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Early therapy in perinatal stroke study

Submission date	Recruitment status	[_] Prospectively registered
30/09/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/09/2021	Neonatal Diseases	

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is a condition which affects movement, posture and coordination. It is caused by an injury to the parts of the brain responsible for controlling muscles, usually before or very soon after birth. Hemiplegic cerebral palsy (HCP) is a type of CP where only one side (hemisphere) of the brain is affected, causing weakness or stiffness on one side of the body. The main cause of HCP is a perinatal stroke (a stroke occurring around the time of birth). Although strokes are usually associated with older people, the risk of a newborn baby having a stroke is just as high in the first 28 days of life. The stroke may be caused by a blood clot or a bleed (haemorrhage), however both lead to the brain being starved of oxygen. During the first six months of life, an infant's nervous system undergoes extensive development. This process is hindered in cases of perinatal strokes and children who go on to develop HCP are unable to use the affected side of the body. Currently there are no early therapy options for infants with perinatal stroke. The aim of this study is to find out whether a home-based therapy given by parents is a practical option for treating infants with perinatal stroke.

Who can participate?
Infants who have had a stroke before the age of three months and aged matched healthy infants.

What does the study involve?
Parents or carers of infants who have suffered from a perinatal stroke are taught how to give therapy to their children using educational materials, as well as supervision and support from a trained therapist. The movement of the children's arms and legs is monitored in monthly visits using lightweight movement detectors. All assessments are videoed and compared to healthy infants of the same age. After five months, the parents or guardians of the infants are interviewed for their opinions of the therapy.

What are the possible benefits and risks of participating?
Participants will benefit from the study as it should be an enjoyable experience and the development of infants who have suffered a perinatal stroke may be improved. There are no notable risks of taking part in the study.

Where is the study run from?
Royal Victoria Infirmary, Newcastle Upon Tyne (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
1. National Institute for Health Research (UK)
2. Newcastle Health Care Charity (UK)

Who is the main contact?
Dr Anna Basu

Contact information

Type(s)
Scientific

Contact name
Dr Anna Basu

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19197

Study information

Scientific Title
Early intervention to improve motor outcome after perinatal stroke: eTIPS pilot feasibility study

Acronym
eTIPS

Study objectives
The aim of this study is to assess the feasibility of using a therapy intervention, from birth or from diagnosis to six months, in babies who have suffered a perinatal stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 03/07/2015, ref: 15/WS/0129

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

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 patient information sheet

Health condition(s) or problem(s) studied
Topic: Children, Reproductive health and childbirth; Subtopic: All Diagnoses, Reproductive Health and Childb (all Subtopics); Disease: Reproductive Health & Childbirth, All Diseases

Interventions
Interventions for infants with stroke: A manualised home-based parent delivered therapy approach with therapist oversight. Additional information and tips for the approach including videos are provided through a website. The approach is pervasive, can be incorporated into everyday life and lasts until the infant is 6 months of age.

Interventions for typically developing infants: No formal intervention is indicated. However, parents are given a baby massage manual and access to the relevant website, and requested to follow the instructions and provide feedback on the materials.

Intervention Type
Other

Primary outcome measure
Current Primary Outcome Measure (as of 10/01/2018)
Feasibility and acceptability of approach determined monthly throughout the intervention period, including at a qualitative interview of therapists working with the infants, with parental consent, towards the end of the infant's involvement in the eTIPS intervention.

Previous Primary Outcome Measure
Feasibility and acceptability of approach determined monthly throughout the intervention period, including at a qualitative interview at 5 months.

Secondary outcome measures
1. Rates of eligibility, consent, participation and retention throughout the study.
2. Infant motor development is measured using the Alberta Infant Motor Scale at baseline, 2, 4 and 6 months, Prechtl's General Movement Assessments at baseline, 1, 2 and 3 months, the Hand Assessment for Infants at 3, 4, 5 and 6 months, and the Pediatric Stroke Outcome Measure at baseline, 3 and 6 months (the latter for infants with perinatal stroke only)
3. Parental well-being and sense of competence are measured using the Warwick-Edinburgh Mental Wellbeing scale and the Parenting Sense of Competence scale respectively at 1 month and 6 months
4. Exploratory outcomes are measured using Accelerometry at each visit (infant limb movements) and the eTIPS feasibility questionnaire (perinatal stroke group only) at 1 month and 6 months

Overall study start date
03/07/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Infants who sustained a predominantly unilateral stroke (arterial ischaemic, haemorrhagic or haemorrhagic periventricular venous infarction) demonstrated on cranial imaging and identified within the first 3 months of life
2. Aged matched health infants (control group)
3. Fully informed parental consent and parent/carer with the ability and willingness to adhere to protocol

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

Key exclusion criteria
Current Participant Exclusion Criteria (as of 10/01/2018)
1. Additional significant medical diagnoses which would render the therapy inappropriate or outcomes uninterpretable in relation to the therapy (e.g. known progressive or

neurodegenerative disorder; severe visual impairment)
2. Evidence of significant bilateral intracerebral pathology
3. Strokes shown radiologically to affect only occipital, prefrontal or temporal areas of the brain (which would not be expected to produce adverse motor outcomes)
4. Ongoing involvement in another research study where this is likely to interfere with the interpretation of either study

Previous Participant Exclusion Criteria
1. Extreme prematurity, of less than 26 weeks gestation
2. Additional significant medical diagnoses which would render the therapy inappropriate or outcomes uninterpretable in relation to the therapy (e.g. known progressive or neurodegenerative disorder; severe visual impairment)
3. Evidence of significant bilateral intracerebral pathology
4. Strokes shown radiologically to affect only occipital, prefrontal or temporal areas of the brain (which would not be expected to produce adverse motor outcomes)
5. Ongoing involvement in another research study where this is likely to interfere with the interpretation of either study

Date of first enrolment
03/08/2015

Date of final enrolment
02/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
North Tees
United Kingdom
TS19 9PE

Study participating centre

South Tees Hospitals NHS Foundation Trust
South Tees
United Kingdom
TS4 3BW

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
Sunderland
United Kingdom
SR4 7TP

Study participating centre
South Tyneside Foundation Trust
South Tyneside District Hospital
Harton Lane
South Shields
Tyne and Wear
United Kingdom
NE34 0PL

Study participating centre
County Durham and Darlington Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
County Durham
United Kingdom
DL3 6HX

Study participating centre
Northumbria Healthcare Trust
Rake Lane
North Shields
Tyne and Wear
United Kingdom
NE29 8NH

Study participating centre
North Cumbria University Hospitals NHS Trust
North Cumbria University Hospital
Newtown Rd

Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Royal Victoria Infirmary
New Victoria Wing
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Newcastle Health Care Charity

Results and Publications

Publication and dissemination plan
The trialists intend that paper summarising the findings of the pilot feasibility study will be published in 2018, as will a paper describing the results of the infant movement analysis and a paper discussing the qualitative research findings.

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 not expected to be made available to preserve confidentiality given the relatively small sample size. The data is held at Newcastle University by Dr Basu.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/07/2018		Yes	No
HRA research summary			28/06/2023	No	No