SodiUm Burden lowered by Lifestyle Intervention: Self-Management and E-health technology

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON40912

Source
ToetsingOnline

Brief title
SUBLIME

Condition

- Nephropathies

Synonym
Chronic kidney disease, renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Zonmw,Nierstichting Nederland

Intervention

Keyword: chronic kidney disease, efficacy, e-health, sodium restriction

Outcome measures

Primary outcome

Primary outcome: sodium intake, assessed from 24h sodium excretion,

Secondary outcome

Secondary outcomes: blood pressure, proteinuria, psychological well-being and

costs-efficiency, efficacy.

Study description

Background summary

In chronic kidney disease (CKD) morbidity, mortality, and costs are high. In the Netherlands 750.000 patients have CKD, and 15.000 patients require dialysis or renal transplantation, with an inflow of 2.000 patients yearly, of whom 1600 in dialysis. The
annual costs of renal replacement therapy amount to 750 million euros! Less progression towards dialysis and less cardiovascular complications can be achieved by even modest reduction in dietary salt. However, current care is not effective in achieving reduction in salt intake, as over 80% of CKD patients fail to adhere to the recommended intake of 6 grams/day. Effective new tools for sustainable, affordable reduction of salt intake in earlier phases of CKD are therefore needed. Recent data support the potential of behavioural intervention for sustainable lifestyle change. We previously developed a) a self-regulation program based on behavioural theory, and b) e-health modules for behaviour change which creates strong synergy between regular care and online self-care, that can partly replace time-investment of health professionals. Pilot data demonstrated excellent acceptance of the tools, and 30 % reduction in salt intake.

Study objective

We aim to assess the cost-effectiveness of a new health care approach for reduction of dietary salt in CKD patients, to provide a basis for widespread implementation of the new approach in CKD. To this purpose an open randomized trial in CKD patients is performed in Dutch university and non-university

hospitals, that addresses the superiority of the new approach.

Study design

Open randomized multi-center study in 150 CKD patients, in academic and non-academic centres with a 3 month intervention, and 6 month follow-up comparing the intervention with regular care.

Intervention

Two group meetings with fellow-patients, motivational interviewing, e-coaching, blood pressure monitoring at home and ICT-based self-regulation as add-on to regular care; control patients receive regular care.

Study burden and risks

Participation in the study is on a free-will base. Test persons will not receive any financial support or priority for treatment of other diseases in the clinic during this study. Test persons will visit the outpatient clinic on a more regular base than standard patient care. During their visit blood pressure, height, waist circumference and weight will be measured. The blood samples will be drawn through venipuncture which forms a minimal risk / discomfort (e.g. haematoma) 3 times in 9 months and 24-h urine will be collected (4 times in 9 months). Test persons will fill out questionnaires three times. During the study, Test persons in the treatment group are actively supported to adhere to a restricted sodium diet with a structured self-regulation program to implement sodium recommendations that are in current guidelines. Test persons participate in group meetings and use a computer program to monitor their dietary sodium intake. A potential risk is excessive sodium restriction. This will be closely monitored by 24-hourly urinary sodium excretion. Sodium depletion might occur during intercurrent events (e.g. febrile or gastro-intestinal illness, antibiotic treatment) that lead to a decline of renal function: a sodium depleted state will then result in a more pronounced decline of renal function due to concomitant fluid depletion. Test persons will be instructed to contact the investigator when complaints, signs or symptoms (e.g. light-headedness, dizziness) or concurrent illnesses occur. Renal function and physical parameters (blood pressure) are routinely measured. Abovementioned interaction of an intercurrent event and renal function is not essentially different from the usual clinical situation. Usual recommendations to monitor and counter sodium depletion, and the (dis)continuation of a participant*s own medication will be given. Due to the close follow-up and increased awareness of the participants, the overall risks can be considered minimal. No further invasive measurements will be executed and therefore risks of participation in this study are minimal.

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

1. Be 18 years or older.
2. Have chronic kidney disease (CKD stage 1-3, CKD 4 if eGFR is not lower than 25 mL/min/1.73m2, or be a renal transplant recipient.)
3. Have a urinary sodium excretion during at least the last 2 subsequent visits of more than 130 mmol per day, or one last urinary sodium excretion of more than 150 mmol per day.
4. Have a systolic blood pressure higher than 135 mmHg, diastolic blood pressure higher than 85 mmHg or a well-controlled blood pressure by treatment with antihypertensives including RAAS-blockade (ACE-inhibitor or ARB).
5. Sufficient command of the Dutch language.
6. Access and ability to use the internet.
7. Written informed consent.

Exclusion criteria

- eGFR < 25 ml/min/1.73m2 or an anticipated need for predialysis work-up within the time frame of the study.
- Unstable disease: defined as rapid, persistent, progressive renal function loss (e.g. > 6 mL/min/1.73m2 per year), not from acute, intermittent origin.
- Blood pressure > 170 mmHg systolic or > 100 mmHg diastolic during medical treatment
- Blood pressure < 95 mmHg systolic not responding to withdrawal of antihypertensives.
- Cardiovascular event (myocardial infarction, cerebrovascular accident) < 6 months ago.
- Renal transplantation <1 year ago.
- Medical conditions that are likely to interfere with completion of the study (such as progressive malignancy or other debilitating illness) at the discretion of the nephrologist.
- Every patient who has participated in the ESMO study (regardless whether intervention or control) cannot participate in the current study.
- Current participation in any clinical trial that might interfere with SUBLIME trial.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2014

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-02-2015
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	NL48079.042.14