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 reducing fatigue (primary outcome) and improving the quality of life (secondary outcome).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22752

Bron
Nationaal Trial Register

Aandoening

End Stage Renal Disease, Dialysis, Fatigue

Ondersteuning

Primaire sponsor: VUmc
Overige ondersteuning: Dutch Kidney Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fatigue severity, measured by a sub-scale of the CIS-fatigue.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

T0 - base-line (prior to intervention start)
T1 - post- treatment (immediately after the intervention period of 16 weeks)
T2 - short term follow up (3 months after the intervention period
T3 - long term follow-up (9 months after the intervention period)

Onderzoeksproduct en/of interventie

Psychosocial counseling (intervention group) VS regular treatment without psychosocial counseling (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 better coping with and reducing fatigue.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 at least 10 minutes with or without supporting device such as a walking stick);

- Are sufficient in Dutch language in order to participate in (group)interviews and to fill out Dutch questionnaires.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	74
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5218
NTR-old	NTR5366
Ander register	METc VUmc : 2015.049

Resultaten