Psychosocial predictors for adjustment to renal transplantation

Published: 20-11-2008
Last updated: 11-05-2024

The purpose of the study is threefold. First, to describe the course of quality of life after renal transplantation and to identify predictors of (un)succesful adjustment. Second, to investigate intra- and interindividual differences that influence...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Observational non invasive

Summary

ID

NL-OMON32153

Source
ToetsingOnline

Brief title
ART

Condition

- Nephropathies
- Renal and urinary tract therapeutic procedures

Synonym
end stage renal disease (ESRD) or kidney failure

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, goal adjustment, kidney transplantation, perceived control

Outcome measures

Primary outcome

Patients quality of life in terms of physical, psychological and social

functioning is the main study parameter.

Secondary outcome

The second endpoint is the the occurrence of complications.

Study description

Background summary

There is strong consensus favoring renal transplantation (RT) as the treatment of choice for End Stage Renal Disease (ESRD) in terms of quality of life (QoL). Although QoL generally increases, it is still unclear how individual characteristics contribute to this improvement. A range of factors - medical, behavioural and psychological - will in concert and in a complex interplay affect the quality of life of the patient. Medical complications, for example will affect patients* QoL, but at the same time the occurrence of complications can at least partly be prevented by strict adherence to the medical regimen. One of the key goals of research into psychosocial adaptation is to determine why some people are better able to adjust to new circumstances than others. Insights in the determinants is necessary to design optimal interventions. The focus of the current study will therefore be, to identify which of these variables can reliably predict the quality of life of patients after renal transplantation.

Study objective

The purpose of the study is threefold. First, to describe the course of quality of life after renal transplantation and to identify predictors of (un)succesful adjustment. Second, to investigate intra- and interindividual differences that influence the process of adjustment and thereby patients* quality of life. Third, to gain more insight into patients* adherence to medication regimes and its contribution to complications and rejection.

Study design

This study consists of two parts. In a cohort study patients who have undergone renal transplantation in the UMCG during the past fifteen years will be included and assessed once. In the prospective study we will include patients that are currently on the waiting list for transplantation at one assessment point before transplantation. To be able to follow the process of adjustment in time, patients will be assessed again at three, six, twelve and twenty-four months after transplantation.

Study burden and risks

In order to gain insight in the adaptation process self-report measures will be employed. Patients have to complete a self-report measure at one time before transplantation (T0) and four points after transplantation (T1-T4). The assessments will take approximately 60 minutes at all assessment points. Patients will be given the opportunity to complete the questionnaires in stages to minimize the burden on the patient. Total assessment time over a two year period will be approximately 5 hours. No adverse events should be expected from participation.

Contacts

Public
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
9713 AV Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
9713 AV Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

on waiting list or approved for kidney transplantation
18 years and older
in command of the Dutch language
not visually disabled

Exclusion criteria

18 years or younger
not in command of the Dutch language
visually disabled

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2008
Enrollment:	1700
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	NL20647.042.07