

QUALITY OF LIFE AND DEVELOPMENTAL CHANGES OF PRETERM INFANTS AT EARLY CHILDHOOD

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The developmental and behavioral disabilities remain high in children and in adults who were born preterm. In this case assessment of quality of life and development of preterm infants can be very informative and interesting. This is a prospective longitudinal (at 3, 6, 9 and 12 months) study of preterm birth and term control infants selected from pediatric polyclinics of Yerevan. The quality of life (QL) measures were done with QUALIN questionnaire and the developmental measures with Battelle Developmental Inventory. A total of 71 preterm and 105 term control infants underwent study. Among 71 preterm birth infants, who selected on the study at 3 months, 40 infant's score on the BDI was <-1 SD and 1 infants' score on the BDI was <-2 SD. However, at the age of 12 months 32 of these same children showed a BDI score >85. Parents and pediatricians reported worse QL for of preterm infants compared with control group. At same time parents of preterm infants reported better QL for their children compared with pediatricians. The lowest QL and developmental scores among preterm children were detected at 3 months. Improvement of QL and developmental score was observed in the next age groups.

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**Introduction.** About 9% of all infants are born preterm, i.e., prior to completing 37 weeks of gestation [1, 2]. Advances in perinatal care during the last decades resulted in a significantly decreased mortality of preterm infants and a reduction of severe organ damage [3, 4]. Nevertheless, preterm born children are still at a higher risk of long-term health and developmental problems compared to their term born counterparts.

Preterm birth is defined by World Health Organization (WHO) as all births before 37 completed weeks of gestation or fewer than 259 days since the first day of a woman's last menstrual period [5]. Preterm birth can be further sub-divided based on gestational age: extremely preterm (<28 weeks), very preterm (28 to <32 weeks) and moderate preterm (32 to <37 completed weeks of gestation).

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According to findings from a large register-based study, increased risk for hospitalization for a wide range of mental disorders was associated with preterm birth [6], and risk was inversely associated with gestational age. Furthermore, psychiatric morbidity in preterm born children has been associated with reduced cognitive functioning, as measured by intellectual quotient (IQ) [7].

Preterm birth is a major cause of death and a significant cause of long-term loss of the human potential amongst survivors all around the world. Complications of preterm birth are the single largest direct cause of the neonatal deaths, responsible for 35% of the world's 3.1 million deaths a year, and the second most common cause of under-5 deaths after pneumonia [8]. Studies reporting global or health-related aspects of quality of life among preterm children are few [9].

Monitoring of emotional and behavioral problems and quality of life (QL) during early childhood has become necessary. Additionally, the measurement of QL in children has become a mandatory component in clinical research because it is useful for understanding the impact on the long-term outcomes [10].

No significant association was found between quality of life and the most frequent neonatal morbidities such as IVH ( $p = 0.699$ ;  $\chi^2 = 0.715$ ), ROP ( $p = 0.477$ ;  $\chi^2 = 1.481$ ), PVL ( $p = 0.52$ ;  $U = 30.0$ ), NEC ( $p = 0.505$ ;  $U = 109.0$ ), intrauterine hypoxia ( $p = 0.132$ ;  $U = 207.0$ ) or intrauterine asphyxia ( $p = 0.509$ ;  $U = 29.5$ ). However, mothers reported significantly lower quality of life in preterm infants with BPD ( $p = 0.025$ ;  $U = 443.5$ ) [11].

Most of the research on child development comes from developed countries; few studies are conducted in underdeveloped ones [12].

Children and adolescents born prematurely, however, reported lower QL than the control group. Moreover, parental reports showed significantly lower QL in toddlers, school-aged children and adolescents compared to the preterm children's self-reports and to those, who were born in time [13–16]. Based on these inconsistent results, QL seems to vary throughout development, thus it is informative to measure it from the earliest ages.

The present study aimed to evaluate the QL and developmental changes of preterm infants at early childhood and compare differences with term control infants.

