ISRCTN96216897 https://doi.org/10.1186/ISRCTN96216897

Evaluation of the effectiveness of the ParentChild+ home visiting programme

Submission date	Recruitment status	[_] Prospectively registered
12/12/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
19/12/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/11/2022	Other	

Plain English summary of protocol

Background and study aims
ParentChild+ (previously the Parent-Child Home Programme) is an intensive home visiting programme developed in the US in the 1960s. ParentChild+ aims to increase parent-child interaction, promote positive behaviours and encourage language and other emerging literacy skills to enhance the home learning environment, promote school readiness and foster academic success. It is a targeted-selective programme primarily aimed at low-income families with children aged 2-3 years of age. It is delivered in the home by specially trained home visitors over a 15 month period. It models positive parent-child interaction using age-appropriate books and toys which are then gifted to programme participants

Who can participate?
Low-income families with children aged 2-3 years who are eligible but not taking up free child care provision or who live in super lower output areas

What does the study involve?
Following pre-test, families are randomly allocated to the intervention or control group. Intervention families receive twice-weekly home visits lasting 30 minutes for a total of 15 months. Control families are asked to continue as normal. The intervention is delivered in the home by specially trained home visitors over a 15-month period. The British Picture Vocabulary Scale (BPVS3) will be used at both pre-test and post-test to assess the impact of the programme on children's receptive vocabulary. Parents can also opt-in to take part in a 20-minute observation (15 control families and 30 intervention families) which measures parent-child interaction and is carried out at pre-test and post-test. Subtests from the Ages and Stages Questionnaire (ASQ: Communication, Fine motor skills, and personal-social skills), and a home learning environment questionnaire are also used at pre- and post-test. Additionally, the researchers use the National Pupil Database to assess the level of school readiness when the child starts school.

What are the possible benefits and risks of participating?
There are no anticipated risks associated with the intervention given that the programme has

been trialled previously. If the programme is effective, the primary benefit should be a greater improvement in the intervention child's receptive vocabulary compared to those in the control group.

Where is the study run from?
The programme is recruiting families in South Yorkshire (Barnsley, Doncaster, Sheffield, and Rotherham) England, and run from the Department of Education at the University of York and Family Lives Midlands and North.

When is the study starting and how long is it expected to run for?
January 2019 to September 2021

Who is funding the study?
Education Endowment Foundation (UK)

Who is the main contact?
Dr Louise Tracey
louise.tracey@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Louise Tracey

ORCID ID
https://orcid.org/0000-0002-8304-613X

Contact details
Department of Education
Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 328160
louise.tracey@york.ac.uk

Type(s)
Public

Contact name
Dr Erin Dysart-Stephenson

ORCID ID
https://orcid.org/0000-0002-5908-0282

Contact details
Department of Education
Heslington

York
United Kingdom
YO10 5DD
+44 (0)1904 328160
erin.dysart@york.ac.uk

Additional identifiers

Study information

Scientific Title
Efficacy trial of the ParentChild+ programme

Acronym
PC+

Study objectives
The primary research question is:
What is the impact of the ParentChild+ programme on children's language development as evidenced by their receptive vocabulary and measured via the British Picture Vocabulary Scale (BPVS)?

The secondary research questions are:
1. What is the impact of the ParentChild+ programme on verbal and non-verbal interaction, developing positive behaviours and early literacy skills, as measured by the Ages & Stages Questionnaire (ASQ)?
2. What is the impact of the ParentChild+ programme on the Home Learning Environment as measured by the Home Learning Environment Index?
3. What are the longer-term impacts of the ParentChild+ programme as measured by the statutory school-based assessments (i.e. the Reception Baseline Assessment (RBA) and the Early Years Foundation Stage (EYFS) profile)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/08/2019, Department of Education Ethics Committee (c/o Research Administrator, Department of Education, University of York, Heslington, York, YO10 5DD; education-research-administrator@york.ac.uk; 01904 324476), ref: 19/20

Study design
Two-arm efficacy randomized controlled trial with allocation at family level with an embedded implementation and process evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
School readiness

Interventions
Recruitment will be of disadvantaged families with children aged 2-3 years who are eligible for, but not taking up, the 2-year free nursery place offer. Recruitment of disadvantaged families will also include families who are not entitled to free child care places but do live in Lower Super Output Areas (LSOA). Parents/carers will be identified through collaboration with local authorities.

