 [site logo]

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

## Participant (Caregiver or teacher) 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. Please contact the number provided below if you have any questions about this study. 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.

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

You have been invited to take part because you are a caregiver or teacher of a child that is taking part in the study and whose parents have named you as someone who knows their child well and can complete the enclosed questionnaire on their behaviour. The parent will also complete a similar questionnaire.

Do I have to take part?

It is up to you to decide whether to complete the questionnaire. If you decide to complete the questionnaire, you need to sign two copies of the consent form. You will keep one for yourself and send the other copy with the completed questionnaire back to us using the pre-stamped and pre-addressed envelope provided for you.

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 this child and family receive.

**What will happen to me if I take part?**

If you agree to take part in the study, researchers will contact you again to complete this questionnaire at two different time points; 4 and 12-months from now.

**What are the possible disadvantages and risk of taking part?**

There should not be any disadvantages or risks to you. If you do find any question difficult to answer, please try your best and move onto the next question.

**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.

**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 researcher know. You do not have to give a reason. The child’s and their family’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 researchers who will do their best to answer your questions, contacting 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?**

The information you provide in the questionnaire will be kept strictly confidential.

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.

No information you provide 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 which suggests the child may be at risk of harm or in immediate danger, then the research team will need to share this information with a professional involved in the child’s 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 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 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> .

[NHS/other site] will use your name, and contact details to contact you about the research study, and to oversee the quality of the study. Individuals from University College London (the sponsor) and regulatory organisations may look at your research records to check the accuracy of the research study. [NHS site] will pass these details to University College London along with the information collected from you. The only people in University College London who will have access to information that identifies you will be people who need to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

[NHS/ other site] 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 you 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.

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

Where this information could identify you, 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 can be identified your 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 on 19/05/2017 by the London – Camden & King’s Cross Research Ethics Committee.

Thank you for reading this.

Division of Psychiatry

University College London

6th Floor, Maple House

149 Tottenham Court Road

London W1T 7NF

**Professor Angela Hassiotis, Chief Investigator**

**[epicc-id@ucl.ac.uk]**

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

**[Site Research Assistant details]**

**[site PI details]**