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The effectiveness of the early intervention program using hybrid coaching approach in improving developmental outcomes among children at risk of developmental disorders: a quasi-randomized controlled trial

Submission date
31/07/2025

Recruitment status
No longer recruiting

Registration date
08/08/2025

Overall study status
Completed

Last Edited
21/09/2026

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 telehealth in various medical fields has been shown to reduce service costs without compromising therapeutic effectiveness. However, telehealth 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 telehealth to consult and coach families raising infants at high risk of developmental disorders.

The planned study will be one of the first of its kind to apply a hybrid, telehealth-supported approach 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 a hybrid EI COPCA-based coaching program, in which parents are guided by a physiotherapist both in person and remotely, on child development, compared 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?
Infants at approximately 3 months' corrected age with absent or abnormal fidgety movements on the General Movements Assessment (a sign of increased risk of later developmental disorders)

What does the study involve?
Parents are informed and invited to participate after absent or abnormal fidgety movements are identified on the General Movements Assessment. After giving informed consent, parents complete a demographic questionnaire developed by the study team, and participants are allocated alternately, in order of enrolment, to one of two groups (Group 1: hybrid coaching, combining home visits with remote consultations via Microsoft Teams; Group 2: standard therapy at rehabilitation centres).
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 via Microsoft Teams
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' corrected age and a final follow-up at 18 months' corrected age.

What are the possible benefits and risks of participating?
Benefits of the study include scientific advancement in early intervention. This is one of the first hybrid COPCA program studies 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, Science and Sport (Lithuania)

Who is the main contact?
Kristina Zalanskiene, kristina.zalanskiene@lsmu.lt

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
The effectiveness of the early intervention program using hybrid coaching approach in improving developmental outcomes among children at risk of developmental disorders: a quasi-randomized controlled trial

Study objectives
Current study objectives as of 21/09/2026:
Infants at risk of developmental disorders who receive a hybrid COPCA-based parent-coaching early intervention (combining home visits and synchronous telehealth) will demonstrate significantly improved motor and cognitive development outcomes compared to infants who receive standard care physiotherapy.

Main objectives:
1. Assess the impact of a hybrid EI COPCA -based coaching program, in which parents are guided by a physiotherapist both in person and remotely, on child development. 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.

Previous 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

Primary study design

Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

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

Health condition(s) or problem(s) studied
Infants at risk of developmental disorders

Interventions
Current interventions as of 21/09/2026:
Infants with absent or abnormal fidgety movements on the General Movements Assessment at approximately 3 months corrected age were allocated in an alternating 1:1 sequence according to their order of enrolment: the first enrolled infant was assigned to the hybrid COPCA-based coaching group, the second to the standard care group, and subsequent participants alternately thereafter. No computer-generated random sequence was used, and allocation was not concealed. Outcome assessments were conducted at 3 (baseline), 9, and 18 months' corrected age; masking was not applied, and participants remained in their assigned groups throughout the study.

Intervention group:
Infants in the hybrid coaching group received a COPCA-based parent-coaching intervention combining eight in-person home visits and 18 synchronous telehealth sessions delivered via Microsoft Teams (institutional licence), from 3 to 9 months' corrected age. A physiotherapist trained in COPCA coached parents to observe and engage their infant in developmentally appropriate activities, focusing on goal-oriented motor learning, environmental enrichment, and active parental participation. A follow-up evaluation was conducted at 18 months' corrected age.

Control group:
Infants in the standard care group received standard pediatric physiotherapy delivered in person within the nationally regulated early rehabilitation service for children with developmental disorders, from 3 to 9 months' corrected age. Sessions were therapist-led, reflecting usual clinical practice (traditional neurodevelopmental treatment principles) rather than a protocol standardized by the study. No telemedicine or structured parent coaching was included.

Previous 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)
Previous primary outcomes as of 21/09/2026:
1. Infant motor development assessed using the 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' corrected age), post-intervention (9 months' corrected age) and follow-up (18 months' corrected 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' corrected age), post-intervention (9 months' corrected age) and follow-up (18 months' corrected age).

Previous primary outcomes:
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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)
Current secondary outcomes as of 21/09/2026:
1. Parental stress and anxiety assessed using the Parenting Stress Index - Short Form (PSI-SF): assesses levels of stress and anxiety experienced by parents in the context of caring for an infant. Evaluated at a baseline (3 months' corrected age), post-intervention (9 months' corrected age) and follow-up (18 months' corrected 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' corrected age), post-intervention (9 months' corrected age) and follow-up (18 months' corrected age).

Previous secondary outcomes:
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
Current inclusion criteria as of 21/09/2026:
Absent or abnormal fidgety movements on the General Movements Assessment at approximately 3 months' corrected age

Previous 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

Key exclusion criteria
Current exclusion criteria as of 21/09/2026:
Known genetic disorders or major congenital malformations

Previous 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 Sciences 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, Science and Sport, Lithuania

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available