

Neuropsychological rehabilitation in patients with impairments in memory and attention after long term occupational exposure to organic solvents

Submission date 11/08/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/08/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/10/2015	Condition category Nervous System Diseases	<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

Background and study aims

Long-term occupational exposure to neurotoxic chemicals like toluene, trichloroethylene and benzene is widespread in many industries all over the world and may result in the syndrome Chronic Solvent induced Encephalopathy (CSE). Most patients with CSE do not recover; the disabilities arising from memory and attentional impairment usually continue, severely affecting daily functioning, social participation, working ability, and therefore quality of life. The aim of this study is to evaluate the effects of a psychological treatment programme for patients diagnosed with CSE.

Who can participate?

Patients diagnosed with CSE.

What does the study involve?

Participants are randomly allocated to either the intervention group or the control group. The intervention group undergo a psychological treatment programme together with care as usual. The control group receive care as usual only.

What are the possible benefits and risks of participating?

Patients may benefit from the psychological treatment being tested. Patients in the control group also received the psychological treatment after the study and therefore may also benefit from the intervention. There are no anticipated side effects from the psychological treatment.

Where is the study run from?

Participants are recruited from the two locations of the Solvent Team in the Netherlands (Amsterdam and Enschede).

When is the study starting and how long is it expected to run for?

March 2002 to June 2006.

Who is funding the study?
Netherlands Center for Occupational Diseases (Netherlands).

Who is the main contact?
Dr Ieke Visser
i.visser@amc.uva.nl

Contact information

Type(s)
Scientific

Contact name
Dr Ieke Visser

Contact details
Meibergdreef 5
Amsterdam
Netherlands
1105 AZ
-
i.visser@amc.uva.nl

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Neuropsychological rehabilitation in workers with chronic solvent induced encephalopathy (CSE): a randomised controlled trial

Study objectives
A neuropsychological rehabilitation programme in patients with chronic solvent induced encephalopathy is beneficial with respect to:
1. Coping with cognitive impairments
2. Subjective cognitive impairments in meta-memory
3. Health related quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Academic Medical Centre (AMC) Amsterdam, 14/02/2011, ref: MEC 01/146

Study design
Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic solvent induced encephalopathy

Interventions

Patient were randomised, either to:

1. Intervention (neuropsychological rehabilitation group programme consisting of: memory training improving coping skills with cognitive impairments, cognitive behavioural therapy and psychosocial interventions aimed at improvement of social functioning)) together with care as usual (continuation of existing treatments) arm (INT + CAU)
2. Care as usual (CAU)

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Coping with cognitive impairment (CAMQ)
2. Subjective cognitive impairment (CFQ)
3. Meta memory (MIA)

Measured pre-intervention (T0), post intervention at 3 months (T1) and at 7 months follow up (T2)

Key secondary outcome(s)

Health related quality of life (SF-36) measured pre-intervention (T0), post intervention at 3 months (T1) and at 7 months follow up (T2)

Completion date

01/06/2006

Eligibility

Key inclusion criteria

1. Age > 17 years
2. Diagnosed with chronic solvent induced encephalopathy
3. 5 years or more exposure to organic solvents
4. Cessation of exposure not longer than three yrs before first diagnostic evaluation for CSE
5. Informed consent
6. Dutch speaking

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Other neurological illness
2. Alcohol or drugs related disorders
3. Psychotic symptoms
4. Radiation therapy
5. Chemotherapy
6. Previous treatment in neuropsychological rehabilitation

Date of first enrolment

01/03/2002

Date of final enrolment

01/06/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Meibergdreef 5

Amsterdam

Netherlands

1105 AZ

Sponsor information**Organisation**

Netherlands Center for Occupational Diseases (Netherlands)

ROR

<https://ror.org/00jtnvh80>

Funder(s)

Funder type

Government

Funder Name

Netherlands Center for Occupational Diseases (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration