Treatment of challenging behaviour with medication; is there another way?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23433

Source
NTR

Brief title
CHALIDIT-CRT

Health condition

Mental health problems

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: ZonMw, Innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

Aberrant Behavior Checklist

Secondary outcome

Behavior Problems Inventory, Quantity and quality of off-label psychotropic drug prescription,

Medical diagnoses, Restrictive measures, Implemented interventions, Type, dosage and frequency of psychotropic drugs, The number and nature of side-effects of psychotropic drug use,
Baselin measures: Minimal Data Set (MDS), Personal Outcome Scale (POS), 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)

Study description

Background summary

This study investigates whether diagnosis and treatment of challenging behaviour, as provided by an integrative team of mental health care specialists and intellectual disability specialists, 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.

Study objective

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 integrative 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 design

Baseline, 8, 16, 24, 32, 40 and 52 weeks

Intervention

Integrative care provided by a specialist mental health care team

Contacts

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Eligibility criteria

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

- One of the following DSM diagnoses:
- 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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2020
Enrollment:	36
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	12-07-2019
Application type:	First submission

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
NTR-new	NL7868
Other	Medisch Ethische Toetsingscommissie UMC Groningen : 201900479

Study results