ISRCTN14716440 https://doi.org/10.1186/ISRCTN14716440

A trial of sensory integration therapy versus usual care for sensory processing difficulties in autism spectrum disorder in children

Submission date
08/11/2016

Recruitment status
No longer recruiting

Registration date
08/11/2016

Overall study status
Completed

Last Edited
19/02/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[ ] Statistical analysis plan

[X] Results

[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a common lifelong condition affecting 1 in 100 people, which affects how a person relates to others and the world around them. Difficulty responding to sensory information (noise, touch, movement, taste and sight) is common in ASD. This might include feeling overwhelmed or distressed by loud or constant low-level noise, such as that in the classroom. Affected children may also show little or no response to these sensory cues. These 'sensory processing difficulties' are associated with behaviour and socialisation problems, and affect education, relationships, and participation in daily life. Sensory Integration Therapy (SIT) is a type of face-to-face therapy or treatment, provided by trained occupational therapists. The therapist uses play -based sensory-motor activities to influence the way the child responds to sensation, reducing distress and improving concentration and interaction with others. Research suggests SIT might be helpful for some children. The aim of this study is to find out whether SIT improves the child's behaviour socialisation and daily functioning more than the treatment normally offered to families (usual care).

Who can participate?
Children aged between 4 and 11 years with ASD or a related disorder, who also has sensory processing difficulties.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive usual care. This could involve some contact with an occupational therapist, who might give parents strategies to practice at home with their child. Those in the second group receive SIT. This involves taking part in 26 sessions over 26 weeks. The first 24 sessions will be face-to-face while the final two will be phone calls. At the start of the study and then again after 6 and 12 months, children's behaviour, daily functioning, socialisation, and parent/carer stress are assessed using questionnaires. A sample of carers is interviewed at six months to gain their views and experiences of taking part in the study and of their child's sensory problems. Therapists are also interviewed in order to get a sense of what participants actually receive in the study. The cost of providing this type of treatment, compared to usual care is also assessed.

Once approximately 10% of study participants have completed the 6-month assessment, a sample of carer diaries is examined to see whether SIT is different (in content or amount of contact) to usual care. The study only continues if this is confirmed. Finally, the study team also looks at the number of people willing to take part and whether they continue to participate in all sessions and assessments.

What are the possible benefits and risks of participating?
Participants benefit from receiving treatment which could imporve their behaviour, social functioning, and well-being. There are no known risks involved with participating.

Where is the study run from?
The study is run from the Centre for Trials Research at Cardiff University and takes place in secondary care NHS and private occupational therapy treatment settings across South Wales and in South West England (UK)

When is the study starting and how long is it expected to run for?
October 2016 to November 2020

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
1. Dr Rachel McNamara (scientific)
McNamara@cardiff.ac.uk
2. Ms Elizabeth Randell (public)
randelle@cardiff.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rachel McNamara

ORCID ID
https://orcid.org/0000-0002-7280-1611

Contact details
Centre for Trials Research
4th Floor Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 2920 687614
McNamara@cardiff.ac.uk

Type(s)
Public

Contact name
Ms Elizabeth Randell

ORCID ID
https://orcid.org/0000-0002-1606-3175

Contact details
Centre for Trials Research
4th Floor Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 2920 687608
randelle@cardiff.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
15/106/04

Study information

Scientific Title
A pragmatic randomised controlled trial of sensory integration therapy versus usual care for sensory processing difficulties in autism spectrum disorder in children: impact on behavioural difficulties, adaptive skills and socialisation

Acronym
SenITA

Study objectives
The aim of this study is to determine the impact of SIT on irritability and agitation, as measured by the corresponding sub-scale of the Aberrant Behaviour Checklist (ABC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 3, 23/02/2017, ref: 17/WA/0031

Study design
Pragmatic randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism Spectrum Disorder in children aged 4-11 years with sensory processing difficulties.

Interventions
Following screening, consent and collection of baseline data, participants will be randomly allocated to usual care or SIT in a 1:1 ratio. Online randomisation will utilise random permuted blocks stratified by region and severity of sensory processing difficulty.

Intervention arm: Participants will receive 24 one-hour sessions of SIT (Ayres Sensory Integration® Therapy) and 2 follow up phone calls, delivered over 26 weeks: two sessions per week for 10 weeks (intensive phase), followed by two sessions per month for two months, then one phone call per month for two months (tailoring phase). The intervention will be delivered by occupational therapists (typically NHS Band 7) trained in SIT meeting fidelity criteria.

Comparator arm: Participants will receive usual care (UC) which is defined as awaiting services or sensory based intervention not meeting SIT fidelity criteria (e.g. 1 face-to-face session per week or less). Focus groups will map the provision of UC.

Follow up assessments will take place at 6 and 12 months post randomisation.

Intervention Type
Other

Primary outcome(s)
Irritability/agitation is measured using the Aberrant Behaviour Checklist (ABC) at baseline, 6 and 12 months.

Key secondary outcome(s))
Current secondary outcome measures as of 14/01/2019:
1. Other problem behaviour is measured using Aberrant Behaviour Checklist (ABC) subscales at baseline, 6 and 12 months
2. Adaptive behaviours, socialisation and functional change are measured using Vineland Adaptive Behavior Scales (VABS-II) at baseline, 6 and 12 months
3. Carer stress is measured using the Autism Parenting Stress Index (APSI) at baseline, 6 and 12 months
4. Quality of life is measured using the EQ5D and CarerQoL questionnaires at baseline, 6 and 12 months

Previous secondary outcome measures:
1. Other problem behaviour is measured using Aberrant Behaviour Checklist (ABC) subscales at baseline, 6 and 12 months
2. Adaptive behaviours and socialisation are measured using Vineland Adaptive Behavior Scales (VABS-II) at baseline, 6 and 12 months
3. Functional change is assessed using the Pediatric Evaluation of Disability Inventory - computer adaptive test (PEDI-CAT) at baseline, 6 and 12 months

4. Carer stress is measured using the Autism Parenting Stress Index (APSI) at baseline, 6 and 12 months
5. Quality of life is measured using the EQ5D and CarerQoL questionnaires at baseline, 6 and 12 months

Completion date
17/12/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/01/2019:
1. Children aged between 4 and 11 years with ASD/related disorder
2. In mainstream primary education until the primary outcome timepoint
3. Definite/probable SP difficulties
4. Carer consent/child assent

Previous inclusion criteria:
1. Children aged between 4 and 11 years with ASD/related disorder
2. In mainstream primary education for the duration of the trial
3. Definite/probable SP difficulties
4. Carer consent/child assent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
11 years

Sex
All

Total final enrolment
138

Key exclusion criteria
1. Current/previous SIT
2. Current Applied Behaviour Analysis therapy

Date of first enrolment
01/04/2017

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Centre for Trials Research
4th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	protocol	01/06/2022	30/06/2022	Yes	No
Protocol article		11/02/2019	08/12/2020	Yes	No
HRA research summary	Process evaluation		28/06/2023	No	No
Other publications		17/02/2024	19/02/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes