The evaluation of a program to promote self management and quality of life of kidney patients (STERK-program)

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To develop a workable and effective programma to encourage the self management abilities of people with progressive chronic kidney disease stage 1-4. The evaluation consists of a process- and an effect evaluation.The process evaluation will evaluate...

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

Summary

ID

NL-OMON35186

Source
ToetsingOnline

Brief title
Self management and quality of life of patients with chronic kidney disease

Condition

- Renal disorders (excl nephropathies)

Synonym
chronic kidney disease, kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Nierstichting Nederland
Source(s) of monetary or material Support: Nierstichting Nederland

Intervention

Keyword: chronic kidney disease, lifestyle intervention, prevention, self management

Outcome measures

Primary outcome

The primary outcomes of the process evaluation is primarily aimed at the workability and the feasibility of the STERK program. The content and the structure of the training will be evaluated at the level of the patient and the professional.

The effect evaluation will focus on the extent in which the training affects self management abilities, perceptions of illness and treatment, self efficacy, proactive competences and quality of life of patients.

Secondary outcome

The secundary outcomes of the study are glomerular filtration rate (GFR), proteinuria blood pressure, Body Mass Index, salt intake, protein intake.

Study description

Background summary

Patients with chronic kidney disease can slow down or stop the decline of their kidney function. To be motivated to take an active role in slowing down or stopping the progression of their disease, patients need to become more capable self managers of their illness. The STERK-program consists of a handbook and a training that can help patients to increase their self management abilities and quality of life.

Study objective

To develop a workable and effective programma to encourage the self management abilities of people with progressive chronic kidney disease stage 1-4.

The evaluation consists of a process- and an effect evaluation.

The process evaluation will evaluate:

1. the experience of patients who participated in the STERK-program;

2. the willingness of patients to participate in the program;

3. the experience of health carers providers with the STERK-program (a.o. approaching the study population, workability of the training) and organisations (workload, logistics) and the encouraging and discouraging factors that may interfere with working with this program.

The effect evaluation will evaluate:

1. the extent to which the program has contributed to improved self management abilities, better perception of illness and treatment, more self-efficacy, pro-active coping competence and an increased level of physical en mental quality of life of patients.

2. the extent to which the training has contributed to improved clinical outcomes (glomerular filtration rate (GFR), proteinuria
blood pressure, Body Mass Index, salt intake, protein intake, HbA1C).

3. the extent to which patients characteristics influence the effect of the training on the self management abilities of patients, distinguishing sociodemographic and illness-related characteristis, quality of life, illness perceptions, self-efficacy and pro-active coping.

Study design

The study involves a multicenter randomised controlled trial design with a control group. Patients who want to participate will be randomised into two groups. Both groups will be asked to fill in a baseline questionnaire (T0), after which Group 1 will receive the STERK-training and Group 2 the care as usual. Both goups will be asked to fill in the next questionnaire (T1). Three and six months after T1 patients will be asked again to fill in questionnaires (T2 en T3).

Intervention

The intervention consists of four meetings lasting two hours in an eighty to twelve weeks period and a meeting three months afterwards.
The meetings are interactive and consist of what it is like to have a kidney disease, the treatment of their disease and the lifestyle factors that may affect the progression of the kidney disease. Meetings consist of activities to

provide patients skills to become a self manager and so, where necessary and advisable, prevent or delay progression of their kidney function.

The Common sense model of self-regulation (Leventhal, et al., 1984), the Theory of pro-active coping (Aspinwall & Taylor, 1997), the Social cognitive theory (Bandura, 1994) and the Transtheoretical model (Prochaska & DiClemente, 1984) have been used as theoretical frameworks during the development of the intervention.

Study burden and risks

Not applicable.

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

Newly diagnosed patients
Patients with progressive chronic kidney disease
18 years of age and older

Exclusion criteria

Non-Dutch spreaking
Not allowed to give informed consent
Mental or cognitive problems
Not able to participate in groups

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2012
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2011

Application type:	First submission
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	NL37599.042.11