Development and evaluation of an intervention to regain autonomy among patients undergoing dialysis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON44803

Source
ToetsingOnline

Brief title
Regaining autonomy during dialysis

Condition

- Renal disorders (excl nephropathies)

Synonym
dialysis, kidney disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nierstichting Nederland

Intervention

Keyword: Autonomy, Dialysis, Loss of control

Outcome measures

Primary outcome

The primary outcome is the level of perception of control, as measured by

Pearlin's Mastery scale.

Secondary outcome

Secondary outcomes include: depression (measured by the BDI-II), fatigue

(measured by the CIS), quality of life (SF-12) and positive and negative affect

(PANAS)

Study description

Background summary

Dialysis is an invasive treatment for patients with end stage renal disease which interferes their daily lives. A frequently mentioned complaint is loss of autonomy. Central to the concept of autonomy is the extent to which patients perceive control over their own lives. These so called perceptions of control are essential to well-being and quality of life. Research shows that patients treated with dialysis indeed report clinically lowered perceptions of control. After transplantation, which is the preferred treatment for end stage renal disease and which is generally associated with an increase in quality of life, perceptions of control increase only limited. Similarly, general interventions aimed at improving quality life or reducing psychological complaints do not result in an increase in perceptions of control. Therefore, there is a need for specific psychological interventions that focus on regaining perceptions of control and hence, regaining autonomy during dialysis.

Study objective

The primary objective of the studie is to develop an intervention specifically aiming at regaining perceptions of control during dialysis and to examine its efficacy.
Secondary aims are (a) to gain insight into mechanisms underlying its efficacy

(mediators) and (b) to gain insight into moderators of efficacy (i.e. for whom and under which circumstances is the intervention efficacious).

Study design

The study applies a unblinded randomized controlled trial (RCT) design. Patients who show clinically lowered levels of perceptions of control are eligible for the intervention. In order to identify them, patients will fill in a brief screening inventory to measure perceptions of control every three months. In case they qualify, they will be randomly assigned to either the intervention condition or the wait list control condition. In the latter condition, patients will receive the intervention after a waiting period of four to five months. One pre-intervention assessment and three follow-up assessments will be administered, the last one six months after the end of the intervention.

Intervention

The intervention will be developed during the study based on an existing intervention that is currently applied in the UMCG, the so called STERK intervention. The STERK intervention is specifically developed for patients with severe kidney disease, aiming at enhancing a healthy lifestyle and improving quality of life. The intervention will be adapted for the current study, focusing on setting attainable life goals by the patients. There will be four sessions of 60 minutes each. The intervention will be offered in addition to care as usual.

Study burden and risks

The burden imposed by the study to the patients consists of (a) filling in a brief screening inventory (5 minutes to fill in) to measure perceptions of control every three months, during the study period (2.5 years, 8 assessments); in case they will receive the treatment: filling in questionnaires at four assessment points, 30 minutes each, and 4 treatment sessions of one hour in the dialysis center. For patients undergoing dialysis, fatigue is a potential side effect. In order to lower the burden as much as possible for fatigued patients, they will be offered the opportunity to fill in questionnaires during dialysis and timing of the sessions will be decided based on preferences of the individual patient.
When the intervention turns out to be successful, this can be considered as an advantage to the patients receiving the intervention. No negative effects or health risks are known regarding the STERK intervention (which forms the basis for the current intervention) or regarding the therapeutic techniques that will be applied, including cognitive-behavioral techniques.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 18 years or older
- receiving dialysis treatment in a center
- clinically decreased absolut level of pereption of control or showing clinically relevant changes over time
- adequte comprehension of Dutch

Exclusion criteria

- presence of a severe psychiatric disorder
- receiving treatment for the secondary outcomes of the intervention, i.e. depression or fatigue

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL50073.042.14