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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

Registration date
31/08/2012

Overall study status
Completed

Last Edited
29/10/2015

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 benefical 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
1. Coping with cognitive impairment (CAMQ)
2. Subjectieve cognitive impairment (CFQ)
3. Meta memory (MIA)
Measured pre-intervention (T0), post intervention at 3 months (T1) and at 7 months follow up (T2)

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

Overall study start date

01/03/2002

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

Age group
Adult

Sex
Both

Target number of participants
2 x 35

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 neuropychological 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)

Sponsor details
Academic Medical Center
Amsterdam
Netherlands
1105 AZ

Sponsor type
Government

ROR
https://ror.org/00jtnvh80

Funder(s)

Funder type
Government

Funder Name
Netherlands Center for Occupational Diseases (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