ISRCTN70290917 https://doi.org/10.1186/ISRCTN70290917

Will early intensive behavioral training improve executive function in young children with autism spectrum disorder?

Submission date
22/12/2016

Recruitment status
No longer recruiting

Registration date
12/01/2017

Overall study status
Completed

Last Edited
20/06/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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 disorder that affects the way that a person communicates and relates to others. It is a spectrum condition the level of disability is spread across a wide range, from almost unnoticeable to completely debilitating. In general the symptoms involve problems with social communication (speech and body language), social interaction (recognising and expressing emotions) and social imagination (being able to understand and predict other people's behaviour). It has also been found that people with ASD often experience problems with executive function (the management of mental processes such as working memory, reasoning, flexibility, and problem solving as well as planning and execution). There is a growing body of evidence that an intensive behavioral treatment program (intensive behavioural interventions) can lead to significant improvement in the functioning of young children with ASD. Early Intensive Behavioral Interventions (EIBI) are programs where this treatment is initiated early. They have been reported to be effective in improving socially significant behaviors to a meaningful degree. The aim of this study is to find out whether an EIBI can help improve executive function in children with autism.

Who can participate?
Children aged between three and six who have been diagnosed with autism.

What does the study involve?
All participants take part in the EIBI. This involves behavioral training from 30 to 40 hours per week, primarily in the kindergarten. The kindergarten teachers are trained to deliver the program and supervised closely by experienced clinicians. Children complete a number of assessments to measure their level of executive functioning at the start of the study and then after six and 12 months. At the start of the study, their IQ is also assessed so that this can be compared to the changes (if any) in executive function.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their behaviour. There are no notable risks involved with participating.

Where is the study run from?
Innlandet Hospital Trust (Norway)

When is the study starting and how long is it expected to run for?
October 2016 to December 2021

Who is funding the study?
Division of habilitation and rehabilitation, Innlandet Hospital Trust (Norway)

Who is the main contact?
Dr Erik Winther Skogli
erik.winther.skogli@sykehuset-innlandet.no

Contact information

Type(s)
Scientific

Contact name
Mr Erik Winther Skogli

Contact details
Division of habilitation and rehabilitation
Innlandet Hospital Trust
Maihaugvegen 4
Lillehammer
Norway
2609
+47 61 05 92 50
erik.winther.skogli@sykehuset-innlandet.no

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
51533

Study information

Scientific Title
Behavior Rating Inventory of Executive Function (BRIEF) in a group of preschool children with autism spectrum disorder

Acronym
BAUS

Study objectives
Early and Intensive Behavioral Intervention (EIBI) based early behavioral intervention will improve executive function in children with autism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Data Protection Official/Officer, 16/12/2016, ref: 51533

Study design
Single-center non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Autism Spectrum Disorder (ASD)

Interventions
Following provision of parental informed consent, all children undergo a clinical assessment featuring a structured diagnostic interview (Autism Diagnostic Interview – Revised), a diagnostic observation schedule (ADOS-2), neuropsychological assessment and a medical examination.

Children receiving an ASD diagnosis will be offered an intensive behavioral intervention based upon the principles of applied behavior analysis (EIBI). This intervention method involves behavioral training from 30 to 40 hours per week, primarily in the kindergarten of these children. The kindergarten teachers will be trained and supervised closely by experienced clinicians at Division of Habilitation and Rehabilitation, Innlandet Hospital Trust. The intervention period will last from 6 to 24 months depending on the age of children at baseline. The effect of intervention will be evaluated with the BRIEF after 6 months, 12 months (at the end of intervention) and 12 months after intervention have been terminated.

Intervention Type
Behavioural

Primary outcome measure

Executive function is measured using the Behavior Rating Inventory of Executive Function (BRIEF) and the Behavior Rating Inventory of Executive Function - preschool Version (BRIEF-P) at baseline, after 6 months and 12 months.

Secondary outcome measures
1. IQ is measured using the Wechsler Preschool and Primary Scale of Intelligence – Fourth Edition (WPPSI-IV) and the Wechsler Intelligence Scale for Children - Fourth edition (WISC-IV) at baseline
2. Non-verbal IQ is measured using the Leiter International Performance Scale- Revised (Leiter-R) at baseline

Overall study start date
01/10/2016

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Children diagnosed with an autism
2. Diagnosis from age 3 - 6 years

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
Minimum 30 participants

Total final enrolment
10

Key exclusion criteria
1. IQ below 49
2. Subjects born prematurely (< 36 weeks)
3. Taking medication for the disorder they are referred for at the time of inclusion

Date of first enrolment

01/01/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Norway

Study participating centre
Innlandet Hospital Trust
Division of habilitation and rehabilitation
Maihaugvegen 4
Lillehammer
Norway
2609

Sponsor information

Organisation
Innlandet Hopital Trust

Sponsor details
Division of habilitation and rehabilitation
Innlandet Hospital Trust
Maihaugvegen 4
Lillehammer
Norway
2609
+47 61 05 92 50
erik.winther.skogli@sykehuset-innlandet.no

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02kn5wf75

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Division of habilitation and rehabilitation, Innlandet Hospital Trust

Results and Publications

Publication and dissemination plan
At least two publications in scientific journals are planned.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from erik.winther.skogli@sykehuset-innlandet.no

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/05/2020	20/06/2023	Yes	No