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Autism spectrum treatment and resilience (ASTAR)

Submission date	Recruitment status	[X] Prospectively registered
18/01/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
06/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/01/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims:
Autism spectrum disorder (ASD) is a condition that affects social interaction, communication, interests and behaviour that occurs in around 1% of children. Previous research has shown that the majority of children aged 4-8 years diagnosed with ASD display concerning emotions and behaviours. These include hyperactivity, difficulties with attention, defiance and aggression, and fears and worries. Parents have reported that these difficulties lead to further impairment and additional family stress, therefore effective intervention is needed. There is emerging evidence that parenting programmes that work on aspects of behaviour could be effective in reducing concerning emotions and behaviours in young children with ASD. The aim of the study is to develop and evaluate a group-based programme for parents (ASTAR B) that could be delivered in the NHS and private and voluntary sectors. ASTAR B will be evaluated against a second group-based programme, ASTAR A.

Who can participate?
Parents/carers of a child aged 4-8 years diagnosed with ASD

What does the study involve?
The ASTAR Study compares two newly developed group programmes for parents of young children with autism spectrum disorders (ASD). Both programmes (ASTAR A and ASTAR B) consist of 12 weekly group sessions. They aim to extend parents' understanding of ASD and associated difficulties but each intervention has a different focus. ASTAR A includes information about ASD, supporting parents to look after themselves, and promoting use of existing supports and resources. ASTAR B focusses on emotional and behavioural problems and discussing ways of managing these.

The ASTAR Study consists of two phases. During the first phase, the study procedures and the group programmes are tested to check that they are acceptable to families. Following this, ASTAR A is directly compared to ASTAR B. During the second phase, families are randomly allocated to one of the two group programmes.

To help develop study procedures and programmes that are acceptable to families, parent and therapist views on the procedures and programmes are obtained and an additional eight to ten

parents who declined to participate in the study are interviewed. To examine the effects of the programmes on children and parents, families complete study assessments before and after the programme. The study assessments include observing how parents and children interact. Measures of child mental health and behaviour in home and education settings, parental confidence to manage concerning emotions and behaviour, parenting practices, parental stress, parental wellbeing and parental quality-of-life are also obtained. Information on participating families' service use and costs are sought and the cost-effectiveness of the programmes is examined.

What are the possible benefits and risks of participating?
Parents may benefit from the opportunity to take part in a group programme and some will receive tailored support provided by the therapists during the home visits. Families also benefit from have a detailed assessment about their child completed by trained professionals. We do not anticipate any risks to participating families.

Where is the study run from?
The study is run in South East London by a team of researchers at King's College London and therapists at the South London and Maudsley (SLaM) NHS Foundation Trust.

When is study starting and how long is it expected to run for?
February 2017 to July 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Melanie Palmer
ASTAR@kcl.ac.uk

Study website
http://iamhealthkcl.net/research-studies/treatment/

Contact information

Type(s)
Public

Contact name
Dr Melanie Palmer

ORCID ID
http://orcid.org/0000-0001-5579-2170

Contact details
Department of Child and Adolescent Psychiatry
Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
King's College London
PO Box 85, De Crespigny Park
London
United Kingdom
SE5 8AF

+44 (0)207 848 5260
ASTAR@kcl.ac.uk

Type(s)
Scientific

Contact name
Prof Tony Charman

ORCID ID
http://orcid.org/0000-0003-1993-6549

Contact details
Department of Psychology
Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
King's College London
Box PO77, De Crespigny Park
London
United Kingdom
SE5 8AF
+44 (0)207 848 5038
tony.charman@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.4, date 04/02/2019

Study information

Scientific Title
Can a parent-focussed intervention reduce mental health problems in young children with ASD? The Autism Spectrum Treatment and Resilience (ASTAR) feasibility and pilot trial

Acronym
ASTAR

Study objectives
The aim of this study is to test whether a group-based parent training intervention specifically focusing on the identification and management of co-existing emotional and behavioural problems in young children with autism spectrum disorder (ASD) will be associated with their subsequent improvement and which other domains, e.g., parent stress, may be affected by more generic supportive interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Camden and Kings Cross Research Ethics Committee, 18/11/2016, ref: 16/LO/1769

Study design
Part 1: Single-centre feasibility study
Part 2: Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Please use the contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Emotional and behavioural problems displayed by 4-8 year old children with autism spectrum disorder.

