

Early education on renal replacement therapy to kidney patients in the pre treatment phase and their social network: A home based approach.

No registrations found.

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

Summary

ID

NL-OMON22472

Source

Nationaal Trial Register

Health condition

Kidney disease

Kidney failure

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam

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

Intervention

Outcome measures

Primary outcome

Patients:

1. Attitude towards renal replacement therapy: T0, T1, T2;
2. Attitude towards communication on renal replacement therapy: T0, T1, T2;
3. Communication about renal replacement therapy: T0, T1, T2;
4. Knowledge about renal replacement therapy: T0, T1, T2;
5. Subjective norm: T0, T1, T2;
6. Perception of control: T0, T1, T2;
7. Anticipated regret: T0, T1, T2;
8. Selfidentity: T0, T1, T2;
9. Intention to communicate about renal replacement therapy options. T0, T1, T2;
10. Moral norm: T0, T1, T2.

Social network (family and friends of the patient):

1. Attitude towards communication on renal replacement therapy: T0, T1;
2. Attitude towards living donation: T0, T1;
3. Communication about renal replacement therapy: T0, T1;
4. Knowledge about renal replacement therapy: T0, T1;
5. Subjective norm: T0, T1;
6. Perception of control: T0, T1;
7. Anticipated regret: T0, T1;
8. Selfidentity: T0, T1;
9. Intention to communicate about renal replacement therapy options. T0, T1.

Secondary outcome

The proportion of patients who undergo dialysis or transplantation as their first renal replacement therapy.

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 deceased 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 main aim of this study is to develop an intervention to change knowledge, communication and attitudes regarding renal replacement therapy (RRT). The second 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.

This is a prospective randomised cross-over study. Patients with a MDRD of 25 ml/min for whom there is an indication for RRT within 1 or 2 years are included. Family and friends of these patients will also be invited to participate.

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. The educational meetings will be carried out by trained medical social workers in 4 hospitals in the Rotterdam area.

Primary study outcome of the study: Change in knowledge, attitude, and communication about RRT among both the patient and their family and friends.

Secondary study outcome of the study: The proportion of patients who undergo haemodialysis, peritoneal dialysis or pre-emptive transplantation as their first form of RRT.

Study objective

1. Participation in an early home-based education programme compared to care as usual will significantly increase knowledge on kidney disease and treatment options, communication on renal replacement options and promote a positive attitude towards transplantation compared to dialysis;
2. Participation in the early home-based education programme will be related to greater likelihood of undergoing a pre-emptive renal transplantation.

Study design

Patients: T0, T1, T2.

At baseline all patients will complete the questionnaire during the first consultation. Between T0 and T1 Group 1 will receive the intervention while Group 2 receives care-as-usual. At T1 (4 weeks later) all patients complete the same questionnaire. Between T1 and T2, Group 1 will receive care-as-usual while Group 2 receives the intervention. All patients will complete the questionnaire at T2 (4 weeks after T1).

Social network: T0, T1.

All family and friends of the patient who are invited to attend the educational meeting will receive an invitation along with the T0 questionnaire. T1 will be handed out after the educational meeting to be completed within one week.

Intervention

An early education programme (consisting of an introductory session and a group education session for patient and their social network in the home of the patient) versus care as usual (regular patient education in the hospital and care from the treating nephrologist).

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients for which there is a medical indication for renal replacement therapy within 1 to 2 years (25 MDRD ml/min taking into account the rate of progression);
2. Patients > 18 years;
3. Family and friends of the patient > 18 years of age.

Exclusion criteria

Patients or family/friends who are unable to read or speak the Dutch language sufficiently.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion	
Date:	03-02-2011
Application type:	First submission

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
NTR-new	NL2605
NTR-old	NTR2733
Other	Nierstichting : SB115
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Massey et al. Justification for a home-based education programme for kidney patients and their social network prior to renal replacement therapy. Submitted.