists of a cross-sectional and a prospective part. Partners will be contacted along with the patients in the ART-study at the set time points.
In the patient cohort study of the ART-project, patients who had undergone renal transplantation in the UMCG during the past fifteen years filled out a questionnaire assessing their quality of life and several psychosocial variables. For the current cross-sectional study, an invitation card for the partners was already sent together with the patient questionnaires. Also, partners already sent back the permission forms allowing the researchers to contact them for further information about the study. After giving informed consent for participation, a self-report questionnaire will also be sent to these partners by mail by the research team.
In the prospective part of the ART-project, the following patients will be included: patients who are currently on the waiting list for transplantation at one assessment point before transplantation and then again at three, six, twelve and twenty-four months after transplantation. For the proposed prospective part of the partner study, the same procedure as for the cross-sectional part will be followed. First, an invitation form will be send together with the patient questionnaires. After getting permission, the informed consent form and the partner questionnaire will be send as well.

Study burden and risks

For the cross-sectional study, partners of the patients who underwent RT will be approached for participation. This will be done as follows: patients in the ART-study (nr. 800616), who were invited also received information about the current partner study to be shared with their partners. Partners who were interested could return an invitation card indicating their permission to be contacted by the research team. Partners who returned the invitation card will

be sent an information letter and an informed consent form. After giving informed consent for participation, a self-report questionnaire will be sent to the partners by the research team. This procedure will be followed in the prospective study as well.
The questionnaire will take approximately one hour to complete. Assessed are psychosocial well-being and several interpersonal factors, such as communication patterns with the couple and provided support. No adverse events should be expected from participation.

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

Patients who have undergone renal transplantation at the UMCG during the past 15 years and their partners will be included in the study. Patients and partners have to be at least 18

years of age at the first assessment. The study is open to both men and women and all ethnic groups as long as participants are in command of the Dutch language.

Exclusion criteria

As blind patients and partners will not be able to read the questionnaires, they will be excluded.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2019
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL25903.042.08