Interventions
Current interventions as of 23/10/2017:
Pilot RCT:
After initial contact, consent is obtained and the baseline assessments are administered. Eligible participants are then randomly allocated to receive either ASTAR A or ASTAR B. Randomisation is done by group (~10-18 families randomised 1:1 into ASTAR A or ASTAR B, stratified by verbal ability level (minimally verbal vs. phrase speech) and by site (locality). Both ASTAR A and ASTAR B use existing strategies from recognised interventions that are designed to help families with children with ASD. They extend parents' understanding of ASD and associated difficulties but each intervention has a different focus. Content for both ASTAR A and ASTAR B is modified for differentiated delivery to groups held with parents of children with ASD who are minimally verbal.

ASTAR A consists of supportive parent groups. It extends parents' understanding of ASD and associated difficulties and includes psychoeducation, supporting parents to look after themselves, and promoting use of existing supports and resources.

ASTAR B, the behavioural parent training intervention, also extends parents' understanding of ASD and associated difficulties. It focuses on emotional and behavioural problems and has a strong behavioural emphasis on ways of managing these problems.

Post-intervention assessments are administered immediately after the end of the intervention (at approximately 18-24 weeks after randomisation).

Previous interventions:
The study consists of two phases: a feasibility phase and a pilot randomised controlled trial.

Feasibility phase:
After initial contact, consent is obtained and the baseline assessments are administered. Eligible participants then receive either ASTAR A or ASTAR B. There is a staggered approach to intervention delivery during the feasibility phase. Participating families receive either ASTAR A or ASTAR B depending on when they are referred into the study and which intervention is due to be delivered next. In addition, eligible families who did not take up the offer of the intervention are interviewed (N~8-10).

Both ASTAR A and ASTAR B use existing strategies from recognised interventions that are designed to help families with children with ASD. They extend parents' understanding of ASD and associated difficulties but each intervention has a different focus. Content for both ASTAR A and ASTAR B will be modified for differentiated delivery to groups held with parents of children with ASD who are minimally verbal.

ASTAR A consists of supportive parent groups. It extends parents' understanding of ASD and associated difficulties and include psychoeducation, supporting parents to look after themselves, and promoting use of existing supports and resources. ASTAR A involves 12 weekly 120-minute group sessions and two 60-minute home visits to support generalisation and individualisation for each family.

ASTAR B, the behavioural parent training intervention, also extends parents' understanding of ASD and associated difficulties. It focuses on emotional and behavioural problems and has a strong behavioural emphasis on ways of managing these problems. ASTAR B involves 12 weekly 120-minute group sessions and two 60-minute home visits to support generalisation and individualisation for each family.

Post-intervention assessments are administered immediately after the end of the intervention (approximately 13-15 weeks after baseline). A sub-sample of families are interviewed to obtain their views of the research procedures and the interventions. In addition, therapist views of the research procedures and the interventions are also be sought.

Once the feasibility phase is complete and any necessary modifications made to the research procedures or intervention manuals, the pilot RCT is conducted. Any changes to the protocol will be approved by the REC and the record on the trial registry will be updated.

Pilot RCT:
After initial contact, consent is obtained and the baseline assessments are administered. Eligible participants are then randomly allocated to receive either ASTAR A or ASTAR B. Randomisation is done by group (~12 families randomised 1:1 into ASTAR A or ASTAR B, stratified by verbal ability level (minimally verbal vs. single words or greater) and by site (locality). Both ASTAR A and ASTAR B use existing strategies from recognised interventions that are designed to help families with children with ASD. They extend parents' understanding of ASD and associated difficulties but each intervention has a different focus. Content for both ASTAR A and ASTAR B is modified for differentiated delivery to groups held with parents of children with ASD who are minimally verbal.

ASTAR A consists of supportive parent groups. It extends parents' understanding of ASD and associated difficulties and include psychoeducation, supporting parents to look after themselves, and promoting use of existing supports and resources. ASTAR A involves 12 weekly 120-minute group sessions and two 60-minute home visits to support generalisation and individualisation for each family.

ASTAR B, the behavioural parent training intervention, also extends parents' understanding of ASD and associated difficulties. It focuses on emotional and behavioural problems and has a strong behavioural emphasis on ways of managing these problems.

Post-intervention assessments are administered immediately after the end of the intervention (at approximately 13-15 weeks after baseline). If staff resources allow, a reduced set of measures are repeated at a follow-up around 12 weeks after post-intervention (approximately 25-27 weeks after baseline).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 15/02/2019:
Child behaviour that challenges observed during a structured researcher-child and parent-child interaction assessment is measured at baseline and 18-24 weeks after randomisation (post-intervention). The measure is new and the trialists first wanted to establish the reliability and validity of the measure. The change back to child behaviour that challenges was made prior to unblinding and any analyses being undertaken, after careful consideration about the primary aim of the intervention and the reliability of the developed measure. This change in primary outcome was approved by the ASTAR Trial Steering Committee on the 21/01/2019.

Previous primary outcome measure from 23/10/2017 to 14/02/2019:
Parent behaviour observed during a parent-child interaction is measured at baseline and 13-15 weeks (post-intervention). This measure is new and is first tested for reliability and validity during the feasibility phase of this study. If it is shown not to be reliable and valid then an alternative primary outcome measure will be selected prior to analysis. Any change in primary outcome measures will be approved by the ASTAR Trial Steering Committee.

Original primary outcome measure:
Child behaviour observed during a parent-child interaction is measured at baseline and 13-15 weeks (post-intervention). This measure is new and is first tested for reliability and validity during the feasibility phase of this study. If it is shown not to be reliable and valid then teacher ABC (see below) will be the primary outcome.

Secondary outcome measures
Current secondary outcome measures for the pilot RCT phase as of 15/02/2019:
1. Child compliance observed during the structured researcher-child and parent-child interaction assessment is measured at baseline and 18-24 weeks (post-intervention)
2. Parent behaviour observed during the structured researcher-child and parent-child interaction assessment is measured at baseline and 18-24 weeks (post-intervention)
3. Teacher-rated child mental health and behaviour is measured using the Aberrant Behaviour Checklist (ABC)-Irritability and Hyperactivity/Non-compliance sub scales and the Assessment of Concerning Behaviour (ACB) at baseline and 18-24 weeks (post-intervention)
4. Parent-rated child mental health and behaviour is measured using the ABC-Irritability and

Hyperactivity/Non-compliance subscales, the ACB, the Home Situations Questionnaire-ASD, and the Preschool Anxiety Scale Revised at baseline and 18-24 weeks (post-intervention)
5. Improvement in parent identified child problems is measured using Parent-Defined Target Symptoms at baseline and 18-24 weeks (post-intervention)
6. Global clinical improvement in children from baseline is measured using clinician-rated Clinical Global Impressions-Improvement Scale at 18-24 weeks (post-intervention)
7. Parenting stress is measured using the Autism Parenting Stress Index at baseline and 18-24 weeks (post-intervention)
8. Parenting competence/self-efficacy is measured using the Child Adjustment and Parent Efficacy Scale-Developmental Disability-Parent Efficacy sub scale at baseline and 18-24 weeks (post-intervention)
9. Health-related parental quality-of-life is measured using the EQ-5D 5L at baseline and 18-24 weeks (post-intervention)
10. Parental wellbeing is measured using the Short Warwick-Edinburgh Mental Wellbeing Scale and the Office of National Statistics Personal Wellbeing questions at baseline and 18-24 weeks (post-intervention)
11. Parenting practices is measured using the Parenting Scale-Short version at baseline and 18-24 weeks (post-intervention)
12. Service use and costs is measured using a Client Service Receipt Inventory developed for the study at baseline and 18-24 weeks (post-intervention)
13. Adverse effects from baseline is measured using an adapted adverse event form at 18-24 weeks and deterioration in primary and secondary outcome measures

Previous secondary outcome measures from 23/10/2017 to 15/02/2019:
For the pilot RCT phase:
1. Child behaviour observed during a parent-child interaction is measured at baseline and 13-15 weeks
2. Teacher-rated child mental health and behaviour is measured using the Aberrant Behaviour Checklist (ABC)-Irritability and Hyperactivity/Non-compliance sub scales and the Assessment of Concerning Behaviour (ACB) at baseline and 13-15 weeks
3. Parent-rated child mental health and behaviour is measured using the ABC-Irritability and Hyperactivity/Non-compliance subscales, the ACB, the Home Situations Questionnaire-ASD, and the Preschool Anxiety Scale Revised at baseline and 13-15 weeks
4. Parent identified child problems is measured using Parent-Defined Target Symptoms at baseline and 13-15 weeks
5. Global clinical improvement in children from baseline is measured using clinician-rated Clinical Global Impressions-Improvement Scale at 13-15 weeks
6. Parenting stress is measured using the Autism Parenting Stress Index at baseline and 13-15 weeks
7. Parenting competence/self-efficacy is measured using the Child Adjustment and Parent Efficacy Scale-Developmental Disability-Parent Efficacy sub scale at baseline and 13-15 weeks
8. Health-related parental quality-of-life is measured using the EQ-5D 5L at baseline and 13-15 weeks
9. Parental wellbeing is measured using the Short Warwick-Edinburgh Mental Wellbeing Scale and the Office of National Statistics Personal Wellbeing questions at baseline and 13-15 weeks
10. Parenting practices is measured using the Parenting Scale-Short version at baseline and 13-15 weeks
11. Service use and costs is measured using a Client Service Receipt Inventory developed for the study at baseline and 13-15 weeks
12. Adverse effects from baseline is measured using an adapted adverse events form at 13-15 weeks and deterioration in primary and secondary outcome measures

