

Therapeutic group for women on the autism spectrum

Submission date 27/10/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/10/2018	Condition category 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

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

Female

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**

United Kingdom

England

Study participating centre**Psicon Limited**

15 New Dover Road

Canterbury

United Kingdom

CT1 3AS

Sponsor information**Organisation**

Psicon Limited

ROR

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

Funder(s)**Funder type**

Industry

Funder Name
Psicon Limited

Results and Publications

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?
HRA research summary			28/06/2023	No	No