Testing a new therapy to prevent anxiety symptoms in autism spectrum conditions

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in a research study investigating a new therapy to prevent anxiety symptoms in people with autism. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Part 1 explains the purpose of the study and what will happen to you if you take part. Part 2 gives more detailed information about how the study is run. This project is a collaboration between Sussex Partnership NHS Trust and Brighton and Sussex Medical School.

Take time to decide whether or not you wish to take part and please feel free to discuss your participation with friends and family. Please remember that your decision about whether to take part or not will not affect your care in any way.

What is the purpose of the study?
Some of our recent work has shown anxiety can be increased if there is a discrepancy between how well you feel you can interpret signals, such as your heartbeat, from your body and how well you are able to do this. We have found that helping people to be more aware of their ability, and to increase this helps reduce and may prevent anxiety symptoms. We would like to try out and compare a new treatment teaching you these skills against the current treatment.

Why have I been invited to take part?
We would like to invite people who have a diagnosis of autism spectrum condition**.**

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form to keep. If you decide to take part you are still free to withdraw at any time, without needing to give a reason.

What will happen to me if I take part?
If you decide to take part, you will be invited to an initial interview where you will be fully briefed about the study. You will then be invited to a follow up interview where you have the opportunity to ask any questions you have about taking part. If you agree to take part, we will ask you to sign a consent form and then conduct a screening interview to make sure that you are eligible to take part. We will ask you to fill out a set of questionnaires. These will ask about symptoms you might have (e.g. anxiety, depression) and about the way in which you experience emotion and signals from your body. We will also administer a questionnaire which asks you questions about your interests and thought patterns, this will allow us to understand more about you and your autism. With your permission, we will inform your GP regarding your inclusion into the study.

As part of the study you will be randomly assigned to one of two therapy groups, receiving either an existing therapy to improve recognition of emotion from the way

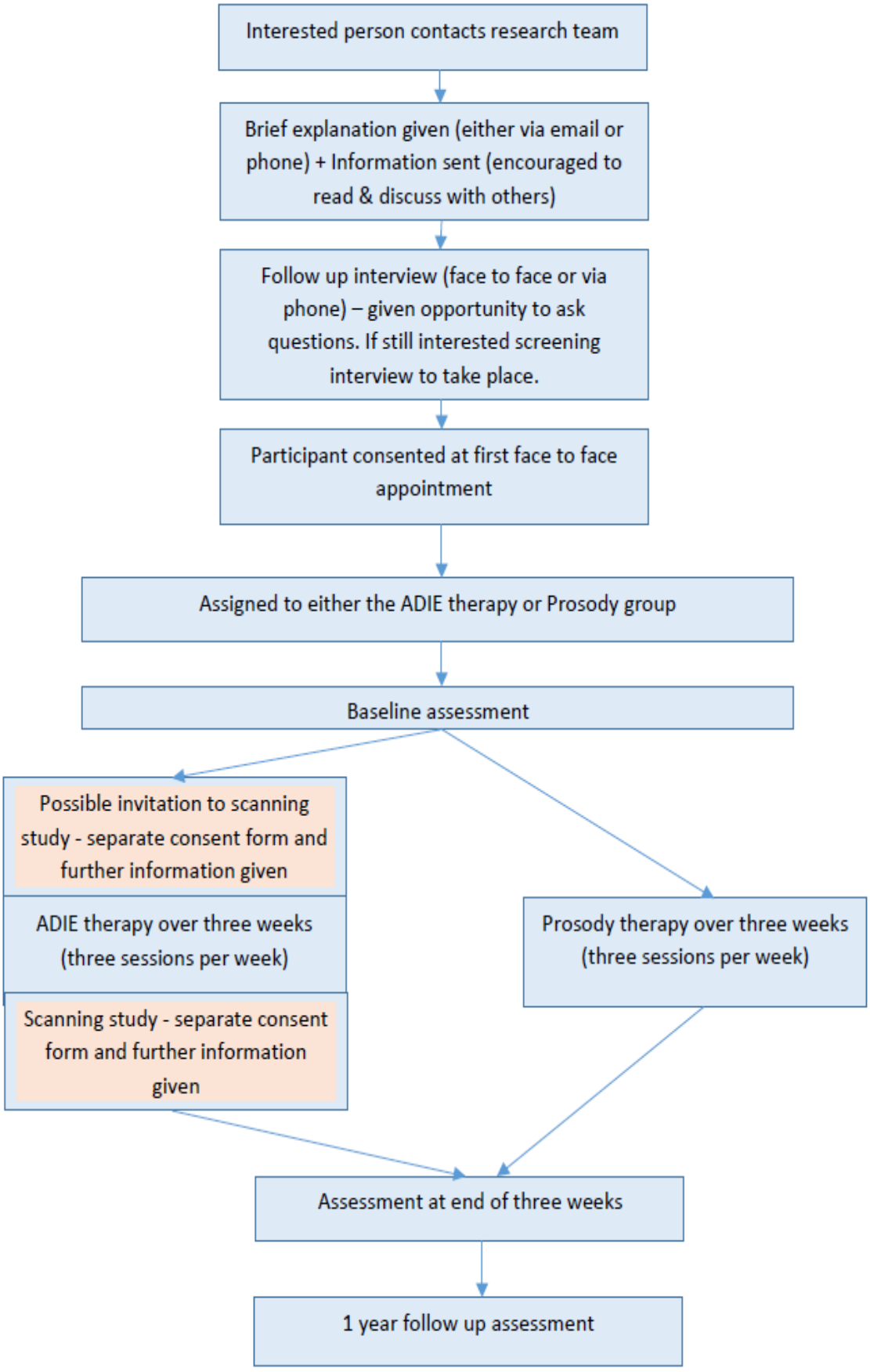
people say things, called prosody, or our new ADIE therapy. You will then receive training according to the group you have been assigned to.

