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Let them grow: a new intensive and multimodal treatment for children with borderline intellectual functioning based on movement, cognition and narration of emotions

Submission date
16/12/2016

Recruitment status
No longer recruiting

Registration date
09/01/2017

Overall study status
Completed

Last Edited
11/05/2020

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Borderline intellectual functioning (BIF) is a catagory of intelligence when a person's intellectual ability is lower than average but not low enough to be an intellectual disability. It affects 7-12% of primary school children and is usually shown through difficulties at school due to poor problem solving, planning and memory skills. In some, language movement and social abilities can also be affected, making it difficult to take part in normal activities. BIF can be caused by many factors, including coming from a disadvantaged background, difficulties at home or prematurity. Dropping out of school and mental problems such as anxiety and depression are common in children with BIF. This study is testing whether an intensive programme which involves all of the areas affected in BIF children (Movement, mental processing, emotions) is more effective than standard speech therapy in children with BIF.

Who can participate?
Children aged between 6 to 11 years who attend a mainstream primary school and have multiple learning difficulties associated to behavioral problems

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive individual treatment with SST for 45 minutes, twice a week for 9 months. This involves a training of the academic abilities such as reading, writing, arithmetic and language comprehension. Those in the second group receive the experimental treatment MCNT for 3 hours per day, 5 days/ week for 9 months and work in small groups of 5-6 children each. The MCNT consists of: a) Movement training to improve fine and gross motor abilities with a Game Therapy approach; b) Cognitive training for empowerment of reasoning and memory abilities with the use of the multimedia interactive whiteboard; and c)an emotion training to learn how to Narrate the emotions to help the child to cope with the experiences of her/his daily life. The third group consists of children on a waiting list for the SST for nine months.

What are the possible benefits and risks of participating?
Participants can benefit from a standard or an experimental treatment if they are allocated in one of the two treatment groups. No notable risks are associated with the participation to this study.

Where is the study run from?
1. Fondazione Don C. Gnocchi Onlus, IRCCS "S.M. Nascente" (Italy)
2. Ospedale San Paolo (Italy)

When is the study starting and how long is it expected to run for?
December 2014 to December 2017

Who is funding the study?
Lombardy Region (Italy)

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
FDG_BIF_MCNT

Study information

Scientific Title
Comparison between a new intensive and multimodal Treatment based on Movement, Cognition and Narration of emotions (MCNT) and standard speech therapy to improve global intelligence in children with borderline intellectual functioning

Acronym
MCNT

Study objectives
An intervention that is intensive (3 hours per day, 5 days/ week for 9 months) and multimodal so to include all compromised domains would be more effective than the Standard Speech Therapy (SST, 45 minutes, twice a week for 9 months) to improve global intelligence to reverse the course of such a complex developmental condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Section of the "IRCCS Don Carlo Gnocchi Foundation" of the IRCCS Central Ethics Committee of Lombardy Region Italy (Il “Comitato Etico della Sezione "IRCCS Fondazione Don Carlo Gnocchi" del comitato etico centrale IRCCS Regione Lombardia”), 18/02 /2015

Study design
Multi-centre interventional single-blind three-arm randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Borderline Intellectual Functioning (BIF)

Interventions
Participants are randomised to one of three groups using a computer algorithm (http://graphpad.com) by an independent operator not involved in neither phase of our research.

Group one: Participants receive two 45-minute sessions of individual SST per week for nine months. SST focuses on training academic abilities which are compromised in the child as assessed by the neuropsychological evaluation at T0 (pre treatment). Typically, the skills mostly involved are text reading comprehension, word-meaning relationship (semantics); writing problems related to the letter-to-sound relationship (phonics), arithmetic abilities and problem solving.

Group two: Participants receive five three-hour sessions of MCNT in small groups (5-6 children) per week for nine months. MCNT focuses on the three domains affected in children with BIF and that are strictly embedded with learning abilities: motor, cognitive and socio-emotional domain. This treatment consists of:
1. Movement training to improve fine and gross motor abilities with a Game Therapy approach with the use of the Wii and Xbox platforms
2. Cognitive training for the empowerment of the executive functions such as working memory, planning abilities, problem solving, reasoning with the use of the multimedia interactive whiteboard (MIW)
3. Emotion training to learn how to Narrate the emotions to help the child to cope with the experiences of her/his daily life.
The technology devices mentioned above are used because they are able to capture attention and are highly motivating for the child. In addition, the use of the MIW represents a visual aid very useful for a visually-oriented teaching strategy that is effective to foster verbal comprehension, memory encoding and storage processes. With both devices, moreover, it is possible to promote little competitions among children which are very effective to motivate the child and to improve information speed processing, positive interdependency and frustration tolerance. Finally, to help the child to narrate the emotions, a psychotherapist promotes several activities such as the narration of fairy tales, or the drawing and the symbolic playing to create a new story, to promote the capacity to think and to recognize the emotions.

