



Positive Family Connections – A positively-oriented, family systems intervention for families of children with developmental disabilities: A feasibility study

Primary Parental Carers Participant Information Leaflet

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Study Title:	Positive Family Connections – A positively-oriented, family systems intervention for families of children with developmental disabilities: A feasibility study
Investigator(s):	Daniel Sutherland, Dr Samantha Flynn, Dr Jo Griffin, Professor Richard Hastings, Dr Paul Thompson.

Introduction

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. If you do decide to take part, please complete the consent form within one week of receiving this information sheet.

Who is organising and funding the study?

The study is being led by researchers at the University of Warwick and is funded by the charity Cerebra jointly with the University of Warwick.

What is the study about?

We have worked with family carers to develop a programme for families of children with developmental disabilities (such as a learning disability or autism) aged 8-13 years called Positive Family Connections. To find out whether this course is effective in helping families would require a big study with lots of family carers. However, before we can do this, we need to carry out this smaller study, called a feasibility study, to work out whether a larger trial would be possible in the future.

In this feasibility study, some family carers will be invited to take part in Positive Family Connections straight away and others will be invited to take part in Positive Family Connections around 12 months later. Whether you are invited to take part in Positive Family Connections straight away or later will be decided by chance (at random). Both groups of families will be asked to complete some questionnaires at the start of the study, and then again 4 and 9 months later.

What would taking part involve?

You can take part in the study if:

- You are aged 18 or over
- You are a primary parental carer of a child with a developmental disability (such as a learning disability or autism) aged 8-13 years. Your family member with a developmental disability must either have a diagnosis of a developmental disability or receive developmental disability services. The primary parental carer is the person that the child with a developmental disability lives with most of the time, typically a biological parent, step-parent, adoptive, or foster parent.
- You are not currently completing a parenting programme or receiving another individual or group therapy for stress, or mental health problems.
- There are no current safeguarding or child protection investigations relating to any member of your family
- You do not feel that your family are in crisis and in need of immediate support. This is important because whether or not you are selected to take part in the programme straight away or in 12 months will be random, and so we can not guarantee that you will receive immediate support as part of the study.
- Your child meets eligibility criteria on the Vineland Adaptive Behaviour Scales (this is explained below).

If there are multiple adults in your family, up to two can take part. If there is a second family carer interested in taking part, we will ask you to pass on information to them so that they can decide for themselves.

To check that you are eligible to take part in the study, we would firstly schedule a video call over Zoom. This call is to tell you more about the study, answer any questions you have, and ask you some questions about you and your family to establish whether you are eligible to take part. This would include questions about your child with a developmental disability's communication, social skills, and daily living skills as part of an assessment called the Vineland Adaptive Behaviour Scales. The researcher will also ask whether there is another family carer in your family who may be interested in taking part.

Overall, we expect that this video call would take around 30 minutes. After this meeting, the researcher will contact you to tell you whether you are eligible to take part in the study. If you are eligible, they will send you a consent form to complete. Additionally, if you tell us that there is another eligible family carer in your family, we will send you an information sheet and consent form to pass on to them.

You will then be asked to complete a questionnaire either online, in a paper format, or over the telephone, whichever you prefer. This questionnaire will include questions about your family relationships, wellbeing, children's behaviour and emotions, positive perceptions of your child with a developmental disability, quality of life, and health services that you use. We anticipate that these questionnaires will take around 30 minutes to complete. If you do not want to answer individual questions, then you can skip them.

Once you have completed the survey, you will be selected at random (a 50-50 chance) to either take part in Positive Family Connections in May or June 2022, or to wait to be invited around 12 months later. There will be an equal chance of you being placed in either of these study groups. This random selection will take place between March and May 2022. The reason we randomly select families like this is so that we can compare the questionnaire answers between the two study groups, which is the best way for us to learn whether Positive Family Connections might help families.

If two family carers from your family take part in the study, the primary parental carer (you) must be happy to be randomised to take part in Positive Family Connections straight away or to be invited later. However, the second family carer may choose whether or not to attend Positive Family Connections with you.

The Positive Family Connections programme consists of 6 weekly, online sessions. These sessions are facilitated by trained family carers of children with developmental disabilities, and there would be 6-8 families in each group. The course aims to develop positive family relationships and wellbeing through interactive activities, skills, and discussions. Because the course is online, you would need access to a device such as a computer, telephone, or tablet that can connect to the internet to take part. If childcare may be a barrier to you taking part in the course, we may be able to help with the costs of this. We understand that unexpected events might mean you have to miss sessions, but to take part in the study we ask that you are happy to commit to attending all of the sessions.

All participants in the study will be asked to complete the questionnaire again around 4 and 9 months after completing the first questionnaire.

After we have collected all of the information, some family carers will be invited to take part in interviews with a researcher. The interview will involve discussing your experiences of participating in the study and taking part in, or waiting for, the Positive Family Connections programme. It is your choice whether you agree to take part in this interview if you are invited and further information will be provided to you to help you make that decision. All we need to know now is if it is okay for us to contact you later to invite you to take part. On the consent form, you can choose not to be contacted about these interviews and you will still be able to take part in the rest of the study.

Do I have to take part?

