

# Integration of medical, psychiatric and behavioural care for the substantiated and appropriate use of psychotropic drugs in individuals with an intellectual disability and challenging behaviour.

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The main objective of this study is: This study investigates whether diagnosis and treatment of challenging behaviour, as provided by an specialist team of mental health care professionals and intellectual disability professionals, when optimising...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Psychiatric and behavioural symptoms NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON55155

### Source

ToetsingOnline

### Brief title

CHALIDIT-CRT

### Condition

- Psychiatric and behavioural symptoms NEC

### Synonym

Challenging behaviour, problem behavior

### Research involving

Human

## Sponsors and support

**Primary sponsor:** GGZ Drenthe (Assen)

**Source(s) of monetary or material Support:** ZonMw;Innovatiefonds Zorgverzekeraars

## Intervention

**Keyword:** Challenging behaviour, Integrative treatment, Intellectual disability, Psychotropic drugs

## Outcome measures

### Primary outcome

The main parameter of this study is the total score of the Aberrant Behavior Checklist (ABC) (Aman, Singh, Stewart, & Field, 1985). The ABC is a symptom checklist that is used to assess problem behavior of children and adults with developmental disorders. It was initially developed to measure the effects of treatment. The ABC has five subscales: Irritability Lethargy; Stereotypic Behavior; Hyperactivity; and Inappropriate Speech. The checklist can be completed by parents and caregivers that have extensive knowledge of the person being assessed. The estimated time needed to complete the entire Aberrant Behavior Checklist is ten to fifteen minutes.

### Secondary outcome

The secondary study parameters of this study are:

- Behavior Problems Inventory (BPI)
- The outcome measure 'Client\*s perspectives on treatments outcomes of challenging behaviour' that is developed in a subproject of this study (METC registration number 2019/178)
- Restrictive measures
- Medical diagnoses

- Implemented interventions
- Psychotropic drugs: type, dosage and frequency; quality of the drug prescription through the TIPT (Toetsingsinstrument Psychofarmaca Toepassing);
- Anticholinergic cognitive burden scale
- Extrapyramidal and autonomous nervous system side effects

Other study parameters of this study are:

- Minimal Data Set (MDS)
- Subscale self-determination of Personal Outcome Scale (POS)
- Subscale \*communicatie en invloed\* of the Quality of Life of Persons with Profound Multiple Disabilities (QOL-PMD)
- Checklist Life Events (CLE)
- Psychiatric Assessment Schedule for Adults with a Developmental Disability Checklist (PAS-ADD Checklist)
- Vragenlijst over Ontwikkeling en Gedrag van kinderen (VOG)
- Analyse processen rondom de zorg en behandeling voor mensen met een verstandelijke beperking en moeilijk verstaanbaar gedrag

## Study description

### Background summary

Challenging behaviour is prevalent in people with intellectual disabilities (ID). (A prevalence of 18.1% as reported by Bowring, Totsika, Hastings, Toogood, & Griffith, 2017). Challenging behaviour consists of a heterogeneous group of behaviours such as aggression, self-injurious behaviour, irritability, stereotyped behaviour and withdrawn behaviour. Individuals with challenging behaviour require appropriate and proper treatment.

Challenging behaviour is often treated with psychotropic drugs. Individuals with challenging behaviour often receive psychotropic drugs for long periods of time and this in turn can contribute to difficulties in reducing the drugs. Evidence for positive effects of psychopharmacological treatment, is scarce and adverse effects are clearly present, negatively affecting the quality of life, yet its use remains widespread.

Endeavours to reduce the prescription of antipsychotic drugs for challenging behaviour have been successful in part only, and the occurrences of unsuccessful reduction have given rise to the exploration of the treatment of challenging behaviour in a broader scope. The newest Dutch guidelines and government policies aim towards the reduction of inappropriate psychotropic drug use and the stimulation of non-pharmaceutical treatment. (The same development can be seen in the British NICE guidelines.)

