The SenITA study
Sensory **I**ntegration **T**herapy versus usual care for sensory processing difficulties in children with **A**utism Spectrum Disorder.

Information Sheet for Parents & Guardians

We are inviting you and the child you have parental responsibility for (referred to as 'your child' in this leaflet) to take part in this research study run by Cardiff University.

Before you decide if you want your child to take part,
we would like you to understand why the research is being done and what it would involve for you.

Please read this information sheet carefully.

One of our team can go through the information sheet with you and will answer any questions you have. Contact details can be found on the last page of this booklet.

Summary page

This page highlights the main points in taking part. Please read the rest of the information sheet for more details.

1. What is the purpose of the study?
To establish whether, compared to treatment normally offered to families ('usual care'), Sensory Integration Therapy (SIT) improves your child's behaviour and daily functioning.

2. Why have I been sent this information sheet?
Because the person who passed on this information thought your child might be eligible to take part in the study. We will not be able to confirm this until you and the child you care for attend an appointment with a researcher.

3. Do I have to take part in this study?
It is up to you to decide whether or not you and the child you care for take part.

4. What will happen?
Either your child will continue to receive their 'usual care' or they will receive regular SIT sessions (26 sessions over 26 weeks). We will also ask you to complete questionnaires after 6 and 12 months. The study lasts for year in total.

5. Who decides if my child receives SIT?
Neither you nor the study staff will have any influence over whether your child receives SIT or have their usual care. This will be selected by a computer on the basis of chance, that is randomly, like flipping a coin.

6. What are the possible benefits of taking part?
We are running this study because we do not know if SIT is better than usual care so taking part may not be of direct benefit to you or your child. It should, however, help us to provide better care for children in the future.

7. What safety assurances will I have if I take part?
If there is any concern about you or the child you care for taking part in the study, you will be withdrawn.

8. Who is organising and funding the research?
This research has been organised by a group of specialists at Cardiff University and is funded by the National Institute for Health Research.

WHY DO WE WANT TO DO THE STUDY?

Autism Spectrum Disorder (ASD) is a common lifelong condition affecting 1 in 100 people. ASD affects how a person relates to others and the world around them and difficulty responding to sensory information (noise, touch, movement, taste, sight) is common. This might include feeling overwhelmed or distressed by loud or constant low-level noise e.g. in the classroom. These 'sensory processing difficulties' can sometimes affect education, relationships, and participation in daily life.

Sensory Integration Therapy (SIT) is a type of face-to-face therapy (or treatment), provided by trained occupational therapists. The therapist uses play -based sensory-motor activities to influence the way children respond to sensation, reducing distress and improving concentration and interaction with others. Research suggests SIT might be helpful for some children so we would like to look at this more. In this study we are interested in whether, compared to treatment normally offered to families ('usual care'), SIT can help with behaviour and daily functioning. We are looking to recruit 216 children aged between 4 to 11 years.

WHY HAS MY CHILD BEEN ASKED TO TAKE PART?

Your child has been identified because they could be eligible for the SenITA study.

DOES MY CHILD HAVE TO TAKE PART?

Your child does not have to take part in this study. Participation is entirely voluntary and you and your child are free to refuse to take part or withdraw from the study at any time without having to give a reason. If you do decide not to take part or to withdraw from the study, this will not affect the care that your child receives. You will also be asked to confirm whether you are happy for us to use the information you have given us or if you wish for it to be destroyed.

WHAT IS THE STUDY TREATMENT?

Your child will either receive Sensory Integration Therapy (SIT) or continue to access care/be referred for treatment as usual. Please note: if your child is allocated to receive SIT, they will still continue to receive any other support or treatment for any aspect of their condition (e.g. speech therapy). SIT would only replace occupational therapy for sensory problems.

SIT involves regular face-to-face sessions with an occupational therapist at a specialised clinic. Initially the therapist will assess your child for specific sensory integration difficulties and will discuss the goals you feel are important to you and your child. You will be asked to complete a brief background history to help to understand your child better. This can be split over more than one appointment if needed. The intervention will then be delivered as 26 1-hour sessions delivered over a 6 month period. This is broken up as follows:

2 x 1-hour face-to-face sessions per week for the first 10 weeks

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2 x 1-hour face-to-face sessions per month for the next 2 months

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1 x 1-hour telephone sessions per month for the final 2 months

If your child receives SIT, they will need to be taken to the clinic regularly (as described above). The researcher will be able to tell you where the clinic is.

WHICH TREATMENT WILL MY CHILD RECEIVE?

To make this decision fair and to ensure that the groups are equal, a computer will decide which group your child is allocated to (SIT or usual care).

Your child will have the same chance of being put in either group.

WHAT HAPPENS IF YOUR CHILD TAKES PART?

- You and your child will see a researcher who will talk to you about the study and assess whether your child is suitable to take part.

- You will be asked if you are happy to take part and if so, you will be asked to sign a consent form. We will also let your child's GP and their school know that they are taking part in the study.

- Your child will also be given information about the study. If appropriate, they will be given an assent form which asks them to write their name to confirm that they would like to take part.

- If you and your child are happy to go ahead, you will be asked some questions about your child's behaviour and daily life. We will also collect some basic information.

- Following this, the researcher will be able to carry out the random allocation so you will know whether your child is going to receive the SIT or carry on being treated as they usually would. We will also let your child's GP know that they are taking part in the study by sending them a letter.

- Even if your child is allocated to receive SIT, the therapist will still be able to recommend alternative treatment at any time if he/she thinks it is in the best interest of your child.

- If your child receives SIT, they will be asked to attend sessions with the occupational therapist as described earlier. Regardless of whether they receive SIT or usual care, we will ask you to complete a diary at home for 6 months to help record the kind of care they have more generally.

- If your child receives SIT, we are able to offer up to £50 at the end of the treatment to help with costs associated with travelling to therapy sessions.

- If your child receives SIT, sessions will be video recorded. This is so that we can check that the therapy is being delivered as it should be. We will ask you to sign another consent form if you are happy for the recording to take place. This form will detail exactly who will have access to the recordings and what they will be used for.

Follow up visits:

So that we can see the effects of the treatment your child receives, we will ask you to complete further questionnaires at two follow up meetings with a researcher (even if your child was in the 'Usual Care' group). These might take place at your home or at another venue that suits. The first meeting will be after 6 months of being in the study. We will also ask your child's teacher to complete a similar questionnaire at this point. The final questionnaire will be after 12 months. Your child does not need to be present for either of these.

To thank you for your help, all those completing a follow up visit will be offered a £10 high street voucher at each visit.

After 12 months, your participation in the study ends.

Parent interviews:

During the study (at about 6 months), we would also like to carry out some interviews with parents who took part. Not everyone will be asked as we will only interview a small number who agree to do so. We will provide more information about the interviews when they take place.

WHAT ARE THE POSSIBLE ADVANTAGES ABOUT TAKING PART?

By participating in this study you will be helping us answer questions about the treatment of sensory processing in children with autism spectrum disorder which may result in better care for children with this condition in the future. You may also be offered a type of therapy (SIT) not currently routinely available on the NHS.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Taking part in the study will mean that we ask you to give up some of your time. This may include taking your child to attend SIT sessions as described.

If you or your child experiences any problems with the treatment you should contact the occupational therapist and the Study Manager (details at the end of this sheet).

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

All information, including any personal information, collected about you and your child during the course of the study will be kept strictly confidential. This will include details held by the University finance department is you receive a payment towards travel costs as part of the study.

We follow ethical and legal practice. Your occupational therapist will know that you have agreed for your child to participate in the study. However, they will not see your answers to the questionnaires or your diary.

Neither your name nor your child's name will be given out or appear on any publications.

We will store the information collected during this research study including your child's details for a minimum time of 15 years, though we may store it for longer. This is because the regulations require storage until the youngest participant has reached 21 years if that has not already happened within the original 15 years. This information will be stored securely and confidentially by the research team at Cardiff University in accordance to the General Data Protection Regulation 2016 and only the study team will have access to this information.

WHAT IF I, OR MY CHILD, DO NOT WANT TO CARRY ON BEING PART OF THE STUDY?

You can decide for you and your child to stop taking part in the study at any time and without needing to give a reason. If you wish, you can contact the Study Manager or let the therapist know next time they contact you. In order for us to understand the reasons why parents withdraw their children from the study, we may ask you why you have decided to withdraw. However, you do not have to give any reasons.

If your child does stop taking part in the trial completely, they may need to be seen one last time to discuss any further care requirements.

If you decide to stop taking part, your child's medical care and the legal rights of either you or your child will not be affected in any way.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

At the end of the study, the results will be published in medical journals and presented at medical conferences. This will allow us to tell other doctors and healthcare professionals about the results of the study.

Information that identifies you or your child will not be presented. We will provide you with information of where to access the published study. We will also update you with newsletters during, and at the end of the study.

WHO HAS FUNDED AND APPROVED THE STUDY?

This study has been funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme and is being managed by Cardiff University.

The study has been approved by Wales REC 3 (reference: 17/WA/0031). The committee makes sure that the study is conducted ethically and in accordance with the requirements of the Clinical Trials Regulations. Their job is to protect your safety, rights, wellbeing and dignity.

WHAT IF THERE IS A PROBLEM?

If at any point you are unhappy with any aspect of the study, please advise the South East Wales Trials Unit (SEWTU) research team (contact numbers overleaf), or your therapist. If you remain unhappy and wish to formally complain, you can do this through contacting:

Research and Innovation Services

Cardiff University

7th Floor, McKenzie House

30-36 Newport Road, Cardiff

Tel: +44(0)29 2087 9277

WHAT DO I NEED TO DO NOW?

If you agree to consider having your child take part in the study please tell your therapist whether or not you are happy for your child to take part. If your child is old enough you will probably want to discuss the study with them.

Thank you for reading this information sheet and considering taking part in this study. Our team is experienced and dedicated to doing this important study to the highest international standards, and helping to improve the future care of children with autism spectrum disorder.

Should you have any further questions or require further information about your child taking part you can contact (during normal working hours):

SenITA Study Manager

South East Wales Trials Unit (SEWTU),

4th Floor, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS

Tel: +44 (0)29 20687608 E-mail: SenITA@cardiff.ac.uk

Please note that this number is only for queries regarding the study;

if you have an urgent health problem please contact your doctor in the normal way.

Alternatively, you can visit our study website on:

www.senitastudy.weebly.com

Local contact for this study is:-