

Improving psychological distress in parents of children with autism using a new behavioural treatment called Acceptance and Commitment Therapy

Submission date 05/05/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/05/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/04/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Acceptance and Commitment Therapy (ACT) can be useful for improving the psychological well-being of parents of children with Autism Spectrum Disorders (ASD), but until now there is no evidence on the effectiveness of the ACT model with respect to other well-known behavioral treatments. The aim of this study is to assess the effectiveness of ACT compared to the Parent Training (PT) program for parents of children with ASD.

Who can participate?

Parents of children with ASD

What does the study involve?

Parents are randomly allocated to attend 24 weekly meetings lasting 90 minutes each following the ACT protocol or conventional PT. The intervention lasts about 6 months.

What are the possible benefits and risks of participating?

The parent training program may promote psychological positive parenting and reduce the behavioral risk of children. No risks are foreseen.

Where is the study run from?

Research unit in accordance with the Sicilian Region health system (Italy)

When is the study starting and how long is it expected to run for?

December 2017 to December 2020

Who is funding the study?

Sicilian Region (Italy)

Who is the main contact?

Giovanni Pioggia

Giovanni.pioggia@cnr.it

Contact information

Type(s)

Scientific

Contact name

Dr Giovanni Pioggia

ORCID ID

<https://orcid.org/0000-0002-8089-7449>

Contact details

Institute for Biomedical Research and Innovation (IRIB), National Research Council of Italy (CNR)

Messina

Italy

98164

+39 (0)3203390892

giovanni.pioggia@cnr.it

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The effect of Acceptance and Commitment Therapy for improving psychological well-being in parents of individuals with autism spectrum disorders: a randomized controlled trial

Acronym

ACT-pA

Study objectives

To evaluate the effectiveness of the Acceptance and Commitment Therapy (ACT) approach with respect to parental training in reducing psychological distress and improving well-being in parents of autism spectrum disorder (ASD) children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/08/2018, National Research Council (Piazzale Aldo Moro, 7, 00185, Rome, Italy; +39 (0)6 4993/7900; cnr.ethics@cnr.it), ref: 0054444/2018

Study design

Single-center interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Psychological distress in parents of children with autism

Interventions

Parent pairs are randomly assigned to the experimental group (ACT matrix protocol) or to the control group (Parent Training (PT) protocol) using a computer-generated randomization code.

The interventions consist of 24 weekly meetings lasting 90 minutes each. The total intervention lasts about 6 months.

The experimental group undergo the Acceptance and Commitment Therapy (ACT) protocol. This consists of two intersecting lines that make up four quadrants, which provide a "point of view" on one's psychological actions and experiences. The vertical line is the line of experience, the upper part corresponds to the experience of life linked to the five senses - sight, hearing, taste, smell and touch - (experience of the five senses), the lower part refers to the experiences internal as thoughts and feelings (internal/mental experience). The horizontal line is the behavior line, the left side concerns the actions that perform the function of moving us away from experiences, emotions, unwanted thoughts (experiential avoidance), the right side indicates the actions we take to get closer and go towards our values (committed action).

The control group undergo the Parental Training (PT) protocol. This consists of a training program for parents to teach behavioral management skills for children. The purpose of a parent training program is to promote positive parenting and reduce the behavioral risk of children.

Intervention Type

Behavioural

Primary outcome(s)

1. Psychological flexibility measured using the Acceptance and Action Questionnaire II (AAQ-II) at baseline and 6 months
2. Perception and influence of children's behavior on parent's life measured using Home Situation Questionnaire (HSQ-ASD) at baseline and 6 months

Key secondary outcome(s)

1. Participants' extent of valued living measured using the Valued Living Questionnaire (VLQ) at baseline and 6 months
2. Tendency of an individual to intentional awareness measured using the Mindfulness Attention Awareness Scale (MAAS) at baseline and 6 months
3. Stress level measured using the Parental Stress Index (PSI) at baseline and 6 months

Completion date

01/12/2020

Eligibility

Key inclusion criteria

Parent of child:

1. Between 4 and 10 years of age
2. Clinical diagnosis of ASD based on the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria from a licensed clinical child neuropsychiatric
3. DSM-5 severity scores from mild (level 1) to moderate (level 2) in both social communication and restricted interests and repetitive behaviors domains
4. A verbal and performance Griffiths Mental Development Scales, Extended Revised: 2 to 8 years (GMDS-ER 2-8) and Wechsler Intelligence Scale for Children (WISC-IV) above 70
5. No hearing, visual, or physical disabilities that would prevent participation in the intervention
6. Not being on psychiatric medication

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

20

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/09/2019

Date of final enrolment

01/09/2020

Locations

Countries of recruitment

Italy

Study participating centre

Institute for Biomedical Research and Innovation (IRIB), National Research Council

c/o Istituto Marino, root Torre Bianca, Mortelle (ME)

Messina

Italy

98164

Sponsor information

Organisation

National Research Council

ROR

<https://ror.org/04zaypm56>

Funder(s)

Funder type

Government

Funder Name

Sicilian Region of Italy (Assessorato Regionale delle Attività Produttive), grant number n. 08SR2620000204, entitled LAB@HOME - Una Casa Intelligente per l'Autismo, P.O. F.E.S.R. Sicilia 2014/2020

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Giovanni Pioggia (Giovanni.pioggia@cnr.it).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/06/2021	12/04/2022	Yes	No