#### **Materials and Methods.**

**Study Design.** This is a prospective observational longitudinal study of preterm birth and term control groups. The subjects of the research were 3 months old early aged children selected from pediatric polyclinics (Yerevan Yerevan State Medical University's Polyclinics ("Mouratsan" and "Heratsi"). 55 pediatricians who worked at Yerevan's pediatric polyclinics were invited to participate in study. Inclusion criteria were pediatrician's agreement to participate on this study and 51 of them agreed. After agreement they had been training to be responsible use of two questionnaires. Every pediatrician asked choose from their district 1–2 preterm infants to a preterm group ( $n=71$ ) and 1–2 practically healthy infants to a term control group ( $n=105$ ). Inclusion criteria for preterm group were gestation age at birth <37 week, parent's agreement and absence of major disabilities. Inclusion criteria for term control group were gestation age at birth 37–42 week, parent's agreement, absence of chronic illness and any disabilities.

**Study Outcomes.** Data collection took a period between September 2016 and February 2019. The QL and developmental scores were collected prospectively at baseline month 3, 6, 9 and 12. QL measures were done at every follow up by parents and pediatricians of selected infants. The developmental measures were done at every follow up by pediatricians. Descriptive covariates (demographic and medical data) were entered by the pediatrician on a printed case report form at inclusion. Baseline demographic data included birth term, age and sex of children, type of family (small, medium and big), etc.

**Sample Size Calculation.** The sample size calculation was made by the following formula:

$$n = \frac{N Z_{\alpha}^2 pq}{N \Delta^2 + Z_{\alpha}^2 pq},$$

where  $n$  is sample size;  $N$  is population size;  $Z_{\alpha}$  the reliability coefficient is the probability of the first type error of 0.05 and is equal to 1.96;  $\Delta$  is the accuracy value (accepted equal to 0.05);  $p$  is the probability of the occurrence of the phenomenon;  $q$  is the probability of absence of the phenomenon (equals  $1 - p$ ).

Total number of preterm (<37 months) infants ( $N$ ) registered at pediatric polyclinics during period between September 2016 and July 2019 were 221. According sample size calculation formula  $n$  was equal 84, from which 71 were eligible to participate in the study.

**Ethics.** A written informed consent was sought from the parents and pediatricians. The study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki. The study project was discussed and approved by the Ethics Committee of the Yerevan State Medical University named after Mkhitar Heratsi.

**Study Instruments.** The QL evaluation of children at early age was performed with the help of validated QUALIN international questionnaire, which was applicable for the both practically healthy and the sick children [17, 18]. In many European countries it was used to carry out the polycentric research, as a result of which the psychometric character of the questionnaire was verified [18]. The questionnaire includes 34 items with 6 possible answers, scored from 0 (quite false) to +5 (entirely true). Thus, the mean score ranges from 0 (poor QL) to +5 (excellent QL). Four topics are addressed: behavior and communication (BC), ability to remain alone (ARA), family environment (FE), psychological and somatic well-being (PSWB). The total score (TS) of all 34 questions was calculated finally. Questionnaire completed by parents and pediatricians at every follow-up.

Battelle Developmental Inventory (BDI) was used to assess infant's development [19]. The BDI is designed to assess the development of children from birth to 8 years of age. The test evaluates child development in five domains: personal-social, adaptive, motor, communication and cognitive development. The BDI includes 341 test items. The BDI results in a total score as well as scores in each of the developmental areas. The sum of the scores for each domain generates a total score. Individual results were classified as either "normal" or "delay" according to a cut-off point of  $-1$  SD in the table of total scores of the reference population. Inventory completed by pediatricians at every follow-up.

**Statistical Analysis.** The statistical analysis has been done with the help of the statistical package SPSS (Statistical package for the Social Sciences Inc., USA 14, 0). Parametric (M, SD, SE) statistical methods have been applied for evaluating the changes of quality of life and developmental scores. Differences in proportions were compared by the Chi-square test or the Fisher Exact Test and differences of means were compared by the Student's t-test. Module t was equal to 2 (CL=95%,  $p<0.05$ ).

