ISRCTN12536062 https://doi.org/10.1186/ISRCTN12536062

Can music-assisted language interventions improve communication skills in children with autism spectrum disorder?

Submission date
26/06/2019

Recruitment status
No longer recruiting

Registration date
05/07/2019

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder characterized by atypical social communication and interaction, and repetitive and restricted behaviours, activities and interests, affecting around 1% of the general population worldwide. It is estimated that about 30% of children with ASD do not develop functional speech, and remain non-verbal or minimally verbal even after years of speech, language and educational interventions. Although a wide range of programmes have been developed for treating language impairments in ASD, none has been effective in eliciting functional speech in ASD children. This study aims to develop a set of multifaceted, individualized, easily implemented, music-assisted intervention programmes (MAP) to increase spoken language ability in 2-4-year-old, nonverbal or minimally verbal children with ASD. Specifically, we will develop a structured training protocol, delivered through naturalistic strategies and interactive activities, to teach language to ASD children through songs and music making. Randomised controlled trials (RCTs) will be conducted to assess and validate the effectiveness of our intervention programmes through the comparison of the outcomes of the treatment group (who receives music-assisted language interventions) with a control group (who receives traditional speech and language therapy).

Who can participate?
We are recruiting nonverbal or minimally verbal children with a clinical diagnosis of autism spectrum disorder, aged between 2 and 4 years, to take part in this study.

What does the study involve?
To take part, participants and their parents/guardians/carers will need to visit our lab or a clinic room in the School of Psychology and Clinical Language Sciences at the University of Reading. Each visit will take under 2 hours, and will include breaks and snacks. Participants will be asked to do one or more of the following tasks during their visit:
1. Take part in a formal interview with a trained researcher
2. Complete a hearing screening test, a short IQ test, and receptive and expressive language tests
3. Take part in language interventions for 18 weeks (two 45-min sessions per week)

All these tasks use speech, music, or environmental sounds, or everyday items and situations, which are not emotionally stressful or scary. Some parts of the tasks such as those involving speaking, singing, and/or imitation of speech/song materials, will be recorded on audio. Some parts of the tasks such as the interview and intervention sessions will be recorded on video.

What are the possible benefits and risks of participating?
Participants are likely to benefit from being in this research study since they will be given language interventions. Through this Proof of Concept project, we aim to develop a novel set of music-assisted programmes (MAP) to provide an easy-to-implement, individualised treatment for language impairments in nonverbal or minimally verbal ASD children in a relaxing, comforting, and stimulating setting. The project outcomes have the potential to break new ground and open up new possibilities for language and communication interventions in ASD. Parents/guardians/carers can receive a copy of the final report once it has been published in a peer-reviewed journal as well as a non-technical summary of the results should they wish.

There are no or only minimal risks involved in our intervention programmes, such as possible fatigue, anxiety, or frustration. We will endeavour to make the sessions enjoyable, engaging, and fun for our participants. Participants can take as many breaks as necessary during the sessions. Parents/guardians/carers will be present during all sessions, and they can choose to terminate their children's participation at any point.

Where is the study run from?
The study will be run in the School of Psychology and Clinical Language Sciences at the University of Reading.

When is the study starting and how long is it expected to run for?
The project runs from 01/09/2019 to February 2022. RCTs will run for 18 weeks.

Who is funding the study?
This project is funded by a European Research Council Proof of Concept Grant (ERC-POC-2018, 838787, MAP, 2019-2021, https://cordis.europa.eu/project/rcn/222085/factsheet/en) to Fang Liu (PI).

Who is the main contact?
Dr Fang Liu
f.liu@reading.ac.uk

Study website
https://research.reading.ac.uk/caasd-project/

Contact information

Type(s)
Scientific

Contact name
Dr Fang Liu

ORCID ID
http://orcid.org/0000-0002-7776-0222

Contact details
Room 158, Harry Pitt Building
School of Psychology & Clinical Language Sciences
University of Reading
Earley Gate
Reading
United Kingdom
RG6 6AL
01183788122
f.liu@reading.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MAP-002

Study information

Scientific Title
Music-assisted programmes: Developing communication in autism spectrum disorder through music making

Acronym
MAP

Study objectives
Autistic children in the treatment group (who receives music-assisted language interventions) will achieve better outcomes than those in the control group (who receives traditional speech and language therapy).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2019, the University of Reading Research Ethics Committee (Academic and Governance Services, Whiteknights House, Whiteknights, PO Box 217, Reading RG6 6AH; +44 (0) 118 378 7119; urec@reading.ac.uk), ref: UREC 19/07.

Study design
This study will involve a randomised controlled trial, in which children will be offered either a music-assisted language intervention or treatment as usual (speech and language therapy).

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Autism spectrum disorder

Interventions
Everyone agreeing to take part will have a 50:50 chance of receiving the music-assisted (MAP) intervention or treatment as usual (TAU). A computer will be used to allocate participants (stratified for gender) randomly to one of the study arms, which will not have any identifying information about the participants apart from gender.

