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# Positive Family Connections: an intervention for families of children with developmental disabilities: a feasibility study

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| **Submission date**<br>08/02/2022 | **Recruitment status**<br>No longer recruiting | ☒ Prospectively registered<br>☐ Protocol |
| **Registration date**<br>10/02/2022 | **Overall study status**<br>Completed | ☐ Statistical analysis plan<br>☒ Results |
| **Last Edited**<br>26/03/2024 | **Condition category**<br>Other | ☐ Individual participant data |

**Plain English summary of protocol**

Background and study aims

Whilst family members of a child with a developmental disability (such as a learning disability or autism) describe lots of positive experiences, they also describe difficulties, including with their mental health and family relationships. Having a family member with a developmental disability impacts the entire family, and the whole family might benefit from support.

A family intervention is one that aims to help the whole family, based on the idea that family members are connected with each other - they are a family system. However, there has been little research into family-level interventions for families of children with developmental disabilities. A second issue is that existing interventions for families of children with developmental disabilities often focus only on reducing negative experiences like mental health problems or stress, and rarely focus on developing positive outcomes like wellbeing and family relationships.

Researchers have worked with family carers to co-produce an intervention for families of children with developmental disabilities called Positive Family Connections. Positive Family Connections is a family intervention with a positive focus towards developing wellbeing and family relationships. The programme involves six online sessions which are facilitated by two trained family carers with groups of 6-8 families (each of which may have up to two family carers).

To learn whether Positive Family Connections helps families, the researchers would need to do a large randomised-controlled trial. However, before we do this, they need to carry out a smaller trial, called a feasibility study, to investigate whether a larger trial is possible. The aim of this feasibility study is to understand the best way to recruit participants, design the study, collect data, and whether the Positive Family Connections programme can be delivered as intended.

Who can participate?

Participants must be aged 18 years or older and be a family carer of a child with a developmental disability aged 8-13 years. From each family, up to two family carers can take part. One of these must be the primary parental carer- 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. However, for second family carers, the researchers are interested in “family” in a broad sense, and somebody may take part if they consider themselves to be a family member of the child with a developmental disability.

### What does the study involve?

At the start of the study, primary parental carers would have a video call with a member of the research team to answer some questions about their child with a developmental disability's communication, social skills, and daily living skills. All family carers would then complete a survey which includes questions about family relationships, wellbeing, their family member with a developmental disability, and if applicable their child's sibling.

Families would then be randomly selected (a 50-50 chance) to either take part in Positive Family Connections in May or June 2022, or to be invited 1 year later. If two family carers from your family take part in the study, the primary parental carer 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.

All family carers would then be invited to recomplete the survey 4 months and 9 months after completing the first questionnaire. After the researchers 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 their experiences of participating in the study and taking part in, or waiting for, the Positive Family Connections programme.

### What are the possible benefits and risks of participating?

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, it is not known whether it might benefit participants. Taking part in the study will help researchers to learn whether Positive Family Connections might be helpful for family carers of children with developmental disabilities. This could therefore benefit families in the future.

Participants who take part may or may not be selected to take part in the Positively Family Connections programme straight away. Whether or not they are invited to take part straight away, they will be asked to complete the questionnaires. The questionnaires and Positive Family Connections sessions include positive things but will also cover topics that some people might find difficult such as thinking about their wellbeing or challenges in their family. However, the researchers do not think that taking part in the study will pose any risk to family carers or their children.

### Where is the study run from?

The Centre for Educational Development, Appraisal, and Research (CEDAR) at the University of Warwick (UK).

### When is the study starting and how long is it expected to run for?

January 2021 to March 2023

### Who is funding the study?

1. Cerebra (UK)
2. University of Warwick (UK)

### Who is the main contact?

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# Contact information

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## Additional identifiers

## Study information

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

### Study objectives
Since the project is a feasibility study, the researchers are not setting out to test specific hypotheses. Rather, the aims of the project are twofold:
1. Evaluate the feasibility of a larger, definitive randomised-controlled trial of Positive Family Connections.
2. Gain initial data to evaluate whether Positive Family Connections is effective at improving family functioning, wellbeing, and child well-being in families of children with developmental disabilities.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 24/01/2022, University of Warwick Humanities & Social Sciences Research Ethics Committee (Kirby Corner Road, Coventry, CV4 8UW, UK; +44 (0)24 765 73123; HSSREC@warwick.ac.uk), ref: HSSREC 57/21-22

### Study design
Single-centre unblinded waitlist control feasibility cluster randomized controlled trial (with families as clusters) with an embedded qualitative evaluation

### Primary study design
Interventional

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Family functioning in families of children with developmental disabilities

### Interventions

Families will be randomly allocated on a 1:1 basis (with each family as a cluster) to take part in Positive Family Connections or to a waitlist group who will be invited to take part in Positive Family Connections 12 months later. Random allocation will be carried out using the software R and the randomizeR package.