Agreement between parents' and children's scores in the different study groups was analyzed by intraclass correlations (ICC).

**Results.** A total of 71 preterm infants (group 1) and 105 controls (group 2) underwent study. Participation rates remained very high throughout the study. At 12 months the response rates on QL and BDI across groups were more than 95% for both pediatricians' and parental reports and 90% for pediatricians', respectively.

The studied preterm infants' group was represented by the boys, which made up 32.4% and the girls, which made up 67.6%. The studied term control infants' group was represented by the boys, which made up 52.4% and the girls, which made up 47.6%. The mean GA was  $27.4\pm 3.7$  weeks for group 1 and  $38.5\pm 1.4$  weeks for controls. The mean BW was  $1420\pm 137$  grams for cases and  $3010\pm 349$  for controls. The mean Apgar's score was  $5.72\pm 0.58$  for cases and  $8.32\pm 1.3$  for controls (Tab. 1).

Table 1

Characteristics of participants at 3 months

Characteristics	Preterm infants group <i>n</i> =71			Term control group <i>n</i> =105		
Sex, <i>n</i> (%)						
Boys	23	32.4		55	52.4	
Girls	48	67.6		50	47.6	
Birth weight (Mean, SD, SE)	1420	137	5.8	3010	349	10.4
Gestation age (weeks) (Mean, SD, SE)	27.4	3.7	0.43	38.5	1.4	0.26
Apgar's score (Mean, SD, SE)	5.72	0.58	0.07	8.32	1.3	0.09
Maternal age at birth (Mean, SD, SE)	30.1	2.7	0.5	25.2	2.9	0.5
Paternal age at birth (Mean, SD, SE)	33.4	6.2	0.74	29.7	6.7	0.8
Mother's educational level, <i>n</i> (%)						
High school or lower	34	47.9		23	21.9	
Vocational school	12	16.9		15	14.3	
University	25	35.2		67	63.8	
Father's educational level, <i>n</i> (%)						
High school or lower	7	9.9		14	13.3	
Vocational school	30	42.2		13	12.4	
University	34	47.9		78	74.3	
Type of family, <i>n</i> (%)						
Two parents	45	62.8		101	96.2	
One of parents	26	37.2		4	3.8	

The QL measures at 3 months showed, that most affected subscales in case group according to pediatrician's report were "Ability to remain alone"  $2.5 \pm 0.06$ , in control group were  $2.7 \pm 0.06$  and "Behavior and communication"  $3.0 \pm 0.08$ , in control group were  $4.1 \pm 0.07$  ( $p < 0.05$ ) (Fig. 1).

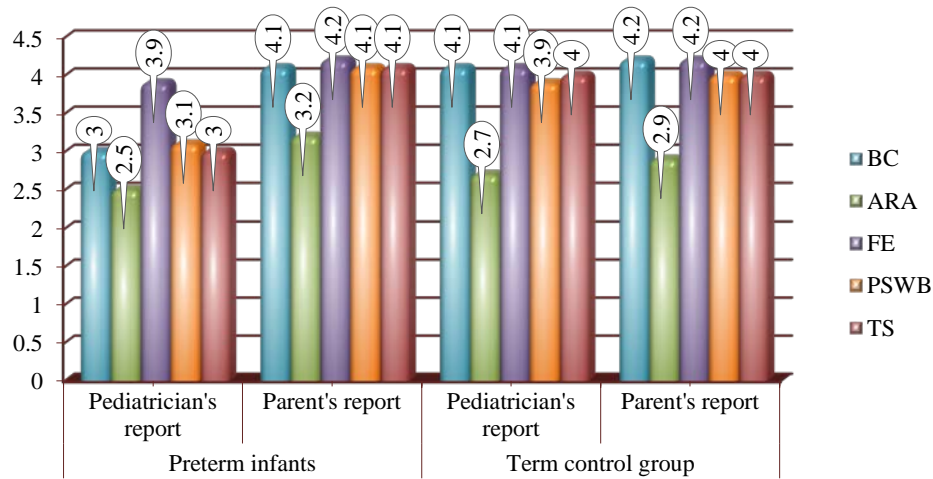


Fig. 1. Mean QL reported at 3 months by pediatricians and parents in preterm infants and term control groups.