Original secondary outcome measures:
For the feasibility phase and pilot RCT phase:
1. Teacher-rated child mental health and behaviour is measured using the Aberrant Behaviour Checklist (ABC)-Irritability and Hyperactivity/Non-compliance sub scales and the Assessment of Concerning Behaviour (ACB) at baseline and 13-15 weeks
2. Parent-rated child mental health and behaviour is measured using the ABC-Irritability and Hyperactivity/Non-compliance subscales, the ACB, the Home Situations Questionnaire-ASD, and the Preschool Anxiety Scale Revised at baseline and 13-15 weeks
3. Parent identified child problems is measured using Parent-Defined Target Symptoms at baseline and 13-15 weeks
4. Global clinical improvement in children from baseline is measured using clinician-rated Clinical Global Impressions-Improvement Scale at 13-15 weeks
5. Parent behaviour observed during a parent-child interaction is measured at baseline and 13-15 weeks
6. Parental expressed emotion is measured using the Autism-Specific Five Minute Speech Sample at baseline and 13-15 weeks
7. Parenting stress is measured using the Autism Parenting Stress Index at baseline and 13-15 weeks
8. Parenting competence/self-efficacy is measured using the Brief Parental Self Efficacy Scale and the Child Adjustment and Parent Efficacy Scale-Developmental Disability-Parent Efficacy sub scale at baseline and 13-15 weeks
9. Health-related parental quality-of-life is measured using the EQ-5D 5L at baseline and 13-15 weeks
10. Parental wellbeing is measured using the Warwick-Edinburgh Mental Wellbeing Scale and the Office of National Statistics Personal Wellbeing questions at baseline and 13-15 weeks
11. Parenting practices is measured using the Parenting Scale-Short version at baseline and 13-15 weeks
12. Service use and costs is measured using a Client Service Receipt Inventory developed for the study at baseline and 13-15 weeks
13. Adverse effects from baseline is measured using deterioration in primary and secondary outcome measures

Overall study start date
01/06/2016

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Parents/carers of children aged 4-8 years with a clinical diagnosis of ASD
2. Sufficient spoken English to participate in the assessments/interventions
3. Agreeing that their family doctor can be informed of their involvement in the study

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
N=24 for feasibility study and N=60 (30/arm) for pilot RCT. In addition, interviews with ~10 families who declined the offer of the intervention will be conducted during the feasibility phase.

Total final enrolment
83

Key exclusion criteria
1. Current participation in another parent training programme
2. Children with epilepsy poorly controlled by medication (more than weekly seizures)
3. Severe hearing or visual impairment in parent or child
4. Current severe parental psychiatric disorder
5. Active safeguarding concerns
6. For the pilot RCT, participation in the ASTAR feasibility study

Date of first enrolment
07/02/2017

Date of final enrolment
16/10/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London, Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
PO Box 85,
16 De Crespigny Park
London
United Kingdom
SE5 8AF

Study participating centre
Croydon Child and Adolescent Mental Health Services (South London and Maudsley NHS Foundation Trust)
Christopher Wren House, 113 High Street
Croydon
United Kingdom
CR0 1QG

Study participating centre
Bromley Healthcare CIC Ltd
Phoenix Children's Resource Centre
40 Masons Hill
Bromley
United Kingdom
BR2 9JG

Study participating centre
Crystal Children’s Development Centre (Croydon Health Services NHS Foundation Trust)
Malling Close
Addiscombe
Croydon
United Kingdom
CR0 7YD

Sponsor information

Organisation
Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King's College London and South London and Maudsley NHS Foundation Trust

Sponsor details
Joint Research & Development Office
Institute of Psychiatry, Psychology & Neuroscience (IoPPN) and South London and Maudsley NHS Foundation Trust
PO05, De Crespigny Park
King's College London
London
England
United Kingdom
SE5 8AF
+44 (0)20 7836 5454
slam-ioppn.research@kcl.ac.uk

Sponsor type
University/education

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol and pilot RCT findings will be published. Other publications will be confirmed at a later date.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
Individual de-identified participant data generated will be available on request from Professor Tony Charman (tony.charman@kcl.ac.uk). As data collection is ongoing, data will not be available until late 2019.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version v1.0	27/04/2019	29/05/2019	No	No
Protocol article	protocol	27/06/2019	15/06/2020	Yes	No
Other publications	outcome reliability and validity discussion	01/01/2021	15/07/2020	Yes	No
Other publications	report	01/01/2021	15/07/2020	Yes	No

Results article		06/05/2021	11/05/2021	Yes	No
Results article	2-year follow-up	11/01/2023	16/01/2023	Yes	No
HRA research summary			28/06/2023	No	No