A pilot study of Acceptance and Commitment Therapy (ACT) for adolescents with autism spectrum disorder (ASD)

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

Summary

ID

NL-OMON56759

Source
ToetsingOnline

Brief title
ACT & Autism

Condition

- Developmental disorders NEC

Synonym
autism spectrum disorder; autism

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Universiteit Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acceptance and Commitment Therapy, Autism, Intervention, Pilot study

Outcome measures

Primary outcome

The goal of the current observational multicenter pilot study is to investigate if an 8-week Acceptance and Commitment group therapy for youth with ASD is an effective intervention to increase adaptive emotion regulation, psychological flexibility and quality of life. For this we have selected several parameters which are suitable for multiple measurements due to brevity and ease (multilevel single case (MSC) design, whilst other parameters are most suitable for pre-post-follow up design to provide more comprehensive insights into the functioning of the participants and the effects of the intervention (pre-post-follow up design).

Primary Objectives:

To assess

- Emotion regulation -->

o FEEL-KJ (Braet et al., 2013) (pre-post-follow up)

o Valuing Questionaire (VQ) (Smout, 2014) (pre-post-follow up and MSC)

- Psychological flexibility -->

o Avoidance and Fusion Questionnaire for Youth (AFQ-Y) (Greco et al., 2008) (pre-post-follow up)

o Valuing Questionaire (VQ) (Smout, 2014) (pre-post-follow up and MSC)

- Quality of life -->

o Mental Health Quality of Life (MHQoL) (van Krugten et al., 2022)

(pre-post-follow up and MSC)

Secondary outcome

Secondary Objective(s):

In addition, we want to investigate if the treatment has any effect on

emotional and behavioral problems and general functioning (e.g., attending

school or not; utilization of other (mental) healthcare).

To assess:

- Emotional and behavioral problems -->

o Youth/Adult Self Report (YSR/ASR) and Child Behavior Checklist (CBCL;

ASEBA,(Verhulst et al., 1989, 1996) (pre-post-follow up)

- Demographic questions -->

o School attendance (pre-post-follow up)

o Utilization of (mental) healthcare (pre-post-follow up)

Lastly, we will use some information for baseline/comparison to ROM data and/or

elements which may be influential on our measurements or potential desired

side-products:

- Autistic traits -->

o Social Responsiveness Scale (SRS-2/SRS-A) (not expected to change, but

possibly an influential factor on the success of the intervention) (Roeyers et

al., 2011)

- Current feeling (start of session) -->

o Visual Analogue Scale (VAS; not expected to change but a potentially

influential factor on our outcome measures and a potential by-product of the

intervention).

Study description

Background summary

Evidence-based treatment for adolescents with autism spectrum disorders (ASD) and comorbid issues such as high levels of anxiety, depression, and persistent physical complaints is scarce. Mental health care professionals seek fitting and effective treatments. Acceptance and Commitment Therapy (ACT) seems to be a promising method, which aims to teach individuals how to cope with complaints (rather than trying to diminish or fight complaints) and develop a meaningful life. However, this form of therapy has not been studied in autistic youth before, therefore making it unclear if ACT could be an effective intervention.

Study objective

The goal of the current observational multicenter pilot study is to investigate if an 8-week Acceptance and Commitment group therapy for youth with ASD is an effective intervention to increase adaptive emotion regulation, psychological flexibility and quality of life? We aim to see if there are effects on a group level from pre-intervention to post intervention, as well as at 6-months follow-up (pre-post-follow-up design). Moreover, we will also investigate if there are effects on an individual level from pre, to during, to after the intervention (multilevel single case design).

Study design

This study will be a multicenter pilot study with a pre-post-follow up and multilevel single case design. In the pre-post-follow up arm participants will fill out a long survey (approx. 45 minutes) 3 times (prior, after and at 6 months follow-up), whilst in the multilevel single case arm participants will fill out a weekly short survey (approx. 5 minutes) from 4 weeks prior to 4 weeks after the last session of the intervention (1st and last week of these measurements are included in the long survey to reduce burden on participants).

Intervention

Before the first session, an individual intake takes place to set personal goals. The ACT group for adolescents with ASD is an 8-week protocol developed

specifically for adolescents with ASD. They join a group treatment covering the six ACT core principles (Present moment, Acceptance, Defusion, Self as Context, Values, Committed Action). After the 8 group sessions, in an individual closing meeting, the goals are evaluated with the adolescent. Two booster sessions are used to repeat the essentials of the theory and exercises and to let the adolescents practice using ACT skills when running into challenging situations in their daily life. After the 4th group session, there will be a parent session to also provide the parents with information on ACT; suggestions on how they may support their child by means of ACT, and connection with other parents of autistic children.

Study burden and risks

The participants will take part in a group treatment which can be considered as care-as-usual, including the booster sessions, as similar care (i.e., group therapy, with a different method, for example psycho-education or music therapy) is already offered at the clinical locations. Different from the care-as-usual, is that participants are asked to fill out a weekly short survey from 4 week prior to treatment to 4 weeks after treatment (16 * 5 min) and 3 times the longer survey prior to treatment, directly after treatment and 6 months after treatment (3 * 45 min). The 1st and last week of the short measurements are included in the long survey to reduce burden on participants. The filing out of questionnaires should then total to a maximum of 215 minutes (i.e., just over 3.5 hours over the span of 10 months). In addition, the parents of the participants will fill out a survey on child emotional and behavioral problems prior and after treatment (2 * 45 min) and attend a parent-session after the 4th group session (45 min).
The time spent may be a burden on the participants and their parents. We have tried to minimize the time spent to reduce the burden, whilst upholding the integrity of the study. Given that the participants can fill out the weekly surveys at their session in no more than 5 minutes, this can be considered part of the treatment as it is integral in the session. In addition, the 1st and last week of the MSC measurements are included in the long survey to reduce burden on participants.
As we intend to investigate the feasibility and efficacy of a new treatment in autistic youth, it is necessary to collect data in this group. By doing this in the current design (the pre-post design combined with the multi-level single case design), we will get rich data which will allow us to analyze the effects in-depth, so we can more accurately estimate potential efficacy, identify who may benefit most, and which sessions may be most beneficial whilst having a limited number of participants. Other than the time investment, we believe there are no other burdens or risks to participating in the study as the intervention can be seen as care-as-usual. In addition, the time spent is spread out of 10 months.

Contacts

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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)

Inclusion criteria

Inclusion criteria are age between 12 and 21 (given child and adolescent healthcare age cut-offs), being referred to one of the participating mental health institutions, and a primary classification of ASD for the youth participants. Also, we ask the parents of the participants to fill out 2 questionnaires (pre and post) and to participate in a parent-session (care as usual)

Exclusion criteria

Exclusion criteria: insufficient knowledge of the Dutch language, acute suicide

risk, drug abuse, and an estimated total IQ below 80.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-05-2024
Enrollment:	64
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-05-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL86185.078.24