

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/10/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/09/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

67

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

Sponsor details

Hanzeplein 1
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Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl>

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

Publication and dissemination plan

Planned publications:

1. Screening study on reasons why dialysis patients do not accept care to regain control in the context of a randomized controlled trial.
2. Study on the effectiveness, feasibility and acceptability of a psychosocial intervention for regaining perceptions of control in patients with chronic kidney disease receiving dialysis: a randomized controlled trial.

The study protocol is available upon request.

Intention to publish date

01/01/2021

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