Fighting fatigue! An intervention to reduce fatigue.

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The objective of this study is to develop, test and evaluate a psychosocial intervention for dialysis patients aimed at better coping with, and reducing fatigue (primary outcome) and thus improving the quality of life (secondary outcome).

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

Summary

ID

NL-OMON43728

Source
ToetsingOnline

Brief title
Fighting fatigue!

Condition

- Other condition
- Renal disorders (excl nephropathies)
- Lifestyle issues

Synonym
Fatigue, tiredness

Health condition

Vermoeidheid

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Dialysis patients, Fatigue, Psychosocial intervention

Outcome measures

Primary outcome

Primary outcome: The difference in perceived fatigue between intervention group

and control group (measured with the CIS-fatigue).

(Note: Repeated measures over time (T0t/mT4), within and between groups).

Secondary outcome

Secondary outcome: The difference in perceived quality of life between the

intervention group and control group (measured by the SF-KDQOL).

(Note: Repeated measures over time (T0 t/m T4), within and between groups).

Study description

Background summary

The prevalence of (severe) fatigue in dialysis patients ranges between 60 - 97%. Fatigue is a common, subjective and complex phenomenon that has an enormous impact on the (quality of) lives of dialysis patients. Fatigue limits patients* daily activity levels and independency and is often perceived as a source of stress. Although fatigue is often seen as a side effect of the kidney disease or dialysis treatment, research shows that psychological and environmental factors also affect perceived fatigue. It involves, for example factors such as stress, anxiety, depression, cognitions, coping style, energy-management and social support. Therefore, the treatment of fatigue does not only require a medical, but also a psychosocial approach. Currently, no psychosocial interventions to reduce fatigue in dialysis patients exist, whereas studies on fatigue in cancer, chronic pain, chronic fatigue, brain injury and muscular diseases, suggest that such interventions are effective in

reducing fatigue that is caused by multiple (interacting) factors.

Study objective

The objective of this study is to develop, test and evaluate a psychosocial intervention for dialysis patients aimed at better coping with, and reducing fatigue (primary outcome) and thus improving the quality of life (secondary outcome).

Study design

Randomized Controlled Trial (RCT): Patients will be randomly assigned to either the intervention group (psychosocial treatment) or the control group (regular treatment /no psychosocial treatment).
In this longitudinal 'mixed methods' study both quantitative and qualitative methods will be applied for data collection (questionnaires (self-report), observations, interviews, focus groups).

Intervention

Psychosocial treatment (intervention group) VS regular treatment without psychosocial treatment (control group). The psychosocial intervention consists of 4-6 individual sessions with a medical social worker (45 min per session) and several practical exercises targeted at coping with and reducing fatigue.

Study burden and risks

To determine the effects of treatment on the short- and long term, repeated quantitative measurements are conducted (4 x questionnaires over a period of 1 year and 1 month). These questionnaires are completed by the participants in both the intervention- and control group. To minimize the burdens for patients, the research team and involved research partners * have critically discussed the selection of questionnaires (e.g. priority of inclusion and average time to fill out questionnaires). The members of the Think Tank * will also be asked to discuss and judge the selected questionnaires. Time to completing the questionnaires will be kept to a minimum and takes max 60 minutes each measurement. Participants can decide themselves at what time they fill out the questionnaires, and whether they do it all at once or at multiple days (within a maximum of days).

Patients participating in the intervention group are offered 4-6 individual sessions with a medical social worker. In these sessions different modules related to fatigue are discussed (+/- 45 min per session). The medical social worker and the patient assess and decide which modules are appropriate. Performing some (home)exercises is part of the treatment.

+/- 15 patients who participate in the intervention group will be selected for an interview in which expectations regarding the treatment and experiences (after treatment) will be discussed. These interviews take 60-90 minutes. The interviews will take place at a time and location that suits best for the patients. Subsequently, 10 patients will be invited for a focus group discussion to share experiences with treatment and discuss suggestions to improve the protocol. The duration of this focus group will depend on the capacity of the participating patients but will not exceed 2.5 hours (including breaks). The overall duration of the study is one year and four months (for both participants in the intervention and the control group).

Treatment sessions with a medical social worker, performing exercises and filling out questionnaires, require certain efforts of patients participating in this study. However, based on previous studies, we expect that fatigue levels of patients who receive the treatment will be reduced and perceived quality of life will increase. If the treatment protocol is proved effective, the protocol will be made available to hospitals and dialysis centers which are interested to offer patients a psychosocial treatment to better cope with/reduce fatigue.
* Two research partners are currently part of the research team. These are experts in the field of kidney diseases / dialysis (lay knowledge). One of them is a patient suffering from a kidney disease, one of them is the father of a patient that has been in dialysis for a long time. Both research partners participate in research activities and contribute to the quality of the study and treatment protocol by bringing in the patient perspective/ their lay knowledge. The Think Tank is a diverse advisory group that monitors the research from different perspectives. Participants are: patients (members of the Kidney Patients Association Netherlands - NVN), medical social workers and nephrologists. The Think Tank contributes to the quality of research and the quality of the treatment protocol.

Contacts

Public
Nierstichting

Groot Hertoginnelaan 34
Bussum 1405 EE
NL
Scientific
Nierstichting

Groot Hertoginnelaan 34
Bussum 1405 EE

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Kidney patients (M / F) who: ;- Undergo daytime dialysis (PD, HD, both at home and in the hospital or dialysis center);
- Experience (severe) fatigue;
- Are 18 years or older;
- Are in the ability of physical activity (walk/move at least 10 minutes with or without supporting device such as a walking stick);
- Are sufficient in Dutch (understanding, conversation, reading) in order to participate in (group)interviews and to fill out Dutch questionnaires.

Exclusion criteria

Patients can not participate in the study under circumstances of:
- Participation in other research or treatment aimed at reducing fatigue;
- Treatment by a psychologist or psychiatrist (for severe psychiatric problems such as depression, psychosis, personality disorders or schizophrenia);
- Alcohol or drug addiction.

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):	30-10-2015
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL50975.029.15