At 6 months most affected subscales in case group according to pediatrician's report were "Ability to remain alone" ( $2.8 \pm 0.08$ ) and "Total Score" ( $3.1 \pm 0.06$ ), in control group – "Ability to remain alone" ( $3.0 \pm 0.08$ ), "Total Score" ( $4.0 \pm 0.07$ ) and "Psychological and somatic well-being" ( $4.0 \pm 0.07$ ) (Fig. 2).

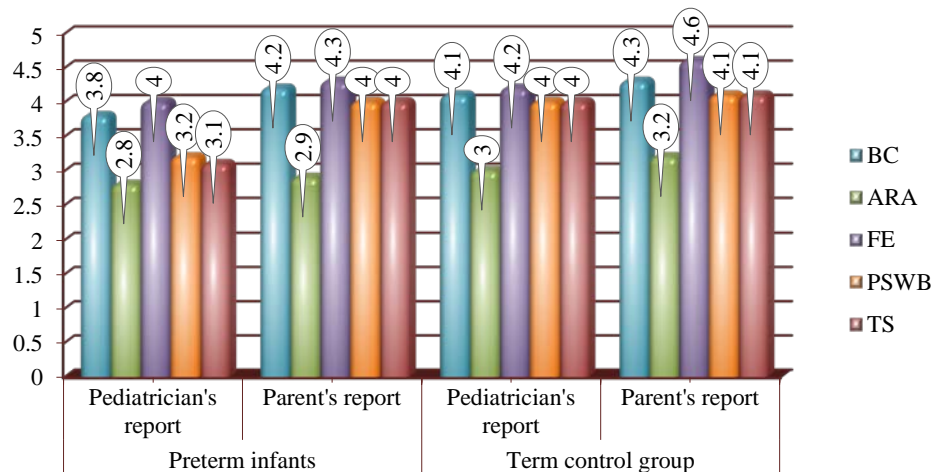


Fig. 2. Mean QL reported at 6 months by pediatricians' and parents in preterm infants and term control groups.

At 9 months most affected subscales in case group according to pediatrician's report were "Ability to remain alone" ( $2.0 \pm 0.05$ ), "Total Score" ( $3.1 \pm 0.06$ ) and "Psychological and somatic well-being" ( $3.1 \pm 0.07$ ), in control group – "Ability to remain alone" ( $3.0 \pm 0.08$ ), and "Psychological and somatic well-being" ( $4.0 \pm 0.07$ ) (Fig. 3).

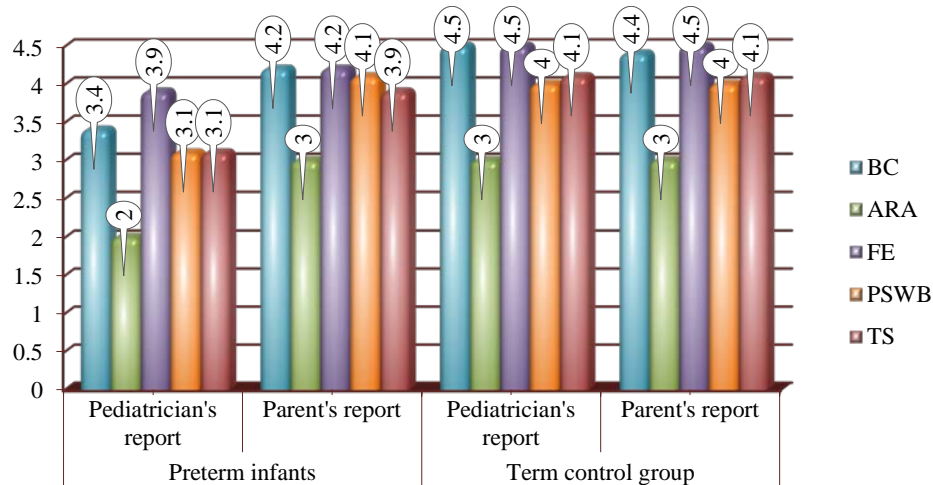


Fig. 3. Mean QL reported at 9 months by pediatricians and parents in preterm infants and term control groups.

At 12 months most affected subscales in case group according to pediatrician's report were "Ability to remain alone" ( $2.9 \pm 0.05$ ), "Behavior and communication" ( $3.9 \pm 0.06$ ) and "Psychological and somatic well-being" ( $3.9 \pm 0.07$ ), in control group – "Ability to remain alone" ( $3.1 \pm 0.08$ ), and "Psychological and somatic well-being" ( $4.0 \pm 0.07$ ) (Fig. 4).

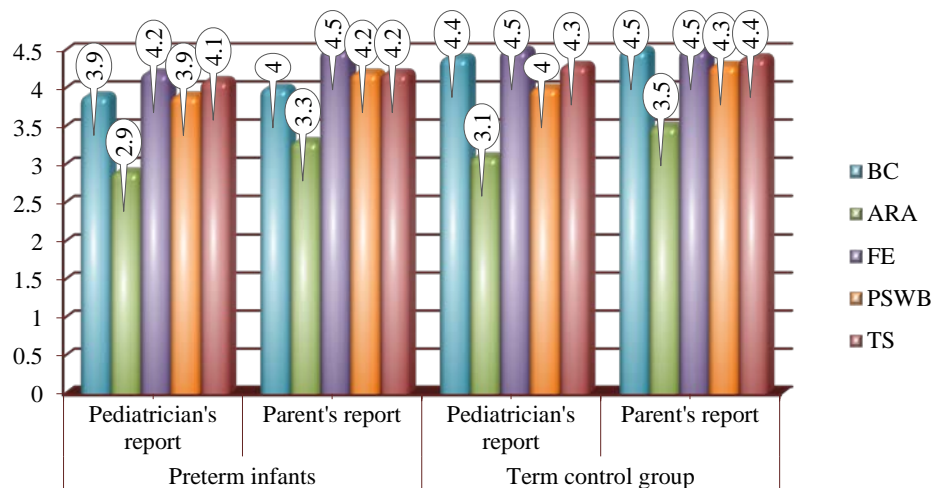


Fig. 4. Mean QL reported at 12 months by pediatricians and parents in preterm infants and term control groups.

The QL measures showed that preterm infants at 3, 6 and 9 months have significantly lower scores compared with controls. Parents of preterm born infants reported worse QL for their children compared with parents of children born full term. At same time parents of preterm born infants reported better QL for their children compared with pediatricians (Tab. 2).

Table 2

*Differences in QL scores between case and control groups during follow-ups*

QUALIN subscales	P value Case vs control							
	3 months		6 months		9 months		12 months	
	pediatricians	parents	pediatricians	parents	pediatricians	parents	pediatricians	parents
BC	<0.05	0.09	<0.05	0.24	<0.05	<0.05	<0.05	<0.05
ARA	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
FE	<0.05	1.00	<0.05	<0.05	<0.05	1.00	<0.05	1.00
PSWB	<0.05	0.09	<0.05	<0.05	0.04	0.22	0.08	0.09
TS	<0.05	0.09	<0.05	0.26	<0.05	0.09	<0.05	0.09

Among 71 preterm birth infants who were selected on the study at 3 months, 40 infant's score on the BDI was  $<-1$  SD and 1 infants' score on the BDI was  $<-2$  SD. However, at the age of 12 months 32 of these same children showed a BDI score  $>85$ .

According to BDI scores at 3 months "Personal", "Adaptive" and "Communication" subscales were significantly lower in preterm group compared with term control. However during follow-ups BDI scores were increased and at 12 months, only "Adaptive" subscale were lower compared with term control infants (Tab. 3).

Table 3

*BDI scores in case and control group during follow-ups*

Battelle subscales	3 months		6 months		9 months		12 months	
	preterm group	term control group	preterm group	term control group	preterm group	term control group	preterm group	term control group
Personal	14.1	16.8*	15.1	17.9*	16.3	18.4	19.8	20.2
Adaptive	11.2	14.7*	10.5	15.7*	12.1	16.7*	16.1	18.4*
Motor	16.8	18.1	17.1	18.1	17.8	18.6	18.9	20.4
Communication	17.4	19.3*	17.8	19.3	18.5	20.0	19.8	22.0
Cognitive	17.0	18.8	17.3	18.8	18.3	19.6	19.8	21.5
Total	76.6	87.8	77.8	89.9	82.9	93.3	94.4	102.6

\* Significant difference in pediatrician-parent agreement between groups ( $p < 0.05$ ).

**Agreement Between Pediatricians' and Parents' Reported QL.** Intraclass correlations between children's and parents' reports of QL varied between the QUALIN subscales and between groups (Tab. 4).

Table 4

*Pediatrician–parent agreement in the study groups and across groups*

QUALIN	Preterm infants group (ICC, n=71)	Term control group (ICC, n=2291)	Across groups (ICC)
BC*	0.06	0.34	0.19
ARA	0.46	0.56	0.51
FE*	0.23	0.57	0.40
PSWB	0.30	0.43	0.57
TS	0.32	0.38	0.41

\* Significant difference in pediatrician-parent agreement between groups ( $p < 0.05$ ).

Significant differences between the case and the control group were detected in the subscales “behavior and communication” and “family environment”. The agreement between pediatricians and parents, in both cases, in the case group were lower compared to the control group.

**Discussion.** A main goal of this study was to identify preterm birth as a predictive risk factors for lower developmental and quality of life scores.

There are some studies reporting QL among preterm children of middle school-age [16, 20–23] and adulthood [24] but the studies reporting QL among preterm children at early childhood are quite rare [25].

It was documented that in term of preterm birth even with clinical practice changes, neurodevelopmental outcomes (mental developmental index, psychomotor developmental index) did not improve compared to earlier eras, even though the incidence of neurosensory impairment decreased [26].

As shown the results of study in case of preterm birth developmental scores according BDI were lower than it in term control group. The finding was detected in the other studies [27, 28].

It must be noted that many studies examining preterm children found correlations between lower birth weight and lower developmental quotients in developmental areas such as gross or fine motor skills or social skills [29]. Regarding the most common neonatal morbidities in preterm infants, we found significant associations exclusively between bronchopulmonary dysplasia (BPD) and quality of life. Mothers of children with BPD reported significantly lower overall quality of life compared to their healthy peers. Thus, children with BPD may be at risk of lower quality of life.

Strength of this study is to be one of the first studies to explore the quality of life of preterm children at early childhood in a country with low income. This study also has some limitations. First, the BDI has not been previously validated in Armenia. Thus, it is likely that the observed accuracy with the population, in which it was first tested does not correspond to the one when applied to Armenian children. Second limitation is the observational nature of the study and short-term follow-ups.



Findings from this study will help to further improve pediatric care programs and provide valuable evidence for decision makers to implement effective comprehensive preventive programs for preterm infants.

**Conclusion.** According to BDI scores at 3 months “Personal”, “Adaptive” and “Communication” subscales were significantly lower in preterm group compared with term control. However, during follow-ups BDI scores were increased and at 12 months, only “Adaptive” subscale was lower compared with term control infants.

In our study, we found the maternal emotional state before and after childbirth to be a more important aspect in the development of quality of life in early childhood, as opposed to birth weight or other biological factors.

Considering our findings, we find it important to help mothers during the early days of motherhood regarding breastfeeding. Implementing interventions like the “golden hour” protocol or the Kangaroo care after childbirth are also vital, and quality of life. The use of these early interventions seems crucial in the later development of at-risk premature children.

The lowest QL and developmental scores among preterm children were detected at 3 months. Improvement of QL and developmental score was observed in the next age groups.

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#### ՎԱՂԱԺԱՄ ԾՆՎԱԾ ՆՈՐԱԾԻՆՆԵՐԻ ԿՅԱՆՔԻ ՈՐԱԿԸ ԵՎ ԶԱՐԳԱՄԱՆ ՓՈՓՈԽՈՑՈՒՄՆԵՐԸ ՎԱՂ ՄԱՆԿՈՒԹՅԱՆ ԾՐՋԱՆՈՒՄ

Երեխաների և մեծահասակների մոտ, որոնք ծնվել են վաղաժամ, զարգացման և վարքագծային թերությունները մնում են բարձր: Այս դեպքում վաղաժամ ծնված նորածինների կյանքի որակի և զարգացման գնահատումը կարող է լինել շատ տեղեկատվական և հետաքրքիր: Կատարվել է վաղաժամ և ժամկետային ծննդաբերված նորածինների հեռանկարային երկայնական (3, 6, 9 և 12 ամսական) ուսումնասիրություն՝ ընտրված Երևանի մանկական պոլիկլինիկաներից: Կյանքի որակի (ԿՈ) գնահատումներն իրականացվել են QUALIN հարցաթերթիկով, իսկ զարգացման գնահատումները՝ Battelle Development Inventory սանդղակով: Ընդհանուր առմամբ ուսումնասիրվել է 71 վաղաժամ ծնված և 105 ժամկետային ծնված, սակայն հսկողության ենթակա նորածին: 71 վաղաժամ ծնված նորածինների մոտ, ովքեր հետազոտության արդյունքում ընտրվել են 3 ամսական հասակում, 40 նորածնի միավորը BDI սանդղակով եղել է <math>-1</math> SD, իսկ մեկ նորածնի գնահատականը՝ <math>-2</math> SD: Այնուամենայնիվ, 12 ամսական հասակում այս նույն երեխաներից 32 -ը ցույց են տվել 85-ից բարձր BDI գնահատական: Ծնողներն ու մանկաբույժները վաղաժամ ծնված նորածինների համար հայտնել են ավելի վատ ԿՈ, քան վերահսկող խմբի համար: Միևնույն ժամանակ, վաղաժամ ծնված նորածինների ծնողները մանկաբույժների համեմատ իրենց երեխաների

համար հայտնել են ավելի լավ ԿՈ: Վաղաժամ ծնված երեխաների շրջանում ԿՈ-ի և զարգացման ամենացածր միավորները հայտնաբերվել են 3 ամսական հասակում: Հաջորդ տարիքային խմբերում նկատվել է ԿՈ-ի և զարգացման գնահատականի բարելավում:

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### КАЧЕСТВО ЖИЗНИ И ИЗМЕНЕНИЯ В РАЗВИТИИ НЕДОНОШЕННЫХ ДЕТЕЙ В РАННЕМ ДЕТСТВЕ

Нарушения развития и поведенческие нарушения остаются высокими у детей и взрослых, родившихся недоношенными. В этом случае оценка качества жизни и развития недоношенных детей может быть очень информативной и интересной. Было проведено проспективное продольное (в возрасте 3, 6, 9 и 12 месяцев) исследование недоношенных детей и детей контрольной группы, отобранных в детских поликлиниках Еревана. Оценка качества жизни (КЖ) проводилась с помощью опросника QUALIN, а показатели развития – с помощью опросника Battelle Developmental Inventory. Были обследованы 71 недоношенные дети и 105 доношенные дети контрольной группы. Среди 71 недоношенных детей, отобранных для исследования в возрасте 3 месяцев, у 40 детей баллы по шкале BDI были меньше  $-1$  SD, а у одного ребенка – меньше  $-2$  SD. Однако в возрасте 12 месяцев 32 из этих детей показали показатель  $BDI > 85$ . Родители и педиатры сообщили о худшем КЖ недоношенных детей по сравнению с контрольной группой. В то же время родители недоношенных детей сообщили о лучшем КЖ для своих детей по сравнению с педиатрами. Самые низкие показатели КЖ и развития среди недоношенных детей были выявлены в 3 месяца. Улучшение качества жизни и показателей развития наблюдалось в следующих возрастных группах.