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The Effect of Care Package on Motor Development among 12-Month-Old Infants in Saqqez-Iran: A Randomized Clinical Trial Study

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Abstract

Background

The initial years of life particularly the first two years are regarded as the most important brain development period. This study attempted to determine the effect of care package on motor development in 12-month-old infants in Saqqez-Iran.

Materials and Methods:This study was a clinical trial conducted in 2016 on 70 infants of 12 months of age selected randomly in intervention and control groups in Saqqez-Iran. The care package was taught to mothers of infants in intervention group) by the researchers based on the book "Ages and Stages Learning Activities 0-5 years". These teachings for gross motor, included walking, pulling and pushing the toys, swinging, playing with ball, crawling, etc. and for fine motor skills included building towers, painting, filling a box with household items and emptying it, giving children books, stringing, etc. Motor skills (gross and fine) were measured by Age and Stage Questionnaire **(**ASQ-2**)** screening tool before intervention, 4 and 8 weeks after the intervention. Data were analyzed using SPSS version 20.0 software.

Results: In the intervention group, 56.2% and in the control group 51.4% were female, respectively. Results showed that 4 and 8 weeks after the intervention in gross movement, average scores in the intervention group were more than the control group (P = 0.02), and mean score in three times (before intervention, 4 and 8 weeks after the intervention) was significant difference (P = 0.002). Also, for fine movement, results showed that in this area average scores in the intervention group were more than the control group (P=0.02); and the average score was a significant difference in that three times (P=0.01).

Conclusion: Results revealed that the impact of care package in intervention group compared with control group in level of significance led to an improvement in motor skills domain (gross and fine movement) in 12-month-old infants in this study.

Key Words: Child, Development, Gross Motor, Fine Motor, Intervention.

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1- INTRODUCTION

Human resource is considered to be the fundamental means of development in all societies and development is only possible through focusing attention on children as the future generation. In this regard, investigating the growth and development of children particularly their development is of paramount importance (1). Development is defined as those aspects of growth which involve physical, mental, emotional and social changes. It is the progressive improvement of skills and functional capacity and is in fact a qualitative change in children's performance (2). Child development is an important determining factor of health in whole lifetime and the initial years of life are regarded as a fundamental opportunity for growth, development and vulnerability (3). The most important brain development period in children is first two years of life which plays a pivotal role in mental, physical, psychological and social functions of children (4). Motor skills make it possible for children to have more control over their environment (5). Gross motor skills development is the general or natural ability of a child to move around and use all body parts. It includes activities like Rolling on the floor, crawling, walking, running, jumping, standing and sitting (2, 6-8).

Motor development abilities constantly change during the lifetime and psychological, cognitive as well as social changes are observed along with motor changes. Thus, paying attention to motor development in children is actually focusing on their total growth (9). Motor development includes both gross and fine movements. Gross motor includes the movement of torso, arms and legs like walking with hand support, trying to stand up and taking the first steps on their own for 12 months of age infants. Fine motor also includes fine movement of hands and fingers the examples of which in 12 months of age infants are putting a cube in a cup, making a tower with two cubes and paging through a book (10). Development of the central nervous system is under the influence of genetics, physical and social environment, biological exposure and cultural conditions. It also depends on prenatal factors and first experience after birth (11-14). Developmental disorders which are classified into different categories (gross motor, fine motor, social skill, speech and mental skill) have a considerable effect on personal and social performances (1, 15). Motor development is a prerequisite for other developmental functions including perceptual, cognitive, language and social abilities (12, 16). Developmental delay is considered as a significant performance delay in two or more developmental fields including motor (gross motor and fine motor), language, cognitive and social-personal developments which is applied to children under five years of age (17). Studies have demonstrated that 16-18 percent of children in different societies suffer from speech and language disorders, mental retardation, learning disorders and emotional and behavioral disorders (18). The incidence of developmental delay in Iran was reported from 7 to 26.3 percent in different cities (18-22).

