

# A trial of Acceptance and Commitment Therapy for caregivers

<b>Submission date</b> 03/01/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/07/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims:

Parents of children with autism can experience more mental health difficulties compared to parents of children without autism. There are many available treatments that provide parents with skills to assist their children, but few address the unique needs of parents themselves. The aim of this study is to test the effectiveness of a specific group intervention (Acceptance and Commitment Therapy, or ACT) for parents of children, adolescents and adults diagnosed with autism. Specifically, the researchers are interested in the impact of the group on the wellbeing and mental health of parents, as well as the impact of the group on child and family functioning, compared to a group who has not received the intervention.

### Who can participate?

Parents of children and adults with autism

### What does the study involve?

All participants receive the same treatment (i.e. go through the intervention), but half of the participants are randomly allocated to receive the treatment immediately and the other half are put on a waiting list for 18 weeks before receiving the workshop. The intervention is provided in a group format to parents.

### What are the benefits and risks of participating?

Preliminary research in this area suggests that participants may experience improved psychological wellbeing after the intervention. The long-term benefits of the study are to empower and improve the psychological wellbeing of parents of children with autism, and to help address the need for more empirically based parent-led interventions. Risks to participating parents may include fatigue related to the completion of questionnaires, as well as potential discomfort elicited from some questions. While it is not anticipated that participants will experience harm or major discomfort, participants will be advised that they do not have to complete questions they feel uncomfortable answering. Group leaders or members of the research team will also be available to answer questions or provide guidance should discomfort arise.

Where is the study run from?

1. Centre for Addiction and Mental Health (Canada; Lead Centre)
2. Surrey Place Centre (Canada)
3. York University (Canada)

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

April 2018 to January 2020

Who is funding the study?

1. York University (generic fund to PI)
2. Participating agencies holding the training (Surrey Place Centre, Centre for Addiction & Mental Health)

Who is the main contact?

Dr Yona Lunsky

yona.lunsky@camh.ca

## Contact information

### Type(s)

Scientific

### Contact name

Dr Yona Lunsky

### ORCID ID

<https://orcid.org/0000-0002-1866-9728>

### Contact details

1001 Queen Street West

Toronto, Ontario

Canada

M6J 1H4

## Additional identifiers

### Protocol serial number

138/2018

## Study information

### Scientific Title

Parent, child and family outcomes following Acceptance and Commitment Therapy for parents of individuals with autism: a randomized controlled trial

### Acronym

ACT RCT

### Study objectives

Treatment group participants will show significant improvements in wellbeing, compared to those in the waitlist control group.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Centre for Addiction and Mental Health Research Ethics Board, 33 Russell St., Toronto, Ontario, M5S 2S1, Tel: +1 (0)416 535 8501 x34020, Email: research.ethics@camh.ca, 27/12/2018, ref: 138/2018
2. Surrey Place Centre Research Ethics Board, 2 Surrey Place, Research Unit, Toronto, Ontario, M5S 2C2, Tel: +1 (0)416 925 5141, reb@surreyplace.on.ca, 03/12/2018
3. York University Ethics Review Board, Office of Research Ethics, 5th Floor, Kaneff Tower, York University, 4700 Keele St., Toronto, Ontario, M3J 1P3, +1 (0)416 736 5914, ore@yorku.ca, 02/01/2019

### **Study design**

One-year randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Parents of children with autism

### **Interventions**

Random assignment will occur after baseline assessment is complete. Once participants are deemed eligible for the study (following telephone screening) they are randomized to treatment immediately or waitlist control condition using a randomly generated list obtained from the following site: <https://www.randomizer.org/>

The intervention is a brief Acceptance and Commitment Therapy (ACT) workshop. ACT helps people to become more aware of their thoughts and feelings, develop acceptance of their difficult experiences, and commit to acting in ways that align with their personal values. The workshop is spread over 3 sessions: one evening, followed by a full day, and a 'refresher' evening 4 weeks later. Parents learn about the ACT model through group experiential activities emphasizing links between emotions, thoughts, behaviours and values, and they gain introductory exposure to mindfulness skills. Workshops are co-facilitated by a clinician and a trained parent of an individual with autism.

For a detailed description of the intervention, see:

Fung, K., Steel, L., Bryce, K., Lake, J., & Lunsky, Y. (2018). Using Acceptance and Commitment Therapy for parents of children with Autism Spectrum Disorder. A Guide to Programs for Parenting Children with Autism Spectrum Disorder, Intellectual Disabilities or Developmental Disabilities: Evidence-Based Guidance for Professionals, 233-250.

### **Intervention Type**

## Behavioural

### Primary outcome(s)

Psychological distress, measured using the Depression and Stress subscales of the Depression Anxiety Stress Scales (DASS14). All measures will be administered at baseline, after which parents will be randomized to treatment and waitlist groups. All measures will be re-administered 6 weeks and 18 weeks post-randomization. Parents will be additionally asked to complete a subset of the survey measures, including the DASS14, at 2 weeks post-randomization.

### Key secondary outcome(s)

1. Health and isolation, measured using the Isolation and Health subscales from the Parenting Stress Index (PSI-4)
2. Psychological acceptance, measured using the Acceptance and Action Questionnaire (AAQ-II)
3. Cognitive fusion, measured using the Cognitive Fusion Questionnaire (CFQ)
4. Consistency of actions toward values, measured using the Valued Living Questionnaire (VLQ)
5. Mindfulness behaviours, measured using the Bangor Mindful Parenting Scale (BMPS)
6. Movement toward personal goals, measured using Goal Attainment Scaling (GAS)
7. Positive affect, measured using the positive subscale of the Positive and Negative Affect Schedule (PANAS)
8. Family current level of crisis, measured using the Brief Family Distress Scale (BFDS)
9. Family functioning, measured using the general functioning subscale of the McMaster Family Assessment Device (FAD)
10. Parent-reported child mental health difficulties, measured using the Strengths and Difficulties Questionnaire (SDQ)
11. Participant experiences with group facilitators, measured using a feedback form

All measures will be administered at baseline, after which parents will be randomized to treatment and waitlist groups. All measures will be re-administered at 6 weeks and 18 weeks post-randomization. Parents will be additionally asked to complete a subset of the survey measures (DASS14, PANAS, BFDS, GAS) at 2 weeks post-randomization.

### Completion date

01/01/2020

## Eligibility

### Key inclusion criteria

1. Child diagnosis of autism
2. Proficiency in English
3. Ability to identify therapy goals

### Participant type(s)

Carer

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

**Total final enrolment**

63

**Key exclusion criteria**

Participants cannot have participated in any previous Acceptance and Commitment Therapy

**Date of first enrolment**

15/01/2019

**Date of final enrolment**

01/12/2019

**Locations**

**Countries of recruitment**

Canada

**Study participating centre**

**Centre for Addiction and Mental Health**

1001 Queen Street West

Toronto, Ontario

Canada

M6J 1H4

**Study participating centre**

**Surrey Place Centre**

2 Surrey Place

Toronto, Ontario

Canada

M5S 2C2

**Study participating centre**

**York University (workshops will not be run at this location)**

4700 Keele Street

Toronto, Ontario

Canada

M3J 1P3

**Sponsor information**

## Organisation

Centre for Addiction and Mental Health

## ROR

<https://ror.org/03e71c577>

## Funder(s)

### Funder type

University/education

### Funder Name

York University (generic fund to PI)

## Results and Publications

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		11/05/2023	10/07/2023	Yes	No