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Lending a helping hand to very preterm babies by enabling play

Submission date 02/10/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/10/2017	**Overall study status** Completed	
Last Edited 09/05/2025	**Condition category** Neonatal Diseases	

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

Study website
https://www.action.org.uk/our-research/tackling-premature-birth

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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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

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
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.

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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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Intervention Type
Other

Primary outcome measure
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 fouur 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

Secondary outcome measures
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)

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.

Overall study start date
01/02/2016

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

Age group
Child

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

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
England

United Kingdom

Study participating centre
Anglia Ruskin University
Department of Psychology
East Road
Cambridge
United Kingdom
CB1 1PT

Study participating centre
Rosie Maternity Hospital
Robinson Way
Cambridge
United Kingdom
CB2 0SW

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Peterborough
United Kingdom
PE3 9GZ

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

Sponsor information

Organisation

Anglia Ruskin University

Sponsor details
East Road
Cambridge
England
United Kingdom
CB1 1PT
+44 1245 493131
answers@anglia.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.anglia.ac.uk

ROR
https://ror.org/0009t4v78

Funder(s)

Funder type
Government

Funder Name
Action Medical Research

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. A protocol can be made available later.

Intention to publish date
31/08/2024

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?
HRA research summary			28/06/2023	No	No
Other unpublished results			20/01/2025	No	No
Results article		01/03/2025	09/05/2025	Yes	No