

The Incredible Years Ireland study

Submission date 22/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/04/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.iyirelandstudy.ie/>

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

An evaluation of the effectiveness of the Incredible Years BASIC parent training and small group DINA programmes for children with symptoms of attention deficit hyperactivity disorder (ADHD)

Study objectives

The Incredible Years BASIC parent training and small group DINA programmes will affect (short-term) emotional and behavioural outcomes for children with symptoms of attention deficit hyperactivity disorder (ADHD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. NUI Maynooth Social Research Ethics Sub-Committee approved in November 2010
2. Health Service Executive Linn Dara and Beechpark Ethics Committee approved in January 2011

Study design

Small-scale multicentre community based parallel group randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

<http://iyirelandstudy.ie/faq-s.html>

Health condition(s) or problem(s) studied

Hyperkinetic disorders

Interventions

1. Incredible Years DINA programme: 18 - 22 week small-group (6 children) weekly training programme
2. Incredible Years BASIC parent training programme: 18 - 20 week programme which involves weekly 2 - 2.5 hour group sessions

Following baseline assessments, parents and children will be randomly allocated on a 2:1 ratio to an intervention or waiting-list control group.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Werry-Weiss Peters Activity Rating Scale
2. Conners Parent Rating scale - Revised short form

All measures will be administered at baseline, February 2011 (prior to randomisation) and approximately 6 months later, August 2011.

Secondary outcome measures

1. Arnold et al. Parenting scale
2. Parent Stress Index
3. Strengths and Difficulties Questionnaire

All measures will be administered at baseline, February 2011 (prior to randomisation) and approximately 6 months later, August 2011.

Overall study start date

01/02/2011

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. The parent must have a child aged 3 - 6 years, either sex
2. The parent must want the training
3. The parent must agree to participate in both the research and the BASIC parent training
4. The identified child must score above the cut-off on a standardised ADHD screening measures (see below)
5. The parent must be willing to be placed on a waiting list for the parent training for approximately 6 months
6. The parent and child must not have previously taken part in any Incredible Years training programme
7. The child must not be taking ADHD-related medication for the duration of the trial

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

6 Years

Sex

Both

Target number of participants

72 parents and 18 children

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/02/2011

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Ireland

Study participating centre

Mental Health and Social Research Unit

Maynooth

Ireland

N/A

Sponsor information

Organisation

Archways Ltd (Ireland)

Sponsor details

Unit 2B

Nangor Road Business Park

Nangor Road

Clondalkin

Dublin

Ireland

D12

Sponsor type

Charity

Website

<http://www.archways.ie>

Funder(s)**Funder type**

Charity

Funder Name

Archways Ltd (Ireland) [Atlantic Philanthropies and Dormant Accounts Fund]

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