

# 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

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>31/07/2025   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered               |
|  |   | <input type="checkbox"/> Protocol                               |
| <b>Registration date</b><br>08/08/2025 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan              |
|  |   | <input type="checkbox"/> Results                                |
| <b>Last Edited</b><br>08/08/2025       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data            |
|  |   | <input checked="" type="checkbox"/> 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

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

### Study type(s)

Prevention, Quality of life, Efficacy

### 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(s)**

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).

### **Key secondary outcome(s)**

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).

### **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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

3 months

**Upper age limit**

5 months

**Sex**

All

**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

### ROR

<https://ror.org/058hsp657>

## Funder(s)

### Funder type

Government

### Funder Name

Ministry of Education and Science, Lithuania

## Results and Publications

### 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