

Effectiveness of Animal Assisted Interventions (AAI) in adults with an Autism Spectrum Disorder

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The overall goal is to gain insight in the effects of Animal Assisted Interventions in adults with autism spectrum disorder. This object is divided into three main research questions: Psychological parameters: What is the effect AAI on self-reported...

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

Summary

ID

NL-OMON40783

Source

ToetsingOnline

Brief title

AAI and Autism Spectrum Disorders

Condition

- Developmental disorders NEC

Synonym

autism, autism spectrum disorder

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)

Source(s) of monetary or material Support: Stichting Olim van de GGZ Oost Brabant

Intervention

Keyword: AAI, Autism Spectrum Disorders, service dog, treatment

Outcome measures

Primary outcome

Self reports on perceived stress: Scores on the PSS

Overall psychological distress: scores on the SCL-90-R

Self confidence rates: Scores on the RSES

Characteristics of ASD: Scores on the SRS-A

Physiological stress: Salivary cortisol, salivary alpha-amylase and heart rate variability

Secondary outcome

Qualitative observations of social behavior: the social behavior list

Explorative: For the intervention group: Physiological stress: Salivary cortisol, salivary alpha-amylase and heart rate variability at session 5

Proces evaluation: Questions after AAI is completed

Study description

Background summary

Autismspectrumdisorder (ASD) is a lifelong disorder that can't be cured. However, people with ASD often experience many problems in daily life. The most common symptoms are anxiety and depression. In addition, they often suffer from chronic stress. This may lead to secondary problems such as a low self esteem, sleeping problems and physical problems. There are only two type of treatments scientifically investigated on their effectiveness in reducing anxiety and depression in adults with ASD, cognitive behavioral therapy and mindfulness. Both show positive results in reducing depressive symptoms. However, there are also disadvantages reported for people with ASD, so it is not effective for all adults with ASD. Animal Assisted Interventions (AAI) is known to have a

positive effect on improving social skills, increasing self confidence, and reducing anxiety and stress. This effect has also been demonstrated in children with ASD. This type of intervening however, has not been studied in adults with ASD. Due to the positive results in other treatment groups and in children with ASD, we expect this intervention to be effective on reducing common problems in ASD. For this purpose, the effectiveness of AAI on adults with ASD is studied in this project to gain insight in the effects of AAI. In addition to the use of self-reports, physiological stress measures and observations will be collected as dependent variables in this study.

Study objective

The overall goal is to gain insight in the effects of Animal Assisted Interventions in adults with autism spectrum disorder.

This object is divided into three main research quentions:

Psychological parameters:

What is the effect AAI on self-reported psychological stress, overall distress and self-confidence?

Biological parameters:

What is the effect of AAI on physiological parameters (salivary cortisol, salivary a-amylase and heart reate variability)?

Social parameters:

What is the effect of AAI on social communicative skills?

Study design

The research is based on a randomized controlled trial with six groups of 6 participants in the intervention and six groups of 6 participants in the waitinglist control group. Participants will be randomly assigned to the intervention or waiting list control group at six different timeframes.

The protocol for the intervention group:

Week 0: Baseline measurement (M0) with self-reports and physiological measurements

Week 1-10: 10 weekly intervention, with physiological measurements during session 5 and obervaties during session 1, 5 and 10

Week 10: Second measurement (M1), with and physiological measurements

Week 20: Follow-up measurement (M2), with and physiological measurements

The protocol for the waiting list control:

Week 0: Baseline measurement (M0), self-reports and physiological measurements

Week 10: Second measurement (M1), self-reports and physiological measurements

Week 20: Follow-up measurement (M2), self-reports and physiological measurements

Intervention

The intervention consists of 10 weekly Animal Assisted Intervention sessions. Each intervention session has a duration of one hour. A therapist who is skilled both on social work and working with canines, will lead the sessions. Before the first session starts, a psychologist makes a treatment plan together with the participant, with concrete goals for the treatment. The intervention has a fixed structure, which is described in a protocol, in order to keep the intervention as identical as possible among participants. During the intervention, techniques are used from the behavioral learning theory and solution-focused therapy. The function of the therapydog is, to practice the techniques with the participant and for visualization of the techniques.

Study burden and risks

Risk: Not applicable

Estimation of burdening:

Intervention group: 10x 1 hour + 1 hour baseline measurement (M0) + 2x measurements after intervention (M1 + M2) for 1 hour each = 13 hours maximum
Waiting list control group: 3 measurements of 1 hour each = 3 hours maximum

Duration of the Protocol: 20 weeks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

A primary diagnosis within the autism spectrum is required for participation in the study. The participants must be diagnosed through, a semi-structured interview based on the DSM-V criteria and the ADI-R

Their age is between 18-60. The WAIS-III or WAIS-IV score > 80. Participants suffer from stress (PSS > 20), and overall psychological distress (SCL-90 > 133).

Exclusion criteria

Psychosis and suicide risk

When participants are allergic to dogs, when they have fear of dogs or when they can express serious aggression towards the dog.

Aversion towards dogs

Use of medication that involves the ingredient cortisone.

Change in medication or treatment

Active psychosocial treatment

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 19-01-2015

Enrollment: 72

Type: Actual

Ethics review

Approved WMO

Date: 25-11-2014

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 25-04-2017

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL48974.091.14