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

Submission date
03/12/2017

Recruitment status
No longer recruiting

Registration date
03/01/2018

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 feasibillty study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

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 measures 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 measure
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

Secondary outcome measures
Drop-out rate during the treatment

Overall study start date
01/04/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 20 participants

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

Sponsor details
Grotestraat 260
Borne
Netherlands
7620 GW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03krr1g45

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Aveleijn Intellectual Disability Services

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal, such as Journal of Intellectual Disability Research. Submission is planned in December 2017.

Intention to publish date
01/02/2018

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) 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?
Thesis results		14/01/2019	07/01/2022	No	No