

# Evaluation of a group-based, early parenting intervention

<b>Submission date</b> 26/11/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/02/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

It is generally considered that the early experiences of children help to shape their development. There is a lot of evidence that suggests that early parenting interventions (programmes) can significantly enhance parenting skills, as well as parent-child relationships and child wellbeing. Parents with children under the age of three may be the best targets for parenting programmes, as children are thought to be particularly receptive during this stage of their development. The Parent and Infant (PIN) Programme is an early parenting intervention which includes a range support for parents, including the Incredible Years programme (a well-established parenting programme designed to strengthen the relationships between parent and child), weaning and healthy eating workshops, first aid and support with language development. The aim of this study is to look at the effectiveness, implementation and cost effectiveness of the PIN programme.

### Who can participate?

Parents aged 16 or over who live in areas where the PIN programme is available.

### What does the study involve?

Participants are recruited into two different study groups. In the first group, parents take part in the PIN programme. In the second group, parents receive the usual care provided by their local health service. Parents will be asked to fill in a number of questionnaires at the start of the study, and then again at follow-up appointments when their babies are 8, 16 and 24 months old. The way the participants interact with their babies is also observed at these times in order to assess parent-infant relationships.

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

Participants may benefit from learning better parenting skills as well as strengthened relationships with their children. Additionally, taking part in the PIN programme could reduce the risk of the participants' children developing behavioural problems as they get older. There are no notable risks of taking part in the study.

Where is the study run from?

A number of public health and community-based services in Dublin West and Dundalk/Drogheda in County Louth (Republic of Ireland)

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

May 2014 to December 2018

Who is funding the study?

Health Research Board (Ireland)

Who is the main contact?

1. Dr Sinead McGilloway (Scientific)

sinead.mcgilloway@nuim.ie

2. Dr Grainne Hickey (Public)

grainne.nimhaille@gmail.com

**Study website**

www.enrichireland.com

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Sinead McGilloway

**Contact details**

Mental Health and Social Research Unit

Maynooth University Department of Psychology

John Hume Building

North Campus

National University of Ireland Maynooth

Maynooth

Ireland

W23 F2H6

+353 1 708 6052

sinead.mcgilloway@nuim.ie

**Type(s)**

Public

**Contact name**

Dr Grainne Hickey

**Contact details**

Mental Health and Social Research Unit

Maynooth University Department of Psychology

John Hume Building

North Campus

National University of Ireland Maynooth

Maynooth  
Ireland  
W23 F2H6  
+353 1 708 6658  
grainne.nimhaille@gmail.com

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

A controlled trial, cost-effectiveness and process evaluation of a group-based early parenting intervention to improve parental competence and infant wellbeing for parents and infants (aged 0-2)

### **Study objectives**

The aim of this study is to assess the effectiveness, implementation and cost-effectiveness of a group-based early parenting intervention – the Parent and Infant (PIN) programme.

Main research questions:

1. Does the PIN programme improve parent and infant outcomes?
2. What resources are involved in programme implementation and how do key stakeholders respond to the intervention?
3. How cost-effective is the intervention when compared with usual services?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Maynooth University Social Research Ethics Sub-Committee, 14/11/2014, ref: SRESC-2014-060
2. The HSE North East Area Research Ethics Committee, 05/08/2015

### **Study design**

Multi-centre non-randomised study

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

**Study setting(s)**

Community

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet.

**Health condition(s) or problem(s) studied**

Emotional and behavioural difficulties (EBD)

**Interventions**

Two groups will be recruited to take part in the research:

Group 1: A treatment or intervention group comprising parents and infants who participate in the Parent and Infant (PIN) programme. The PIN programme is a group-based early parenting intervention, which combines a range of developmentally-appropriate parent and infant supports which are delivered in a single intervention process from birth to two years of age. Parents who have recently given birth are offered a 16-week Incredible Years Parent and Baby (IY-PBP) program straddling the first six months of development. During this period, the IY program is delivered on alternate weeks in conjunction with information and awareness-raising and practical workshops and classes for new mothers (e.g. baby massage classes, weaning workshops, paediatric first aid, dental health and child safety). Tailor-made play workshops, as well as oral language development supports are also offered to parents when the infant is between the 8-12 months old. Subsequently, when the child reaches 18 months, the Incredible Years Parent and Toddler Program (IY-PTP) will be delivered. The programme is rooted in the principles of wraparound intervention and multidisciplinary, community based care, whilst the programme sub-components, particularly the Incredible Years programmes, draw on the principles of behavioural and social learning theory.

Group : A comparison/control group comprising parents and infants who receive "services as usual" (SAU). Usual services for parent-infant dyads involve: one home visit from a PHN in the first six weeks after birth and regular developmental check-ups with a GP/PHN.

**Intervention Type**

Behavioural

**Primary outcome measure**

Parental satisfaction and self-efficacy are measured using the Parental Sense of Competence (PSOC) scale at baseline and at follow-ups when the infant is 8-months old, 16-months old and 24 months old.

**Secondary outcome measures**

1. Parental wellbeing is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and at follow-ups when the infant is 8-months old, 16-months old and 24 months old
2. Parent and infant relationships are measured using the Maternal Postnatal Attachment Scale - Quality of Attachment Subscale (MPAS) at baseline and at follow-ups when the infant is 8-months old, 16-months old and 24 months old
3. Child development and socioemotional adjustment is measured using the Ages and Stages

Questionnaire-3 (ASQ-3) and the Ages and Stages Questionnaire: Social and Emotional (ASQ: SE) parent-report tools at baseline and at follow-ups when the infant is 8-months old, 16-months old and 24 months old.

4. Infant temperament is measured using the Infant Characteristic Questionnaire – fussy-difficult Subscale (ICQ) at baseline and at follow-ups when the infant is 8-months old, 16-months old and 24 months old

5. Cognitive stimulation and emotional support is measured using the Infant and Toddler Home Observation for Measurement of the Environment – Short Form (HOME-SF). The HOME-SF will be completed by researchers observing the home environment and parent-infant interactions at baseline and at follow-ups when the infant is 8, 16 and 24 months old.

**Overall study start date**

01/05/2014

**Completion date**

21/12/2018

## **Eligibility**

**Key inclusion criteria**

1. Parents are aged 16 years or older
2. Parents are willing and able to participate in the programme and/or are willing and able to participate in the research
3. Parents are living in the target research areas
4. Parents must have a very good working knowledge of English

**Participant type(s)**

Healthy volunteer

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

180

**Key exclusion criteria**

1. Parents are younger than 15 years of age
2. Parents are unwilling to take part in the research
3. Parents do not live in the target research areas
4. Parents do not have a good working knowledge of English

**Date of first enrolment**

01/08/2014

**Date of final enrolment**

01/06/2016

# Locations

## Countries of recruitment

Ireland

## Study participating centre

### The Blue Skies Initiative

Unit 2B

Nangor Road Business Park

Nangor Road

Dublin

Ireland

D12

## Study participating centre

### The Genesis Programme

Chester House

Fair Green

Drogheda

Ireland

Co. Louth

## Study participating centre

### Dublin West Public Health Nursing Service

Cherry Orchard Hospital

Ballyfermot

Dublin

Ireland

Dublin 10

## Study participating centre

### Louth Public Health Nursing Service

Louth PCC

Dublin Road

Dundalk

Ireland

Co. Louth

# Sponsor information

**Organisation**

National University of Ireland Maynooth

**Sponsor details**

National University of Ireland Maynooth  
Co. Kildare  
Maynooth  
Ireland  
W23 F2H6

**Sponsor type**

University/education

**Website**

[www.maynoothuniversity.ie](http://www.maynoothuniversity.ie)

**ROR**

<https://ror.org/048nfjm95>

**Funder(s)****Funder type**

Government

**Funder Name**

Health Research Board

**Alternative Name(s)**

HRB

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Ireland

**Results and Publications****Publication and dissemination plan**

Planned publication of reports and journal articles of short- and long-term results from mid-2016 up until and beyond the end of funding in December 2018. These publications will include results from the controlled trial, the cost-effectiveness analysis and the process evaluation. Our

reports (and journal articles) will be disseminated to participating services, as well as to other relevant agencies nationally and internationally. We will also attend conferences both nationally and internationally and publicise the findings through national media.

**Intention to publish date**

01/09/2016

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

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	15/09/2016	02/12/2020	Yes	No
<a href="#">Results article</a>		08/02/2024	09/02/2024	Yes	No