

Participant Information Sheet – Parent (Phase 2,3)

Relationships in Good Hands Trial (RIGHT):



Clinical and cost-effectiveness of Dyadic Developmental Psychotherapy (DDP) for abused and neglected young children with maltreatment-associated problems and their parents.

We would like to invite you to take part in a research project, the **Relationships in Good Hands Trial (RIGHT)**. Before deciding about taking part, it is important that you understand what we want to do. Please take the time to read this information and discuss it with others if you wish.

If you would like more information, call us on 0141 201 9239.

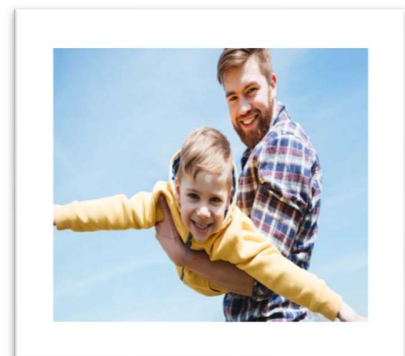
■ *What is the purpose of the study?*

Often, children who are adopted or in care experience psychological or relationship problems. There are many different health and social care services available to help, and they all aim to improve the child's mental health and/or the family relationships.

This study is trying to find out which type of service works best and whether these services are worth the costs and the effort families have to put in to receive these services.

We are inviting foster and adoptive families to take part in this study if they were referred for support with a child aged between 5 and 12 years of age.

If they decide to take part, families would be offered either Dyadic Developmental Psychotherapy (DDP) or the services already being provided locally, which can be a range of social and health care supports. We call these wide-ranging health and social services "Services-As-Usual" (SAU). We will be using a computer to randomly choose whether each family gets SAU or DDP, a bit like tossing a coin.



■ *What are the two services like?*

Services as Usual and DDP work differently, but both services will meet with families regularly and put them in touch with other services they might need. Some services ask families to meet weekly for several months, while others see families less frequently.

No-one yet knows which type of service is best for improving the mental health of children in foster or adoptive families. It is very important that we find out, so we can support these children and their families in the best way possible.

■ Why have I been invited?

We are inviting you because you are an adoptive or permanent foster parent with a child aged 5–12 years and you were referred for support. Over the next four years, we plan to ask around 240 foster and adoptive families to take part in this study from different areas across the UK.

■ Do I have to take part?

No. It is up to you to decide if you want to take part in the study or not. If you take part, you are free to withdraw from the study at any time until the end of study in July 2024, without giving a reason.

Your rights and access to the standard local services you receive will not be affected if you withdraw.

■ What will happen to me if I take part?

If you take part in the study, we will invite you and your child for 2 study visits each taking 2-3 hours. The first visit will be in the coming days and there will be a second visit after 12 months. These visits could be arranged as remote visits.

The researcher will meet you and your child using remote meeting tools recommended and supported by the organization you are recruited from. If this is the case, each visit might need to be split in 2 shorter sessions rather than one 2–3-hour block.

During the visit we will ask a series of questions to learn about your child and yourself. We will ask your child to take part in a game and we would like to video record a 10-minute refreshment and play session break. If we are unable to record the video during the visit, we will ask you to record it after the visit. We will ask you to send it to us following instructions which we will provide.

We will give or send you a questionnaire to take away with you and ask your child's teacher to complete and return it to us.



After the first visit, we will find out which service the computer selected for your child. We will let the team that referred you in the study know, and they will arrange the support sessions for you. We will give you a diary to record few details about the support sessions, such as the date, duration, and type of session. We will ask you to give this diary to the practitioner delivering the support sessions who will help to complete these details. We will collect this diary from you when you come back to see us after 12 months.

Throughout your involvement in the study, we will ask you to complete a short 5-minute questionnaire every 3 months. This can be done by phone, email or online, depending on what you prefer. With your permission, we might contact you later during the study to invite you for an interview or discussion group about your experience with the services.

In Scotland and England, a range of information called routine data is regularly collected on every citizen. This includes information about births, deaths, child protection, schooling, criminal justice, health, and hospital visits. The RIGHT study researchers wish to gain access to this routine data to learn about your child's pre-care and care history which we would like to collect on an individual basis prior to 12-month assessment.