No. Participation in this study is completely voluntary and choosing not to take part will not affect you in any way. You can also choose to withdraw your participation without giving a reason by contacting one of the research team. Further details about withdrawing from the study are provided later on in this document. Note, however, that if you decide not to take part, another family carer from your family will not be able to take part without you (if they are not also a primary parental carer).

What are the possible benefits of taking part in this study?

The Positive Family Connections programme was developed by a team of family carers of children with developmental disabilities and researchers. It is based on family carers' experiences and research into what kinds of interventions might best help families' relationships and wellbeing. However, because the programme has not yet been fully tested, we do not know whether it might benefit you. By taking part in the study, you will be helping researchers to learn whether Positive Family Connections might be helpful for family carers of children with developmental disabilities. Through doing this, you could benefit families in the future.

What are the possible disadvantages, side effects or risks, of taking part in this study?

If you decide to take part, you may be selected to take part in the Positively Family Connections programme straight away. Whether or not you are invited to take part straight away, you will be asked to complete the questionnaires. The questionnaires and Positive Family Connections sessions include positive things but will also cover topics that you might find difficult such as thinking about your wellbeing or challenges in your family. However, we do not think that taking part in the study will pose any risk to family carers or their children. Should you have any concerns, please contact the research team using the contact information at the end of this information sheet.

If any of the survey questions make you concerned for yourself or another family member's well-being, we recommend that you make contact with your General Practitioner (GP) or one of the helplines listed below:

Mencap: 0808 808 1111, Contact: 0808 808 3555, Family Lives 0808 800 2222
Mencap Cymru: 0808 8000 300

Expenses and payments

Each family carer will be eligible to receive up to £50 in Love2Shop vouchers during the study. Family carers will be emailed a £15 Love2Shop e-voucher for completing the survey at 4-month follow-up, a £25 e-voucher for completing the survey at 9-month follow-up and will receive an additional £10 e-voucher after 9-month follow-up if they completed both follow-up surveys. Additionally, we might be able to help with the cost of childcare during Positive Family Connections sessions if this might be a barrier to you being able to take part.

Will my taking part be kept confidential?

Yes, all information about you will be handled in confidence and will be stored securely. Your data will be collected in an online survey or a paper format if you request this. This data will be exported from the online survey or entered from the paper copy into a database by a member of the research team. This database will be stored in a secure University server and will only be accessible to members of the research team. Furthermore, personally identifiable data such as your name or contact details will be stored in a separate folder to all other data. This means that instead of being labelled with personally identifiable information such as your name, your data will be labelled with pseudonymous ID numbers. Paper copies of surveys and consent forms will be stored inside a locked drawer in an office on the University of Warwick campus.

The only instance in which we may have to breach confidentiality is if you were to disclose that you or somebody else was at risk of harm. In this circumstance, we would have a legal responsibility to pass this information on to appropriate services. Where possible, we would endeavour to discuss this with you first and ensure you are aware of available support services.

Only members of the research team will have access to data. However, in some instances, officials from regulatory authorities may need to access data for checking the quality of the research. All members of the research team and regulatory bodies are trained in data protection issues. Study research data will be kept securely for at least 10 years from the date of any publication which is based upon it in line with the University of Warwick's policies. No personal data will be transferred outside of the UK. Research data will be reviewed after 10 years to see if the data should be retained or can be deleted.

What will happen to the data collected about me?

As a publicly-funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study.

We will be using information from you in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Warwick will keep identifiable information about you for 10 years after the study has finished.

Research data will be **pseudonymised** as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data and will be replaced with a participant number. The key to identification will be stored separately and securely to the research data to safeguard your identity.

You will be able to withdraw your data from the study at any point up until we begin analysing data, which we estimate to be approximately May 2023.

If after the video call to discuss whether you are eligible to take part in the study, we tell you that you are not eligible to take part, we will delete all of your contact details and information collected about you.

Data Sharing

Data collected as part of the project will not be shared outside of the UK. 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. The University of Warwick has in place policies and procedures to keep your data safe.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here: <https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice> or by contacting the Legal and Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

You can withdraw from the study at any time without any negative consequences and without giving any reason. If you wish to do this, you should contact a member of the study team informing them, and they will ask you whether you wish to withdraw: 1) from future data collection; 2) previously collected data; 3) from the Positive Family Connections programme; 4) all of the above. Please note that if you withdraw from the study, it will not be possible to withdraw your data after approximately May 2023 after which point the data will have been anonymised. To safeguard your rights, we will use the minimum personally-identifiable information possible and keep the data secure in line with the University's Information and Data Compliance policies.

What will happen to the results of the study?

The responses of everybody in the study will be collated and written up in academic papers and a PhD thesis which will be made publicly available indefinitely. Results will also be presented at academic conferences in poster or oral formats. You and your family will not be identified in any report or presentation about the study.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Humanities and Social Science Research Ethics Committee (HSSREC).

HSSREC reference number: HSSREC 57/21-22

Who should I contact if I want further information?

If you would like further information and/or have any questions, please contact Daniel Sutherland (PhD student) of the Centre for Educational Development, Appraisal and Research, University of Warwick at positivefamilies@warwick.ac.uk or 07392125603.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services

University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this Participant Information Leaflet