Evaluation Of **P**arent **I**ntervention For **C**hallenging Behaviour In **C**hildren With **I**ntellectual **D**isabilities (**EPICC-ID)**

Participant (Parent) Information Sheet

The study

We are inviting you to take part in a research study. Before you decide it is important to understand why the research is being done and what it would involve. Please take the time to read the following information carefully. A researcher will go through it with you and answer any questions. Feel free to discuss it with friends, relatives, or anyone else you normally talk to. It explains why the research is being done and what it will mean for you. **Part 1** tells you the reason for the study and what will happen if you take part. **Part 2** gives you more details about the way the study is managed.

Part 1

What is the purpose of the study?

Stepping Stones Triple P (SSTP) is an intervention (also called therapy) for parents of children with intellectual (also called learning) disabilities and challenging behaviour. It provides parents with information and support about how to manage such behaviours in their child. Trained therapists follow a manual and deliver the intervention in groups of 5-7 parents for 5 weeks, followed by 3 individual sessions and a final group meeting. Parents receive a certificate at the end of the course.

One parent (the main caregiver for the child) will attend each of the groups. The study will include young children aged 30-59 months with moderate to severe intellectual disabilities. SSTP is not yet rolled out in the NHS, so it is important to find out if it can make a difference before deciding if it should be offered to more families. A team at University College London is leading a study to answer this question. The study will compare two groups. Some will have the usual NHS care; others will have usual NHS care and will also receive SSTP.

It is important to understand that if you agree to be part of the study you will not be able to choose which group you are in. You may be in the group that has the usual NHS care and you may be in the other group that has the usual NHS care and also SSTP. This decision is made by a random computer process (a bit like flipping a coin) which helps to make sure that both groups are very similar to start with. Doing the study this way means that we can be more sure that any differences between the groups are because one group has received SSTP.

Why have I been invited to take part in the study?

You have been invited to take part because you live in one of the four areas in England which have agreed to host the study and your child is in the right age group (3-5 years), has moderate to severe intellectual disability and presents with challenging behaviours, e.g. tantrums, irritability, poor sleep

etc.

Do I have to take part?
It is up to you to decide. You can keep this information sheet and you will be asked in a day or so if you would like to sign a consent form agreeing to take part in the research. If you do consent you are free to withdraw at any time, without giving a reason. Taking part will not affect the standard of medical or other care you and your child receive.

What will happen to me if I take part?

We will ask you some background information about your child and also carry out an assessment of their disability. If the child is eligible to take part in the study we will carry out the first assessment after which the study administrator will tell you whether you will be receiving SSTP or usual NHS care. There is a 60% chance that you will be allocated to the group receiving SSTP or to the control group. We will also ask you to nominate a caregiver or teacher who knows your child and can complete a questionnaire on their behaviour. This can be a nursery worker, school teacher or another family member who also cares for your child.

If you are in the group receiving SSTP your contact details will be given to the therapists who will contact you with details of when and where the sessions will take place.

There will be another two study assessments, at 4 months and at 12 months. During all of the 3 study assessments, in addition to the questionnaires, we will ask you, if you are willing to take part in a short exercise with your child, and a video will be made of you and your child playing together. This is about 20 minutes and includes a section where you and your child play together, followed by a section where each of you does a different task, e.g. the parent reading and the child playing on his/her own, and a final section where you ask your child to follow a simple instruction, e.g. put his or her toys away.

The first interview will last about 2 hours and the second and third interviews will last about 90 minutes.

After each of the three home interviews we will give you a £15 shopping voucher to show our appreciation for your time.

If you are in the group receiving SSTP, we would like to ask you to complete a brief questionnaire regarding your views on how you found the group and the therapy. This should take approximately 5-10 minutes and would take place at the end of the final SSTP group session.

Some parents will also be given the opportunity to take part in an additional interview to share their experiences of receiving the intervention. These interviews will be audio-recorded. You may be contacted about this at a later date. Another shopping voucher for £15 will be given after this interview.

During the study we shall also produce a newsletter that will talk about how the study is progressing and we shall send this out to all participants. If anything changes during the course of the study that is relevant to your participation, e.g., other evidence emerges that makes the study redundant, we shall let know immediately.

What are the possible disadvantages and risk of taking part?

