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The evaluation of the Preparing For Life early childhood Intervention programme

Submission date
07/06/2013

Recruitment status
No longer recruiting

Registration date
20/06/2013

Overall study status
Completed

Last Edited
01/05/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
This study is to test the effectiveness of the Preparing for Life (PFL) programme which aims to improve school readiness and life outcomes of socioeconomically disadvantaged children. The programme is operating in several disadvantaged communities in Dublin with above national average rates of unemployment, early school leavers, lone parent households and social housing. The PFL programme, which began in 2008, works with families right from pregnancy until school entry to promote positive child development through improved parental behaviour and social support.

Who can participate?
All pregnant women from the target communities in Dublin were eligible to participate. 233 pregnant were recruited into the PFL Programme between January 2008 and August 2010.

What does the study involve?
On recruitment during pregnancy, participants were randomly assigned to either a low-treatment group or a high-treatment group. In addition, 99 pregnant women were recruited into a comparison group from a comparable community. Both the high and low treatment groups receive 100 worth of developmental toys annually and facilitated access to one year of high-quality preschool. In addition, the high-treatment group will receive two additional supports that are not available to the low-treatment group. First, participants in the high-treatment group receive home-visiting mentoring support. The home visit aims to support and help the parents with key parenting issues. Secondly, participants in the high-treatment group also participate in the Triple P Positive Parenting Programme which aims to improve positive parenting in a group-based setting for eight consecutive weeks. Data collected from all three groups (high treatment, low treatment, comparison group) at baseline during pregnancy (t0), and when the child is six months (t1), 12 months (t2), 18 months (t3), 24 months (t4), three years (t5), and four years old (t6) are compared. To determine if the effects of the programme are sustained later in childhood, data are collected from the high and low treatment groups at 7-11 years (age 9 on average) and ~age 14 as part of a follow-up study.

What are the possible benefits and risks of participating?
If the programme is effective, families in the high-treatment group may benefit by gaining

greater parenting knowledge and skills and their children will be better prepared for school. The risks of participation are few. The main risk is that some study questions are personal and may cause discomfort or stress to the participant.

Where is the study run from?
The study is run from the Geary Institute at the University College Dublin, Ireland.

When is the study starting and how long is it expected to run for?
Recruitment took place from 2008 to 2010. The evaluation continues until all children are 4 years of age, in March 2015.
A follow-up study from January 2019 to September 2019 examines the impact of receiving the PFL programme between the ages of 0 and 5 on children's outcomes later in childhood (approximately age 9).
A follow-up study from Sept 2023 to May 2024 examines the impact of receiving the PFL programme between the ages of 0 and 5 on children's outcomes later in childhood (approximately age 14).

Who is funding the study?
The study is funded by the Northside Partnership through the Department of Children and Youth Affairs, Ireland and the Atlantic Philanthropies (USA)
The follow-up study at about age 9 and age 14 is funded by the Northside Partnership

Who is the main contact?
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Study website
http://geary.ucd.ie/preparingforlife/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised trial to determine the effectiveness of the Preparing For Life programme which aims to improve the school readiness skills of socioeconomically disadvantaged children in Dublin, Ireland

Acronym
PFL

Study objectives
Current study hypothesis as of 12/12/2023:
It is hypothesised that the children participating in the Preparing for Life Programme will be significantly better prepared for school than those in the control group.

For the Age 9 follow-up study, it is hypothesised that children who participated in the Preparing for Life Programme will have significantly better child health and development outcomes than those in the control group.

For the Age 14 follow-up study, it is hypothesised that children who participated in the Preparing for Life Programme will have significantly better child health and development outcomes than those in the control group.

The null hypothesis for the follow-up study is that there will be no difference in children's health and development outcomes between treatment groups; this may arise if the impacts of the intervention are not sustained.

Previous study hypothesis as of 24/01/2019 to 12/12/2023:
It is hypothesised that the children participating in the Preparing for Life Programme will be significantly better prepared for school than those in the control group.

For the Age 9 follow-up study, it is hypothesised that children who participated in the Preparing for Life Programme will have significantly better child health and development outcomes than those in the control group.

The null hypothesis for the follow-up study is that there will be no difference in children's health and development outcomes between treatment groups; this may arise if the impacts of the intervention are not sustained.

Previous study hypothesis:
It is hypothesised that the children participating in the Preparing for Life Programme will be significantly better prepared for school than those in the control group.

The null hypothesis is that there will be no difference in school readiness between treatment groups; this may arise if the intervention is not effective or if there is contamination between groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 08/05/2008, UCD Human Research Ethics Committee (University College Dublin, Dublin 4, -, Ireland; +35317162000; hrec@ucd.ie), ref: HS-07-26-Harmon-Doyle

2. Approved 11/12/2018, UCD Human Research Ethics Committee (University College Dublin, Dublin 4, -, Ireland; +35317162000; hrec@ucd.ie), ref: HS-18-90-Doyle: Preparing for Life Age 9 Follow-Up Study

3. Approved 01/10/2023, UCD Human Research Ethics Committee (University College Dublin, Dublin 4, -, Ireland; +35317162000; hrec@ucd.ie), ref: HS-23-47-Doyle: Preparing for Life Age 14 Follow-Up Study

The Rotunda Hospital Ethic Committee, 12/05/2008
National Maternity Hospital ethic committee 28/07/2008

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Other

Study type(s)
Prevention, Quality of life

Participant information sheet
Patient information can be found at http://www.preparingforlife.ie/parents-resources/participants-information

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

Interventions
Current interventions as of 12/12/2023:
On recruitment during pregnancy, participants were randomly assigned to either a low-treatment group or a high-treatment group. High and low-treatment groups receive 100 euros worth of developmental toys annually and facilitated access to one year of high-quality preschool. The high-treatment group will receive three additional services. First, participants in

the high-treatment group receive a home-visiting mentoring support service starting during pregnancy and continuing until the children start school at age 4/5. Secondly, participants in the high-treatment group participate in group parent training when the target child is 3 years old. Thirdly, participants in the high-treatment group will receive baby massage classes in the first year.

Previous interventions:
On recruitment during pregnancy, participants were randomly assigned to either a low-treatment group or a high-treatment group. High- and low-treatment groups receive 100 worth of developmental toys annually and facilitated access to one year of high-quality preschool. The high-treatment group will receive two additional services. First, participants in the high-treatment group receive a home-visiting mentoring support service starting during pregnancy and continuing until the children start school at age 4/5. Secondly, participants in the high-treatment group participate in group parent training when the target child is 3 years old.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 12/12/2023:
School Readiness Skills
1. Cognitive development: measured using Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); Developmental Profile 3 (at 12, 18, 24, 36, 48); British Ability Scales (at 48 months); Executive functioning & delay of gratification (48 months)
2. Physical health and motor skills: measured using Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); hospital records (at 48 months); parent-reported child health (at 6, 12, 18, 24, 36, 48 months)
3. Socio-emotional development: measured using Temperament and Atypical Behaviour Scale (at 12 months); Difficult temperament (at 6 & 12 months); ASQ-Socio-Emotional scale (at 6, 12, 18, 24, 36, 48 months); Brief Infant Toddler 4. Social and Emotional Assessment (at 12, 18 24, 36 months)
4. Behavioural skills: measured using Temperament and Atypical Behaviour Scale (at 12 months); Child Behaviour Checklist (at 18, 36, 48 months); Peer Problems and Prosocial Behaviour (at 48 months)
5. Language development and emergent literacy: measured using Mac-Arthur Bates Communicative Development Inventories (at 12, 18, 24 months); Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); British Ability Scales (at 48 months)

Age 9 follow-up study, Child Health and Development Outcomes (~age 9)
1. Cognitive development measured using British Ability Scales; Executive functions NIH Toolbox measures: Flanker task, dimensional change card sort task, & list sorting task
2. Physical health and motor skills: parent-reported child health, measured height & weight, Harvard step-test
3. Socio-emotional development measured using parent-report Brief Problems Monitor, Strengths and Difficulties Questionnaire, and child self-report of problem behaviours using Social Skills Improvement System
5. School attendance and performance measured using standardised test score data from primary schools (SIGMA/MICRA-T or Drumcondra tests), school attendance records, and resource supports
6. Differential susceptibility measured using DNA sampling through a non-invasive saliva swab procedure

Age 14 follow-up study, Child Health and Development Outcomes (~age 14)
1. Cognitive development measured using British Ability Scales; Executive functions NIH Toolbox measures: Flanker task, dimensional change card sort task, & list sorting task
2. Physical health: Measured height & waist measurements
3. Child self-complete interview: Socio-emotional skills, health behaviors, puberty development, school behaviors, time use, parental attachment, antisocial behaviour, risk preferences, time preferences
6. Biological ageing measured using DNA sampling through a non-invasive saliva procedure

Previous primary outcome measures as of 24/01/2019 to 12/12/2023:
School Readiness Skills
1. Cognitive development: measured using Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); Developmental Profile 3 (at 12, 18, 24, 36, 48); British Ability Scales (at 48 months); Executive functioning & delay of gratification (48 months)
2. Physical health and motor skills: measured using Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); hospital records (at 48 months); parent-reported child health (at 6, 12, 18, 24, 36, 48 months)
3. Socio-emotional development: measured using Temperament and Atypical Behaviour Scale (at 12 months); Difficult temperament (at 6 & 12 months); ASQ-Socio-Emotional scale (at 6, 12, 18, 24, 36, 48 months); Brief Infant Toddler 4. Social and Emotional Assessment (at 12, 18 24, 36 months)
4. Behavioural skills: measured using Temperament and Atypical Behaviour Scale (at 12 months); Child Behaviour Checklist (at 18, 36, 48 months); Peer Problems and Prosocial Behaviour (at 48 months)
5. Language development and emergent literacy: measured using Mac-Arthur Bates Communicative Development Inventories (at 12, 18, 24 months); Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); British Ability Scales (at 48 months)

Age 9 follow-up study, Child Health and Development Outcomes (~age 9)
1. Cognitive development measured using British Ability Scales; Executive functions NIH Toolbox measures: Flanker task, dimensional change card sort task, & list sorting task
2. Physical health and motor skills: parent-reported child health, measured height & weight, Harvard step-test
3. Socio-emotional development measured using parent-report Brief Problems Monitor, Strengths and Difficulties Questionnaire, and child self-report of problem behaviours using Social Skills Improvement System
5. School attendance and performance measured using standardised test score data from primary schools (SIGMA/MICRA-T or Drumcondra tests), school attendance records, and resource supports
6. Differential susceptibility measured using DNA sampling through a non-invasive saliva swab procedure

Previous primary outcome measures:
School Readiness Skills
1. Cognitive development: measured using Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); Developmental Profile 3 (at 12, 18, 24, 36, 48); British Ability Scales (at 48 months); Executive functioning & delay of gratification (48 months)
2. Physical health and motor skills: measured using Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); hospital records (at 48 months); parent-reported child health (at 6, 12, 18, 24, 36, 48 months)
3. Socio-emotional development: measured using Temperament and Atypical Behaviour Scale (at 12 months); Difficult temperament (at 6 & 12 months); ASQ-Socio-Emotional scale (at 6, 12, 18,

24, 36, 48 months); Brief Infant Toddler 4. Social and Emotional Assessment (at 12, 18 24, 36 months)
4. Behavioural skills: measured using Temperament and Atypical Behaviour Scale (at 12 months); Child Behaviour Checklist (at 18, 36, 48 months); Peer Problems and Prosocial Behaviour (at 48 months)
5. Language development and emergent literacy: measured using Mac-Arthur Bates Communicative Development Inventories (at 12, 18, 24 months); Ages and Stages Questionnaire (at 6, 12, 18, 24, 36, 48 months); British Ability Scales (at 48 months)

Secondary outcome measures
1. Birth outcomes: maternity hospital records at birth (birth weight, gestational age, prematurity, Apgar score)
2. Labour outcomes: maternity hospital records at birth (instrumental delivery, caesarean section- elective, emergency
3. Parenting skills: Adult Adolescence Parenting Inventory (at baseline &12 months); Knowledge of Infant Development (at baseline & 12 months); Parental locus of control (at 6 months); Condon Maternal Attachment Scale (at 6 & 24 months); Parenting Stress Index (at 6, 24 & 48 months); Parenting Daily Hassles Scale (at 18, 36 & 48 months).; Maternal Separation Anxiety (at 18 months); Parental Cognitions and Conduct Towards Infant Scale (at 6 & 24 months); Parenting Styles and Dimensions Questionnaire (at 36 & 48 months); Parental Acceptance -Rejection Questionnaire (at 36 months)
4. Quality of the home environment: Home Observation for Measurement of the Environment scale (at 6, 18 & 36 months); Activities with child (at 6, 18, 36 months); Home Learning Environment (at 48 months); Material Deprivation scale (at 18 months); Framingham Safety Survey (at 6, 18, & 48 months); Family Environment Scale (at 12 &36 months); Difficult Life Circumstances (18 & 36 months); Neighbourhood Quality Evaluation Scale (at 36 months); Family Routine Inventory (at 36 months)
5. Parent health: physical health outcomes (self-reported) (at baseline, 6, 12, 18, 24, 36, 48 months); personality (Tem-Item Personality Inventory (baseline), Rosenberg self-esteem (at baseline12, 18, 48 months) Pearlin Self-Efficacy Scale (at baseline,12 & 48 months) ; Vulnerable Attachment Style Questionnaire (baseline); Considerations of Future Consequences (at baseline & 24 months); Future Outlook Inventory (at 12, 36 months); Self-control (at 18 months); mental health outcomes (Edinburgh Postnatal Depression Scale at 6, 18, 24, 36, & 48); WHO-5 Index (at baseline, 6, 12, 36, 48)
6. Social support and service use: Level from support from various people (at 6, 18, 24, 36, & 48 months); community integration (at 6, 12, 18, 24, 36, 48 months); use of services (at 6, 18, 36 months); partner satisfaction (at 6, 12, 24, 48 months); Maternal Social Support Index (at 18 & 36 month); Family Quality of Life (at 36 months); Relationship Quality Index (at 36 months)

Added 24/01/2019:
Age 9 follow-up study (~age 9)
1. Quality of the home environment measured using Family Involvement Questionnaire
2. Parental attention measured using Attentional Control Scale

Overall study start date
31/07/2008

Completion date
30/10/2024

Eligibility

Key inclusion criteria
1. Women (age 16+ years) pregnant between 2008 and 2010
2. Residing in the PFL catchment area
3. Willing to be assigned to either of the study intervention groups

Participant type(s)
Patient, Population

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
300

Total final enrolment
233

Key exclusion criteria
Potential participants were excluded if they did not meet inclusion criteria

Date of first enrolment
31/07/2008

Date of final enrolment
30/03/2015

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Dublin
Ireland
4

Sponsor information

Organisation
University College Dublin (Ireland)

Sponsor details
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Sponsor type
University/education

Website
http://www.ucd.ie/

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Government

Funder Name
Northside Partnership through the Department of Children and Youth Affairs and The Atlantic Philanthropies (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Participant level data for the evaluation to date from 2008-2015 is already available in the Irish Social Science Data Archive (https://www.ucd.ie/issda/data/pfl/). Consent to anonymise the 2008-2015 data was sought on recruitment into the PFL programme and evaluation. For the age 9 follow-up study, participant level data will also be archived within

the Irish Social Science Data Archive once the study is complete. The will be available for research purposes through the ISSDA application process. Consent to anonymise and archive the data is sought from participants when they are asked to take part in the Age 9 follow-up study.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/04/2012		Yes	No
Other publications	analysis of programme engagement	01/01/2014		Yes	No
Results article	perinatal results	01/09/2014		Yes	No
Results article	child health results	01/12/2015		Yes	No
Other publications	process evaluation	01/01/2016		Yes	No
Other publications	resilience and children's perspectives	01/04/2016		Yes	No
Results article	socioemotional results	02/06/2016		Yes	No
Results article	dietary intake results	01/01/2017		Yes	No
Results article	well-being results	17/01/2017		Yes	No
Other publications	children's perspectives school experiences	04/03/2017		Yes	No
Other publications	early life outcomes	01/04/2017		Yes	No
Other publications	maternal warmth and toddler development	01/04/2017		Yes	No
Other publications	children's perspectives on toileting	01/06/2017		Yes	No
Other publications	cognitive and socioemotional results	18/08/2017		Yes	No
Results article	archiving results	01/01/2018		Yes	No
Results article	shared book reading results	01/01/2018		Yes	No
Results article	behaviour, cognition, and health results	01/05/2018		Yes	No
Results article	results	01/07/2019	08/07/2020	Yes	No
Results article	Child skills	16/04/2020	12/12/2023	Yes	No