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The effectiveness of the early intervention program using telemedicine in improving motor developmental outcomes among children at risk of developmental disorders: a randomized controlled trial

Submission date
31/07/2025

Recruitment status
No longer recruiting

Registration date
08/08/2025

Overall study status
Completed

Last Edited
08/08/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Findings from research over the past decade suggest that high-quality early intervention (EI) can reduce developmental delays and disabilities caused by brain injuries. EI is considered the most effective service system when it is goal-oriented and tailored to the needs of both the child and the family. It helps prevent the development of incorrect movement patterns (including those related to speech, behavior, etc). Key components of such EI include intensity, focus, active participation by the child and family, and a safe and stimulating environment.

Initial studies evaluating the effectiveness of new, principle-based EI programs have been launched. Early results indicate that implementing these new EI concepts in practice is effective, though it requires more specialist time and financial resources. The use of telemedicine in various medical fields has been shown to reduce service costs without compromising therapeutic effectiveness. However, telemedicine tools have so far only been studied for consulting families of older children with autism, speech delays, or hearing impairments. No research has yet been conducted on using telemedicine to consult and coach families raising infants at high risk of developmental disorders.

The planned study will be the first of its kind to apply telemedicine elements in early rehabilitation, potentially reducing costs while maintaining intervention quality, and it will contribute to expanding scientific evidence on the effectiveness of EI methods.

This study aims to assess the impact of the EI COPCA program led using telemedicine on child development when parents are guided by a physiotherapist both in person and remotely. Compare this with interventions provided in early rehabilitation centers. It will also evaluate how different intervention methods relate to the stress and anxiety experienced by parents, and assess the relationship between child development and the home environment.

Who can participate?
Patients aged 3 months with abnormal general movements (atypical movements that can be a sign of neurological problems)

What does the study involve?
Parents are informed and invited to participate after abnormal general movements (GMs) are identified. Upon receiving informed consent, parents complete an anonymous questionnaire and participants are divided into two groups (Group 1: in-person and via Zoom; Group 2: standard therapy at clinics).
The early intervention COPCA program's approach:
1. Coaches parents to observe their child, define abilities/needs, set realistic goals, select activities, and enrich the home environment
2. Promotes cooperation between parents and professionals
3. Includes regular remote consultations (Zoom)
4. Emphasizes empowering parents to take initiative
Unlike standard therapy (which may rely on passive techniques and leave parents feeling unsure), COPCA is family-centered, home-based, and seeks to integrate interventions into daily life. Participants are evaluated again at 9 months of age and a final follow-up at 18 months.

What are the possible benefits and risks of participating?
Benefits of the study include scientific advancement in early intervention. This is the first COPCA program and telemedicine-led study in Lithuania. Parents gain knowledge and confidence to help their child's development. Home-based EI models may be integrated into national care systems. Risks of the study are minimal. Some parents may find the required time commitment inconvenient.

Where is the study run from?
Hospital of Lithuanian University of Health Sciences Kaunas Clinics (Lithuania)

When is the study starting and how long is it expected to run for?
September 2018 to March 2024

Who is funding the study?
Ministry of Education and Science (Lithuania)

Who is the main contact?
Kristina Zalanskiene, kristina.janaviciute@lsmuni.lt

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Mrs Kristina Zalanskiene

Contact details
Eiveniu str. 2
Kaunas
Lithuania
LT50161

+370 (0)65373384
kristina.janaviciute@lsmuni.lt

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of the home-based early intervention program on infant development: a comparative study of in-person versus hybrid (in-person and telehealth) delivery

Study objectives
Infants at risk of developmental disorders who receive the home-based, telemedicine-led early intervention program will demonstrate significantly improved motor and cognitive development outcomes compared to infants who receive standard care at local clinics.

Main objectives:
1. Assess the impact of the EI COPCA program led using telemedicine on child development when parents are guided by a physiotherapist both in person and remotely. Compare this with interventions provided in early rehabilitation centers
2. Evaluate how different intervention methods relate to the stress and anxiety experienced by parents. Assess the relationship between child development and the home environment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/09/2018, Kaunas Regional Biomedical Research Ethics Committee (A. Mickeviciaus Str. 9, Kaunas, LT44307, Lithuania; +370 (0)37327229; kaunorbtek@lsmuni.lt), ref: BE-2-66

Study design
Two-arm single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual

Study type(s)
Prevention, Quality of life, Efficacy

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

Health condition(s) or problem(s) studied
Developmental disorders

Interventions
Infants with abnormal general movements at 3 months of age were randomly assigned (1:1) using a computer-generated sequence to either a home-based telemedicine lead COPCA intervention group (with therapist-guided teleconsultation) or a control group receiving standard early intervention at local rehabilitation centers, with follow-up assessments conducted at 9 and 18 months of age; allocation was concealed, masking was not applied, and participants remained in their assigned groups throughout the study.

Intervention group:
Infants received the COPCA early intervention program delivered in the home environment and via a telemedicine setting. Parents were coached by a physiotherapist/COPCA coacher to observe and engage their infant in developmentally appropriate activities. Consultations were delivered both in-person and via telemedicine (Zoom video calls). The intervention focused on goal-oriented motor learning, environmental enrichment, and active parental participation. Duration: early intervention for 6 months (from 3 months until 9 months of age) and then follow-up evaluation at 18 months of age.

Control group:
Infants received standard early intervention services at public rehabilitation centers. Therapy sessions were delivered by local specialists, based on existing protocols. No telemedicine or structured parent coaching was included.

Intervention Type
Behavioural

Primary outcome measure
1. Infant motor development assessed using Infant Motor Profile (IMP): assesses the quality of spontaneous and voluntary motor behaviour in infants, focusing on motor coordination, variability, and performance. Evaluated at a baseline (3 months of age), post-intervention (6 months of age) and follow-up (18 months of age).
2. Infant cognitive and motor development assessed using the Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III), a standardised assessment of fine motor, gross motor, and cognitive development in infants. Evaluated at a baseline (3 months of age), post-intervention (6 months of age) and follow-up (18 months of age).

Secondary outcome measures
1. Parental stress and anxiety assessed using the Parenting Stress Index - Short Form (PSI-IS): assesses levels of stress and anxiety experienced by parents in the context of caring for an

infant. Evaluated at a baseline (3 months of age), post-intervention (6 months of age) and follow-up (18 months of age).
2. Home environment affordances assessed using the Affordances in the Home Environment for Motor Development - Infant Scale (AHEMD-IS): quality and quantity of motor development opportunities available in the infant's home environment. Evaluated at a baseline (3 months of age), post-intervention (6 months of age) and follow-up (18 months of age).

Overall study start date
01/09/2018

Completion date
30/03/2024

Eligibility

Key inclusion criteria
1. 3 months of age at enrolment
2. Abnormal General Movement (GMs)
3. Parental consent
4. Lithuanian-speaking families living in Lithuania

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
5 Months

Sex
Both

Target number of participants
60

Total final enrolment
51

Key exclusion criteria
1. Genetic syndromes
2. Severe sensory impairments (blindness, deafness)
3. Progressive neurological disorders
4. Families unwilling to participate in follow-up

Date of first enrolment
15/09/2018

Date of final enrolment
11/11/2022

Locations

Countries of recruitment
Lithuania

Study participating centre
Lithuanian University of Health Science Kaunas Clinics
Eiveniu str. 2
Kaunas
Lithuania
LT-50161

Sponsor information

Organisation
Hospital of Lithuanian University of Health Sciences Kaunas Clinics

Sponsor details
Eiveniu str. 2
Kaunas
Lithuania
LT50161
+370 (0)37260425
lopselis@kaunoklinikos.lt

Sponsor type
Hospital/treatment centre

Website
http://www.kaunoklinikos.lt/kk/en-GB/

ROR
https://ror.org/058hsp657

Funder(s)

Funder type
Government

Funder Name
Ministry of Education and Science, Lithuania

Results and Publications

Publication and dissemination plan
Results will be presented at international and national conferences, published in academic journals, and used in the researcher's PhD dissertation.

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
The raw data analysed in the current study are not expected to be made available due to an agreement with the national ethical committee that all data will be available for the PhD dissertation.

IPD sharing plan summary
Not expected to be made available