The programme is delivered in the home by specially trained home visitors over a 15 month period (twice-weekly visits of 30 minutes). It models positive parent-child interaction using age-appropriate books and toys which are then gifted to programme participants.

In order to identify eligible participants the Delivery Team (DT) coordinators (one for each of the four Local Authorities) will work with local authority Heads of Service for Early Years, Early Years Inclusion Officers and Family Centre/Children's Centre Outreach Teams to recruit families and work with key staff such as Health Visiting Teams, Family Support and other locality team staff to promote and generate referrals to the study.

Eligible families will be classed as recruited when they have:
1. Signed a consent form
2. Agreed to participate in the programme, if offered
3. Completed the pre-test measures
4. Met the minimum English threshold

Once parents have consented to participate and all baseline testing has been completed, the household will be randomly allocated 1:1 to receive either the intervention or business as usual. Stratified block randomisation will be used with variable block sizes, by Local Authority (Barnsley, Doncaster, Sheffield and Rotherham). An independent trial statistician at the York Trials Unit will be responsible for generating the allocation schedule.

Intervention families will receive twice-weekly home visits lasting 30 minutes for a total of 15 months. Control families as asked to continue as normal. Further testing will take place after 15 months for both intervention and control groups.

Intervention Type
Behavioural

Primary outcome(s)
Receptive vocabulary assessed using the British Picture Vocabulary Scale (BPVS-III) at pre-test and 15 months later at post-test

Key secondary outcome(s))
1. Communication, personal-social skills and fine motor skills measured using the Ages & Stages Questionnaire (ASQ-3) and Home Learning Environment (HLE) Index at pre-test and post-test
2. School attainment recorded in the National Pupil Database (NPD) e.g. Reception Baseline Assessment (RBA), EYFS Profile at post-test only

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Recruitment will be of disadvantaged families with children aged 2-3 years (not gender specific) who are eligible for, but not taking up, the 2-year free nursery place offer. 2. Recruitment of disadvantaged families will also include families who are not entitled to free child care places but do live in Lower Super Output Areas (LSOA) i.e. families who fall within the lowest 20% of the population based on deprivation of: income, employment, education skills and training, health and disability, crime, barriers to housing and services and living environment.
3. A minimum threshold for spoken English language fluency will be applied as an inclusion criterion as this would potentially impact on ability to complete the measures used in the trial and to participate fully in the programme (where resources, materials and a suitable home visitor fluent in the primary language used in the home may not be available).
4. Children experiencing language delay will be included providing that they meet the other eligibility criteria (eligible, but not taking up, the 2-year old offer or living in a LSOA). Similarly, children will not be excluded due to special needs if it was felt that the family could benefit from inclusion, providing the other criteria were met.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
3 years

Sex
All

Total final enrolment
283

Key exclusion criteria
1. If a minimum threshold criteria of English is not met as this would potentially impact on ability to complete the measures used in the trial and to participate fully in the programme (where resources, materials and a suitable home visitor fluent in the primary language used in the home may not be available).

Date of first enrolment
01/07/2019

Date of final enrolment
26/02/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Education
University of York
Heslington
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
Education Endowment Foundation

Funder(s)

Funder type
Charity

Funder Name
Education Endowment Foundation

Alternative Name(s)
EducEndowFoundn, The Education Endowment Foundation (EEF), Education Endowment Foundation | London, EEF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available on reasonable request from Dr Erin Dysart (erin.dysart@york.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results		22/09/2022	11/10/2022	Yes	No
Protocol (other)	version 1.1	04/12/2019	18/11/2021	No	No
Protocol (other)	version 1.0	11/09/2019	21/11/2022	No	No
Protocol (other)	version 1.3	15/02/2021	21/11/2022	No	No
Statistical Analysis Plan	version 1.0	22/01/2021	21/11/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes