promoting Medication AdheRence and Self-management among kidney transplant recipients: a randomized controlled trial (the MARS Trial)

Published: 06-09-2018
Last updated: 11-04-2024

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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46035

Source
ToetsingOnline

Brief title
MARS-Trial

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
kidney transplantation, Renal transplantation

Health condition

Transplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Astellas Pharma,Nierstichting en Astellas (Farmacie)

Intervention

Keyword: Medication Adherence, Psychotherapeutic Intervention, Social Support, Transplantation

Outcome measures

Primary outcome

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. The electronic monitoring device can be adjusted to the dosette box for medication which is used by the majority of patients after transplantation. After taking the immunosuppressive medication the patient needs to push the button of the device, so medication intake can be registered.

Secondary outcome

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 description

Background summary

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.

Study objective

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.

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 .

Study burden and risks

Participating in the current study does not add a high medical or psychological risk. On the contrary, it is believed that the patient will benefit from the intervention. Since only non-adherent patients are eligible for inclusion, these patients also run a high risk of serious consequences due to the problems associated with non-adherence to the medical regimen. The intervention aims to improve adherence and selfmanagement, which decreases the occurrence of consequences. Furthermore, when psychological risks are noticed, psychological strategies to anticipate these risks are carried out. When risks are beyond to the scope of the intervention, patients will be referred to a professional.

The time spent participating in the intervention can be experienced as a burden. However, given the seriousness of the problem and the possibility to intervene with this intervention this burden is justified. Involving the social network may be demanding but it is hypothesized that results will be more sustainable when empowering both the patient and the network. Furthermore, several measures are taken to minimize the burden for the patients. Firstly, the intervention is outreaching and can take place on a location the patient prefers, for example at home which safes the patient some time. Secondly, the intervention is tailored to the needs of the patient and the social network. Therefore, we are not restricted to unnecessary yet protocolized steps predetermined in an intervention protocol. Duration and frequency of appointments are also adjusted to the preferences of the patient and social network. Moreover, patients can refuse participation or withdraw at any time.

The burden of the use of an electronic monitoring device can be considered as very little since it only requires for the patient to push a button. The dosette box which the device can be adjusted is already used by the majority of the patients, but can also be used with other ways of storing medication. Therefore, using the device does not require an adaptation to the medication

routine apart from pushing the button.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Functioning kidney transplant
- Aged 12 years and above (no upper limit set)
- Report of nonadherence (to immunosuppressive medication) by either the patient (self-report), medical specialist (collateral report) or important other (collateral report)

Exclusion criteria

- Patients who are not classified as non-adherent to the immunosuppressive medication based on a composite adherence score
- 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2018
Enrollment:	324
Type:	Actual

Ethics review

Approved WMO Date:	06-09-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2019
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2020
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL66382.078.18