

# Therapeutic group for women on the autism spectrum

<b>Submission date</b> 27/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/10/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Plain English summary as of 09/10/2018:

### Background and study aims

Autism spectrum condition (ASC) is a common disorder that affects the way that a person communicates and relates to others. It is a spectrum condition the level of disability is spread across a wide range, from almost unnoticeable to completely debilitating. In general however, the difficulties sufferers experience tend to fall into social communication (speech and body language), social interaction (recognising and expressing emotions) and social imagination (being able to understand and predict other people's behaviour). There is a link between ASC and a deficit in Theory of Mind, the ability to attribute mental states (such as beliefs, intents, desires) to oneself and others and to understand that others have beliefs, desires, intentions, and perspectives that are different from one's own. This is far more common in men and so there is little research looking at women. Some research has shown that women with ASC tend to have better imaginative play as children, show more interest in social relations (although not necessarily better ability in social relations), and have more socially accepted special interests. As a result, high-functioning adult women on the autism spectrum tend to be overlooked but nevertheless experience difficulties, which are often unsupported. Cognitive behavioural therapy (CBT; a type of talking therapy that helps change the way people think and behave) has been used in children with ASC, however it has not yet been adapted for adults with ASC. The aim of this study is to find out whether a CBT program adapted for adults with ASC is an effective treatment in women with ASC.

### Who can participate?

Women aged 18-65 who have been diagnosed with autism.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in six, hour-long weekly group sessions of CBT for ASC and cover a different topic every week. These include an introduction (getting to know the group), social skills and understanding emotions, managing and understanding relationships, self-esteem and assertiveness, dealing with social situations and a summary session. Those in the second group are placed on a waiting list to take part in the group therapy program for the duration of the study. At the start of the study and after the six weeks of treatment, participants in both groups complete a number of

questionnaires to measure various aspects of mental health and wellbeing, such as depression or low mood, anxiety, stress and self-esteem and general quality of life. The participants who received the group therapy also complete another questionnaire about their experiences of the program.

What are the possible benefits and risks of participating?

Benefits of taking part include the chance to receive treatment in the form of a therapeutic group, and to discuss experiences with other women who may well have similar experiences. There is little provision available for adults, and particularly women on the autism spectrum and this group will enable participants to receive intervention tailored to their specific needs. There are no notable risks involved with participating.

Where is the study run from?

A private psychological service in Canterbury, Kent (UK)

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

January 2016 to April 2018

Who is funding the study?

The study has not received any external funding.

Who is the main contact?

Ms Lucy Elias

Previous plain English summary:

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Where is the study run from?

Arizona State University (USA)

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

January 2016 to April 2018

Who is funding the study?

OmniActive Health Technologies Ltd. (India)

Who is the main contact?

Miss Beckie Bundy

## Contact information

**Type(s)**

Public

**Contact name**

Ms Lucy Elias

**Contact details**

Psicon Limited  
15 New Dover Road  
Canterbury  
United Kingdom  
CT1 3AS

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

Psicon001

# Study information

## Scientific Title

A randomised controlled trial: A trans-diagnostic theory based therapeutic group for women on the autism spectrum investigating the impact and management of a diagnosis of an autism spectrum condition given in adulthood

## Study objectives

1. Participants' psychological wellbeing will be significantly improved following the group-based intervention compared to participants in the control group
2. Participants self-reported measure of self-esteem will increase following the intervention

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NHS Health Research Authority; London - Bromley Research Ethics Committee, 13/02/2017, ref. 16/LO/1872

## Study design

Single-centre double-blind randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Quality of life

## Participant information sheet

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

Mental health and autism spectrum conditions

## Interventions

Participants are randomised to one of two groups using a computer-based system.

Intervention group: A pilot trans-diagnostic group-based intervention encompassing CBT and mindfulness-based therapy over a period of six weeks. Sessions will be 90 minutes to 2 hours including a break. The program involves six sessions, which cover the following topics:  
Week 1 – Introduction: Getting to know each other and what you hope to gain from the group and what we hope to give you. Rules and boundaries of the group e.g. when to talk and for how

long. Setting limits.

Week 2 – Social skills and understanding emotions: What are emotions (Recognising Faces and Emotions - ACS). Exploring individual differences in understanding emotion. How to read other people.

Week 3 – Managing and understanding relationships: What is a relationship? Individual differences in relationships. Managing expectations in a relationship.

Week 4 – Self-esteem and assertiveness: Rights of individuals and being able to recognise and apply your rights. The difference between aggression and assertiveness: Understanding what is appropriate and when.

Week 5 – Social situations (avoidance and challenges), plans for exposure challenges: Challenges for each individual – nothing is too small! Advice on legalities in various situations.

Week 6 – Summary and relapse prevention: What next and where to go from here? Signposting (e.g. to Social Care Team, Kent Autistic Trust etc.). Maintaining change and relationships within the group – rules for this? Resource pack- what's available in Kent.

Control group: Participants receive no treatment (although they will be told that they will receive group intervention after the pilot group and research is complete).

At the start of the study (session one for those in the intervention group) and the end (session six for those in the intervention group), participants in both groups complete a battery of questionnaires.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Anxiety will be measured using the Generalised Anxiety Disorder 7-item scale (GAD-7) at baseline and 6 weeks
2. Depression and low mood will be measured using the Patient Health Questionnaire 9-item (PHQ-9) at baseline and 6 weeks
3. Self-esteem will be measured using the Rosenberg Self-Esteem Scale at baseline and 6 weeks
4. Any trauma will be measured using the Impact of Events Scale - Revised at baseline and 6 weeks

## **Secondary outcome measures**

General quality of life and experienced strengths and difficulties will be measured using the CORE-10, World Health Organisation Quality of Life Scale and Strengths and Difficulties Questionnaire at baseline and 6 weeks.

## **Overall study start date**

29/09/2016

## **Completion date**

30/04/2018

## **Eligibility**

### **Key inclusion criteria**

1. Female
2. With a diagnosis of Autism Spectrum Condition
3. Aged 18-65 years
4. Any racial and cultural background and any religious belief or sexuality

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Female

**Target number of participants**

30

**Key exclusion criteria**

1. Men
2. Those without ASD diagnosis
3. Those not referred to Psicon
4. Those that present 'at risk' after initial risk assessment

**Date of first enrolment**

11/11/2016

**Date of final enrolment**

13/12/2017

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Psicon Limited**

15 New Dover Road

Canterbury

United Kingdom

CT1 3AS

# Sponsor information

## Organisation

Psicon Limited

## Sponsor details

15 New Dover Road  
Canterbury  
England  
United Kingdom  
CT1 3AS

## Sponsor type

Hospital/treatment centre

## Website

[www.psicon.co.uk](http://www.psicon.co.uk)

## ROR

<https://ror.org/051mqhp34>

# Funder(s)

## Funder type

Industry

## Funder Name

Psicon Limited

# Results and Publications

## Publication and dissemination plan

Planned publication of the results of both the qualitative and quantitative aspects of the group in a relevant autism journal.

## Intention to publish date

30/04/2019

## Individual participant data (IPD) sharing plan

Data will not be made available as we feel this may affect participants' ability to feel able to openly share within the group. Of course, all information will be entirely anonymous and

confidential, but due to the population of participants, the study team do not wish to increase any anxiety and therefore wish to ensure the data is not shared and only written up as a piece of research.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No