Group training for Hepatitis C patients to improve quality of life

Published: 22-02-2007
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The objective of the study is to improve quality of life of patients with Hepatitis C, by teaching patients psychological skills that aid in coping with the consequences of the disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON35694

Source
ToetsingOnline

Brief title
Intervention for Hepatitis C patients

Condition

- Hepatic and hepatobiliary disorders

Synonym
Quality of life in patients with Hepatitis C

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Zorgverzekeraar Stichting Nuts Ohra

Intervention

Keyword: Hepatitis C, intervention, psychosocial, quality of life

Outcome measures

Primary outcome

The primary outcome measure of the study is the Short-Form 36 (SF-36), a generic, detailed quality of life measure that consists of 36 questions.

Secondary outcome

The secundary outcome measures are the EQ-5D, also a quality of life measure, a questionnaire on medical costs, illness & work, and the Beck Depression Inventory (BDI), a widely used questionnaire that measures depression and depressive symptoms.

Study description

Background summary

Patients with a chronic liver disease have a reduced quality of life, compared to healthy peers. Remarkably, within the group of liver patients, patients with Hepatitis C experience the lowest quality of life, even though physiologically speaking there is no clear explanation for this finding.

Study objective

The objective of the study is to improve quality of life of patients with Hepatitis C, by teaching patients psychological skills that aid in coping with the consequences of the disease.

Study design

The study will be organised nationally. The aim is to include 150 patients in the training group.

Intervention

The intervention is based on Problem Solving Therapy, a widely used and practical intervention method based on a general model of coping with stress.

Study burden and risks

Risks, that can be related to participation in the study, are not expected. Participation can be taxing when it comes to the investment in terms of time, that is expected of the patients.

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

- Hepatitis C
- Age 18 years or older

Exclusion criteria

- Patients with an insufficient grasp of the Dutch language to be able to participate in a training project.
- Patients with a psychiatric illness
- Patients who are /have been succesfully treated with Interferon

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:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	22-02-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL11560.078.06