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Development and evaluation of a psychosocial treatment to increase perceptions of control among patients who undergo dialysis

Submission date
23/07/2020

Recruitment status
No longer recruiting

Registration date
23/10/2020

Overall study status
Completed

Last Edited
16/10/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys don't work as well as they should. Perceiving that one has little control over one's life is a frequently reported problem among people with CKD who are on dialysis, and it has been shown to be related to lower well-being and quality of life. This study aims to develop a psychosocial intervention for enhancing perceptions of control in people on dialysis and evaluate its effectiveness.

Who can participate?
Patients undergoing dialysis (hemodialysis or peritoneal dialysis) in a center or at home, aged 18 or older, reporting low perceived control

What does the study involve?
Participants are randomly allocated to either the intervention group or the waiting list control group. Participants in the intervention group receive the psychosocial intervention directly. Participants in the waiting list control group receive the intervention after the waiting period. The intervention includes four sessions of 45-60 minutes, every week or every other week and 1 follow-up session after 1 month, administered by medical social workers of the dialysis units or the responsible researcher (with a Master's degree in clinical psychology). The intervention is administered at a location and time most suitable to dialysis patients. Perceptions of control are assessed with a questionnaire before and after the start of the intervention in the intervention group, or with a time-interval of 4-6 weeks in the waiting list control group.

What are the possible benefits and risks of participating?
The possible benefits are that the intervention could potentially enhance perceptions of control in participants and therefore increase feelings of well-being. There are no expected risks associated with participation, apart from the time and effort people invest in their participation.

Where is the study run from?
University Medical Center in Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
September 2014 to August 2017

Who is funding the study?
Dutch Kidney Foundation (Netherlands)

Who is the main contact?
1. Alicia M. de Vries
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2. Dr Maya J. Schroevers
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
201500047

Study information

Scientific Title
Development and evaluation of a psychosocial intervention aimed at regaining perceptions of control among patients undergoing dialysis

Study objectives
Participants in the intervention condition will show more pronounced improvements in perceived control and measures of well-being compared to participants in the waitinglist control condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2015, University Medical Center Groningen Medical Ethical Committee (Medisch Ethische Toetsingscommissie UMCG, HPC LA15, POB 30001, 9700 RB Groningen, Netherlands; +31 (0)50 361 4204; metc@umcg.nl), ref: METc 2014/321

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with chronic kidney disease on dialysis

Interventions
Participants are randomized to either the intervention condition or waiting list control condition via randomization software with a 1:1 ratio. Given the nature of the study, participants cannot be blinded with regard to condition allocation.

Intervention: self-regulation psychosocial intervention aimed at increasing perceptions of control in dialysis patients. The intervention includes four sessions of 45-60 minutes, every week or every other week and 1 follow-up session after 1 month, administered by medical social workers of the dialysis units or the responsible researcher (with a Master's degree in clinical psychology). The intervention is administered at a location and time most suitable to dialysis patients.

Participants in the waiting list control condition are offered the psychosocial intervention after the waiting list period.

Intervention Type
Behavioural

Primary outcome(s)
Perceptions of control, assessed with the self-report Mastery Questionnaire before and after the start of the intervention in the intervention condition, or with a time-interval of 4-6 weeks in the waiting list control condition.

Key secondary outcome(s))
Assessed with self-report questionnaires:
1. Depression measured with the Patient Health Questionnaire (PHQ-9)
2. Anxiety measured with the Generalized Anxiety Disorder Questionnaire (GAD-7)
3. Well-being measured with the World Health Organization - Five Well-being index (WHO-5).
Assessments took place before and after the start of the intervention in the intervention condition, or with a time-interval of 4-6 weeks for the waiting list control condition.

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Receiving dialysis treatment (at the hospital or at home)
3. Having low perceived control as indicated by a score of 23 or below on the Mastery scale (Pearlin & Schooler, 1978)
4. Sufficient knowledge of the Dutch language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
21

Key exclusion criteria
1. Unable to speak/write/read Dutch
2. Severe psychiatric comorbidity
3. Receiving a psychological treatment
4. Recent start or unstable pharmacological treatment (e.g. antidepressants, anxiolytics)

Date of first enrolment
01/08/2015

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Center Groningen
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Study participating centre
Martini Ziekenhuis
Van Swietenplein 1
Groningen
Netherlands
9728 NT

Study participating centre
Scheper Ziekenhuis
Boermarkeweg 60
Emmen
Netherlands
7824 AA

Study participating centre
Dialyse Centrum Groningen
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Study participating centre
Dianet
Brennerbaan 130
Utrecht
Netherlands
3524 BN

Sponsor information

Organisation
University Medical Center Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Charity

Funder Name
Nierstichting

Alternative Name(s)
Dutch Kidney Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Maya J. Schroevers (m.j.schroevers@umcg.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes