Transplantatie begeleiding op maat

No registrations found.

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

Summary

ID

NL-OMON21249

Source
Nationaal Trial Register

Brief title
MARS trial

Health condition

Kidney transplantation, adherence, self-management, health psychology

Niertransplantatie, therapietrouw, zelfmanagement, medische psychologie

Sponsors and support

Primary sponsor: Performer: Erasmus MC, University Medical Center Rotterdam
Source(s) of monetary or material Support: Sponsor project: Dutch Kidney Foundation

Sponsoring Electronic Monitoring Devices: Astellas

Intervention

Outcome measures

Primary outcome

The primary outcome of this RCT is adherence to the immunosuppressive medication (IM) regimen as measured with electronic monitoring.

Secondary outcome

The secondary outcomes of the intervention are:

- Adherence to the IM regimen as measured with a composite adherence score

- Medical outcomes such as intra patient variability, rejection, kidney functioning, and hospitalisations

- Psychosocial outcomes for the patient, such as self-managament skills, quality of life, self-efficacy, mental health and social support.

- Psychosocial outcomes for important other in the social network of the patient, such as mental health, quality of life, and social support.

Study description

Background summary

Background of the study:

Nonadherence to the lifelong medication and lifestyle recommendations after transplantation has been identified as a major cause of acute and chronic rejection, mortality and decreased quality of life. However, studies have shown the prevalence of nonadherence to be relatively high among all age groups (30% - 65%). Among other chronic diseases, interventions promoting adherence and self-management appear to be effective in influencing aforementioned consequences of nonadherence. Ellis et al. showed that a multisystemic intervention among diabetes, asthma and HIV patients was effective in promoting medication adherence. Effective interventions for promoting adherence and self-management among kidney transplant recipients are however scarce and the urgent need for these interventions has been highlighted in a number of systematic reviews.

Objective of the study:

In this project we aim to anticipate the need for effective interventions and develop an outreaching systemic intervention for promoting adherence and self-management among adolescent and adult kidney transplant recipients aged from 12 years. The effectiveness of the intervention will be tested in a Randomized Controlled Trial (RCT). Consecutively, we aim to develop a manual and training module in order to facilitate implementation of the intervention.

Study design:

A RCT will be conducted to assess the effectiveness of the intervention. Data will be collected at baseline (T0), after a run-in period of 35 days necessary for patients to get adjusted to the electronic monitoring (T1), at the end of the intervention (T2) and after a 6 month follow-up (T3). The data collection of participants in the control group will be at similar time points.

Study population:

The aim is to recruit 162 patients; 81 patients in the experimental condition (intervention group), 81 patients in the control group. The study population consists of kidney transplant recipients aged 12 years and older. To be eligible for inclusion it is necessary that the patient is non-adherent as specified by either an indication from the nephrologist and/or nurse practitioner, themselves (self-report) or by an important other of the patient. Patients eligible for inclusion received a deceased or living donor kidney transplant in the Erasmus Medical Center Rotterdam. However, it is not necessary for patients to have their regular check-up in the Erasmus Medical Center Rotterdam, as long as they have their annual check-up in Erasmus Medical Center Rotterdam. In the time between the annual check-ups in de Erasmus Medical Center Rotterdam, nephrologists from local hospitals can also refer patients for inclusion when inclusion criteria are met.

Intervention

During the RCT participants will be assigned to the experimental condition (intervention group) or the control group. Intervention group: Patients assigned to the intervention group will receive an outreaching, systemic, adherence promoting intervention in addition to the treatment as usual. The social network of the patient will be involved in the intervention. The patient and an important other of the patient will complete baseline and follow-up measures. Control group: Patients assigned to the control group will receive treatment as usual, which consists of consultations with the nephrologist and nurse practitioner, and upon indication with the social worker. Non-adherence issues are addressed during these consultations in the outpatient clinic on indication. Patients in the control group will complete the same baseline and follow-up measures as participants in the intervention group .

Primary study parameters/outcome of the study:

The main parameter/endpoint of the study is the difference in adherence to the immunosuppressive medication between patients in the control group and patients in the experimental condition, as measured with electronic monitoring.

Secundary study parameters/outcome of the study: Medication nonadherence will be primarily measured with electronic measuring. However, measuring medication adherence is very complex. Therefore, secondary measures for medication nonadherence are included. A composite adherence score will be calculated, based on self-report of the patient, collateral report of an important person in the social network of the patient and a collateral report of

the nephrologist of the patient. Furthermore, biological markers such as intrapatient variability of medication bloodlevels will be assessed as well. Other secondary outcome measures are self-management, quality of life and other mental health outcomes. Since the social network plays in important role in the intervention relationship quality will be assessed, as well as quality of life and mental health of an important other in the social network.

Study objective

- It is hypothesized that a tailored, outreaching and systemic intervention promotes medication adherence

- It is hypothesized that a tailored, outreaching and systemic intervention has a beneficiary effect on other medical as well as psychological and social outcomes.

Study design

T0 - Baseline measurement

T1 - Measurement after 35 days run-in period

T2 - Measurement at end of intervention (6 months ofter T1)

T3 - Follow-up measure (6 months after end intervention)

Intervention

During the study the experimental group will receive an outreaching, systemic (involving family & social network), tailored intervention to promote medication adherence and self-management after transplantation. The intervention is outreaching as the sessions will be held outside the hospital setting so as to make participation as easy as possible and to create a safe and open environment. The intervention is systemic since individuals in the social network can positively and negatively influence behavior. We aim to harness and promote facilitating factors in the environment to promote adherence and ensure continuity once the intervention had finished. The intervention is tailored as an assessment is made of each patient and the determinants of their behavior and strategies are employed to fit this specific situation. The intervention consists of five different phases, assessment phase, goal setting phase, treatment phase, consolidation & adjustment phase, and a generalization & evaluation phase. During the assessment phase specific problems and its determinants are assessed after which specific goals are set during the goal setting phase. In the treatment phase evidence-based strategies for anticipating the determinants are discussed with the patient and the network. During the last two phases necessary adjustments will be made, new behavior will be ratified and evaluated. There is no pre-set number of sessions per patient. Assessing the number of sessions required to achieve results will be part of the evaluation. The maximum duration of the intervention will be 6 months.

Contacts

Public
Erasmus MC
Postbus 2040
E.K. Massey
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033451
Scientific
Erasmus MC
Postbus 2040
E.K. Massey
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033451

Eligibility criteria

Inclusion criteria

- Functioning kidney transplant

- Aged 12 years and above (no upper limit is set)

- Report of nonadherence (to immunosuppressive medication) by either the patient (self-report), the health care professional (collateral report) or an important person from the social network of the patient (collateral report)

Exclusion criteria

- Patients who are not classified as non-adherent to the immunosuppressive medication

- Patients on dialysis at the start of the intervention

- Insufficient level of speaking and understanding Dutch language to complete the questionnaires

- pre-transplant patients

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2018
Enrollment:	162
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-09-2018
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	NL7264
NTR-old	NTR7462
Other	Erasmus MC : MEC-2018-125

Study results