

# Group training for hepatitis C patients to improve quality of life

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| <b>Submission date</b><br>02/05/2007   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
|  |  | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>02/05/2007 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>23/09/2021       | <b>Condition category</b><br>Infections and Infestations | <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

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## 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 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)

**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