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A study to test feasibility of carrying out a programme to support self-management after kidney transplantation.

Submission date
20/07/2018

Recruitment status
No longer recruiting

Registration date
27/07/2018

Overall study status
Completed

Last Edited
29/04/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
After kidney transplantation, patients need to adapt to life with a transplant. Often, patients have undergone a period of dialysis before transplantation, which can have a large impact on physical and mental health. Transplantation means a life without dialysis, but also with new recommendations for lifestyle and other challenges. The new post-transplant lifestyle includes taking medication to suppress the immune system, picking up daily activities and social roles again, and dealing with the emotions the transplant may have caused. In order to support this process of adjustment, a 'self-management support' programme was developed. The programme focuses not only on medical challenges after transplant, but also emotional and social ones.
This study aimed to test if we could carry out the programme in the out-patient clinic, whether the nurses were able to carry out the protocol as intended, and to assess the perceived benefits and areas for improvement by patients and professionals. We also looked at whether there were any changes in behaviour, emotions or thoughts of patients regarding self-management after transplantation.

Who can participate?
Adult kidney transplant receipts who received their kidney transplant 1-8 months ago

What does the study involve?
Patients were randomised into either the intervention group or the control group.
The intervention group receive the self-management support programme. Before the first session, this group will be asked to complete questionnaires relating to prior knowledge of self-management, along with quality of life, general health, transplantation experience and quality of care received. This is repeated after the final session of the programme, with some additional questions.
The self-management support programme was divided over four sessions. In the first session the nurse practitioner guided the patient in evaluating 14 life areas on the Self-Management Web. This Web was a communication aid to help both patient and professionals discuss a broad range of topics, rather than only medical ones. Patients could indicate how things were going in each

area. In the following sessions, the nurse supported the patient in setting priorities for change, goals, action plans to pursue these goals, monitoring progress, and where necessary adapting their strategy. They also discussed how to use these skills to solve other self-management challenges. Motivation for change and feelings of confidence were also discussed.
The control group, who do not receive the self-management support programme, are asked to complete the same questionnaires as the intervention group after the period of time the programme takes.
To assess how the programme was carried out and experiences with it, the nurses, patients and kidney experts (nephrologists) were interviewed. A number of consultations were videoed to assess whether the nurse carried the programme out as intended. The questionnaires completed before and after the programme were used to determine the impact of the programme on the patient and this was compared to the responses of the control group. Before starting the programme, nurses were trained in the protocol and communications skills needed to effectively carry out the programme.

What are the possible benefits and risks of participating?
The possible benefit of taking part is that participants in the intervention group will receive an extra 4 nurse consultations, which enables them to discuss challenges and potential improvements to life after transplantation. This may lead to improvements in the medical, emotional and role management of the transplant. There are no known risks to participants taking part in this study.

Where is the study run from?
Erasmus MC, Rotterdam, The Netherlands.

When is the study starting and how long is it expected to run for?
February 2015 to June 2017

Who is funding the study?
Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)
Dutch Kidney Foundation (The Netherlands)
Rotterdam University of Applied Sciences (The Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
520001004

Study information

Scientific Title
Evaluating the feasibility and preliminary results of a nurse-led self-management support intervention for kidney transplant recipients

Acronym
ZENN

Study objectives
To support effective SM after kidney transplantation, a holistic nurse-led self-management support intervention was developed using the Intervention Mapping approach. This pilot study aimed to evaluate the feasibility and preliminary results of the intervention for kidney transplant recipients and professionals.
Hypothesis: the nurse-led self-management intervention will improve patients self-management knowledge and behaviour

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the University Medical Center Rotterdam, 04/06/2015, MEC-2015-317

Study design
Interventional controlled before-after mixed-methods non-randomised pilot study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Kidney transplant

Interventions
The intervention was called ZENN, an acronym derived from the Dutch translation of Self-Management After Kidney Transplantation (ZElfmanagement Na Niertransplantatie).
The following key elements were included in the intervention: opportunities for tailoring within a general structure; open assessment of patients' needs and preferences using a holistic approach; principles of shared-decision making; and patient empowerment/ in the lead. The

