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# Personalised anxiety treatment for autism - the PAT-A trial

**Submission date**
29/07/2019

**Recruitment status**
No longer recruiting

**Registration date**
09/08/2019

**Overall study status**
Completed

**Last Edited**
17/11/2023

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Anxiety is common in people on the autism spectrum, and leads to everyday difficulties affecting quality of life. National guidance suggests current National Health Service treatments for anxiety be modified to make them appropriate for autistic adults. Recently, the autism community rated anxiety treatment as a top research priority.

This study aims to investigate the feasibility and acceptability of providing a personalised, psychological anxiety treatment package to autistic adults, and its effects.

Who can participate?
Adults aged 18 and over who have a diagnosis of autism spectrum disorder and who live in the geographical area covered by the sponsoring NHS Trust. Autistic adults are eligible to take part if their health professional identifies them as someone who is experiencing clinically significant anxiety. People who are unable to provide informed consent and those who are experiencing a mental or physical health problem that may impact on their ability to take part in talking therapy may not be able to take part.

What does the study involve?
There are two treatment groups in this study. Participants will be randomly allocated to one treatment group. Allocating people to treatment groups in this way avoids bias and means that everyone has a 50/50 chance of being in either group. The two treatment groups are described below:

Personalised Anxiety Treatment – Autism (PAT-A): The therapy will be provided by a clinician who works for the NHS and has experience in delivering anxiety therapies to autistic adults. Participants will receive weekly sessions based on cognitive behavioural therapy (CBT) that will last approximately one hour each time. The number of sessions will likely be between 4 and 12 and the content of the sessions will be personalised to match the participant's needs. The modular nature of the PAT-A intervention allows it to be individualised. Modules may be used as stand-alone or any combination with one another and are designed to support with (but not limited to): understanding and communicating about emotions, specific phobias, social anxiety, intolerance of uncertainty and distress tolerance.

Current Clinical Services (CCS): Participants will receive two training sessions that will focus on supporting them in understanding and describing their emotions. These sessions will last between 50 minutes – 60 minutes each. Towards the end of the second training session, the therapist will signpost the participant to existing services that are available to support them with their mental health, should this be required.

What are the possible benefits and risks of participating?
Benefits: Based on the research evidence that we have, both the PAT-A and CCS treatments have the potential to reduce anxiety and therefore improve quality of life. This will help us to establish if the new PAT-A treatment programme is acceptable to autistic people and whether it will be possible to deliver in health care services (such as the NHS) in the future. We hope that by sharing our findings, treatments for anxiety in autistic people will improve in the future. Autistic people have recently rated anxiety as being a top research priority, and we hope that this research is a response to this.

Risks: Some people may find it difficult to talk about their anxiety. As with many talking therapies, participants receiving PAT-A will be invited, to some extent, to 'face their fears' and expose themselves to situations that may be cause them anxiety. Within this type of treatment, this is seen as an important part of learning to overcome anxiety. To reduce risk, this is managed in a controlled way that is tolerabke to the participant, and all members of the research team have clinical training that allows them to respond to any distress. Completing the research questionnaires and the interviews can take some time which may cause some inconvenience. We have tried to keep this time to a minimum.

Where is the study run from?
1. Newcastle University, UK
2. Northumberland, Tyne and Wear NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
January 2018 to March 2022

Who is funding the study?
Autistica, UK
(This study has been adopted to the NIHR portfolio)

Who is the main contact?
1. Professor Jeremy Parr
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2. Professor Jacqui Rodgers
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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
37244

# Study information

### Scientific Title
Exploring the effectiveness of personalised non-pharmacological anxiety treatment for autistic adults and older people

### Acronym
PAT-A

### Study objectives
To examine the feasibility and efficacy of a personalised, non-pharmacological anxiety intervention for autistic adults that has been designed by the research team (PAT-A)

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 19/01/2018, NHS HRA Wales REC 5 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; +442920785741; WalesREC5@wales.nhs.uk), ref: 18/WA/0014

### Study design
Interventional randomised controlled trial

### Primary study design
Interventional

### Study type(s)
Treatment

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

### Interventions
Anxiety is common in people on the autism spectrum, and leads to everyday difficulties affecting quality of life. This study will investigate the feasibility of providing a personalised anxiety treatment package to autistic adults, and its effects.

There are four work packages (WPs) comprising this research, however this trial registration will only cover WP4 (the RCT component).

WPs 1-3 involved a national autism and anxiety survey (WP1), an assessment of the correlates of anxiety in autistic adults and children and examination of the suitability of the anxiety measures designed by the team (WP2). This information, alongside consultation (WP3) supported the development of a Personalised Anxiety Treatment for Autism (PAT-A) (WP4).

In WP4, the feasibility and effectiveness of delivering an adapted personalised treatment plan through the NHS will be investigated. Up to 40 people will be allocated by chance to one of two groups – personalised anxiety treatment - autism (PAT-A), or improved treatment as usual (Current Clinical Services; CCS). We will measure whether the treatment is acceptable to autistic adults (and where relevant, their relatives). We will investigate effectiveness by comparing the impact of anxiety on the individual's daily life before and after treatment.

The PAT-A treatment will be individualised for each participant (based on the formulation of their anxiety difficulties) and will include a flexible, modular range of evidence-based CBT techniques. The PAT-A treatment modules will address:
1. Understanding and describing emotion
2. Emotional acceptance
3. Social anxiety
4. Intolerance of uncertainty
5. Situation specific fears/phobias
Participants may receive any combination of these modules based on their needs. Treatment sessions will be undertaken by either a band 7 clinical psychologist or a high-intensity CBT therapist. We anticipate that the total amount of sessions that participants in the PAT-A group will receive is between 4-12.

Data collection:
At baseline, immediately post-intervention, and 3 and 12 months post-intervention outcome measures will be completed as detailed in the outcome measures section below.
3 months post-treatment, the research associate (who will be blind to treatment group) will conduct qualitative interviews with participants. These interviews will be designed to assess the acceptability of PAT-A and CCS. Subjects covered in the interview will include the acceptability of randomisation, the treatment itself and whether treatment should be modified for a future trial or delivery in the NHS. We will also contact all participants 12 months post-treatment to obtain an update on progress and to evaluate the longer term efficacy of CCS and PAT-A.

## Intervention Type
Behavioural

## Primary outcome(s)
WP4 is a pilot and feasibility trial of the treatment package developed by the research team, where the main hypothesised outcome is a reduction of anxiety in the autistic adults who participate. We do not have a primary outcome as this is a pilot/feasibility trial. However, based upon our current research, the outcome we anticipate being most useful and acceptable is the Target Behaviours scale (a description of the participant's behaviour in relation to a specific real-life anxiety-related goal). This research will evaluate whether that is correct or whether a questionnaire might be more appropriate.
In addition, acceptability of trial procedures and treatment received will be measured using a bespoke semi-structured interview administered 3 months post-intervention.

## Key secondary outcome(s))

1. Adaptive functioning is measured by the Waisman Activities of Daily Living Scale – Adaptive (W-ADL) at baseline
2. Ability to recognise and describe emotions is measured by the Toronto Alexithymia Scale (TAS-20) at baseline.
3. Quality of life is measured by the World Health Organisation Qualify of Life – BREF (WHOQOL-BREF) scale plus the disabilities module and ASD addendum at baseline.
4. Health-related quality of life is measured by the EQ-5D at baseline.
5. Anxiety disorders and other related diagnoses are measured by the Anxiety and Other Related Disorders Interview Schedule (ADIS-5) at baseline.
6. Anxiety is measured by the Anxiety Scale – Autism (ASA) and the Hospital Anxiety and Depression Scale (HADS) at baseline, immediately post-intervention and three months post-intervention.

### Completion date
31/03/2022

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 03/10/2019:
1. Adults aged 18+ who are able to provide informed consent
2. With a diagnosed autism spectrum disorder
3. Experiencing clinically significant anxiety
4. Living in the area serviced by the sponsoring NHS Foundation Trust

Previous inclusion criteria:
1. Adults aged 18+ with a diagnosed autism spectrum disorder
2. Relatives of adults with ASD; where both relatives and adults are over the ages of 18
3. Relatives of children with ASD; where the relative is over the age of 18 and the child is under the age of 18
4. Health professionals with experience of working clinically with adults with ASD

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Sex
All

### Total final enrolment
34

### Key exclusion criteria
1. Co-morbid physical or mental health condition that would significantly inhibit their ability to engage in the interventions delivered as part of the trial
2. Do not have the capacity to provide informed consent

### Date of first enrolment
01/10/2018

### Date of final enrolment
01/11/2019

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust**
St. Nicholas Hospital
Jubilee Road
Gosforth
Newcastle Upon Tyne
United Kingdom
NE3 3XT

## Sponsor information

### Organisation
Northumberland, Tyne And Wear NHS Foundation Trust

### ROR
https://ror.org/01ajv0n48

## Funder(s)

### Funder type
Charity

### Funder Name
Autistica

### Alternative Name(s)

### Funding Body Type
Government organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United Kingdom

### Funder Name
National Institute for Health Research (NIHR); Grant Codes: 7245

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Anonymised, quantitative data may be made available on request from Professor Jeremy Parr (Jeremy.parr@ncl.ac.uk). Data will not be available until the trialists have published their findings. No identifiable information that may jeopardise the anonymity of participants will be shared beyond the research team.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | protocol | 20/09/2023 | 17/11/2023 | Yes | No |
| Protocol article | | 14/03/2020 | 17/03/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |