

Lending a helping hand to very preterm babies by enabling play

Submission date 02/10/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/05/2025	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Around 1-2% of babies are born at least eight weeks before their due date, making them very preterm. While medical advances have improved the survival chances of very preterm babies, their fragile health status places them at risk of brain injuries that can lead to learning difficulties. The considerable cost to the UK of supporting the special educational needs of very preterm children means that there is an urgent demand for effective treatments, especially ones that can be carried out during early infancy while the brain is still developing rapidly. Studies with three-month-old babies who were born full term have shown that they benefit from play involving 'sticky mittens'. Sticky mittens are Velcro-covered mittens that can be used with Velcro-covered toys to enable babies who have not yet learned to reach for things to grab toys simply by swiping and touching them. Play experiences with sticky mittens give babies a head start in moving and exploring objects, activities that boost their learning. To date, however, sticky mittens have never been used with very preterm babies. The goal of our study is to find out whether sticky mittens can improve the intellectual, social and motor skills of very preterm babies. Arranging play activities for babies using sticky mittens is easy and inexpensive. If the mittens are found to be helpful to very preterm babies then their use could be recommended to parents as a simple means of supporting their child's development.

Who can participate?

Very preterm babies aged three months relative to their due date, who have no obvious physical or sensory disabilities (e.g., cerebral palsy, blindness, deafness).

What does the study involve?

Participants are allocated randomly to one of two groups. In the first group, parents allow their baby to wear sticky mittens for up to 10 minutes per day for three weeks while interacting with Velcro-covered toys. In the second group, each baby wears ordinary mittens for up to 10 minutes per day for three weeks while watching their parent pick up the toys, move them around, and touch them to the palms of the baby's hands. The two groups are compared from three to 15 months corrected age on tests of intellectual, social and motor development to see whether babies who wore sticky mittens show an advantage.

What are the possible benefits and risks of participating?

There are no direct benefits with participation. There are no foreseeable risks to the babies in either group from participating in this study. We are hopeful that experience with sticky mittens will be effective in improving the development of babies in the treatment group. In the long term, the results from this project will be used to inform parents of very preterm babies of ways they can enhance their child's learning using simple play activities.

Where is the study run from?

Anglia Ruskin University (UK)

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

February 2016 to August 2023

Who is funding the study?

Action Medical Research UK (UK)

Who is the main contact?

Dr Ruth Ford, ruth.ford@aru.ac.uk

Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

CPMS 35419

Study information

Scientific Title

Lending a helping hand to very preterm infants: Evaluating the effectiveness of 'sticky mittens' for enhancing cognitive development from ages 3 to 15 months

Study objectives

Current hypothesis as of 21/03/2022:

The aim of this study is to evaluate the effectiveness of sticky mittens, administered at 3-months corrected age, for improving the cognitive development of very preterm infants from 4- to 15-months corrected age.

Previous hypothesis:

The aim of this study is to evaluate the effectiveness of sticky mittens, administered at 3-months corrected age, for improving the cognitive, motor, and social development of very preterm infants from 4- to 15-months corrected age.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Cambridgeshire and Hertfordshire Research Ethics, 02/10/2017, ref: 17/EE/0329

Study design

Randomized; Interventional; Design type: Prevention, Psychological & Behavioural

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neurodevelopment of very preterm babies

Interventions

Current intervention as of 21/03/2022:

Participants are assigned to either the intervention group or the control group using stratified randomised sampling, the groups are matched for gender, and family socio-economic status (SES; low vs. average vs. high) as gauged by a parent-report demographics questionnaire administered at the time of recruitment.

Following the pre-intervention assessments, and using the pre-determined sequence for group allocation relevant to the family's strata, the research assistant (RA) shows parents how to use the mittens and toys while seated at a table with the infant on their lap (supported by a pillow if necessary). They then video-record proceedings as the parent conducts their infant's first play session. Subsequently, parents are asked to use the materials as instructed at home, up to 10 minutes per day for 3 weeks. Each session involves the parent putting the mittens (either sticky or non-sticky depending on group) on their baby's hands before holding them on their lap and sitting at a low table on which they have placed the three sets of toys within reach of the baby. Parents are asked to video-record some mittens sessions using either a digital camera or mobile phone so that we can check the fidelity of the intervention, and to record the length of each session in a daily log book.

In the intervention group, the babies wear sticky mittens (mittens with Velcro sewn on, that can be used to snag and manipulate toys that also have Velcro attached). Parents are asked to encourage their child to explore each set of toys in turn (with timing and order variable across sessions), for example, by tapping the toys or guiding the infant's hand towards the toys until contact is made. They are also advised to praise the infant for inspecting the toys. It is made clear that after infants have mastered the technique of touching and manipulating the toys, parents should allow them to take the initiative in selecting items to explore. If the infant makes contact with an object then the parent should remove the toy from the mitten and place it back on the table to allow them to try again.

