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Evaluation of a group-based, early parenting intervention

Submission date
26/11/2015

Recruitment status
No longer recruiting

Registration date
27/11/2015

Overall study status
Completed

Last Edited
09/02/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
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2. Dr Grainne Hickey (Public)
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Study website
www.enrichireland.com

Contact information

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Scientific

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Public

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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
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Co. Louth

Sponsor information

Organisation
National University of Ireland Maynooth

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Sponsor type
University/education

Website
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?
Protocol article	protocol	15/09/2016	02/12/2020	Yes	No
Results article		08/02/2024	09/02/2024	Yes	No