Prosody therapy
You will receive an initial assessment where you will be asked to complete some computer tasks. The computer tasks require application of finger sensors to measure your pulse. You will then receive three therapy sessions per week for three weeks. These will focus on elements of speech such as intonation and rhythm. You will be played phrases which are spoken in ways which convey different emotions (e.g. happy, sad, fearful etc.). The aim of this therapy is to help you better identify the emotion underlying the way in which things are said. You will match phrases to different emotional faces and words, feedback will be provided to help you improve your perception of emotion from the way people say things.

ADIE therapy
You will be asked to complete some computer tasks. The computer tasks require application of finger sensors to measure your pulse. You will then receive three therapy sessions per week for three weeks. These will focus on your ability to read signals from inside your body (what we call interoception) with feedback and guidance. You will be asked to monitor your own heartbeat, but without physically feeling for it (i.e. just by sensing it internally). These tasks of interoception will ask you to count how many heartbeats you feel during a period of time or decide if you think a rhythmic beep is in time or out of time with your own heartbeat. We will give you feedback on how you have done in order to help you become more accurate in your awareness of your own heartbeats.

Both types of therapy will be accompanied by tasks which assess prosody (matching phrases to emotional faces or words), interoception (monitoring your own heartbeat), empathy (the ability to feel for others) and joint hypermobility (how bendy your joints are).

As compensation for your time spent taking part in the study, you will receive £7.50 per hour of your time. Assessment sessions takes 1-2 hours, training sessions take around 30 minutes. At the end of the study you will be debriefed and asked about your experience and have the opportunity to ask any questions.


Interested person contacts research team
Brief explanation given (either via email or phone) + Information sent (encouraged to read & discuss with others)
Follow up interview (face to face or via phone) – given opportunity to ask questions. If still interested screening interview to take place.
Participant consented at first face to face appointment
Assigned to either the ADIE therapy or Prosody group
Baseline assessment
Possible invitation to scanning study - separate consent form and further information given
ADIE therapy over three weeks (three sessions per week)
Scanning study - separate consent form and further information given
Prosody therapy over three weeks (three sessions per week)
Assessment at end of three weeks
1 year follow up assessment

Time Table (without brain scans)

Week	Day	Session	Content	Time
1	1	Baseline Assessment	• Questionnaires 1-3 • Computer Task 1 • Questionnaire 4 • Computer Task 2 • Questionnaires 5-7 • Computer Task 3 • Questionnaires 8-10 • Computer Task 4 • Reading Task	• 15 minutes • 15 minutes • 10 minutes • 15 minutes • 15 minutes • 15 minutes • 15 minutes • 15 minutes • 5 minutes Total ~2 hours
	2	Training Session 1	Prosody or Interoception Training	30 minutes
	3	Training Session 2	Training	30 minutes
2	4	Training Session 3	Training	30 minutes
	5	Midline Assessment	• Questionnaires 1-2 • Computer Task 1 • Questionnaires 3-4 • Computer Task 2 • Questionnaire 5-6 • Computer Task 3	• 10 minutes • 15 minutes • 10 minutes • 15 minutes • 10 minutes • 15 minutes Total ~1,5 hours
	6	Training Session	Training	30 minutes
3	7	Training Session	Training	30 minutes
	8	Training Session	Training	30 minutes
	9	Final Assessment	• Questionnaires 1-3 • Computer Task 1 • Questionnaire 4 • Computer Task 2 • Questionnaires 5-7 • Computer Task 3 • Questionnaires 8-10 • Computer Task 4 • Reading Task	• 15 minutes • 15 minutes • 10 minutes • 15 minutes • 15 minutes • 15 minutes • 15 minutes • 15 minutes • 5 minutes Total ~2 hours
After 1 year	10	1 year follow-up	• Questionnaires 1-3 • Computer Task 1 • Questionnaire 4 • Computer Task 2 • Questionnaires 5-7 • Computer Task 3 • Questionnaires 8-10 • Computer Task 4 • Reading Task	• 15 minutes • 15 minutes • 10 minutes • 15 minutes • 15 minutes • 15 minutes • 15 minutes • 15 minutes • 5 minutes Total ~2 hours

What are the possible risks in taking part?
As far as we know there are no risks to taking part. Information from the study will be protected and anonymous so that people will not have access to the information about who took part or find out results of any one individual.

What are the possible benefits of taking part?
Anxiety symptoms are common in people with autism spectrum conditions and we anticipate that the training you receive will help reduce or prevent any anxiety symptoms you may experience. This research could result in new ways of treating and preventing anxiety in people with autism spectrum conditions.

What will happen if I don't want to carry on with the study?
You may withdraw at any point during the study. If you withdraw from the study we would like, with your consent, to still use the data and results associated with your participation. You are free to not consent to us using data associated with your participation in which case all results will be securely deleted. This will not affect your future care in any way.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers (Dr Sarah Garfinkel: 01273 678584; Dr Clara Strauss: 01273 265896; Dr Yoko Nagai: 01273 876828) or the chief investigator (Prof Hugo Critchley: 01273 678336) in the first instance, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this either by contacting the Research and Development department at Sussex Partnership NHS Trust (01273 265896) or the Service Experience Team - also known as PALS (01903 843026).

Any complaint about the way you have been dealt with during the study or any issues will be taken very seriously. If taking part in this research project harms you, then you may have grounds for legal action.

Will my taking part in the study be kept confidential?
Yes. We want to emphasise that all results obtained will be strictly confidential and will only be used for research purposes. All the information about your participation in this study will be secured against any unauthorised access. Although the overall results will be published in medical journals, no individual participants will be identifiable from this. Confidential information regarding identity of participants will be kept secure for 10 years. After 10 years, this information will be securely destroyed.

What will happen to the results of the research study?
The results will be anonymised (removed of identifying information) and kept in a locked office at Brighton and Sussex Medical School.

The results of the questionnaires, along with all other information collected from you during this research will be kept strictly confidential. The results will be statistically analysed and findings subsequently published in peer reviewed journals. You will not be identified in any publication. You are welcome to a copy of any publication resulting from this work which can be obtained by giving us your email address or postal address.

Who has funded this study?
This study is funded by a grant from the MQ Transforming mental health through research charity. Their research aims include finding ways to prevent mental illness,

such as anxiety, from developing. Their web page about the study can be found here: https://www.mqmentalhealth.org/research/profiles/breaking-the-link-between-autism-and-anxiety

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.

Contact for further Information
Many thanks for reading this. We hope you feel able to take part in our study. If you have any questions, please contact the following people:

Charmaine Kohn,
Email: AskAboutResearch@sussexpartnership.nhs.uk,
Tel: 0300 304 0088

Prof Hugo Critchley (Chief investigator): H.Critchley@bsms.ac.uk
01273 678336