aanZET study - A positive approach to self-management after transplantation

No registrations found.

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

Summary

ID

NL-OMON24150

Source
Nationaal Trial Register

Brief title
aanZET

Health condition

Heart transplantation, liver transplantation, lung transplantation, kidney transplantation

Sponsors and support

Primary sponsor: Performer: Erasmus Medical Center
Source(s) of monetary or material Support: Chiesi Pharmaceuticals B.V.

Intervention

Outcome measures

Primary outcome

Test if the intervention has an actual effect on patients’ self-regulation and self-management skills in the context of transplantation

Secondary outcome

- To test the effectiveness of the intervention in improving secondary patient-outcomes:
* Self-regulation skills
* Quality of life
* Medication adherence
* Coping
* Self-efficacy
* Quality of nurse-led care
- To test the experience of nurse-led care and experience of the self-management intervention
- To test the effect of the programme on nurse-outcomes of self-management support competencies and confidence levels
among NPs who implement the programme.
- To conduct a process evaluation to assess patient and nurse-related factors which may influence the effectiveness of the
intervention, such as protocol adherence.

Study description

Background summary

Background: Patients report the need for a more holistic approach to health care after organ transplantation. After organ transplantation, recipients face a number of challenges and changes in behaviour are often required. Challenges include lifelong immunosuppressive medication, monitoring symptoms and side effects, clinic appointments, communication with healthcare professionals, lifestyle changes and coping with psychological consequences of transplantation such as acceptance of the organ and changes in roles and relationships. Optimal self-management is essential for patients and graft survival and can impact on quality of life. However, there are few interventions aimed at promoting post-transplant self-management. The interventions that exist tend to focus on promoting medication adherence, to the detriment of other social, role and emotional challenges that are, for patients, equally important. In order to fill this gap, together with patients, nurses, and self-management experts, we developed a nurse-led, holistic, solution-focused self-management support intervention to promote self-management after transplantation. Whether the intervention has an effect on outcomes will be tested in this multi-center randomized study.

Objective: The main focus of this study will be whether or not the intervention has an effect of behaviour, cognitions and emotions of patients and on nurses' self-management support skills.

Study design & procedure: Stepped wedge cluster randomized design. Randomization is on the level of the department. Patients will be required to complete a baseline questionnaire (T0), a questionnaire six months after inclusion (post-intervention for the patient in the intervention period) (T1) and a questionnaire twelve months after inclusion (T2). The nurse practitioner will fill in a questionnaire at the baseline (T0), which is the transition period from

control to intervention period and at the end of the intervention period. During the control period patients in each department will receive questionnaires to complete but will not receive the intervention. During the experimental period patients in each department will receive questionnaires to complete plus the programme.

Study population: Recipients two to six months after transplantation will be invited to participate. Inclusion criteria include age (over 18 years), sufficient command of Dutch language, and a functioning graft.

Intervention: Over four sessions combined with the standard consultations, patient-centered self-management support is offered. In the first step, 14 life areas will be assessed and discussed using a conversation aid, the Self-Management Web. Patients indicate priorities for goal setting and thus determine the agenda of subsequent sessions. In the subsequent sessions nurse practitioners support patients in setting personal goals, action plans, and monitoring in areas where the patient felt improvement is a priority. Motivation, self-efficacy and attributions of success are discussed. The final step is generalization to other self-management challenges. Prior to implementation, at the moment of conversion from control to intervention period, nurse practitioners are trained in implementation of the protocol.

Study parameters/endpoints: The main study parameter is the difference between patients and controls in self-management skills in the context of transplantation. The secondary study parameters for patients are self-regulation skills, quality of life, medication adherence, coping, self-efficacy and perceived experience of nurse-led care and perceived experience of the self-management intervention. For nurses are the study parameters self-management support skills after organ transplantation and perceived experience of the self-management intervention.

Study objective

- Hypothesis 1: We expect to see an increase in primary and secondary outcomes among participants in the experimental
group when compared to those in the control group.
- Hypothesis 2: After receiving the intervention training, nurses’ self-management support skills are improved.

Study design

T0 – Baseline
T1 – Six months after baseline (for experimental period this is the post-intervention questionnaire)
T2 – Twelve months after baseline (follow-up)

Intervention

The ZENN intervention aims to optimize self-management skills of participants and self-management support skills of NPs after transplantation. The intervention is based on the theoretical framework of the Self-Regulation Theory and the intervention strategies are based

on evidence-based techniques, namely goal setting and pursuit, Motivational Interviewing and Solution-Focused Brief-Therapy. The intervention consists of steps, which are divided in serval sessions and need to be taken to complete the intervention and empower patients to take control over their own situation. In the initial session, a holistic discussion of how things are going in 14 life areas is achieved through the communication aid, the Self-Management Web. The NP stimulates the patient to prioritize an area and set a SMART goal. A global plan of action for goal attainment is agreed upon. This structure fits the key elements of the intervention and the need for support with a general structure with room for individual tailoring and shared decision between patient and professional. In addition, participants' motivation for change and self-efficacy in relation to the goal will be discussed using a visual analogue scale. The second and third session are used to evaluate the progress of goal attainment, facilitators and barriers are explored and if necessary, the action plan will be revised. In addition, motivation and self-efficacy will be evaluated and encouraged, alongside a discussion of internal versus external attribution of success. The aim of the fourth session is to evaluate and discuss the goal attainment, relapse prevention and generalization of the learned skills to other situations.

Contacts

Public
Erasmus MC
Regina van Zanten

N/A
Scientific
Erasmus MC
Regina van Zanten

N/A

Eligibility criteria

Inclusion criteria

- Being at least two months and no more than thirteen months after transplantation
- Age (over 18 years)
- Sufficient command of Dutch Language
- Stable medical situation

Exclusion criteria

- Cognitive limitations
- Insufficient command of Dutch Language
- Participating in other lifestyle or self-management promoting programmes which could impact the outcome
- Undergoing dialysis (kidney transplantation)
- Expected start dialysis within three months (kidney transplantation)

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):	01-09-2020
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	19-03-2020

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	NL8469
Other	METC Erasmus MC : MEC-2019-0671

Study results

Summary results
N/A