

# Fighting fatigue! An intervention to reduce fatigue.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22752

### Source

NTR

### Health condition

End Stage Renal Disease, Dialysis, Fatigue

## Sponsors and support

**Primary sponsor:** VUmc

**Source(s) of monetary or material Support:** Dutch Kidney Foundation

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

Quality of Life (kidney disease specific) as measured by the KDQOL.

Questionnaires on coping style (CERQ), illness cognitions/perceptions (ZCL + IPQ-R), catastrophising thoughts (J-FCS), depression (PHQ-9) and overall perceptions of mastery and control (Mastery-scale) are included since these outcomes may be potential moderating or mediating factors.

In addition, various medical parameters and demographics will be studied as potential modifiers.

## 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. 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).

### Study objective

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### Study design

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)

### Intervention

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.

## Contacts

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## Eligibility criteria

### **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 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.

## 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)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2015
Enrollment:	74
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	17-08-2015
Application type:	First submission

## 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
NTR-new	NL5218
NTR-old	NTR5366
Other	METc VUmc : 2015.049

## Study results