'Kidney Team At Home'; Health education on kidney transplantation and the different transplantation options for kidney patients and their family and friends'

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The main objective of this research is to contribute to the elimination of disparities in care between Dutch and non-Dutch kidney patients where living donation is concerned. The primary objective is evaluating the effectiveness of an intervention...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract disorders congenital
Study type	Interventional

Summary

ID

NL-OMON36497

Source
ToetsingOnline

Brief title
'Kidney Team at Home'

Condition

- Renal and urinary tract disorders congenital
- Nephropathies
- Family issues

Synonym
Kidney failure; Kidney disease

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: Family and friends, Health education, Homebased, Kidney Transplantatie

Outcome measures

Primary outcome

The primary parameters of the intervention were based on the concepts two theories namely, the "Protection Motivation Theory' (PMT) and the 'Theory of Planned Behaviour* (TPB). These theories have their roots in the behavioral health psychology and are aimed at promoting health behaviour. The choice for the PMT was made because this theory can explain why people don*t follow through with health promoting behaviours. However, this theory doesn*t reckon social influence. Therefore, also parts of the Theory of Planned Behaviour (TPB) will be used. On the other hand, we also partially defined our concepts by the identified barriers from our previous research which was conducted within our patient population. Primary outcomes with respect to living donation have become: knowledge, risk perception, subjective norm, communication and intention to engage in a certain behavior. These concepts will be measured in the patients population as well as the invitees. In addition, we evaluated the educational session (in terms of product- and process evaluation) through the patients and the invitees but also through the researchers).

Secondary outcome

Secondary outcomes are the number applications for evaluation with respect to living donation from potential donors, the number of evaluations for living donation and the number of live kidney transplants among patients who participated in the study. We will also record additional information such as the number of attendees.

Study description

Background summary

Living kidney donation offers an alternative for many patients with a cadaveric kidney transplantation: in the Netherlands about half of all kidney transplantations are performed with a living kidney donor. In Rotterdam, even towards 72% (august 2010). Advantages of live transplantation include a shorter waiting time, a planned operation and a better graft and patient survival (Hariharan et al., 2000). However, patients of non-Dutch origin make less use of living donation: 15% of patients transplanted using a kidney from a living donor are of non-Dutch origin, while 44% of patients on the waiting list for a cadaveric kidney are from non-Dutch origin. The reasons for this difference between the Dutch and the non-Dutch are unclear and have in the Netherlands so far not been investigated. It may be that the hospital informational material is not sufficient enough or that communication about living donation in the family and the community entails other aspects than with Dutch patients. Previous research has actually shown that the jamming of the communication about living donation can easily lead to not fulfilling a living donation wish (Kranenburg et al., 2007).

Study objective

The main objective of this research is to contribute to the elimination of disparities in care between Dutch and non-Dutch kidney patients where living donation is concerned. The primary objective is evaluating the effectiveness of an intervention aimed at improving knowledge and commucation between patient and relatives about living kidney donation. This is done by evaluating whether our patients have reached a stage of informed decision-making, while taking into account the stability of relationships and respect for the individual autonomy and feelings. The secondary objective is evaluating whether the inequality in health usage regarding living donation is elevated. This latter is done by looking at the numbers of preformed living donations between the

Dutch and the non-Dutch patients.

Study design

This is a prospective randomized study. Patients will be divided into two groups (a control group and an experimental group) after giving their consent to participate. The experimental group will receive a home-based educational program in addition to the regular care while the control group continues receiving the regular care. We will ensure an equal distribution between the control and experimental group regarding the Dutch and the non-Dutch. In total 80 participants will be included per year in the study (40 Dutch and 40 non-Dutch participants per group). During a previsit we will discuss the invitational list (family and/or friends) with the patient.

Intervention

Patients will receive the study information after their second consultation with the nephrologist at the outpatient pretransplantation clinic. After this a request for participation will be made to them. The intervention consists primarily of two sessions at the patient's home. The first session (familiarization session) will occur 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) may possibly attend the the educational session. The second session (educational session) includes 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 will perform pre- (before the familiarization session) and post (a couple days after the educational session) measures regarding several relevant concepts (e.g. knowledge, attitudes, risk perception, intentions, etc.).

Study burden and risks

Discuss a subject like living kidney donation can be difficult for patients and their family and/or friends. Using elements of Multi System Therapy can be helpful. Multi System Therapy (MST) is originally an evidence-based family intervention, respecting the roles, interests and wishs of the members of the family. In this therapy genuine communication, autonomy and self (patient empowerment) are crucial rather than behavioral problems.
Kidney patients who end up in the intervention group, are hosts for the meeting at their houses this too can be seen as a burden. We can, if desired, let the meetings take place at another location. Because of this patient-centered approach, patients do not have to allocate extra time and effort for the intervention like visiting the hospital. No additional physical examinations are performed. All this is done, to make the intervention as comfortable as

possible for the participants.

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: Patients invited for this study consist out of kidney patients from the treatment region Rotterdam who are new to the outpatient preplantation clinic (incidence cases) or who are already on the waiting list of Eurotransplant (prevalence cases). With regard to the objective of the study we will only include patients without a living donor. Only kidney patients of 18 years or older will participate. ;The to be included invitees must also be 18 years or older.

Exclusion criteria

There will not be an exclusion criteria for patients and invitees.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-04-2011
Enrollment:	480
Type:	Actual

Ethics review

Approved WMO

Date:	07-04-2011
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

ID: 21827
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34535.078.10
OMON	NL-OMON21827