However, reducing the use of unfit psychotropic drugs and stimulating non-pharmaceutical treatment is often difficult in practice due to several reasons. First of all, the assessment and treatment of challenging behaviour is complicated. Secondly, stimulating non-drug treatment for behavioural problems in individuals with an intellectual disability is difficult, because individuals with ID can be served in two separate health care systems, namely the care for people with an intellectual disability and mental health care. The care provided to individuals with ID is specialized in problems occurring with an intellectual disability (often in a residential setting) but is not necessarily specialized in the assessment and treatment of psychiatric problems; psychiatric care, on the other hand, does not necessarily include knowledge of and experience with providing care to people with ID.

The amount of psychological and psychosocial treatment that people receive in addition to pharmacological treatment is lower in specialized care for individuals with ID than in mental health care. This indicates that a proper and uniform health care offer is needed, to reduce unfit psychotropic drug use, in which the expertise from mental health care and the expertise from the care for individuals with ID are integrated.

In this study, the knowledge of patient experts, medical experts, psychiatric experts and behavioural experts will be integrated into one treatment that is provided to the client by one team. This study is aimed at testing how effective the integrative approach is in reducing challenging behaviour, and reducing unfit psychotropic drug use.

The hypothesis of this study is that treatment and diagnosis of challenging behavioural symptoms, (which are or have been reason for off-label psychotropic drug prescription), as provided by this specialist team, when optimising the use of off-label psychotropic drugs amongst individuals with a moderate to severe intellectual disability and challenging behaviour, leads to better

results as measured with the Aberrant Behavior Checklist than care-as-usual.

## **Study objective**

The main objective of this study is:

This study investigates whether diagnosis and treatment of challenging behaviour, as provided by an specialist team of mental health care professionals and intellectual disability professionals, when optimising the use of off-label psychotropic drugs amongst individuals with a moderate to profound intellectual disability and challenging behaviour, leads to better results as measured with the Aberrant Behavior Checklist than care-as-usual.

The secondary objectives of this study are:

To compare the results of treatment of challenging behaviour when optimising off-label psychotropic drug use, provided by the integrative health care team versus care-as-usual, regarding:

- a. the effect on behaviour as measured with the Behavior Problems Inventory (BPI) (Rojahn, Matson, Lott, Esbensen, & Smalls, 2001)
- b. the effect on quantity and quality (adherence to guideline recommendations) of off-label psychotropic drug prescription.
- c. the effect on Health-related Quality of Life (HQOL) and daily functioning as measured with an Outcome Measure \*Client\*s perspectives on treatments outcomes of CB\* (that is developed in a subproject of the research project).
- d. the number and nature of side-effects of psychotropic drug use.

## **Study design**

The study is a cluster-randomized controlled trial. The outcome of the intervention group will be compared to a care-as-usual control group, to assess its possible additional value. This design is chosen because there is no option for a control group without treatment, since the care-as-usual treatment is already ongoing, and pausing this would not be ethically justifiable. The intervention cannot be blinded, because it is obvious which group the participants are in. The randomization has to be clustered due to the risk of contamination. (If a participant of the control group lives in the same department/house as a participant in the intervention group, their environment-focussed interventions could be interacting.)

## **Intervention**

Participants in the intervention group will receive integrative care by a specialized mental health care team, consisting of mental health care professionals and health care professionals for individuals with ID (generally

consisting of a psychiatrist, physician for individuals with ID, psychiatric nurse/social worker, psychologist and/or behavioural scientist).

The professionals will provide care according to professional standards and guidelines. The specific diagnostic and treatment interventions are selected by their professional opinion of the best fit for the situation the participant is in. The professionals of the specialized mental health care team will be provided with training about the assessment and treatment of challenging behaviour, to ensure a unified approach and level of knowledge in each intervention-team.

A general care path is described here, to give an impression of the general range of possibilities. This description is not an exhaustive or complete overview. The care path consists of two parts: the diagnostic phase and the treatment phase.

