

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

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<b>Registration date</b> 15/07/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/07/2009	<b>Condition category</b> Mental and Behavioural Disorders	<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**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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)

## **Study design**

Multicentre randomised controlled trial

## **Primary study design**

Interventional

## **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, RU

**Funding Body Type**

Private sector 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