overall goal was to enhance recipients' self-management skills in order to integrate treatment and life goals and subsequently optimize recipients' quality of life and health-related outcomes. The steps of the intervention were divided over four sessions. In the first session, self-management challenges were assessed with the so-called Self-Management Web. This visual communication aid offers an overview of fourteen life areas (e.g. work, emotional well-being, sexuality, and transport and mobility), thereby structuring the consultation and opening the range of topics the recipient and Nurse practitioner (NP) could address. Recipients evaluate each area by indicating whether they are doing well (1=green), neither good /nor bad (2=orange) or bad (3=red). When multiple areas were red the NP encouraged the patient to rank them according to priority and impact on post-transplant health. Once the challenges had been identified by the recipient, the NPs employed solution-focused communication techniques to discuss recipients' desired outcomes, self-efficacy, to encourage them to set SMART-goals and to make an action plan. A SMART-goal was defined as one that is specific, measurable, achievable, result-focused, and time-bound. Progression on goal attainment and outcome expectations were discussed in the second and third session. Goal progress, relapse prevention and generalization of learned skills to other challenges were discussed in the fourth session. Over the course of these sessions NPs and recipients re-assessed the original 14 life areas to detect other emerging issues and assess priorities.
Two NPs received two half-day training sessions, an intervention protocol and a booster session during which problems encountered could be discussed and techniques practiced.

Intervention Type
Behavioural

Primary outcome(s)
Self-management knowledge & behaviour, assessed using the 12 item Partners in Health Scale at the baseline (T0) and after completion of the intervention (T1) for the intervention group, and just at T1 for the control group. The following subscales were used:
1. Knowledge and coping
2. Recognition and management of symptoms

Key secondary outcome(s))
The following were measured at the baseline (T0) and after completion of the intervention (T1) for the intervention group, and just at T1 for the control group:
1. Quality of life, assessed using:
1.1.Short Form-36 (SF-36) with the following subscales:
1.1.1. Role limitations due to physical health problems
1.1.2. Vitality
1.1.3. Role limitations due to emotional problems
1.1.4. General mental health
1.2. Two questions from the WHO Quality of Life Instrument (WHOQol-Bref), rated on a 5 point Likert scale:
1.2.1. "How would you rate your quality of life?"
1.2.2. "How satisfied are you with your health?"
2. Self-efficacy, assessed using the Self-Efficacy for Managing Chronic Disease 6-item scale (SECD-6)
3. General health, pain and fatigue, assessed using a 10-point Visual Analog Scale (VAS)
4. Experience of transplantation, assessed using the Transplant Effects Questionnaire (TxEQ), with the following subscales:
4.1. Worries about the transplant
4.2. Feelings of guilt towards the donor

4.3. Disclosure about having a transplant
4.4. Feelings and behaviour regarding medication adherence
4.5. Perceived responsibility to others
5. Quality of care, assessed using the "patient-centeredness" subscale of the American Consumer Assessment of Health Plan Surveys (CAHPS)
6. Social integration and support, assessed using the social integration and support subscale of the Health Education Impact Questionnaire (HEIQ)
7. Importance and attention to life domains, assessed using a 15-item scale using a 3-point Likert scale where answers of "1" or "2" were recorded as negative and "3" was recorded as negative

8. Fidelity - delivery of the intervention according to protocol, assessed using a self-developed 16-item Therapy Adherence Measurement (TAM), measured amongst the intervention group only at T1.

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Kidney transplant patient
2. Aged 18 years or older
3. Functioning graft
4. Underwent kidney transplantation 1 to 8 months ago
5. Visited outpatients post transplant clinic of a Dutch University Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Cognitive limitations
2. Acute psychiatric problems
3. Unable to speak Dutch
4. More than 2 consultations with a Nurse Practitioner after their transplantation
5. Treated in isolation after transplantation
6. Participating in other studies
7. Undergoing dialysis or expecting to start dialysis within 3 months

Date of first enrolment
01/12/2015

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC
Doctor Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Study participating centre
Rotterdam University of Applied Science - Research Centre Innovations in care
Rochussenstraat 198
Rotterdam
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3015 EK

Sponsor information

Organisation
the Netherlands Organization for Health Research and Development (ZonMw) (Grant number 520001004)

Organisation
Erasmus MC, Unviersity Medical Center Rotterdam

Organisation
Netherlands Organisation for Health Research and Development

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Not defined

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the Netherlands Organization for Health Research and Development (ZonMw) (Grant number 520001004);

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the Dutch Kidney Foundation (Grant number sw012.03)

Funder Name
a doctoral grant of the Rotterdam University of Applied Sciences, The Netherlands.

Results and Publications

Individual participant data (IPD) sharing plan
Anonymized outcome data can be accessed by an email to Emma Massey at e.massey@erasmusmc.nl. This data is available from July 2018 and can be shared with other researchers wishing to combine data using the same variables. As no permission was obtained in the original study to share data with third parties, permission may be required. For privacy reasons video observations of consultations cannot be shared. Anonymized transcripts of interviews with professionals can also be obtained from this author.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/04/2019	29/04/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes