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Research Article

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Effect of Goal Directed Physiotherapy vs a Goal Directed Home Program in At-Risk Infants: A Randomized Clinical Trial

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Abstract

Background: *Goal directed physiotherapy is a task oriented therapy based on neurodevelopmental principles used in rehabilitation process. The aim of this study is to compare the neurodevelopmental effects of early goal directed physiotherapy with a detailed goal directed home program in infants with risk.*

Methods: *Forty at-risk infants (18 male, 22 female, median age 5.69 mo) were assigned to early goal directed physiotherapy and detailed goal directed home program group randomely. Both early goal directed physiotherapy and detailed goal directed home program continued for 12 weeks. The outcome measures were Hammersmith Infant Neurological Examination, Alberta Infant Motor Scale and Goal Attainment Scale.*

Results: *Significant difference was found in Hammersmith Infant Neurological Examination in early goal directed physiotherapy group ($p<0.05$) whereas no difference was found in Alberta Infant Motor Scale and Goal Attainment Scale between the groups ($p>0.05$). In all test results the effect size of early goal directed physiotherapy was more than detailed goal directed home program.*

Conclusions: *According to our results, though Hammersmith Infant Neurological Examination results are better in the early goal directed physiotherapy group, it can be concluded that if parents had good, attainable and eligible guidelines received from the physiotherapist, detailed goal directed home program is also a useful approach in rehabilitation programs of infants with risk.*

Keywords: Goal Attainment Scaling, Intervention, Physical Therapy, Infant, Goal Setting.

Introduction

Infants with risk are characterized by having negative environmental and biologic factors that contribute risk of neurodevelopmental disorders and mortality. Factors such as prematurity, perinatal asphyxia, hypoxic ischemic encephalopathy, periventricular leucomalacia, intraventricular hemorahage, chronic lung disease, seizures, meningitis, hyperbilirubinemia, twins/triplets and intrauterine growth restriction can cause the risk of morbidty and mortality in infants [1, 2].

There has been an improvement in the survival rates of at-risk infants in recently. However, more than 50% of these infants experience later neurobehavioural impairments, including motor incoordination, cognitive impairment, behavioural problems, minor neurologic disfunction and between 5-15% suffer from cerebral palsy (CP) [3, 4].

Early intervention programmes are used for the treatment of infants with risk for developmental disorders and provide minimizing developmental delays, remediate existing or emerging disabilities, prevent functional deterioration, and promote adaptive parenting and overall family functioning in infants from birth to 24

months of age [5-7]. Early intervention programmes also include early physiotherapy interventions (EP). In the past few decades the importance of EP has become widely recognized. These EP have the aim of optimizing motor development and modifying sensory information and movement patterns in order to improve motor development through passive and active exercise techniques. Physiotherapy based on motor development with a collaboration by the infant in order to stimulate motor development learning primarily addressed improvement in motor skills in at-risk infants. A large number of EP studies concluded that physiotherapy treatment must be initiated as soon as possible within the first trimester of life [8]. Studies showed the effect of intervention in children with at risk for developmental disorders. In the literature, Oghi et al. found EP programme has beneficial effects on neonatal neurobehavioural development and maternal mental health of low birthweight infants with cerebral injuries [9]. Nelson et al. and Badr et al. showed central nervous system injured experimental infants tended to exhibit better motor and mental performance than control group [10, 11]. Heathcock et al. and Park et al. also concluded that neonatal developmental intervention programme promote motor and growth outcome of premature infants [12, 13].

Early physiotherapy programmes include neurodevelopmental treatment approach, home program, family-centered therapy, constrained induced movement therapy and goal directed physiotherapy (GDP). GDP is referred to as 'task-oriented' and is built on contemporary system theories of motor control. The development and learning of new skills occur in an interaction between the child, the task to be performed and the particular environment in which the activity takes place [14, 15]. Studies showed that this treatment method has positive effects on motor development in infants and children with neurologic conditions [16-21].

GDP is used to directly address the infant's limitations in everyday life situations. Thereby the infant's possibilities to actively participate in daily life activities increase with normalized movements and transfer to improved skill performance. Today the infant is given the possibility to be more of an active problem solver instead of a passive recipient of treatment [21]. Home based physiotherapy is also one of the programmes in which the physiotherapists and parents design a programme to stimulate the motor skills of the infants with risk. Today, in EP programmes, focusing on home based therapy together with the family has a lot of advantages. The EP in hospital does not give the enough therapy sessions, inadequacy of family facilities like transport to hospital or economic situations. Also, infant's adaptation to home environment become easer with therapy [22, 23]. To this end, the aim of this study is to compare the neurodevelopmental effects of GDP with a detailed goal directed home program (DGDHP) in infants with risk.

Materials and Methods

Participants

This stratified randomized clinical trial study was conducted at Hacettepe University, Department of Physiotherapy and Rehabilitation, Ankara, Turkey. The study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from the ethics committee of Hacettepe University (GO13 186-01). The data were collected after informed parental consent. The flow diagram of the study is shown in [Figure 1].

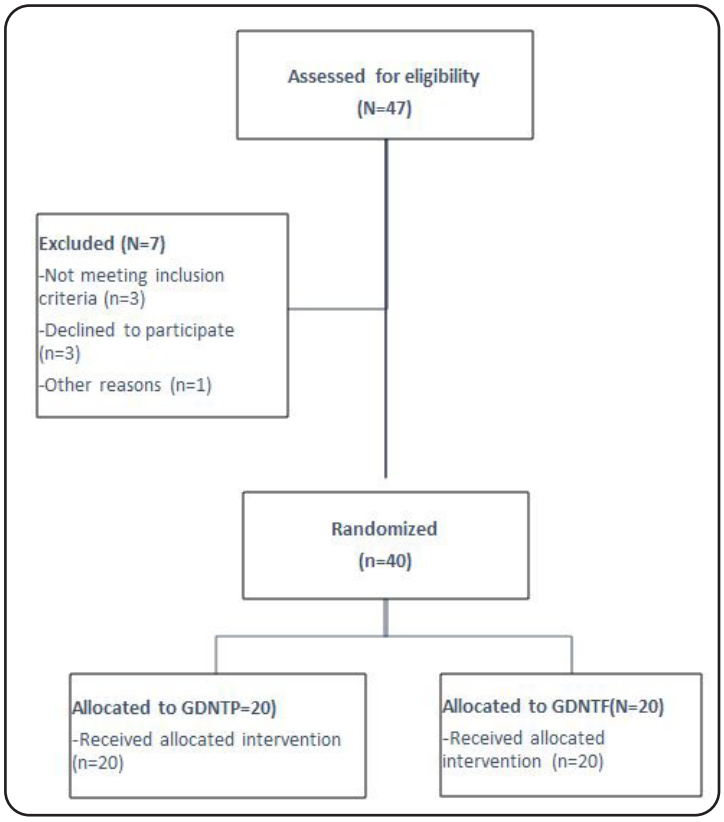

Figure 1: Flow diagram of the process through the phases of two groups.

Inclusion criteria were: at-risk infants,

1. discharged from neonatal intensive care unit;
2. age between 0 - 15 months old (corrected age for premature infants);
3. Having a family acceptance for the participation in 12 weeks of therapy programme.
4. Exclusion criteria were:
5. having congenital anomalies, musculoskeletal disorders, cyanotic congenital heart disease and mechanical dependency, and
6. Lack of informed consent by the parents.

Clinical trial protocol

Interventions

An independent physiotherapist allocated the 40 infants to GDP group or DGDHP group by stratified sampling according to infants' ages, risk level and maternal education according to a random-number table. Therefore the infants in the two groups had the same number of age, risk level and maternal education level. The risk level is determined by the criteria of Turkish Neonatal Society Guideline for High-Risk Infants for each infant [24]. [Ta-

ble 1] shows sociodemogrophic and physical properties of infants and their families. For the GDP the therapist and family chose the goal for each of the babies before the therapy. When choosing the goal for the baby, the physioterapist considered infant's age and capabilities according to evaluation outcomes of the infant and the family took into account their motor expectations from the infant. The goals are defined specific for each of the babies. Each goal for each baby was SMART (specific, measurable, attainable, relevant, timed) [17].

Table 1: Sociodemographic and Physical Properties of İnfant and Parents.

	GDP (N=20) N (%)	**DGDHP (N=20) N (%)**	**p**
Sex			
Male	10 (50)	8 (40)	0.537
Female	10 (50)	12 (60)	
Gestational Age			
Preterm	14 (70)	15 (75)	0.502
Term	6 (30)	5 (25)	
Risk Level			
High risk	15 (75)	15 (75)	
Moderate risk	4 (20)	4 (20)	1.000
Low risk	1 (5)	1 (5)	
Delivery method			
Normal	8 (40)	2 (10)	0.028*
Cesarean	12 (60)	18 (90)	
Maternal Education			
Primary school	4 (20)	4 (20)	
Secondary school	0 (0)	0 (0)	1.000
High school	5 (25)	5 (25)	
University	11 (55)	11 (55)	
Paternal Education			
Primary school	1 (5)	2 (10)	
Secondary school	1 (5)	1 (5)	
High school	6 (30)	8 (40)	0.380
University	12 (60)	9 (45)	
AIMS <10%	15 (75)	11 (55)	0.194
Number of infants achieved goal	17 (85)	14 (70)	0.579
	X±SD	**X±SD**	
Gestational Age (weeks)	33.79±5.17	33.07±4.57	0.849
Infant's Age (months)	5.56±3.54	5.03±3.77	0.499
Birth Weight (gr)	2131±1100	1914±822	0.665
Maternal Age (years)	31.30±5.27	32.15±5.06	0.588
Paternal Age (years)	34.95±7.85	34.80±6.09	0.765
Mother's Height (cm)	163.60±4.12	161.10±6.59	0.105
Mother's Weight (kg)	68.55±11.17	67.65±8.27	0.989
Incubation period (days)	33.50±35.29	22.62±23.29	0.440
*p<0.05			

The physiotherapist that applied GDP and administered DGDHP was the same who is an experienced therapist in EP. After choosing the goals, the infants assigned to the groups. GDP group received 45 min physiotherapy based on neurodevelopmental principles from the physiotherapist 3 days in a week in the physiotherapy unit of the hospital. In the first session of therapy, physiotherapist also informed family about positionig, feeding positions and handling of the infant for 15 min. In DGDHP group, the physiotherapist visited the family at home once a week. First visit went on for 1 hour. At first visit, the physiotherapist informed family about the exercises depend on neurodevelopmental approach according to goal that had chosen before and the family applied the exercises. Also physiotehrapist taught positioning, feeding positions and handling of the infant to the family. In the other home visits, physiotherapist rearranged exercise programme of the infant. The remained visits went on approximately 30 min. The application continued for 12 weeks for each group.

Measurements

The effectivenes of the therapy was measured with Hammersmith Infant Neurological Examination (HINE), Alberta Infant Motor Scale (AIMS) and Goal Attainment Scale (GAS) instruments.

HINE

The HINE includes three sections, the Neurological Examination, the Development of Motor Functions and the State of Behaviour. The first section evaluates cranial nerve, posture, movements, tone and reflexes. These items are not age-dependent. The second section evaluates head control, sitting, voluntary grasping, rolling, crawling and walking. The third section evaluates state of consciousness, emotional state and social orientation. The data obtained in the second and third sections are not included in the calculation of global optimality scores. They give additional information on the interpretation of neurological findings, but a frequency distribution for these two age-dependent sections was not calculated. The overall score ranges from a minimum of 0 to a maximum of 78. At 9 or 12 months, the scores equal or above 73 are regarded as optimal, if below 73 as sub-optimal; while at 3 and 6 months healthy term infants scored equal or above 67 and 70 (median) respectively [25, 26].

AIMS

Gross motor development was assessed by using the AIMS. This scale is a norm-referenced observational tool designed for the evaluation of gross motor development in infants from birth to 18 months of age or the acquisition of independent walking. It consists of 58 items and four subscales: supine (9 items), prone (21 items), sitting (12 items) and standing (16 items), which are observed in postural alignment, antigravity movements and surface contact. The motor skills observed correspond to the infant's motor window consisting of all items located between the less and more mature capabilities observed in the motor repertoire. Assessment was based on the free observation of the child in different positions (prone, supine, sitting, and standing) according to the age of the child. A score is obtained between 0–60 points. The obtained score can be converted to a normative age-dependent percentile rank 5th,10th, 25th, 50th, 75th or 90th percentiles. A score less than the 10th percentile was classified as possibly delayed motor development [27, 28].

GAS

Goal Attainment Scaling methods required practitioners to set rehabilitation goals in collaboration with the client and family or significant others, such as a carer. For each goal, the client and practitioner developed detailed and very specific observable and quantifiable descriptions of possible outcomes (refer to Table 2 for examples of goal attainment scales) [Table 2]. Five outcome levels were identified, including the expected or desired level of performance or outcome, 2 levels that would be seen as less favourable and 2 levels that were more favourable. The 5 recommended outcome levels for each goal were assigned numeric values from –2 (the least favourable outcome) to +2 (the mostfavourable outcome). The expected outcome or goal was assigned 0. The client and practitioner reviewed the outcome after the planned intervention or a predetermined length of time, and a score between –2 to +2 was allocated to that goal. The goals are weighted using the importance and difficulty criteria set for each individual. Then baseline and outcome GAS scores have been calculated following and this was converted into a T score. A score of 50 or more indicates that goals were attained. There is good evidence for the reliability, validity and sensitivity of the GAS method in rehabilitation settings [29-33].

Table 2: GAS Examples of İnfants.

Level of expected outcome	Goal 1	Goal 2
+2 (Much greater than expected outcome)	Reaching for toy with trunk rotation in independent sitting position.	Standing independently for a while
+1 (Greater than expected outcome)	Reaching for toy without trunk rotation in independent sitting position.	Controlled lowering through standing
0 (Expected outcome)	Sitting independentlly	Cruising sideways independently
-1 (Less than expected outcome)	Reaching forward and sideways in supported sitting position	Pulling to stand with support from half-kneeling position
-2 (Baseline)	Feet to mouth in supine position	Pulling to half-kneeling position from sitting position

Sample Size Justification

The sample size was determined based on statistical power analysis procedures using PASS 2005 software (NCSS, Kaysville, UT, USA). The power analysis indicated that 17 subjects for each group were needed with 90% power and a 5% type 1 error. Indicating 20% drop out of the study we recruited 20 subjects for each group in order to ensure 90% power. The power analysis of our study showed a power of 90% with postural control as the primary outcome.

Statistical Analysis

The results of tests were expressed as the number of observations (n), mean ± standard deviation, median and min-max values. The results of the homogenity (Levene's Test) and normality tests (Shapiro Wilk) were used to decide which statistical methods to apply in the comparison of the study groups. Normally distributed and with homogeneous variances groups were compared two groups by Student's t test and compared dependent two groups by Paired t test. According to those tests results parametric test assumptions were not available for some variables, so the comparisons of two independent groups were performed by Mann-Whitney U test, comparisons of two dependent groups by Willcoxon test. Categorical data was analysed with Fischer's Exact Test and Chi-square test. Expected to be less than 20% of cells in cases for inclusion in the analysis of those cells "Monte Carlo Simulation Method" and the values were determined. All statistical analyses were performed with the SPSS software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0 Armonk, NY: IBM Corp.). p value of < .05 and < .01 was considered statistically significant.

Results

Although the comparison of pre-treatment and post-treatment evaluations within groups showed significant results [Table 3], significant difference was found in HINE test results as positive in GDP group ($p<0.05$), no difference was found in AIMS and GAS results ($p>0.05$) between the groups [Table 3, 4].

Table 3. Comparison of pre-treatment and post-treatment evaluations within groups.

	GDP (N=20)		DGDHP (N=20)	
	t	p	*t*	p
AIMS (0-60 points)	-7.189	0.000*	-5.370	0.000*
HINE (0-78 points)	-12.804	0.000*	-7.680	0.000*
GAS T score	-12.352	0.000*	-9.798	0.000*
*p<0.05				

Table 4: Comparison of Before and after Treatment Scores between Two Groups

		GDP (N=20) X±SD	DGDHP (N=20) X±SD	p
AIMS (0-60 points)	BT	10.15±6.61	8.90±6.73	0.557
	AT	27.25±17.78	19.35±14.03	0.141
HINE (0-78 points)	BT	41.87±12.56	43.20±11.56	0.731
	AT	67.27±6.70	57.52±13.12	0.005*
GAS Baseline		45.84±1.30	45.32±1.06	0.176
GAS T score		52.21±3.07	51.56±3.31	0.524
*p<0.05				

Discussion

In this study we compared the neurodevelopmental effects of GDP with DGDHP in infants with risk. We found significant difference in HINE in GDP group whereas no difference was found in AIMS and GAS between the groups.

Studies in which the effect of a goal or activity-focused therapy has been investigated show promising results. Löwing et al., Ahl et al. and Katelaar et al.investigated the effects of goal directed therapy for at least 12 weeks in children with spastic CP and found scientific improvements in gross motor functions, daily life activites and functional independence [16-18]. Sorsdahl et al. applied goal directed group therapy approach for 3 weeks in children with CP [19]. Although the short-time duration, functional independence scores of children increased. Similarly, Storvold et al. showed that 6 week of treatment with goal directed therapy has positive effects on motor development in children [20]. Similarly, our primary findings indicate that GDP had beneficial neurodevelopmental outcomes in each group. Encouragement of to allow the infants to play on a mattress and provide opportunities to for exercise of the infants' muscles and which promoted motivation appeared to be active for this population.

The earliest studies on EP programmes primarily addressed improvement in motor skills. Later, the focus shifted towards home programs and other functional outcomes. Family-centered home-programs to facilitate rehabilitation outcomes come into prominence for children with special needs (9). In many countries,

hospitals and rehabilitation services for infants with risk, good team collaboration is needed to optimally coordinate services. The very first study that involves home program through the EP is Rice's study in 1979 [34]. In this study, 15 premature infant's had one-month home programme and found infant's neurologic and mental improvements better than the control group. Dirks et al. developed a family-centered home program method in early intervention programme [23]. They indicated that encouraging the familiy's own capacities can solve the problems of daily care of the infant. Lekskulchai et al. demonstrated that motor development intervention programme that is applied at home showed succesful results than the no-treatment group [35]. They indicated that the effectivennes of the programme relied-on the caregivers' understanding and cooperation. Similarly in our DGDHP group family played a major role in carrying out the programme for their infants. Also, they offered the primary researcher's contact number that they could call any time.

In recent years, the HINE has been identified as one of the best and simplest neurological examinations for the early diagnosis of neurological impairment in both low and high-risk infants, as it can even be easily performed in clinics. The assessment includes several aspects of neurological functions, including cranial nerve assessment, posture, movements, tone, reflexes, and behavior, and it also provides additional information on the type and severity of the overall disability, which is not limited to motor impairment. It measures neurological function detecting disorders of posture. A recent International Clinical Guideline for the early identification of CP recommends the use of the HINE for early detection of CP beside neuroimaging [36-40]. Although the HINE is not the only standardized neurologic examination in infancy and is by no means comprehensive, it is the only one with published optimality and cutoff scores (<56 points at 3 months, <59 points at 6 months, <62 points at 9 months are high risk of CP) [41]. The HINE allows early detection of typology of CP and additionally provides a longitudinal evaluation of impairment severity in infants [42]. In conclusion, the HINE confirms its role as one of the early neurological examination tools for the diagnosis of high risk infants [43]. While AIMS, which we use in our study, provides information about the motor development and postural control of the infant, GAS provides information about the effectiveness of the treatment. In our findings, HINE showed better results in GDP group than DGDHP group. In high risk population HINE has an important role in detecting early neurologic results. Therefore, may be we can think that GDP group has more therapy effect on neurologic functions in infants than DGDHP.

Limitations

The limitation of this study was that the lack of long-term follow up of the infants. Further studies needed to conduct with future follow up programmes, after applying EP programmes including GDP or DGDHP and comparing with other early intervention techniques.

Conclusions

According to our results, although HINE results are better in the GDP group, it can be concluded that GDP is as beneficial as DGDHP. In at-risk infants. However, if parents had good, attainable and eligible guidelines received from the physiotherapist, DGDHP is also a useful approach in rehabilitation programs for infants with risk.

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