

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	<input type="checkbox"/> Prospectively registered
Registration date 19/04/2016	Overall study status Completed	<input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/02/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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 Occupational Therapist and a Psychologist at baseline and six months.

Intervention Type

Other

Primary outcome(s)

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 using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI-IV) at baseline and 6 months

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 years

Upper age limit

4 years

Sex

All

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

Ireland

D02YH21

Sponsor information**Organisation**

National Maternity Hospital

ROR

<https://ror.org/03jcx214>

Funder(s)**Funder type**

Other

Funder Name

Private individual

Results and Publications

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

IPD sharing plan summary

Available on request

Study outputs

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