

# Cognitive behavior therapy for adults with intellectual disabilities and substance use disorders

<b>Submission date</b> 03/12/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/01/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cognitive Behavior Therapy (CBT) has been successfully used in the treatment of persons with mild to borderline intellectual disabilities (MBID) with other psychiatric symptoms. However, little is known about cognitive behavioral interventions for substance use disorders (SUD) in persons with MBID. Studies of CBT as a treatment of SUD in persons with MBID has been limited to single case studies and small group settings to date. These studies indicate that with a few changes in treatment approach and communication style these early attempts may be a successful treatment for people with MBID and SUD. The aim of this study is to find out whether CBT could be useful for persons with MBID and SUD.

### Who participated?

Patients aged over 18 with a MBID who are referred to an outpatient SUD treatment facility

### What does the study involve?

All participants attend a nine-week CBT program. A questionnaire is used to assess substance use in order to examine treatment effectiveness, along with feasibility questionnaires and interviews. Therapists are also interviewed, focusing on acceptability and practicality.

### What are the possible benefits and risks of participating?

Participants may benefit from reduced substance use. There are no expected side effects.

### Where is the study run from?

Tactus Addiction Care (Netherlands)

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

April 2014 to February 2017

### Who is funding the study?

Aveleijn Intellectual Disabilities; Tactus Addiction Care (Netherlands)

Who is the main contact?

Marion Kiewik

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Marion Kiewik

### ORCID ID

<https://orcid.org/0000-0002-2802-6910>

### Contact details

Grotestraat 260

Borne

Netherlands

7620 GW

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Pilot study of a cognitive behavior therapy for adults with mild or borderline intellectual disabilities (MBID) and substance use disorders (SUD)

### Study objectives

CBT helps clients with mild and borderline intellectual disabilities (MBID) to identify risk situations for substance use, to avoid these situations and to increase motivation to reduce and quit substance use. After the treatment (post-treatment) clients use less substances than at the beginning of the treatment (pre-treatment).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Because of the nature of this study, the study didn't need to be assessed by the reviewing METC (Dutch medical research ethics committee)

### Study design

Interventional non-randomised feasibility study

### Primary study design

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Participants with MBID with a history of Substance Use Disorder (SUD) who were referred to an outpatient SUD treatment facility

## **Interventions**

Participants and their direct caregivers were both individually informed by an information letter. Active informed consent was used in which participants can refuse to participate in the study by email or telephone during the whole study period. All client information sheets and consent forms were in easy-read versions.

The treatment program was based on the original CBT manual for the general population, modified for persons with MBID (VanDerNagel, Kiewik & Didden, 2014; VanDerNagel & Kiewik, 2016). The original manual (for individuals without MBID) consisted of a nine-week CBT program, in which the participants covered one topic each week. To adapt the original protocol to the needs of persons with MBID, the trialists firstly adjusted the treatment materials to facilitate the reading and understanding. Moreover, in order to improve comprehension, a client workbook was used in conjunction with the therapist manual. The workbook contains worksheets with easy-to-understand text and images. Secondly, the trialists changed the structure of the CBT program by doubling the amount of the sessions compared to the original CBT manual (from 9 to 18 sessions). Further, half of the sessions were accompanied by a confidant (mostly a direct caregiver) to reinforce skill acquisition outside the therapy sessions and helping out the participant with homework tasks. Inclusion of confidants in CBT therapy may enhance treatment effects. Specifically, by teaching confidants about CBT and the background of SUD they can then encourage and help the person with MBID use these skills within natural and real-life contexts, outside the therapy sessions, and after the therapy has ended.

### **Acceptability questionnaire:**

To measure protocol acceptability, the number of sessions attended and completed were recorded as a measure of treatment compliance. Further, therapists were asked whether they stayed close to the CBT+ protocol after each session. The answers were measured on a 3-point Likert scale: 'Could you accomplish all different topics during this session?', (1) yes; (2) partly or; (3) no. If they could not accomplish one or more topics during the session, they were asked about the reasons. These answers were measured on a multiple choice option (lack of time; goal unclear; not relevant; other problems of the client were more important; comorbidity problems; too complex; other problems). In addition, clients and confidants were asked to rate their general impression with the program (score 0 -10). Clients and confidants were also asked to rate the number and length of the sessions and the information in the workbook. The answers, except the open questions, were measured on a 4-point Likert scale (e.g. 'How do you rate the length of the sessions?', (1) 'too many/lengthy'; (2) 'good'; (3) 'too little/short' or (4) 'I don't know'). Clients and confidants were also given the opportunity to respond to two open-ended questions that asked for suggestions for improvement of the treatment program.

### **Feasibility questionnaire:**

After the CBT program, therapists were asked to rate the manual, the information, the workbook, the exercises and the information for the confidant. The answers were measured on a 5-point Likert scale (very good/too many (1); good/many (2); neutral/good (3); bad/little (4) or too bad/too little (5)).

## Substance use:

Substance use was measured by the Substance use and misuse in Intellectual Disability - Questionnaire (SumID-Q, VanDerNagel, Kiewik, VanDijk, DeJong, & Didden, 2011; VanDerNagel, Kemna, & Didden, 2013). The SumID-Q comprised questions assessing lifetime, last month, and recent use of tobacco, alcohol, cannabis, and stimulants (cocaine and amphetamines) and its risk factors and consequences among persons with MBID. The administration of the SumID-Q took approximately 45 to 60 minutes.

A qualitative process evaluation was also conducted by means of individual face to face interviews with five participants and four therapists. For this purpose, a semi-structured questionnaire of five open-ended questions was used which were designed to explore the participants' view of 1) the CBT+ protocol in general; 2) the role of the confidant; 3) the treatment materials; 4) the treatment exercises and 5) suggestions for improvement. The answers provided by participants were audiotaped with the participants' consent. Two students then transcribed them verbatim. Each substantive response was analyzed by the two students and was grouped into the five topics for further thematic analysis.

## Intervention Type

Behavioural

## Primary outcome(s)

1. Feasibility of the CBT protocol in terms of acceptability and practicality:
  - 1.1. Therapists complete an acceptability questionnaire after each session. In total therapists completed 18 questionnaires per client
  - 1.2. Both clients and therapists complete a feasibility questionnaire 0 -2 weeks after ending the entire CBT+ protocol
2. Preliminary effectiveness of the treatment (in terms of decreased alcohol, stimulants and cannabis use), measured with the SumID-Q at baseline (0 - 2 weeks before the start of the treatment), post-treatment (0 - 2 weeks after ending the treatment) and at 3-months follow-up

## Key secondary outcome(s)

Drop-out rate during the treatment

## Completion date

01/02/2017

## Eligibility

### Key inclusion criteria

Between June 2014 and September 2015 twenty-three participants with MBID with a history of SUD who were referred to an outpatient SUD treatment facility were included. Criteria for inclusion in this study were:

1. Dutch as a first language
2. Sufficient oral communication skills (i.e., fluent verbal speakers)
3. A mild to borderline intellectual disability (i.e., full scale IQ between 50 – 85 according to DSM-IV criteria measured by regular intelligence tests, or, when a regular intelligence test were absent the full scale IQ was estimated by the first responsible caregivers)
4. Older than 18 years of age

Participants had no restrictions in remaining in other mental health treatment that they were currently receiving (e.g. EMDR or medication management)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Non-Dutch speaking
2. Insufficient oral communication skills
3. A moderate or severe intellectual disability (i.e., full scale IQ below 50) or a normal intelligence according to DSM-IV criteria measured by regular intelligence tests, or, when a regular intelligence test were absent the full scale IQ was estimated by the first responsible caregivers)
4. Younger than 18 years of age
5. Serious psychiatric illnesses with a chance to decompensate

**Date of first enrolment**

01/06/2014

**Date of final enrolment**

01/09/2015

**Locations****Countries of recruitment**

Netherlands

**Study participating centre****Tactus**

Keulenstraat 3

Deventer

Netherlands

7418 ET

**Sponsor information**

## Organisation

Aveleijn

## ROR

<https://ror.org/03krr1g45>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Aveleijn Intellectual Disability Services

## Results and Publications

### Individual participant data (IPD) sharing plan

An anonymized, modified dataset will be available on request and deposited in a public online data repository ([www.researchgate.com](http://www.researchgate.com)) as soon as possible. To access the data before that time, please contact Marion Kiewik.

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Thesis results</a>		14/01/2019	07/01/2022	No	No