The effect on fluid restriction adherence by monitoring with the MySleeve device, a randomized controlled trail.

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The objective of this study is to achieve better adherence to fluid restriction by providing insight to patient*s drinking behavior, by using the MySleeve device (MS).

Ethical review	Approved WMO
Status	Pending
Health condition type	Electrolyte and fluid balance conditions
Study type	Observational non invasive

Summary

ID

NL-OMON42773

Source
ToetsingOnline

Brief title
MySleeve study.

Condition

- Electrolyte and fluid balance conditions
- Renal disorders (excl nephropathies)

Synonym
fluid restriction

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: NWO (JSTP),Technische Universiteit Eindhoven

Intervention

Keyword: Dialysis, Fluid restriction

Outcome measures

Primary outcome

less IDWG.

Secondary outcome

Improved sleep quality measured by the activity tracker.

Increased physical activity, measured by the activity tracker.

Evaluation of user experience, and possible suggestions of improvemend, of the

MySleeve device and the BCM sock at the end of the study.

Study description

Background summary

In anuric hemodialysis (HD) patients a fluid restriction of 1L to 1.5L per 24 hours is applied to minimize fluid accumulation between two consecutive dialysis sessions. The amount of fluid accumulated can be estimated by the patients weight before dialysis, minus the weight at the end of the previous dialysis session also called inter-dialysis weight gain (IDWG). High IDWG can lead to symptoms of fluid overload as dyspnea as the result of pulmonary edema, decreased appetite or pain and discomfort due to peripheral edema. It is also associated with lower overall survival in this patients* group. Due to multiple factors that influence the adherence to fluid restriction, for example thirst, personal habits and social factors, only 30-60% of the HD patients are able to adhere to their fluid restriction.

Hypothesis:
Better adherence to fluid restriction by profiding insight in drinking behaviour by using the MySleeve.

Study objective

The objective of this study is to achieve better adherence to fluid restriction by providing insight to patient*s drinking behavior, by using the MySleeve

device (MS).

Study design

Randomized controlled trial.

All patients will receive an activity tracker to wear throughout the total study period. Also two questionnaires (one at the beginning and one at the end of the study period) need to be filled out. Also patients participating in this study will receive weekly in-clinic (at the dialysis ward) BCM measurements instead of 2-4 four times per year. Patients randomized for the intervention group will also receive a BCM sock and are asked to perform a daily in-home BCM measurement of approximately two minutes, throughout the total study period of four months. They will also receive the MySleeve vessel with accompanying ceramic cup, to use for all drinks during the intervention period of one month.

The activity tracker is used to observe their activity levels during the study period. Both the BCM sock and activity tracker will only measure data and not present any results to the participants directly.

Study burden and risks

Minimal, only non-invasive measurements are used.

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

- Prevalent hemodialysis patients with a dialysis vintage of at least 3 months.
- Anuric (defined as a urine output of <300ml over 24hours).
- Hemodynamically stable on dialysis, defined as less than 10% hypotensive episodes during the dialysis sessions.
- On a fluid restriction.
- Age above 18 years of age.
- Experience or ability to use a smart-phone.
- On a salt restricted diet educated by the dietician.
- Informed consent.

Exclusion criteria

- withdrawal of consent
- acute intercurrent illness (infection, malignancy, cardiovascular event, uncontrolled diabetes)
- physically constrained to use the required devices
- mentally unable to use the required devices

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2015
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Three different devices namely;the My Sleeve device;BCM sock and activity tracker (Fitbit)
Registration:	No

Ethics review

Approved WMO

Date:	09-10-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL53778.100.15