Education on renal replacement therapy to kidney patients in the pre treatment phase and their social network: a home based approach

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

Summary

ID

NL-OMON34599

Source
ToetsingOnline

Brief title
Kidney patient education

Condition

- Renal disorders (excl nephropathies)

Synonym
Kidney disease, renal failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Dialysis, Patient education, Renal failure, Transplantation

Outcome measures

Primary outcome

The primary outcomes are change in knowledge, attitude, and communication about

RRT among both the patient and their family and friends.

Secondary outcome

The secondary outcome is the proportion of patients who undergo haemodialysis,

peritoneal dialysis or pre-emptive transplantation as their first form of RRT.

Study description

Background summary

Transplantation with the kidney from a living donor has significant advantages for patient and transplant survival when compared to transplantation with a kidney from a cadaveric donor. Moreover, patient and transplant survival is most optimal when dialysis can be completely avoided. However, a large proportion of patients first start dialysis before they are transplanted with a kidney from a living donor. The goal of this project is to gain insights into the factors which play a roll in pre-emptive transplantation and based on this knowledge to improve the patient education in the pre treatment phase.

Study objective

The main aim is to develop an intervention to change knowledge, communication and attitudes regarding renal replacement therapy (RRT). The second main aim is to investigate whether this intervention has an impact on the proportion of patients undergoing haemodialysis, peritoneal dialysis or transplantation as their first form of RRT.

Study design

Prospective randomised cross-over study.

Intervention

The intervention consists of a first intake consultation and a home-based educational meeting. The patient invites their family and friends to attend the house-call educational meeting. During this meeting the social worker will discuss the kidney, kidney disease, possible treatment options, and the consequences for quality of life. There will be the possibility to ask questions and to discuss these topics. Written information (leaflets) will be left behind after the meeting.

Study burden and risks

Participants will be asked to complete 3 questionnaires (T0, T1, & T2). The kidney patient will host the meeting in their home which could be stressful. If desired the meeting can therefore take place at another location outside the hospital. Participation in the educational meeting could be confronting for both the patient and their family as this will take place early in the clinical course during a largely asymptomatic phase. Due to the patient-centred nature of this study participants will not be asked to make extra trips to the hospital and no extra physical test will be carried out. Those under 18 years of age will not be included in the study.

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

1. Indication for renal replacement therapy within 1 or 2 years (MDRD 25 ml/min)
2. 18 years and above

Exclusion criteria

1. Participants must have sufficient understanding of written and spoken Dutch (in order to be able to give fully informed consent and to complete the questionnaires).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	240

Type:	Actual

Ethics review

Approved WMO Date:	01-11-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL33591.078.10