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The evaluation of a training for patients with hepatitis C to improve their quality of life

Submission date
23/10/2015

Recruitment status
No longer recruiting

Registration date
03/11/2015

Overall study status
Completed

Last Edited
03/11/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hepatitis is a disease which causes inflammation (swelling) of the liver, which is caused by a viral infection or long-term alcohol abuse. Hepatitis C is the most common type of viral hepatitis. In an infected person, the hepatitis C virus is particularly concentrated in the blood, and so it can is easily spread through blood-to-blood contact, such as sharing needles amongst drug abusers or receiving contaminated blood products in hospital. In the early stages (acute hepatitis) a person often has no symptoms, and so does not know that they are infected. This means that about 80% of infections are able to move to the long-lasting stage. Chronic hepatitis C (CHC) is where a person has been infected for more than six months. Sufferers tend to feel extremely tired, achy and generally unwell. Left untreated, the infection causes the liver to become irreversibly scarred (cirrhosis) which can lead to liver failure. Many studies have shown that people suffering from CHC have a lower quality of life than a healthy person. As well as the physical symptoms, more than a third of people with CHC suffer from mental health problems such as anxiety and depression, which many find difficult to cope with. Problem solving therapy (PST) is a type of talking therapy which has been very effective in treating depression. It aims to teach people how to identify and solve their own problems without becoming stressed or upset. The aim of this study is to find out if PST can help improve the quality of life in patients suffering from CHC.

Who can participate?
Adults with a chronic hepatitis C infection.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in weekly sessions of PST for seven weeks. During these sessions, participants are given a chance to talk about problems they experience in their day-to-day life and are taught techniques to help them solve these problems when they next face them. Participants in the second group are placed on a waiting list for the PST and do not receive any therapy. At the start of the study, after the final session and 6 months later, participants in both groups are asked to fill out a questionnaire to find out how they are coping and whether their quality of life has improved. After the final testing point (6 months after the last PST session), participants in the second group are given the chance to take part in PST.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their quality of life. There are no risks of taking part in the study.

Where is the study run from?
Erasmus MC and seven other hospitals in the Netherlands.

When is the study starting and how long is it expected to run for?
March 2007 to September 2010

Who is funding the study?
1. NutsOhra (Netherlands)
2. The Stomach-Liver-Bowel Foundation (Netherlands)

Who is the main contact?
Dr Annemerle Beerthuizen

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Problem solving therapy for patients with hepatitis C to improve quality of life

Study objectives
Problem solving therapy will improve the quality of life of patients with hepatitis C.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the Erasmus MC (Netherlands), 22/02/2007, ref: MEC-2007-001

Study design
Multi-centre randomised wait-list controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Chronic hepatitis C

Interventions
The participants are randomly allocated to one of two groups.

Group 1: Participants take part in seven 1.5-hour sessions of problem solving therapy (PST). PST involves a training in systematic problem solving skills. During training, patients discuss practical problems in daily life and use a standardized way of generating solutions for these problems. This discussion is facilitated by a trained psychologist. At the end of the last session the participants were given the second questionnaire that had to be filled in and sent back to the researcher within one week.

Group 2: Participants are placed on a waiting list for the duration of the study. Participants who are wait-list controlled are given the opportunity to take part in the intervention after the study is complete.

All participants in both groups are asked to fill out a questionnaire on quality of life at three moments of measurements: baseline just before the start of the first training session, right after the last session (7 weeks) and 6 months later.

Intervention Type
Behavioural

Primary outcome measure
Quality of life measured using the Short Form Health Survey (SF-36) at baseline, after the last session (7 weeks), and 6 months after the intervention.

Secondary outcome measures
1. Liver disease symptoms measured using the Liver Disease Symptom Index (LDSI) at baseline, after the last session (7 weeks), and 6 months after the intervention
2. Depression measured using the Beck Depression Inventory (BDI) at baseline, after the last session (7 weeks), and 6 months after the intervention
3. Health care utilisation and production loss measured using the Trimbos and iMTA questionnaire on Costs associated with Psychiatric illness (TiC-P) at baseline, after the last session (7 weeks), and 6 months after the intervention

Overall study start date
01/03/2007

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Chronic hepatitis C

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Experimental group: 150, wait list control group: 150

Key exclusion criteria
1. Unable to fill out a questionnaire (e.g. because of language problems or cognitive impairment)
2. Patients with a psychiatric disorder
3. Patients who are being treated with Interferon

Date of first enrolment
01/05/2007

Date of final enrolment

01/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC
's-Gravendijkwal 230
Rotterdam
Netherlands
3015 CE

Study participating centre
Reinier de Graaf Hospital (Reinier de Graaf Gasthuis)
Reinier de Graafweg 5
Delft
Netherlands
2625 AD

Study participating centre
Gelre Hospital Apeldoorn (Gelre Ziekenhuizen Apeldoorn)
Albert Schweitzerlaan 31
Apeldoorn
Netherlands
7334 DZ

Study participating centre
Deventer Hospital (Deventer Ziekenhuis)
Nico Bolkesteinlaan 75
Deventer
Netherlands
7416 SE

Study participating centre
Academic Medical Center
Meibergdreef 9
Amsterdam Zuid-Oost
Netherlands
1105 AZ

Study participating centre
Haga Hospital (Haga Ziekenhuis)
Leyweg 275
Den Haag
Netherlands
2545 CH

Study participating centre
VU University Medical Center
De Boelelaan 1118
Amsterdam
Netherlands
1081 HV

Study participating centre
OLVG Hospital
Oosterpark 9
Amsterdam
1091 AC

Sponsor information

Organisation
Erasmus MC

Sponsor details
Medical Psychology section
Wytemaweg 80
Rotterdam
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3015 CN

Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
NutsOhra

Funder Name
The Stomach-Liver-Bowel Foundation (Maag Lever Darm Stichting)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available