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Can exercises involving movement and the senses improve behavior and life skills in non-speaking children with severe autism?

Submission date
11/09/2018

Recruitment status
No longer recruiting

Registration date
20/09/2018

Overall study status
Completed

Last Edited
20/09/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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. The level of disability is spread across a wide range, from almost unnoticeable to completely debilitating. In general, ASD involves problems with social communication (speech and body language) and social interaction (recognising and expressing emotions).

About half of individuals with ASD have a learning disability, slower development, problems with language and self-injury behavior (SIB). SIB has been estimated to occur in approximately half of children and adolescents with autism. SIB is an extreme form of self-stimulation and can harm physical health, child development, and quality of life. People with ASD sometimes do not express pain in a way that is understood by others and the SIB might not be used as a way to interact with their social environment (for example, to get attention or to avoid doing something they don't want to do). Watching children harm themselves to the point of causing visible injury and not knowing the reasons why or how to stop it is both frightening and frustrating to parents and caregivers. Children with severe autism can be unable to adapt to different situations and often have uncontrollable tantrums and movement problems. Assessment of movement problems is not included in the diagnosis of autism and therefore is not often targeted in autism treatment. The aims of this study were to investigate movement problems in non-speaking children diagnosed with severe autism compared with typically developing children and also investigate whether a treatment involving senses and movement can improve body perception and daily living and social interactions in children with ASD.

Who can participate?
Children aged between 3 and 10 years who have been diagnosed with autism.

What does the study involve?
This treatment involves exercises combining sensory and movement actions in natural settings, with friendly engagement between the child and caregivers/instructors. Each session at home /playground took about 40-45 minutes followed by additional 10 minutes for the child's

relaxation and calming. It was performed daily throughout the intervention period. All exercises were suitable for pre-school and elementary school children aged 3 to 10 years. The activities included different combinations of senses, including smell, touch, temperature, hearing, seeing, sense of body position and balance. The children were assessed before the treatment started and after 3 years of the intervention.

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.

When is the study starting and how long is it expected to run for?
February 2014 to January 2018

Who is funding the study?
Emily Fenichel Foundation

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

Study information

Scientific Title
A follow-up interpersonal-ecological sensorimotor (IES) program in severe non-verbal ASD children: outcomes in behavior, sensory motor processing and daily living skills

Acronym
IES

Study objectives
About half of individuals with ASD have an intellectual disability, developmental regression, impaired language and self-injury behavior (SIB). Although disruptive behaviors have not been included within the core diagnostic features of autism, episodes of SIB have been estimated to occur in approximately 50% of children and adolescents with autism. Children with severe autism are the most in need of help, yet the most overlooked in research because they are unpredictable and not cooperative. These children present low adaptive functioning and can have uncontrollable tantrums. Since most of them are nonverbal or minimally verbal, they cannot answer even simple questions. As a whole, these children have not been well described or included in research studies, which has negatively affected the possibilities to develop adequate rehabilitation therapies to effectively treat this specific subpopulation of ASC children. Profound motor system deficits are implicate in ASD. Despite this, the only motor abnormalities currently included in the diagnostic criteria for ASD are stereotypical, repetitive motor movements (DSM-5; American Psychiatric Association 2013). Assessment of the level of motor skills is not part of the diagnostic, and therefore is an underestimated area in the current autism rehabilitation programs. The existing evidence of the disturbances of posture, locomotion and prospective motor control in most ASD children, highlight the need to focus in a sensorimotor rehabilitation protocol.
Our hypothesis is that severe ASD children have impairments on their somatosensory perception and sensory motor processing in comparison with healthy peers. We hypothesize that our interpersonal-ecological-sensorimotor (IES) intervention is significantly effective to improve sensorimotor processing and daily living skills in severe non-verbal autistic children and will have positive impact on body perception, and therefore in daily living and social interactions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Leonidas Lucero Hospital, Bahía Blanca city, Argentina, 14/09/2014, Expedient Number: 43-30690-2014, Approval number: 6-155 1144-2014