Group three: Participants receive no additional treatment and continue as normal for the nine month duration of the study.

Participants in all groups are followed up within two months after the end of the treatment .

Intervention Type
Behavioural

Primary outcome measure

All outcome measures are performed at two time points: within two months prior to the beginning of the treatment (T0) and within two months after the end of the treatment (T1).

1. Intellectual functioning is assessed with the Wechsler Intelligent Scale for Children-III (WISC-III) at T0 and T1
2. Movement skills is assessed with Movement Assessment Battery for Children (M-ABC) at T0 and T1
3. Emotional intelligence is assessed with the Emotional Quotient Inventory-Youth Version at T0 and T1
4. Child behavior is assessed with the Child Behaviour CheckList 6-18, CBCL and Vineland 2 at T0 and T1

Secondary outcome measures
All outcome measures are performed at two time points: within two months prior to the beginning of the treatment (T0) and within two months after the end of the treatment (T1).

1. Executive function is assessed using the Modified Bells Test (to assess selective attention), the Tower of London test (to assess planning ability and inhibitory control) and the Neuropsychological Evaluation Battery for developmental age 5-11 (to assess speech fluency) at T0 and T1
2. Language comprehension is assessed using the Test of Reception of Grammar-2 (TROG2) at T0 and T1
3. Memory is assessed using selective word retrieval and visual memory is assessed with the Corsi Test using Neuropsychological Evaluation Battery for developmental (age 5-11) at T0 and T1
4. Modifications of brain function and morphology are evaluated with magnetic resonance imaging advanced techniques, such as diffusion tensor imaging (DTI), functional MRI (fMRI), resting state fMRI and high resolution volumetric acquisition at T0 and T1

Overall study start date
12/12/2014

Completion date
12/12/2017

Eligibility

Key inclusion criteria
1. Aged between 6 to 11 years old and attending primary mainstream school
2. Full Scale Intelligence Quotient score ranging from 71 to 85 determined with the WISC-III
3. Presence of learning disabilities assessed with the standardized test battery for developmental dyslexia and dysorthographia and dyscalculia
4. Difficulties in executive functions and or verbal comprehension assessed with Modified Barrage bell test;Tower of London (TOL) and the Test of Reception of Grammar (TROG2)
5. Presence of an impact on daily life of the above mentioned difficulties as measure by the Child Behavioral Checklist and Vineland2

Participant type(s)
Patient

Age group

Child

Lower age limit
6 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Presence of major neuropsychiatric disorders (such as ADHD and autism spectrum disorder)
2. Presence of neurological conditions:epilepsy; traumatic brain injury; brain malformations; infectious disease involving the central nervous system
3. Presence of systemic diseases such as diabetes or dysimmune disorders
4. Presence of genetic syndromes such as Down syndrome or Fragile X syndrome
5. Positive history for psychoactive drugs, particularly referring to current or past use of psychostimulants, neuroleptics, antidepressants, benzodiazepines and antiepileptic drugs

Date of first enrolment
01/01/2015

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione Don C. Gnocchi Onlus, IRCCS "S.M. Nascente"
Via Capecelatro 66
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Study participating centre
Ospedale San Paolo
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Sponsor information

Organisation
Fondazione Don Gnocchi - Centro IRCCS S. Maria Nascente

Sponsor details
Via Alfonso Capecelatro, 66
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20148

Sponsor type
Hospital/treatment centre

Website
http://www.fondazionedongnocchi.it/

ROR
https://ror.org/02e3ssq97

Funder(s)

Funder type
Government

Funder Name
Regione Lombardia Italy (Lombardy regional government)

Results and Publications

Publication and dissemination plan
The results of the study will be submitted for publication in a high-impact peer reviewed journal upon completion of data analyses after the end of the trial that will occur in December 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from vblasi@dongnocchi.it

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/04/2017		Yes	No
Results article	results	21/04/2020	11/05/2020	Yes	No