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Therapeutic group for women on the autism spectrum

Submission date	Recruitment status	[ ] Prospectively registered
27/10/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/01/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/10/2018	Mental and Behavioural Disorders	[ ] 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
Metal 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

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?
HRA research summary			28/06/2023	No	No