This study is planned to run for about 4 years, and it might not be long enough to know all we need about the services we are assessing. We would like to ask your permission to contact you by the research team and access your routinely collected data about care history in the future. This would always relate to the research associated with this trial.

■ **Can something go wrong?**

We do not expect anything to go wrong. The visits you have with us will be led by experienced research staff who will lead you through collecting the information we need for the study, and there will be tea/coffee breaks unless, of course, we are meeting you remotely. In case you or your child become unsettled, the research team will work closely with you to provide comfort, and if necessary, end the visit earlier or rearrange for another day.

■ **Are there any benefits of taking part?**

There are no direct benefits to your family from taking part in this study. However, the information we collect during the study will give us a better understanding about which services are better for fostered and adopted children's mental health and this is likely to help families like yours in the future.

■ **Will I receive any compensation?**

Yes, we will reimburse your travel with up to £25 for each study visit. Also, to show our appreciation for your time and contribution to the study, you will receive a £35 voucher for each (baseline and follow-up) visit.

■ **Will my taking part in this study be confidential?**

The Research Team will keep you and your child's name, contact and GP details stored in a confidential database in the Robertson Centre for Biostatistics (RCB), at the University of Glasgow, a specialist centre for managing and analysing data from clinical trials. We will not pass this information on to anyone else.

The Research Team will use this information as needed, 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.

Your data will have a unique study number and will be stored for at least 10 years in a secure database at the University of Glasgow within the RCB. Information will be stored in accordance with the *General Data Protection Regulation 2018*. Any data in paper form will be stored in secured locked cabinets accessible to the research team only. All data will be kept confidentially within the research and clinical team, except in the unlikely event of

concerns about the safety of the child or others. Some people may look at the study research records to check the accuracy of the research study and will only receive information that does not include anything that identifies your family. 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.

We will also ask whether you are happy for us to inform your General Practitioner of your participation in the study. If you have particular concerns about the child and would like us to inform other professionals such as a paediatrician, then we would be happy to do that too - with your permission.



■ What will happen to my data?

NHS Lanarkshire and University of Glasgow are the sponsors for this study based in Scotland and England. We will be using information from you and your child's medical and social work records in relation to your child in order to undertake this study and NHS Lanarkshire and the University of Glasgow will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The lawful basis for processing your data is the research, a task carried out in the public interest.

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 unless you instruct us not to. In some cases, it may not be possible to completely remove your data from our research records. To safeguard your rights, we will use the minimum personally identifiable information possible. The Research Team at the University of Glasgow will keep information collected about you from this study for 10 years after the study has finished.

Your data will form part of the study results that will be published in a study report, in academic journals and conference proceedings for other researchers to use. All information will be in a format that it will not be possible to recognise you.

You will have the option to agree that the information we collect may be provided to other genuine researchers in universities, NHS organisations or companies involved in health and care research. This information will be in the format that no one could recognise you. This would involve us storing your research data with the UK Data Archive a center of expertise who store research and scientific data. You can find out more about how we use your information on 0141 201 9239.

■ Who is conducting the research?

The trial is sponsored by NHS Lanarkshire and University of Glasgow who coordinate the trial on behalf of National Institute of Health Research which has provided funding to the Institute of Health and Wellbeing in collaboration with colleagues from the University of Oxford and the University of Nottingham.

■ **Who has reviewed this study?**

The study has been reviewed by the West of Scotland Research Ethics Committee which has responsibility for reviewing research with people in health care services. They have examined the proposal and has raised no objections for this research to go ahead. It is a requirement that your records in this research, be made available for scrutiny by monitors from NHS Lanarkshire and University of Glasgow whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

■ **If you have any further questions?**

If you need an independent advice about the study, please contact Research Fellow Dr Lucy Thompson on 0141 201 9239 or lucy.thompson@glasgow.ac.uk

Researcher(s) Contact Details:

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What if you have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanism is also available to you. For information on NHS Lanarkshire complaints procedures or advice on how to make a complaint, please telephone 0300 3030 243 or email corporatecomplaints.lanarkshire@nhs.net. Alternatively, you can also contact Barnardo's Strategic Impact Team Joelle.bradly@barnardos.org.uk (Head of Strategic Impact)

THANK YOU for taking the time to read this information sheet.