After assessing the receptive and expressive language level of each participant, 36 target words will be chosen for all participants to learn during the intervention sessions. These target words will relate to naturalistic, everyday activities that the child spontaneously engages in, so the adult can follow the child's lead or focus of attention and the child's activities can be turned into a social routine, with music.

All intervention sessions will be videotaped, individually delivered in a quiet room. Each intervention session will last about 45 minutes, happening 2 days a week, for 18 weeks. For the music-assisted (MAP) language interventions, we will use a structured protocol, delivered through naturalistic strategies such as incidental learning, high-density repetition, time-delay and mand-modelling. For each of the 36 target words, we will create a set of songs defining its meaning and the contexts where it occurs. During each session, the songs will be delivered using a digital piano or a guitar, and a range of music instruments commonly used in music therapy. The children will be taught to sing the songs, where the target words will be occurring repetitively, together with other engaging and interactive activities such as dancing, vocalizing, improvising, and playing musical games. For the treatment-as-usual (TAU) control group, regular speech and language therapy sessions will be delivered, focusing on the learning of the 36 target words using conventional methods, in line with the PACT approach (Green et al., 2010) and the NICE guideline on psychosocial interventions (https://www.nice.org.uk/guidance/cg170/chapter/1-Recommendations#specific-interventions-for-the-core-features-of-autism).

Intervention Type
Behavioural

Primary outcome measure

The production of 36 target words is assessed by a blinded outcome data assessor at baseline, post-intervention, and 1-month follow-up.

Secondary outcome measures
1. IQ is measured using Mullen Scales of Early Learning, 1995 at baseline, post-intervention, and 1-month follow-up.
2. Receptive and expressive language is measured using Receptive and Expressive One-Word Picture Vocabulary Tests, Fourth Edition; ROWPVT-4, EOWPVT-4 at baseline, post-intervention, and 1-month follow-up.
3. ASD symptomatology is measured using the ADOS-2 at baseline, post-intervention, and 1-month follow-up.
4. Vocal production throughout 3 days is measured using audio recordings at baseline, post-intervention, and 1-month follow-up.

Overall study start date
09/09/2018

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Aged between 2-4 at entry.
2. Nonverbal or minimally verbal, with fewer than 20 functional words (Kasari, Brady, Lord, & Tager-Flusberg, 2013).
3. Meet criteria for ASD on the Toddler Module of the ADOS-2 (Autism Diagnostic Observation Schedule, Second Edition; Esler et al., 2015; Luyster et al., 2009; Randall et al., 2018), and a clinical diagnosis based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; American Psychiatric Association, 2013) criteria using all available information.
4. Willingness to complete the intervention.

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
4 Years

Sex
Both

Target number of participants

We anticipate to include 30 2-4-year-old, nonverbal or minimally verbal children with ASD in our randomised controlled trials (RCTs), 15 in the treatment group and 15 in the control group. This would be a sufficient number for our proof of concept study. However, considering the possible attrition and drop-out of the participants, we aim to recruit 50 participants at the outset.

Total final enrolment
27

Key exclusion criteria
1. A neurodevelopmental disorder of known etiology (e.g., fragile X syndrome).
2. Significant sensory or motor impairment.
3. Major physical problems such as a chronic serious health condition.
4. Seizures at time of entry.
5. Use of psychoactive medications.
6. History of a serious head injury and/or neurologic disease.
7. Alcohol or drug exposure during the prenatal period.
8. Ratio IQ below 35 as measured by mean age equivalence score/chronological age on the visual reception and fine motor subscales of the Mullen Scales of Early Learning (Mullen, 1995).

Date of first enrolment
01/09/2019

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Autism
School of Psychology and Clinical Language Sciences
University of Reading
Earley Gate
Reading
United Kingdom
RG6 6AL

Sponsor information

Organisation
University of Reading

Sponsor details
School of Psychology and Clinical Language Sciences
University of Reading
Earley Gate
Reading
England
United Kingdom
RG6 6AL
+44 (0)118 378 8523
pcls@reading.ac.uk

Sponsor type
University/education

Website
https://www.reading.ac.uk/PsychologyHome/pcls-home.aspx

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Government

Funder Name
European Research Council

Alternative Name(s)
ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
1. We plan to publish our protocol, the findings of our RCT, and the methodological issues related to our feasibility study in peer-reviewed scientific journals.
2. We plan to present our findings at academic conferences (e.g., the 2020 annual meeting of the International Society for Autism Research) and local parent workshops and training events as

well as in the media (e.g., https://theconversation.com/uk).
3. We also plan to host a public event to disseminate our research findings to the general public, including individuals with ASD and their families.
4. We will also prepare a written lay summary that will be made available to all participants and their parents/guardians/carers.

Intention to publish date
01/05/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2	02/07/2019	16/07/2019	No	No
Protocol article		01/10/2021	04/10/2021	Yes	No
Results article		03/03/2024	08/03/2024	Yes	No