

Evaluation of the Incredible Years Infant programme

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| Submission date 17/09/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/10/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 04/10/2017 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Study website

<http://incredible-years-wales-research.bangor.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3; 10/WNo01/40

Study information

Scientific Title

Prevention of conduct problems and anti-social behaviour in at risk infants: a small scale cluster, non-randomised trial

Acronym

IY Infant evaluation

Study objectives

The main hypothesis is that attendance at an Incredible Years Infant group for 8 weeks will increase parental confidence and encourage positive parenting as measured using the coded observed interactions and expressed emotion at the 6- and 12-month post baseline follow-up visit.

Other areas of interest in this study are the level of appropriate stimulation provided to the infants, which could encourage the developmental quotient of the infants. Parental mental well-being may be improved through the supportive environment and encouragement of participants to link up with other group members for support both during and after the group. The emphasis on safety issues may raise parents' awareness of the potential hazards and action needed to prevent unintentional injury in the home. As the results of the toddler study suggests maternal mental well-being may increase following attendance on the infant programme.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Bangor University School of Psychology Ethics Committee, 16/07/2010
2. NHS North Wales Research Ethics Committee (REC), 19/07/2010, ref: 10/WNo01/40
3. NHS R&D Internal review panel, 05/08/2010

Study design

Small scale cluster non-randomised trial using a stepped wedge design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact Mrs Catrin Jones [pspae8@bangor.ac.uk] to request a patient information sheet

Health condition(s) or problem(s) studied

Infant development, carer well being

Interventions

The Incredible Years Infant programme (Webster-Stratton, 2008) is delivered in a group format to parents and their babies over 8 x 2 hour sessions. The programme is aimed at encouraging parent understanding of parenting and infant development in the first 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Video recorded coding of interactions between the primary caregiver and their child at the 6- and 12-month post -baseline follow-up visit.

Secondary outcome measures

1. Assessment of the home environment: provision of suitable environment and safety awareness of the parent
2. Assessment of maternal mental health
3. Child developmental assessment

All outcomes will be measured at baseline, 6 months post-baseline and 12 months post-baseline.

Overall study start date

21/09/2010

Completion date

01/11/2012

Eligibility**Key inclusion criteria**

1. Participants must have babies that are 2 - 16 weeks old at the baseline visits and are deemed by their Health visitor to live on a low income
2. Intervention families must agree to attend the 8-week programme with their baby

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

78 families in total. We aim to recruit families on a 2:1 ratio (Intervention:control) in the research (54 Intervention and 24 control)

Key exclusion criteria

1. Parents that have previously attended a Baby parenting programme are excluded from the research
2. Families that live beyond North and Mid Wales are excluded as Group leaders will need to attend weekly supervisory meetings and families will need home visits by the researcher. One Intervention cluster will provide parent-completed measures collected by their group leader.

Date of first enrolment

21/09/2010

Date of final enrolment

01/11/2012

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre**Incredible Years Centre**

Bangor

United Kingdom

LL57 2PZ

Sponsor information**Organisation**

Bangor University (UK)

Sponsor details

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Head of School of Psychology

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Sponsor type

University/education

Website

<http://www.bangor.ac.uk/>

ROR

<https://ror.org/006jb1a24>

Funder(s)**Funder type**

Other

Funder Name

European Social Funded Knowledge Economy Skills Scholarship (KESS) managed by

Funder Name

Bangor University (UK)

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

Incredible Years Wales charity (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 15/07/2016 | | Yes | No |