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

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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...

Ethische beoordeling Positief advies **Status** Werving gestart

Type aandoening -

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON21827

Bron

NTR

Verkorte titel

Kidney Team At Home

Aandoening

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).

Ondersteuning

Primaire sponsor: Nierstichting Nederland; Dutch Kidney Foundation

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Overige ondersteuning: = Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

At start, 4 weeks later and 3 months later.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Gerandomiseerd

Blindering: Enkelblind

Controle: Geneesmiddel

Deelname

Nederland

Status: Werving gestart

(Verwachte) startdatum: 01-03-2011

Aantal proefpersonen: 160

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 02-02-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36497

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

RegisterIDNTR-newNL2602NTR-oldNTR2730

CCMO NL34535.078.10

ISRCTN wordt niet meer aangevraagd.

OMON NL-OMON36497

Resultaten

Samenvatting resultaten

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.