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Group training for hepatitis C patients to improve quality of life

Submission date	Recruitment status	[_] Prospectively registered
02/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/09/2021	Infections and Infestations	[_] 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. Beerthuizen

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure
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).

Secondary outcome measures
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).

Overall study start date
01/03/2007

Completion date
31/08/2008

Eligibility

Key inclusion criteria
1. Hepatitis C
2. Age 18 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
300

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 succesfully 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)

Sponsor details
Department of Medical Psychology and Psychotherapy
P.O. Box 1738
Rotterdam
Netherlands
3000 DR

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/content/englishindex.htm

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration