Multisystemic Engagement & Nephrology Based Educational Intervention: A Randomized Controlled Trial Protocol on the Kidney Team at Home-Study (KTAH-Study)

No registrations found.

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

Summary

ID

NL-OMON21827

Source
NTR

Brief title
Kidney Team At Home

Health condition

Living kidney transplantation rates have been increasing and now even exceed those of deceased donor kidney transplantation in the Netherlands (Roodnat, et al., 2009). However, there is inequality in access to the living kidney donation program between European and the non-European patients. In our center we have 44% non-European patients with terminal kidney failure who are on the waiting list for a deceased donor kidney. However, these patients represent only 17% of the patients in the living kidney program (period: 2000-2010).

Sponsors and support

Primary sponsor: Nierstichting Nederland; Dutch Kidney Foundation
Source(s) of monetary or material Support: = Sponsor

Intervention

Outcome measures

Primary outcome

The primary parameters of the intervention are derived from the ASE-Model. This model is based on the theory of Theory of Planned Behaviour (TPB) of Fishbein and Ajzen (19) and is supplemented by elements from the Social Cognitive Theory (SCT) of Bandura (20). The ASE-Model has a wide scientific acceptance and represents a theoretical framework for explaining behaviour by connecting attitude, social influence, self-efficacy, knowledge, skills (communication), and barriers and resources (risk perception) to intention and behaviour.

Secondary outcome

Secondary outcomes are the number applications for donor evaluation, the number of evaluations for living donation and the number of live kidney transplants among patients who participated in the study.

Study description

Background summary

We found nearly all patients to be in favour of LDKT (96%). However, multiple prohibiting and interrelated factors played a role in considering LDKT. We propose a model which addresses these factors as barriers to LDKT in our non-European patients. These barriers are:

1. A perceived gap in information;

2. Cognitions and emotions;

3. Social interference;

4. Non-communication with family and friends.

Additionally, we found that our patients held a welcoming attitude towards tailored education program, for instance a home-based education.

Study objective

Primary outcomes with respect to living donation are: Knowledge, risk perception, subjective norm, communication and intention to engage in a certain behavior (choosing living donation). These concepts will be measured among the patient as well as their family and

friends. We expect that they will show increased scores on the post-measurements compared to the pre-measurements. Secondary outcomes are the number applications for donor evaluation, the number of evaluations for living donation and the number of live kidney transplants among patients who participated in the study. Three months after the intervention we will compare the groups on these measures.

Study design

At start, 4 weeks later and 3 months later.

Intervention

Patients will receive the study information after their second consultation with the nephrologist at the outpatient pre-transplantation clinic. The intervention consists primarily of two sessions at the patient's home. The first session (familiarization session) will be planned after patients have given their consent to participate. This interview is held with the patient alone. During this first session, a sociogram of the social environment will be constructed in order to determine which family members and/or friends (invitees) will be invited to the educational session. The second session (educational session) consists a meeting at the patient's home. This time it is intended that the invitees are present at the patient's home. In this session topics about kidney disease and possible forms of treatment will be discussed. We grant our patients that this discussion will be held in a save ambiance. In order to realize a save communication environment we will work with the therapeutic framework of systemic therapy.

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Eligibility criteria

Inclusion criteria

The participants consist of kidney patients from the Rotterdam region who are new to the outpatient pre-transplantation clinic (incidence cases) or who are already on the EuroTransplant waiting list (prevalence cases).

Exclusion criteria

We will only include patients without a living donor and patients and family/friends who are 18 years or over.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-02-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36497
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2602
NTR-old	NTR2730
CCMO	NL34535.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36497

Study results

Summary results
Ismail SY, Luchtenburg AE, Massey EK, Claassens L, Busschbach JJ, Weimar W. Living kidney donation among ethnic minorities: A Dutch qualitative study on attitudes, communication, knowledge and needs of kidney patients. http://repubeurnl/resource/pub_20862/indexhtml. 2010;8.