Determinants of succesful discontinuation of antipsychotics used for behavioural symptoms in people with intellectual disability

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Succesful discontinuation of antipsychotics used for behavioural symptoms in people with intellectual disability is determined by staff-related factors and by neurological withdrawal symptoms.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21589

Bron
NTR

Verkorte titel
AFBAP2

Aandoening

off-label use; antipsychotics;long-term use; behavioural symptoms; challenging behaviours; problem behaviours, intellectual disability; staff-related factors; attitudes; cognitions;knowledge; neurological withdrawal symptoms; extrapyramidal symptoms; autonomic symptoms; quality of life

Ondersteuning

Primaire sponsor: University Medical Centre Groningen/department psychiatry
Overige ondersteuning: Stichting Zorgondersteuningsfonds
the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Achievement of complete discontinuation at the time point of 16 weeks (two weeks after the study discontinuation schedule)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: People with intellectual disability (ID) frequently use long-term antipsychotic drugs for challenging behaviors, although the efficacy in this indication has not been proven. Moreover, antipsychotics may cause harmful side effects, which may negatively influence quality of life. Especially neurological side-effects may be serious and sometimes life threatening or irreversible. In order to prevent iatrogenic damage caused by unnecessary antipsychotic drug use discontinuation should be considered.

In daily practice successful discontinuation of antipsychotics may be hampered by neurological withdrawal symptoms, which may remain clinically undiagnosed. Withdrawal symptoms may cause distress and an increase in behavioural symptoms, thus likely leading to higher dosage and ongoing use of the antipsychotic drug. Also, staff- related factors like knowledge and cognitions of psychotropic drug use and attitudes towards challenging behaviours of their clients may influence a successful discontinuation trajectory.
Objectives: To investigate whether the occurrence and severity of neurological withdrawal symptoms during the discontinuation trajectory is associated with achievement of complete discontinuation. To investigate staff-related factors which may be associated with successful discontinuation of antipsychotics used for challenging behaviours in people with ID.
Secondary objectives: To study the effect of discontinuation on health related quality of life. To study whether there is an association of severity of neurological side effects with health related quality of life
Study design: Prospective study
Study population: People with intellectual disability aged six years and over, who use antipsychotic drugs for challenging behaviours for more than one year and who are presented a treatment proposal of an attempt to scheduled discontinuation by their physicians, as part of their regular treatment.

Intervention: A series of eight brief medical exams during the discontinuation trajectory, in which antipsychotics will be tapered off by lowering the dose every 2 weeks with 12.5% of baseline dosage.

Main study parameters: Study parameters are scores of extrapyramidal symptoms, scores of behavioral measurements, scores of questionnaires of staff-related factors and scores of questionnaires of health related quality of life.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The proposed treatment is part of regular medical practice. Also, the medical assessments of physical symptoms are part of regular medical medication controls whereby the burden is minimal. It is obvious that study of medication discontinuation in patients with intellectual disability can only be performed in intellectually disabled participants.

Doel van het onderzoek

Succesful discontinuation of antipsychotics used for behavioural symptoms in people with intellectual disability is determined by staff-related factors and by neurological withdrawal symptoms.

Onderzoeksopzet

Data collection will take place at baseline and at 4, 8, 12, and 16 weeks after the first dose reduction. Follow-up data collection is at 6, 12, and 26 weeks after the scheduled time point of complete discontinuation.

Onderzoeksproduct en/of interventie

discontinuation of long-term used antipsychotics for behavioural symptoms whereby dosereduction will take place every two weeks with appr. 12.5 % of baseline dosage in a time schedule of 14 weeks

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Any sex or ethnicity

• Age ≥ 6 years

• Functioning below an IQ level of 70 as assessed by an authorized behavioral scientist

• Subjects have used one or more antipsychotics for more than one year for challenging behavior

• Subjects have been presented a treatment proposal of an attempt to discontinue antipsychotics by their physician.

Written informed consent of the legal representative.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• A history of schizophrenia, a bipolar disorder, or affective psychosis according to DSM IV or ICD-10 criteria

• A history of unsuccessful withdrawal of antipsychotics in the past 6 months

• Use of risperidone

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-11-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5394
NTR-old	NTR5519
Ander register	2014-002686-30 : Eudra CT

Resultaten