Study design
Interventional non-randomized single-center trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Autism Spectrum Disorders

Interventions
Autistic children were recruited at regular schools and in pediatric public clinics that provide services and support to children with developmental delays. The diagnosis of autism was based on DSM-V criteria. Diagnoses were confirmed through clinical examinations using the Autism Diagnostic Observation Schedule (ADOS). Typically developing (TD) children (control group) attended the same schools as the children with ASD (experimental group) .
This therapeutic approach (IES program) is a “three-component” model that emphasizes the need to work effectively in real-world settings and to have a fluid communication between parents/caregivers, clinicians and teachers. This protocol uses a multidisciplinary approach that combines motor-sensory strategies performed in natural settings and in friendly engagement between the child and caregivers/instructors.
Each session at home/playground took about 40-45 minutes followed by additional 10 minutes for the child’s relaxation and autoregulation and it was performed daily during all the intervention period. All exercises included in the protocol were appropriate for pre-school and elementary school physical programs to improve gross motor abilities in children aged 3 to 10 years.
All sensory-motor activities were performed in naturalistic routinely used environments that ensured activation of different combinations of senses, including olfactory, tactile, thermal, auditory, visual, proprioceptive and vestibular systems. The program mixed global and more specific exercises involving balance, coordination, rhythm, isometric and isotonic muscle work.
The TD control group did not receive the IES intervention.

Intervention Type
Behavioural

Primary outcome measure
1. Severity of autism assessed using Childhood Autism Rating Scale (CARS) in combination with clinical assessment.
2. Severity of five subscales (irritability, lethargy, stereotypy, hyperactivity, and excessive speech) was assessed using the Aberrant Behavior Checklist (ABC)
3. Pressure stimuli thresholds were determined bilaterally on arms and legs using a manual aneroid sphygmomanometer according to the recommendations of Sociedad Argentina de Hipertensión Arterial for children and adolescents. The assessment was performed with the guidance of pediatric clinicians.
4. Sensory profiles were evaluated using the Short Sensory Profile and Short Sensory Profile 2 (SSP-2).
5. Gross motor-skill proficiency was assessed using the Test of Gross Motor Development-2 (TGMD-2).
Assessment of outcomes occurred at baseline (December 2014) and after the end of the intervention program (January 2018).

Secondary outcome measures
N/A

Overall study start date

06/02/2014

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Children (males and females) diagnosed with autism.
2. Age range for control and experimental groups was 3-10 years.
3. Parental consent.

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
Sample size: 50 for experimental group and 50 for control group

Key exclusion criteria
1. Developmental disability other than ASD (e.g. cerebral palsy, Down's syndrome, attention deficit hyperactivity disorder).
2. Obvious deformity (e.g. scoliosis, bow leg), orthopedic injury in both upper and lower extremities within 6 months before the beginning of the study.
3. Epilepsy
4. Psychiatric disorders
5. Hypotonia of genetic origin, motor disabilities of accidental origin
6. Children who showed severe anguish at the moment of performing the tests

Date of first enrolment
01/10/2014

Date of final enrolment
23/12/2014

Locations

Countries of recruitment
Argentina

Study participating centre
Emily Fenichel Foundation
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Sponsor information

Organisation
Emily Fenichel Foundation

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Sponsor type
Other

Website
https://www.fundacionemilyfenichel.com

Organisation
Consejo Nacional de Investigaciones Científicas y Técnicas (CONICET)

Sponsor details
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Sponsor type
Research council

Website
https://www.conicet.gov.ar

Funder(s)

Funder type
Not defined

Funder Name
Emily Fenichel Foundation

Results and Publications

Publication and dissemination plan
Our dissemination and impact activities will include peer-reviewed open-access academic publications in high-impact journals, presentations at local and international scientific conferences and through local autism community organizations during 2018-2020.

Intention to publish date
05/06/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. This study involves a vulnerable child population whose personal data and clinical histories should be protected under strict confidentiality and anonymization.

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