There should not be any disadvantages or risks to you, however there is a time commitment. If you are part of the group that receive the SSTP intervention you will need to make the time to attend the 6 weekly therapy sessions each lasting 2.5 hours. The therapists will also call you three times for about 30 minutes to find out how you are managing. However, we find that most parents find talking about their child's difficulties helpful and appreciate the time to reflect on their

experiences as they try to cope with the challenges of having a child with disabilities. If you do find any question difficult to answer you can stop the interview, or move on to other topics.

What are the possible benefits of taking part?

There are several reports about SSTP but it has never been tested in the UK/England. If this intervention were proven to help children with difficulties at an early age, we would use that information to try and convince health and social services to offer it to more parents with a child who has similar problems. Without that information it is not likely that SSTP will be made available to more families across the country. You may benefit from talking to a researcher about your own experience of parenting a child with challenging behaviour.

This completes Part 1.

If the information in Part 1 about the study has interested you and you are thinking about taking part, please read Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

If you agree and then do not want to carry on in the study, let the study manager, Dr Poppe know. You do not have to give a reason. Your and your child's health and other services will not be affected.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the Principle Investigator for EPICC-ID in the North East, Dr Aditya Sharma (07880823452) who will do their best to answer your questions, or contacting Professor Angela Hassiotis at 0207 974 3788. If you remain unhappy and wish to complain formally you can do this by using the NHS complaints procedure making your complaint to your local health trust http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx.

Will my taking part in this study be kept confidential?

Information about you will be kept strictly confidential and any identifying information such as your name and address will be removed so that you cannot be recognised. Participants are identified in computer records only by a number. No one outside the research team is given access to the information. According to Data Protection guidelines after research reports are written and published the information is kept for 20 years, then disposed of securely by shredding paper documents and cleaning computer storage. Any audio and/or video recordings made during the research will be used only for the analysis of the data. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings. We shall keep all videotapes and study materials stored according to the UCL's data handling policy encrypted and only with study number. All recordings will be deleted from the devices once in storage.

No information about you will be shared with any other agency except where UK law requires otherwise. What this means is that if you say something to the researcher in an interview or therapists during the intervention that suggests you or your child are at risk of harm or in immediate danger, or if you tell them about thoughts of harming yourself, then an appropriate person will need to share this information with a professional involved in your care so that additional help can be arranged. You will be told if this occurs.

Transparency information

University College London (UCL) is the sponsor for this study based in the United Kingdom. We will be using information from you and your child and/or your child's medical records in order to conduct and analyse this research study and UCL will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University College London will keep identifiable information about you for 20 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you and your child that we have already obtained for the sole purpose of this study unless you specifically request for this to be withdrawn. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at http://www.ucl.ac.uk/priment/participant-info/#confidentiality .

Northumberland, Tyne and Wear NHS Foundation Trust (NTW) will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study. Individuals from University College London (the sponsor) and regulatory organisations may look at your child's medical records and you and your child's research records to check the accuracy of the research study. NTW will pass these details to University College London along with the information collected from you and your child and/or your child's medical records. The only people in University College London who will have access to information that identifies you and your child will be people who need to contact you to safely advise you about your child's care in the study or to audit the data collection process. The people who analyse the information will not be able to identify you and your child and will not be able to find out your name or contact details.

NTW will keep identifiable information about you from this study for 20 years after the study has finished.

When you agree to take part in a research study, with your permission, the information about your child's health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities or NHS organisations who are involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

You and your child's information could be used for research in any aspect of health or care, and could be combined with information about you and your child from other sources held by researchers, the NHS or government.

Where this information could identify you or your child, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate

in research with your permission. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you or your child can be identified you and your child's data will only be used in research that has been independently reviewed by an ethics committee.

What will happen to the results of the research study?

The results of the study should be available about six months after the study ends. This will probably be in the Autumn of 2021. We will keep you informed about progress and share the main findings, through newsletters, twitter or other electronic means, and local meetings. The results will be presented in government reports, in academic journals and in other formats for non-academic audiences.

Who is organising and funding the research?

The Division of Psychiatry at University College London is leading the research and the NHS National Institute for Health Research (NIHR) is funding the research. If you have any questions please do not hesitate to contact us at the telephone number or address given below.

Who has reviewed the study?

Before funds were given for the study the NIHR obtained independent expert reviews of the plans. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. It was approved in 19.05.17 by the London - Camden & Kings Cross Research Ethics Committee.

Thank you for reading this.

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[http://www.ucl.ac.uk/psychiatry/research/epidemiology/pis/hassiotis-research-portfolio/challenging-behaviour-early-intervention]

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