ISRCTN99326699 https://doi.org/10.1186/ISRCTN99326699

Music is the Key: The impact of therapeutic listening on the development of children born preterm

Submission date
04/04/2016

Recruitment status
No longer recruiting

Registration date
19/04/2016

Overall study status
Completed

Last Edited
05/02/2020

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
About 11% of all babies born worldwide are preterm (premature) meaning that they are born more than three weeks before their due date. Premature babies have had less time to develop in the womb, and so often have a low birth weight. Although some premature children do very well at school, generally they have a higher chance of developing attention problems or learning difficulties than other children of the same age. It is thought that the earlier a child was born and the lower the weight at birth, the higher this risk becomes. Therapeutic Listening is a programme designed to improve cognitive function (learning, thinking and memory) and attention by using different sounds designed to stimulate brain activity. The aim of this study is to find out what effect Therapeutic Listening has on the cognitive development of children born prematurely who had a very low birth weight.

Who can participate?
Children aged three to four with attention and/or learning difficulties who had an extremely low weight when they were born.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the Therapeutic Listening Programme. This involves children listening to modified music for 20-30 minutes twice per day for five days per week for a period of 6 months. The modified music sections is played on a San Disk Sports Clip (MP3 player) and played through sennheiser HD500A headphones which are specifically designed for the Therapeutic Listening programme. Those in the second group continue as normal and do not take part in any additional therapy. Participants in both groups are assessed by a Speech and Language Therapist, an Occupational Therapist and a Psychologist at the start of the study and after six months. Children who receive the Therapeutic Listening are also assessed every six weeks throughout the programme to monitor their progress.

What are the possible benefits and risks of participating?
Participants may benefit from improved attention and listening skills, language skills and motor

skills, which will enhance learning skills. There are no notable risks involved with taking part in the study.

Where is the study run from?
National Maternity Hospital (Ireland)

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

Who is funding the study?
Private individual (Ireland)

Who is the main contact?
1. Ms Marie Slevin (public)
2. Ms Karen O'Connor (scientific)
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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
N/A

Study information

Scientific Title
A Pilot RCT showing feasibility of Therapeutic Listening for Preterm Infants with Sensory Dysregulation, Attention and Cognitive Problems

Study objectives
The aim of this study is to identify an effective treatment programme within this population of preterm children that could become an integral part of their developmental pathway going forward to ensure that they achieve their full potential in listening, attention, motor,language and learning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Research Committee Board, National Maternity Hospital, Holles Street, Dublin, 04/012016

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Please see additional files

Health condition(s) or problem(s) studied
Development in premature infants

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants undergo the home Therapeutic Listening Programme. This involves listening to modified music for 20-30 minutes twice per day for five days per week for a period of 6 months. The intervention group will be reviewed at 6 weekly intervals for monitoring, parent reviews and updating programme input as determined by progress being made.

Control group: Participants continue as normal without receiving any intervention.

Participants in both groups undergo 6 tests administered by a Speech and Language Therapist, and Ocupational Therpist and a Psychologist at baseline and six months.

Intervention Type
Other

Primary outcome measure
1. Speech and language skills are measured using the Preschool Language Scales–5 and the Renfrew Action Picture Test (RAPT) at baseline and 6 months
2. Motor skills are measured using the Development of Attention Skill Scale at baseline and 6 months
3. Sensory skills are measured using the Winnie –Dunn Sensory Profile at baseline and 6 months
4. Cognitive development ((Verbal Comprehension Index; Visual Spatial Index; Working Memory Index; Full Scale IQ) is measured uisng the Wechsler Preschool and Primary Scale of Intelligence (WPPSI-IV) at baseline and 6 months

Secondary outcome measures
Intervention group only:
1. Child's response to the programme, how consistent the programme has been, motor changes, speech and language changes, behavioural changes, social changes, self-care routine changes and learning changes are measured using the Home Listening Follow-up Form completed by parents on review dates (Wed 30th March 2016; Wed 4th May 2016; Wed 1st June 2016; Wed 6th July 2016 and during final review Wed 17th Aug 2016)
2. Emotional tone changes (i.e. more irritable/more animated, arousal level changes, motor changes, speech and language changes and behavioural changes) are measured through the listening therapist’s observations on review dates (Wed 30th March 2016; Wed 4th May 2016; Wed 1st June 2016; Wed 6th July 2016 and during final review Wed 17th Aug 2016)

Overall study start date
16/10/2015

Completion date
20/12/2016

Eligibility

Key inclusion criteria

1. Aged 3 to 4 years
2. Extremely Low Birth Weight Infant (<1500g)
3. Identified as being at risk for attention/learning difficulties when assessed at 2 years corrected age

Participant type(s)
Other

Age group
Child

Lower age limit
3 Years

Upper age limit
4 Years

Sex
Both

Target number of participants
24

Total final enrolment
22

Key exclusion criteria
1. Major complications/intellectual impairment i.e. Bayley scores >2SD below the mean
2. Hearing/visual impairment
3. Cerebral palsy
4. Currently taking medication
5. Life-limiting condition/acquired brain injury/seizures
6. Undergoing therapeutic listening.

Date of first enrolment
25/09/2015

Date of final enrolment
15/02/2016

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Holles Street

Dublin
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Sponsor information

Organisation
National Maternity Hospital

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Sponsor type
Other

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Other

Funder Name
Private individual

Results and Publications

Publication and dissemination plan
Plan to publish study results in a peer reviewed journal.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Marie Slevin, email: mslevin @nmh.ie subject to ethical approval from the

National Maternity Hospital’s Ethics Committee’s board approval and data protection legislation
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/04/2016	No	Yes
Basic results		14/12/2017	25/01/2018	No	No
Results article	results	01/01/2020	05/02/2020	Yes	No