

Group training for hepatitis C patients to improve quality of life

Submission date 02/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/09/2021	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms A. Beerthuisen

Contact details
Erasmus Medical Centre
Department of Psychiatry and Psychotherapy
P.O. Box 2040
Rotterdam
Netherlands
3000 CA
+31 (0)10 408 8234
a.beerthuisen@erasmusmc.nl

Additional identifiers

Protocol serial number
NL920 (NTR944)

Study information

Scientific Title
Group training for hepatitis C patients to improve quality of life

Acronym

Intervention for hepatitis C patients

Study objectives

Problem solving therapy improves the quality of life in patients with hepatitis C.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethical Board of the Erasmus MC on the 22nd of February 2007 (ref: MEC-2007-001).

Study design

Randomised, controlled, parallel group, multicentre trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Hepatitis C patients' quality of life

Interventions

150 patients will participate in a group training (problem solving therapy), to improve quality of life by teaching patients skills that aid in coping with the consequences of the disease. This training consists of eight sessions of two hours.

To evaluate this training, participants as well as the 150 controls will complete a questionnaire before the start of the training, right after and six months after the training. When the intervention is effective, controls will participate in this training after the end of this research project.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Quality of life (36-item Short Form [SF-36] questionnaire); the participants will complete this questionnaire at baseline, T1 (right after the training) and at T2 (six months after the last session of the training).

Key secondary outcome(s)

1. Health status (European Quality of Life [EuroQoL-5D] questionnaire)
2. Health & Labour Questionnaire
3. Depression (Beck Depression Inventory [BDI])
4. Problem orientation and problem solving skills (Social Problem Solving Inventory [SPSI])

The participants will complete these questionnaires at baseline, T1 and T2 (see primary outcome).

Completion date

31/08/2008

Eligibility

Key inclusion criteria

1. Hepatitis C
2. Age 18 years or older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Patients with an insufficient grasp of the Dutch language to be able to participate in a training project
2. Patients with a psychiatric illness
3. Patients who are/have been successfully treated with interferon

Date of first enrolment

01/03/2007

Date of final enrolment

31/08/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Centre
Rotterdam

Netherlands
3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Government

Funder Name

Health Insurance Company Nuts Ohra (Stichting Nuts Ohra) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration