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You've got family: the add-on effects of family involvement in cognitive behavioural therapy in substance dependent patients

Submission date 10/06/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/07/2009	**Overall study status** Completed	
Last Edited 15/07/2009	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Cor DeJong

Contact details
Radboud Universiteit Nijmegen
NISPA/ACSW
Postbus 9104
Nijmegen
Netherlands
6500
+31 (0)24 361 1150
c.dejong@acsw.ru.nl

Additional identifiers

Study information

Scientific Title
A multicentre randomised controlled trial to investigate the add-on effect of family involvement in cognitive behavioural therapy patients with a substance use disorder: the you've got family trial

Study objectives
The main focus of this study is to improve adherence from the lifestyle training by adding family meetings to the lifestyle training. The main study parameter is the proportion of patients finishing treatment (the lifestyle training). A patient finished the treatment when he or she attended the last session of the lifestyle training. We hypothesise that family involvement will increase patient adherence in the lifestyle training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board of the Medisch Spectrum Twente approved on the 27th April 2009 (ref: NL27609.044.09)

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Addiction, substance abuse

Interventions
A non-pharmacological treatment. In the experimental group, the treatment consists of the modules "lifestyle training III or IV", family meetings will be held with a significant other person present. The treatment of the control group consists of the same treatment module, but does not incorporate the family meetings.

In the experimental group the first family meeting treatment will be held after the first session of lifestyle training III. At the end of the treatment period the second family meeting will be held before the last session (= 6) of lifestyle training III. The first session consists a short explanation of the lifestyle training and the importance of giving support to the patient during treatment to enhance treatment compliance. In this session a form of psycho-education concerning substance abuse will be given. The second session is to evaluate the giving of support, answering questions and sharing experiences. In the lifestyle training IV, the first family meeting treatment will be held after the first session of lifestyle training IV. The second session will be held before the sixth session. At the end of the treatment period the last family meeting will be held before the last session (= 12) of lifestyle training IV.

At least seven months are needed: approximately four months of treatment and a three-month post-treatment follow up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Proportion of patients finishing treatment (the lifestyle training). A patient has finished the treatment when he or she attended the last session of the lifestyle training.

Measured after treatment measurement (after four months, during the last session of the Lifestyle training.

Key secondary outcome(s)
1. Number of sessions (percentage) attended by patients
2. Reduction of substance use (measured with the Meten van Addicties voor Triage en Evaluatie [MATE])
3. Improving quality of life (measured with the European Quality of Life Instrument [EuroQOL /5D], and 28-item General Health Questionnaire [GHQ-28])
4. Patient (measured with the GGZ thermometer) and family satisfaction (measured with the Family Contact, Information and Support [Family CIS], Family Member Impact Scale [FMIS] and Hopefulness-hopelessness scale [HOPE])

Measured after treatment measurement (after four months, during the last session of the Lifestyle training.

Completion date
01/04/2011

Eligibility

Key inclusion criteria
The patients who belong to the population of this study have been presented at one of the four Nijmegen Institute for Scientist-Practitioners in Addiction (NISPA) members for their substance use problem and undergo at this institution an out-patient treatment. All patients eligible for the lifestyle training and fulfilling inclusion criteria are invited to participate this study.

Characteristics of the participant to be included into the lifestyle training III:
1. The participant uses one of the following substances in a problematic way: cannabis, alcohol, cocaine, 3,4-methylenedioxymethamphetamine (MDMA - also known as ecstasy), amphetamines, medicines, or there are problems with gambling
2. The participant has never or only once been treated for his or her problems with the substance or with gambling
3. The social integration is average to very well. This can be shown by several facts, for example the presence of an average to strong social network and activities to fill the daily hours.

Characteristics of the participant to be included into the lifestyle training IV:
1. The participant uses one or more of the following substances in a problematic way: cannabis, alcohol, cocaine, ecstasy, amphetamines, heroine, medicines, or there are problems with gambling (sometimes combined with problematic substance use)
2. The participant has at least twice been treated for his or her addiction problems in a treatment that was less intensive and not successful
3. The participant has not been treated more than once for addiction problems, but has a very severe addiction and/or a lot of comorbid psychopathology

Other criteria:
1. Informed consent
2. Between 18 and 65 years of age, either sex
3. Have a well enough understanding of the Dutch language to fulfil the questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Insufficient capacity to speak and read the Dutch language

Date of first enrolment
01/04/2009

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud Universiteit Nijmegen
Nijmegen
Netherlands
6500

Sponsor information

Organisation
Radboud University Nijmegen (Netherlands)

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
University/education

Funder Name
Radboud University Nijmegen (Netherlands)

Alternative Name(s)
Radboud University, Radboud University Nijmegen, Radboud Uni. Nijmegen, RU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration