

PALACES – Parenting for autism, language, and communication evaluation study

Submission date 30/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/09/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/07/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The Incredible Years Parenting Programme is a group-based programme developed to support parents, children and teachers. Its aim is to help autistic children to develop emotional and social skills, language skills and help them build relationships with other people. This study aims to pilot the programme in three children's services in North and Mid Wales. An initial pilot showed promising results with a group of nine parents however there was no control comparison group (that is a similar group that have not been on the programme). Researchers now want to run a more rigorous pilot of the programme.

Who can participate?

Parents of children aged 3-8 years with a diagnosis, or strongly suspected diagnosis, of Autism.

What does the study involve?

Families are recruited through Specialist Children's Services (SCS) and/or Child and Adolescent Mental Health Services (CAMHS). SCS and CAMHS staff are provided with a checklist of eligibility criteria to help them identify eligible families. Once an eligible family is identified, staff introduce the project and ask if they would be interested in learning more about it. If parents agree, they are asked to complete a Note of Interest form and to give their permission for the form to be forwarded to the research team. On receipt of the form, a member of the research team contacts the parent to arrange a home visit to provide further details about the study and obtain informed consent. Once consent is obtained, the researcher asks the parent to complete a number of questionnaires and a 10-minute observation that is filmed. During the observation session, parents are asked to play with their child as they normally would. Once all initial data (known as baseline) has been collected from all participating families, they are randomly allocated to either the IY Autism intervention or a wait-list control condition. Families in the intervention condition start the IY Autism parent programme immediately, whilst control families are offered the programme nine months later. Every family is required to complete the baseline (first) data collection visit and a 6-month follow-up visit, which follows the same pattern as the initial visit. Families in the intervention condition are asked to complete a 12-month and an 18-month follow-up visit, which is the same as the other data collection visits. Group leaders and families in the intervention condition will also be interviewed to gain their views on delivering/attending the programme.

What are the possible benefits and risks of participating?

By participating in the study there is an opportunity for parents to get support for their child's behaviour. This is the first rigorous evaluation of this programme, however evaluations of other similar programmes have shown improvements in child behaviour, parental mental health, and positive parenting skills. All participants will be given access to the programme, although for some participants this will be after the 6-month follow-up data collection point rather than immediately. There are no obvious risks to participants.

Where is the study run from?

Four Specialist Children's Services/ Child and Adolescent Mental Health Services in Wales.

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

June 2016 to August 2018

Who is funding the study?

Autistica (UK)

Who is the main contact?

1. Dr Margiad Elen Williams (public)

margiad.williams@bangor.ac.uk

2. Professor Judy Hutchings (scientific)

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A pilot randomised controlled trial of the Incredible Years® Autistic Spectrum and Language Delays parent programme

Acronym

PALACES

Study objectives

Aim is to pilot the IY Autism parent programme in three children's services in Wales. The primary objectives are to determine whether:

1. It is possible to recruit and randomise to IY parent training versus wait-list control
2. Group facilitators are able to deliver the programme with fidelity
3. Parents engage with programme at the intended level
4. Retention remains high at every data collection time points
5. Parents report good levels of satisfaction with the intervention

Secondary objectives include:

1. Evaluating the effectiveness of the IY Autism parent programme versus wait-list control
2. Explore the costs of delivering the IY Autism parent programme, service use by parents/ children, and any reported improvement in parents' quality of life

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. School of Psychology Ethics Committee, Bangor University, 04/07/2016, 2016-15768
2. Betsi Cadwaladr University Health Board Wales Research Ethics Committee 5, 26/07/2016, 16 /WA/0224. Ethics amendment for inclusion of qualitative interviews: Betsi Cadwaladr University Health Board Wales Research Ethics Committee 5, 29/03/2017, ref: 16/WA/0224/AM01

Study design

Randomised controlled trial with waiting-list control group

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Autism Spectrum Disorder

Interventions

The IY Autism and Language Delays programme is a group-based intervention consisting of 12–16 sessions (Webster-Stratton, 2015). It is offered to parents of children (aged 2-8) on the Autism spectrum or with language delays. The aim is to promote children's emotional regulation, social competence, language skills, school readiness, and relationships with others. The programme is delivered in weekly, two-hour sessions. The families are randomised to two conditions: either the intervention condition (they receive the programme immediately) or the wait-list condition (they will be offered the intervention after the 6-month data collection visit).

Intervention Type

Behavioural

Primary outcome measure

The externalizing subscale of the Child Behaviour Checklist, measured at baseline, 6-months, 12-months, and 18-months (all time points)

Secondary outcome measures

1. Family Demographics (Family Characteristics), measured at baseline only
2. The Arnold-O'Leary Parenting Scale (Parenting Skills), measured at all time points
3. The Beck Depression Inventory II (Parental Depression), measured at all time points
4. Parenting Stress Index-Short Form (Parental Stress), measured at all time points
5. Social Communication Questionnaire (Child Autistic Symptoms), measured at all time points;
6. The Vineland Adaptive Behaviour Scales (Child Adaptive Behaviour), measured at baseline, 12 months, and 18 months
7. Family APGAR (Family Functioning), measured at all time points
8. Strengths and Difficulties Questionnaire (Sibling Behaviour), measured at all time points
9. Client Service Receipt Inventory (Family Service Use), measured at all time points
10. EQ-5D (Parent Quality of Life), measured at all time points
11. Observation of parent-child interaction (Parent and Child Behaviour), measured at all time points

All time points: baseline, 6 months, 12 months, and 18 months

Overall study start date

01/06/2016

Completion date

31/08/2018

Eligibility

Key inclusion criteria

1. Parent/caregiver of child aged 3-8 years
2. Child with diagnosis, or strongly suspected diagnosis, of autism
3. Parent/carer speaks good English and/or Welsh
4. Parent/carer consents to take part in research

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

72 parents and children

Total final enrolment

58

Key exclusion criteria

1. Parent/carer attending other parent programme during intervention phase
2. Family is in crisis (e.g. child at risk of residential placement)
3. Child is in foster care without a long-term plan in that placement
4. Child is on child protection register; Refusal of consent to take part in research

Date of first enrolment

01/09/2016

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre
Child and Adolescent Mental Health Service
Talarfon
Holyhead Road
Bangor
Gwynedd
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LL57 2PZ

Study participating centre
Child and Adolescent Mental Health Service
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Study participating centre
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Study participating centre
Child and Adolescent Mental Health Service
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Sponsor information

Organisation
Bangor University

Sponsor details
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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Autistica

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

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

1. Study protocol and main study findings will be published
2. Other papers to be confirmed at a later date

Intention to publish date

01/01/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during this study will be available upon request from Dr Margiad Williams (email: margiad.williams@bangor.ac.uk) once the main results paper has been published. All data will be anonymous (no identifiable information).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/02/2017		Yes	No
Basic results	results	02/09/2019	02/09/2019	No	No
Results article		01/06/2020	06/07/2020	Yes	No
HRA research summary			28/06/2023	No	No