

The effect of dialectical behavior therapy in autism spectrum patients with suicidality and/or self destructive behaviour: a multi-site randomized controlled trial.

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1. The first aim is to evaluate the effect of a short term DBT treatment program (26 weeks) versus treatment as usual, in terms of reduction of suicidal and/or self-harming behaviour in outpatient with autism, suicidality and self-destructive...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON53092

Source

ToetsingOnline

Brief title

DIASS

Condition

- Developmental disorders NEC

Synonym

autism, suicidality and destructive behavior

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Parnassia Groep innovatiefonds;GGZ Altrecht ;GGZ Rivierduinen;GGZ Parnassia Groep;GGZ Pro Persona;crowdfunding

Intervention

Keyword: Autism, Dialectical behaviour therapy, Self destructive behaviour, Suicidality

Outcome measures

Primary outcome

The first objective is to assess the effect of a short term DBT treatment program (26 weeks) versus treatment as usual, in terms of reduction of suicidal and/or self-harming behaviour in adult patients with autism

Secondary outcome

Secondly, the effects of DBT treatment are determined on anxiety and social performance, depression, core symptoms of ASD, quality of life and cost-effectiveness and cost-utility.

Thirdly, predictors, moderators, and mediators for treatment success will be explored. These include emotion regulation; strength of the therapeutic alliance; difficulties engaging in goal-directed behaviours; demographic characteristics and alexithymia

Study description

Background summary

The prevalence of ASD is 1%: 170.000 patients the Netherlands (Brugha et al., 2011). Many patients with ASD are treated in long-term specialized care and

suicidal behavior is an issue that troubles patients, families and specialists in the field. Suicidality in autism is more common than previously thought. A meta-analysis with the studies in the review by Segers et al. (2014) found 20.4 % of suicidal ideation and 10.0% suicidal behavior in patients with ASD. At this moment, there is no documented effective therapy for suicidal behavior in ASD. Yet, there are promising clinical trials conducted with Dialectical Behavior therapy (DBT) in the participating institutes. DBT is the most researched and best empirically validated treatment program for chronically suicidal patients with borderline personality.

Subjects receiving DBT were half as likely to make a suicide attempt, required less hospitalization for suicide ideation and had lower medical risk across all suicide attempts and self-injurious acts combined. Subjects receiving DBT were less likely to drop out of treatment and had fewer psychiatric hospitalizations and psychiatric emergency department visits. ASD and BPD have many features in common: both experience problems in emotion regulation, impulse control and have deficient social skills. DBT addresses these issues. Especially the strict and repeated behavioral character of the interventions and the building of emotion regulation skills will be welcomed by the autistic preference for predictable instruction and rules of conduct.

Study objective

1. The first aim is to evaluate the effect of a short term DBT treatment program (26 weeks) versus treatment as usual, in terms of reduction of suicidal and/or self-harming behaviour in outpatient with autism, suicidality and self-destructive behavior
2. Secondly, the effects of DBT treatment are assessed on anxiety and social performance, depression, core symptoms of ASD, quality of life and cost-effectiveness and cost-utility.

Study design

A multicenter single blind randomized clinical trial with two arms and 12-month follow up.

Intervention

Dialectical behaviour therapy will be compared with *treatment as usual*. In the DBT condition, patients combine weekly individual cognitive behavioral psychotherapy sessions given by primary therapist with two times a week skills-training groups lasting 2.5 hours per session. The control condition is treatment as usual which consists of, at least, weekly sessions of 30-45 minutes with a psychotherapist or social worker

Study burden and risks

Measurement moments will be at baseline, at end-of-treatment at 6 months and at follow-up at 12 months. This will take approximately 7 hours in total. There is no practice-nor evidence based treatment for treating suicidal behavior in autism. Based on previous positive clinical experiences, we expect patients to benefit from the therapy. We expect that DBT would be effective in decreasing suicidal and self-destructive behavioral and to increase quality of life and increase social functioning.

Research has shown that the participation of suicidal persons to experimental studies does not lead to more suicides or more suicide attempts and exclusion of suicidal subjects does not lead to less suicides or suicide attempts in research trials. The questions to the own suicidality of subjects from both the general population and vulnerable and suicidal populations does not lead to increase in suicidality. A small group of participants find the questions to unpleasant confrontational and suicidality (light) but this concerns short-term effects and participation is nevertheless, typically seen as valuable (Huisman en Kerkhof 2017). Dialectical Behaviour therapy (DBT) is the most researched and best empirically validated treatment program for chronically suicidal patients with borderline personality. Prior use of Dialectic Behaviour therapy (DBT) have caused little or no damage. Damage can occur in emotional stress , similar to regular cognitive -behavioral treatment. Generally, the group is rigid in behavior and habit and we see no additional risks with standard treatment DBT. Therefore, we estimate the risk of injury as small. We do not expect any aversive events and these are not documented

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- 1) age between 18 and 65 years
- 2) Meets DSM V criteria for autism spectrum disorder
- 3) Suicidal and / or self destructive behavior have shown in year before starting treatment
- 4) Sufficient mastery of the Dutch language
- 5) Outpatient

Exclusion criteria

- 1) IQ <80
- 2) Addiction to illicit drugs in need of clinical detoxification

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2018

Enrollment:	128
Type:	Actual

Ethics review

Approved WMO	
Date:	16-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	03-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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

CCMO

ID

NL59497.029.17