Study Document Cover Page

Official Title: Effectiveness of Telerehabilitation-Based Family-Centered Goal-Directed Physiotherapy Approach in High-Risk Infants

NCT Number: NCT05333224

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Ethics Committee Approval:
Marmara University Clinical Research Ethics Committee
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This document represents the complete, pre-specified study protocol and statistical analysis plan (SAP) approved by the human subjects protection review board and utilized for the conduct of the study.

Study Protocol and Statistical Analysis Plan (SAP)

Title:

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1. Background

High-risk infants, characterized by exposure to adverse biological and environmental factors, are prone to neuromotor developmental problems. Conditions such as premature birth (<32 weeks, <1500 grams), periventricular leukomalacia, hypoxic ischemic encephalopathy, intraventricular hemorrhage, and intrauterine growth retardation increase the risk of neurodevelopmental disorders, including cerebral palsy (CP).

Early intervention is critical during the high neuroplasticity period of infancy. The primary condition for early intervention is to identify babies who may have CP. Early detection can be beneficial in terms of starting early intervention during the period when neuroplasticity is high. It is thought that with the prominence of early intervention and protective approaches based on neuroplasticity knowledge, it will be beneficial for babies at risk during development and it will be possible to prevent neurodevelopmental problems and permanent disabilities. The early intervention approach generally includes supporting the development of babies at risk for developmental delay or disability by providing the necessary support, treatment and training starting from the neonatal period and up to 24 months. Early intervention methods have many components and require a multidisciplinary approach. Methods can focus on different approaches according to the determined goals. Physiotherapy and rehabilitation approaches are of great importance in supporting development and improving functional outcomes in early intervention. It is aimed to provide normal sensory input and gain normal functional movements by using the rapid learning ability originating from brain plasticity, and to reach the most independent level that the child can reach in terms of physical, cognitive and psychosocial aspects within the anatomical and physiological deficiencies and environmental limitations. There are many early physiotherapy and rehabilitation approaches that focus on motor development and normalization. Goal-focused therapy is known as an approach that facilitates the participation and adaptation of infants and children with motor developmental delays in daily life activities. Goal-focused neuromotor treatment approach is a set of movements organized around a functional target and provides the formation of environmental movement. Studies on rehabilitation have recently focused on treatment approaches that focus on functionality in accordance with the “Activity and Participation” area of ICF. It is known that babies also have levels of functionality that enable them to participate in daily life activities. In a study where goal-focused neuromotor treatment was applied in early rehabilitation practices, it was stated that this approach can be applied by both the

physiotherapist and the family under the control of the physiotherapist. Family-centered physiotherapy practices have come to the fore in recent years, and are a treatment approach applied by the family that focuses on the environment and what the child can do. Motor reactions are activated by providing normal sensory input. Telerehabilitation is the provision of rehabilitation services by rehabilitation specialists with computer-based technologies and communication tools. It is a developing method that provides rehabilitation services by reducing time, distance and cost barriers and using technological tools. There are previously studies on a portable smart system that is monitored remotely and created for early assessment and intervention.

Although the importance of early physiotherapy approaches is known today, when the literature is examined, it is seen that the number of studies is insufficient and there is no consensus yet on which therapy approach is more successful. No previous study has been found in which family education of risky babies was followed up with telerehabilitation.

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2. Objectives

Primary Objective

Evaluate the effectiveness of family-centered, goal-directed early physiotherapy approaches in high-risk infants using telerehabilitation.

Secondary Objectives

1. Compare the motor, cognitive, and language developmental progress of infants in telerehabilitation and single-session education groups.
2. Assess family satisfaction with telerehabilitation-based physiotherapy.
3. Measure neurological outcomes using Hammersmith Infant Neurological Examination (HINE).
4. Determine the achievement of individualized treatment goals using the Goal Attainment Scale (GAS).

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3. Study Design

Type of Study

A prospective, randomized, controlled trial conducted at the Risky Infants Polyclinic.

Duration

12 weeks, with evaluations conducted at baseline, 4th, 8th, and 12th weeks.

Groups

1. **Telerehabilitation-Based Group**: Families received exercise training in the clinic, followed by weekly real-time video-conference sessions (1 day/week) and follow-up phone calls (2 days/week).
2. **Single-Session Education Group**: Families received a single session of exercise training in the clinic and were asked to continue the exercises independently.

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4. Participants

Inclusion Criteria

- Premature infants (<37 weeks) treated in neonatal intensive care units.
- Infants with neurological abnormalities (muscle hypertonia, hypotonia, overstimulation, abnormal general movements, or cranial ultrasound abnormalities).
- Infants aged 0-12 months (corrected age for prematurity applied).
- Diagnosed as at-risk for motor or developmental delay.
- Infants whose medical treatments are complete and are no longer in neonatal intensive care.
- Families who agree to participate and provide informed consent.

Exclusion Criteria

- Infants with congenital cyanotic heart disease, cystic fibrosis, genetic diseases, or congenital anomalies.
- Infants on ventilators.
- Families unable to attend regular check-ups or weekly communication.
- Infants already enrolled in special education or rehabilitation centers.

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5. Outcome Measures

Primary Outcomes

1. Changes in neuromotor development using the Hammersmith Infant Neurological Examination (HINE).
2. Cognitive, motor, and language development using Bayley III.
3. Goal achievement using the Goal Attainment Scale (GAS).

Secondary Outcome

4. Family satisfaction using a custom Satisfaction Survey.

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6. Intervention

Training Protocol

- Exercises tailored to neuromotor developmental stages, delivered by experienced pediatric physiotherapists.
- Families instructed to perform exercises for 30-45 minutes, 3 days per week, for 12 weeks.
- Telerehabilitation group received one supervised video-conference session weekly, with phone call follow-ups for the remaining two days.
- Single-session group received instructions during one in-clinic session with no additional follow-up.

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7. Data Collection and Tools

Demographics

- Collected using forms capturing infant and family data (age, education, marital status, economic status, number of children, etc.).

Developmental Assessments

1. **Bayley III**: Evaluates cognitive, motor, and language development.
2. **HINE**: Assesses cranial nerve function, posture, tone, reflexes, and orientation.
3. **GAS**: Tracks individualized treatment goal achievement.

Satisfaction Survey

Assesses family satisfaction with treatment.

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8. Statistical Analysis Plan (SAP)

Sample Size Calculation

- Based on a similar study (Pineda et al., 2020), the effect size was calculated as 1.09.
- Using G*Power 3.1.9.2, a total sample size of 24 infants (12 per group) was determined for $\alpha=0.05$ and power=0.95.

Statistical Methods

- **Descriptive Statistics**: Mean, standard deviation, minimum, and maximum values for quantitative data; frequency and percentage for qualitative data.
- **Group Comparisons**:
    - Mann-Whitney U and chi-square tests for continuous and categorical demographic data.
    - Wilcoxon Signed-Ranks Test for pre- and post-treatment comparisons of Bayley III, HINE, and GAS scores.
- **Significance Level**: $p<0.05$.

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9. Ethical Considerations

- The study received ethical approval from the relevant institutional review board.
- Signed informed consent obtained from all participating families.
- Data confidentiality and anonymity maintained throughout the study.
