Pegasus: Equine-Assisted Therapy for therapy-resistant adolescents with autism spectrum disorders, a multiple baseline AB-study

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OBJECTIVE: To quantify the short-term (15 weeks) and long-term (1 year) (cost-)effectiveness of Equine-Assisted Therapy (EAT) in adolescents with therapy-resistant ASD (aged 11-18) and, when proven (cost-) effective, implement EAT in clinical...

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

Summary

ID

NL-OMON54442

Source
ToetsingOnline

Brief title
Pegasus

Condition

- Developmental disorders NEC

Synonym
autism, emotion dysregulation

Research involving
Human

Sponsors and support

Primary sponsor: Karakter

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Adolescent, Autism, Emotion dysregulation, Equine-Assisted Therapy (EAT)

Outcome measures

Primary outcome

The primary outcome will be emotion dysregulation measured by the Emotion Dysregulation Inventory (EDI). The EDI is an informant report measure of emotion dysregulation rated on a five-point scale.

Emotion Dysregulation Inventory (EDI) is specifically designed to measure emotion regulation impairments in youths and adolescents with ASD. The EDI-short form is a validated, change-sensitive, 13-item caregiver report measure of emotion regulation impairment for individuals who are at least 6 years of age. The EDI was developed using the item response theory (IRT) analysis and none of the final items had evidence of differential item functioning (e.g., psychometric biases) by gender, age, intellectual ability and verbal ability, making it suitable for use across heterogeneous populations. Items on the EDI measure how problematic behaviors have been during the past day. The scale used is Not at all=0, Mild=1, Moderate=2, Severe=3, or Very Severe=4. The EDI short form includes two scales: a 7-item Reactivity Index and a 6-item Dysphoria Index. Index raw scores can be converted into t-scores or theta scores based on a sample of 1755 individuals with ASD or based on a sample of 1000 youths matching the US census as general population norms [27]. For the purposes of this study we will administer the

13-item EDI short form three times a week (for 23 weeks).

Secondary outcome

Secondary outcomes will be assessed by multiple informants (adolescents, parents, teachers) and include quality of life, communication and social functioning (SRS-2), self-esteem, global functioning and goal attainment. Before and after each session, the Outcome Rating Scale (ORS) and Session Rating Scale (SRS) will be used to assess the well-being of the child and the way the child is experiencing the intervention. Furthermore, general information on medical history, level of education of parents/caregivers and medication will be included, as well as prior beliefs/satisfaction and family function.

Study description

Background summary

BACKGROUND: For people with autism spectrum disorder (ASD), daily life is highly stressful and traumatic with many unpredictable events that can evoke emotion dysregulation (ED): a strong difficulty with appropriately regulating negative affect. Heightened levels of ED may aggravate social dysfunctioning in ASD and vice versa. For a part of the patients with ASD, treatment as usual does not have any effect at all on ED. As ASD with severe levels of ED can be considered to have an ultra-high risk profile for developing other disorders (psychosis, anxiety, eating disorders, depression), this treatment-resistant subgroup of patients may end up needing life-long psychiatric treatment. Particularly problematic is that these patients often lack motivation for typically initiated forms of therapy, thereby further limiting their chances for a more favorable outcome. A highly promising method that may prove effective for therapy-resistant individuals with ASD is Equine-Assisted Therapy (EAT). While often met with prejudgment and skepticism, reports from parents and therapists as well as a recent systematic review suggest that EAT may have beneficial effects in youths with ASD.
We further argue that an ideal (and perhaps last?) *window of opportunity* for intervention in treatment-resistant patients with ASD is adolescence, because

of the major genetically pre-programmed neurological changes occurring in this period that heighten the sensitivity for environmental input. EAT targeting severe ED offered within this timeframe may improve clinical outcomes both in the short and in the long term in otherwise treatment-resistant adolescents with ASD.

Study objective

OBJECTIVE: To quantify the short-term (15 weeks) and long-term (1 year) (cost-)effectiveness of Equine-Assisted Therapy (EAT) in adolescents with therapy-resistant ASD (aged 11-18) and, when proven (cost-) effective, implement EAT in clinical practice.

Study design

STUDY DESIGN: Mixed-methods strategy consisting of three elements: a randomized, multiple-baseline single-case design (n=35), a qualitative study (n=8-10) and a cost-effectiveness study (n=6). Participants will be randomly assigned to one of the five pre-defined baseline lengths (2-6 weeks) to increase the internal validity of the design with a 1:1 allocation using permuted blocks of random sizes.

Intervention

15 weekly sessions of 60 minutes EAT using a standardized protocol (ORS, homework discussion, activity, feedback, rehearsal of activity, SRS, new homework) by certified EAT therapists.

Study burden and risks

During the baseline, intervention and post-intervention phases, parents will be asked to fill in the EDI items three times a week. This will take one to two minutes to complete. In multiple baseline design studies it is common to include multiple data points. Although the time involved for each measurement is limited, the number of measurements is substantial and therefore the burden for participants is estimated as being moderate. Patients can choose if they prefer to complete the EDI through an app or by pen or pencil. None of the parents in the pilot felt completing these questions as a burden. Although the participants found the time (less than a minute) completely acceptable we will build an application for filling out the assessments on-line and also allow using pen and pencil in conformity with their recommendation to take the preference of the participants into account. We will further support parents to complete their questionnaires by regular contact.

For all other assessments by questionnaires (baseline (T0), at the end of phase A (T1), after completion of phase B (T2), after the end of phase C (T3) and

after one year (T4)) we will use the questionnaire platform (CASTOR). We have performed a pilot and the participants found the time (25 minutes for parents and 15 minutes for participants) completely acceptable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- between 11-18 years old;
- a clinical diagnosis of autism spectrum disorders according the DSM 5 as diagnosed by a BIG registered healthcare professional;
- insufficient emotion regulation after regular therapy for at least 1,5 years as indicated by a score above clinical cut-off

(T-score = 65) on the EDI;
- comorbidities are allowed except for those interfering with safety.

Exclusion criteria

- unable to respond to questions (parents or adolescents);
- no access to an Internet connection;
- insufficient mastery of Dutch language in parents or adolescents;
- physically incapable to work with the horses;
- unstable medication use;
- total IQ equal to or below 80 on the WISC-III-R or WISC-V;
- allergic or phobic to horses;
- insufficient regulation to safely handle the horses;
- therapy with horses within the last two years.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2022
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2021

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-08-2023
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	NL77902.091.21