The intervention will last 9 months. The first 6-8 weeks are needed for diagnostic assessment; the remaining months are meant for treatment. Re-evaluating the diagnostic assessment remains an opportunity throughout the intervention. After 9 months, if treatment is still ongoing, this can be continued outside of the study setting. The start of intervention is spread over the first 6 months of the study, so that the last participant will finish the intervention in month 15.

## Diagnostic phase

### Initial interview

To assess main problem(s) and direction of further plan

### Diagnostic assessment, basic:

- File study (incl. course of the symptoms in the past, comorbidities, previous psychological and pedagogical evaluations, previous treatments)
- Hetero-anamnesis
- Observation of participants\* behaviour and interaction, preferably in participants\* daily environment
- Physical examination.
- Medication review, including the assessment of the efficacy and side-effects

### Diagnostic assessment, extended:

- Psychological assessments
- System assessment
- Psychiatric assessment
- Applied behavioural analysis
- Assessment of communication needs
- Assessment of problems and needs related to motor functioning and aids
- Assessment of visual and auditory functioning
- Assessment of problems with eating and swallowing

The diagnostic findings will be discussed in a multidisciplinary meeting of the specialist team and a treatment options will be identified. The treatment

options will be discussed with participant and legal representatives, as well as caregiver and when applicable his/her own clinicians. Since treatments may have advantageous and disadvantageous effects, these effects will be discussed and balanced (shared decision making with participants\* representatives), and the final plan will be written down as the treatment plan. As usual in health care, informed consent (as stated by the WGBO) by the participants and/or legal representatives is required before the treatment can start.

## Treatment phase

Some of the possible treatments are listed here:

- treatment (advice) of underlying somatic disorder
- behaviour analysis and treatment by means of a structured method such as ABA
- interventions to improve social interaction and participation
- (non-verbal) psychotherapy
- systemic therapy
- team coaching
- psychoeducation
- psychopharmacologic optimization
- psychomotor therapy
- paramedical interventions (such as supportive communication, physiotherapy, sensory integration therapy, creative therapy)

Treatment evaluations are part of the treatment phase. They consist of evaluations of treatment execution, effects and - goals, and if necessary adaptation of the treatment plan along with the participant and/or legal representatives.

The outcomes of the physical study parameters will be available to the professionals, to minimize the impact on the participant and his/her environment (e.g. prevent double physical examination), and because this could support good treatment outcomes of the participant, which is more generally the purpose of this study.

## Study burden and risks

With changes in medication there is a chance of physical and psychological reactions, for example withdrawal symptoms or a (temporary) increase in challenging behaviour can occur. This is no more the case in this randomised controlled trial than in usual care. Any unexpected effects of treatments by medical professionals cannot be foreseen.

The results of the study can lead to an improved treatment for all persons with an intellectual disability. Therefore, the risk and burden on the subject are in proportion to the potential value of the study.

The study can also be beneficial for the subjects participating in the study, because the research may improve their use of psychotropic drugs and / or challenging behavior. The burden and risks for participants of the study are no greater than in the usual care.

The research can be regarded as group-related, because it is clear that optimising the treatment of individuals with an intellectual disability and challenging behaviour cannot be conducted without the participation of these individuals.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Person with a moderate to profound intellectual disability (level of cognitive development < 6 years)
- Age > 12 years
- Off-label psychotropic drug use for more than one year



- Informed consent (IC) signed by participant and/or participant representative (depending on the competence of the participant)

## Exclusion criteria

A diagnosis of, classified according to DSM-5 criteria:

- Dementia
- Chronic psychotic disorder
- Schizoaffective disorder
- Bipolar disorder type I
- Significant life event in the past six months

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Health services research

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2020
Enrollment:	106
Type:	Actual

## Ethics review

Approved WMO	
Date:	02-12-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	10-09-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	23-11-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	04-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	23-03-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL70909.042.19
Other	NL7868