

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

<b>Submission date</b> 23/07/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/10/2020	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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  
a.m.de.vries@umcg.nl  
2. Dr Maya J. Schroevers  
m.j.schroevers@umcg.nl

## Contact information

**Type(s)**  
Public

**Contact name**  
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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](mailto:m.j.schroevers@umcg.nl)).

**IPD sharing plan summary**

Available on request