In the control group, the babies wear non-sticky mittens and they simply observe the toys being moved and touched to their palms by their caregiver. As for the intervention group, parents are requested to draw the infant's attention to different sets of toys in turn and to offer verbal encouragement for inspecting them.

Previous intervention:

Participants are assigned to either the intervention group or the control group using stratified randomised sampling, the groups are matched for gender, and family socio-economic status (SES; low vs. average vs. high) as gauged by a parent-report demographics questionnaire administered at the time of recruitment.

Following the pre-intervention assessments, and using the pre-determined sequence for group allocation relevant to the family's strata, the research assistance (RA) shows parents how to use the mittens and toys while seated at a table with the infant on their lap (supported by a pillow if necessary). They then video-record proceedings as the parent conducts their infant's first play session. Subsequently, parents are asked to use the materials as instructed at home, 10 minutes per day for three weeks. Each session involves the parent putting the mittens (either sticky or non-sticky depending on group) on their baby's hands before holding them on their lap and sitting at a low table on which they have placed the three sets of toys within reach of the baby. Parents are asked to video-record all mittens sessions using either a digital camera or mobile phone so that we can check the fidelity of the intervention, and to record the length of each session in a daily log book. The RA visits the family 7- and 14 days later. During these visits, they video-record the infant's progress in using the mittens. They answer any questions that the parents may have and (if necessary) conduct further training in the use of the mittens.

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In the control group, the babies wear non-sticky mittens and they simply observe the toys being moved and touched to their palms by their caregiver. As for the intervention group, parents are requested to draw the infant's attention to different sets of toys in turn and to offer verbal encouragement for inspecting them.

Intervention Type

Other

Primary outcome(s)

Current primary outcome measure as of 21/03/2022:

Cognitive development is measured using observational tests of exploratory/reaching behaviour at corrected ages of 3 and 4 months, plus parent-report questionnaires at corrected ages of 3, 4, 8 and 15 months. The observational tests were carried out face-to-face in the family home prior to the COVID-19 pandemic but are now being done via Zoom.

Previous primary outcome measures:

1. Cognitive development is measured using the Bayley Scales of Infant and Toddler Development 3rd Edition (Bayley-III) at 3 and 15 months of age, and observational tests of exploratory/reaching behaviour at 3, 4, 8 and 15 months of age
2. Motor development is assessed using the Bayley Scales of Infant and Toddler Development 3rd Edition (Bayley-III) at 3 and 15 months of age, and the parent-report Early Motor Questionnaire (EMQ) at 3 and 15 months of age
3. Social development is assessed via habituation tests of attention (measuring infants' looking time in seconds) to images of human faces and hands at four and eight months of age, the Early Social Communication Scales (ESCS) at 15 months of age, and the parent-report Early Childhood Behaviour Questionnaire (ECBQ) at 15 months of age

Key secondary outcome(s)

Current secondary outcome measures as of 21/03/2022:

1. Parent levels of confidence in interacting with their very preterm baby is measured using the parent-report Interacting with my Premature Infant Questionnaire (IPIQ) at 3 months of age (corrected)
 2. Parent levels of stress in interacting with their very preterm baby is measured using the parent-report Parenting Stress Index (PSI) at 15 months of age (corrected)
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Previous secondary outcome measure:

Parent levels of confidence and stress in interacting with their very preterm baby is measured using the parent-report Interacting with my Premature Infant Questionnaire (IPIQ) at three months of age, and the parent-report Parenting Stress Index (PSI) at 15 months of age.

Completion date

31/08/2023

Eligibility

Key inclusion criteria

1. Babies who were born very preterm or nearly so (i.e., ≤ 33 weeks gestation)
2. Babies who are free of major sensory and physical disabilities (e.g., blindness, deafness)
3. Babies who are living within the study catchment area
4. Babies whose parents/caregivers are fluent English speakers
5. Babies who have reached 3 months corrected age
6. Both boys and girls are eligible

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

62

Key exclusion criteria

1. Babies with major sensory or physical disability (e.g., blindness, deafness)
2. Babies participating in another clinical trial
3. Babies living outside the project catchment area
4. Babies whose parents are not fluent English speakers

Date of first enrolment

01/01/2018

Date of final enrolment

31/07/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Anglia Ruskin University

Department of Psychology

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Study participating centre

Rosie Maternity Hospital

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Cambridge

United Kingdom

CB2 0SW

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
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PE3 9GZ

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
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NR4 7UY

Sponsor information

Organisation
Anglia Ruskin University

ROR
<https://ror.org/0009t4v78>

Funder(s)

Funder type
Government

Funder Name
Action Medical Research

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/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?
Results article		01/03/2025	09/05/2025	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results			20/01/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes