ISRCTN17497289 https://doi.org/10.1186/ISRCTN17497289

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

Registration date
17/05/2021

Overall study status
Completed

Last Edited
12/04/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

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
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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