Positive Family Connections is an intervention for families of children with developmental disabilities. It is a positively-oriented intervention, which means that it is focused on helping families to thrive through developing positive family relationships and wellbeing, rather than as a “treatment” for mental health problems, stress, or other family difficulties. Secondly, it is a family-systems-informed intervention, which means it is focused on the family as an interconnected unit, the interactions between family members, and the meanings that families make of themselves. The programme was co-produced by a team of researchers and five family carers of children with developmental disabilities to ensure its relevance and acceptability to families.

Positive Family Connections aims to improve family relationships and the wellbeing of all family members. The programme seeks to do this by developing family resources through social and emotional peer support, increased awareness of family systems, and practical knowledge and strategies to support family life.

The intervention consists of 6 weekly sessions delivered over Zoom to 6-8 families (each of which may have up to 2 family carers). Each session lasts approximately 2 hours and is facilitated by 2 trained family carers. The programme sessions cover the following six topics: 1) Family systems and positive connections; 2) Managing family life; 3) Communication; 4) Noticing; 5) Activities; 6) Bringing it all together. Sessions involve a range of activities including facilitator-led content, group discussions of scenarios and ideas, individual reflection and activities, and practising skills. In each session, group members are encouraged to discuss skills or ideas that they can try out with their family that week, which they then reflect upon at the start of the subsequent session. Group members are also posted and emailed notes each week which give information about the topics they discussed for future reference.

The waitlist group will not receive any support as part of the study during the period of data collection. However, they may obtain support from alternative sources independent of the study. Participants in the waitlist group will be invited to take part in Positive Family Connections 12 months after randomisation.

### Intervention Type

Behavioural

### Primary outcome(s)

Family functioning measured using family carer report on the Family APGAR scale at baseline and 4- and 9-month follow-up post-randomisation

### Key secondary outcome(s))

All outcome measures are collected at baseline and 4- and 9-month follow-up post-randomisation:
1. Family carer wellbeing as measured using the Warwick Edinburgh Mental WellBeing Scale (WEMWBS)
2. Sibling relationships as reported by family carers using the Sibling Relationship Questionnaire
3. Family-carer relationship with the child with a developmental disability and their sibling using the Child-Parent Relationship Scale

4. Satisfaction with the couple relationship using a single-item rating of satisfaction with the relationship (Hansen, 2012)
5. Disagreement over issues related to parenting/care of the child (Hansen, 2012)
6. Support from and conflict with grandparents (Hastings et al., 2002)
7. Family carer psychological distress as measured using the K6 (Kessler et al., 2002)
8. Family carers' reports of the behavioural and emotional well-being of the child with a developmental disability and a sibling using the Strengths and Difficulties Questionnaire
9. Family carer's perceptions of the positive impact of ther child with a developmental disability using the Positive Gains Scale

### Completion date
07/03/2023

## Eligibility

### Key inclusion criteria
1. Family carer of a child with a developmental disability. Child must be aged 8-13 years and have a developmental disability as defined by family carers reporting that the child has received a diagnosis, and/or is in receipt of developmental disability services.
2. One family carer from each family must be the primary parental carer- 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. However, for second family carers, "family" will be subjectively defined by whether somebody considers themselves to be a family member of a child with a developmental disability. This means that participants may include immediate family members (e.g., parents, adult siblings, foster, adoptive, or step-family members), extended family members (e.g., grandparents, aunties, uncles) and other figures (e.g., neighbours, support workers, close friends).
3. Family carers must be aged ≥18 years
4. Family carers must be willing and able to participate in intervention sessions remotely over Zoom
5. The child with a developmental disability has an adaptive behaviour composite of <80 on the Vineland Adaptive Behaviour scales, third edition, domain-level interview

### Participant type(s)
Carer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
73

**Key exclusion criteria**

1. The primary parental carer is currently completing a parenting programme or receiving another individual or group therapy for stress, or mental health problems
2. The family is in acute crisis and in need of immediate support from other mental health or family services
3. There are safeguarding or child protection concerns relating to any of the family members
4. A primary carer in the family does not provide informed consent to take part in the study
5. The primary carer is not able to take part in the intervention and/or complete measures in English
6. The research team has significant concerns about the primary carer's readiness to take part in the intervention. For example, during the eligibility assessment they describe having had significant previous difficulties in group programmes, or do not appear able to engage with the positive orientation or family focus of Positive Family Connections

**Date of first enrolment**

17/02/2022

**Date of final enrolment**

09/05/2022

## Locations

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**

**Centre for Educational Development, Appraisal, and Research (CEDAR)**
New Education Building
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## Sponsor information

**Organisation**

University of Warwick

**ROR**
https://ror.org/01a77tt86

## Funder(s)

**Funder type**
Industry

**Funder Name**
Cerebra

**Alternative Name(s)**
Fondation Paralysie Cérébrale

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
France

**Funder Name**
University of Warwick

**Alternative Name(s)**
The University of Warwick, Warwick

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of the data. The data will be entered into an electronic database and stored securely on the University of Warwick M Drive.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 18/03/2024 | 26/03/2024 | Yes | No |
| Participant information sheet | version 1.0 | 16/12/2021 | 10/02/2022 | No | Yes |