In their meta-analysis study of development of children in Iran, Sajedi et al. (23) estimated the prevalence of developmental delay as 14.6 percent. The most important reason why it is necessary to assess children development is to be able to diagnose mental, motor, visual and hearing disorders timely and early. If therapeutic intervention occurs at the right time, these disorders can be treated; otherwise, they can result in severe neurological disorders and complications (4). Early diagnosis and timely therapeutic intervention have been the center of considerable attention in recent years. More emphasis is placed on diagnosing

disabilities at an early age particularly under two years of age (20). Early intervention leads to the rapid growth of brain and may change and improve the developing neural pathways (24). According to the point that human development takes place through a progressive mutual process between personal growth, environmental activities and stimuli (25); different studies proved home environment and stimuli as the main source of promoting cognitive, motor and other sorts of development (6, 11, 13, 26-32). In an intervention on the importance of role of playing in improving developmental skills in infants between 13 to 17 months of age, Eickmann et al. (2003), revealed a significant relationship in improving mental and motor developmental skills in the intervention group rather than in the control one (6). With an emphasis on home environment and the importance of the role of parents and educating them to providing children with toys appropriate to their age and understanding different developmental stages, Nagar and Sharma (2009), concluded that there was a statistically significant relationship between developmental age and psychomotor development concerning home environment (33). However, in the clinical trial conducted by Alidoosti Shahraki et al. (2008) on the effect of training mothers about developmental skills on growth and development of 5-7- month infants, no statistically significant relationship was observed concerning the improvement of gross motor skills (34).

Given that most clinical trials in Iran were conducted on pre elementary and elementary school children and according to the contradictory results of different studies of which no one included 12-month-old infants, no one was carried out in Saqqez-Iran and a few of them used ASQ tool and guidelines and instructions by ministry of health, the present study attempted to determine, the effect of care package on motor development among 12-month-old infants taken to healthcare centers in Saqqez-Iran in 2016.

2- MATERIALS AND METHODS

2-1. Study Design and Population

This study was part of a larger study with a clinical trial nature (IRCT Number: 2016012526193N1) whose objective was to determine the influence of care package on motor skills in 12-month-old infants who have been taken to healthcare centers in Saqqez city, Kurdistan province, Iran. The research population consisted of all 12-month-old infants and their mothers who referred to healthcare centers in Saqqez.

2-2. Methods

Multistage sampling was employed in this study and samples had the same socio-economic status. After compiling a complete list of healthcare centers in Saqqez, healthcare centers in Saqqez were taken as the cluster. Thereafter, two clusters were selected randomly, one for training (Khatamol Anbiya Healthcare Center) and the other (Zagros Healthcare Center) for control. Sampling was done purposively and the qualified people were chosen as samples of the study. The sample size of this research was calculated as 32 persons using the formula "to determine minimum sample size for comparing the mean of two independent populations" and based on data collected from similar studies. Finally, sample size was calculated as 35 persons for each group and 70 persons in total with 10 percent probability of loss, 95 percent confidence level (CI) and 80 percent power of test.

$$n \geq 2\frac{\left(z_{\alpha/2}+z_{\beta}\right)^2\sigma^2}{\left(\mu_1-\mu_2\right)^2}$$

Where,

$\alpha = 0.05 \Rightarrow z_{\alpha/2} = 1.96$	**type 1** error probability
$\beta = 0.20 \Rightarrow z_{\beta} = 0.85$	**type 2** error probability
$1 - \beta = 0.90$	**Power**
$(\mu_1 - \mu_2)/\sigma = 0.70$	**Size** of observed influence
$n = 2(1.96 + 0.85)^2 \left(\frac{1}{0.70}\right)^2 = 32$	**Minimum** sample required

Training was provided based on identified behavioral objectives within four sessions. The interventions were designed as four training sessions every two weeks since the beginning of the intervention for 2 hours within 2 months. For each training session, behavioral objectives were determined. In order to prevent infants from being board and also to control the impact of interventions, the training package was changed every two weeks based on the age of infants and gross motor and fine motor skills were taught in each session.

The training sessions were held in the first, third, fifth and seventh weeks. Gross motor, for example, included walking, pulling and pushing the toys, swinging, playing with ball, crawling, dancing, etc. and fine motor skills included building towers, painting, filling a box with household items and emptying it, giving children books, stringing, etc. The training was presented through lectures, question and answer as well as group discussions. At the end of each session, questions were asked on the topics of the same session and the educational pamphlet was given to mothers. Before beginning each session, a checklist of intervention assessment of the previous session was filled out by mothers. It is worth mentioning that the control group received no training from researchers and only some routine training was provided to them by healthcare centers. Gross and fine motor skills were measured 4 and 8 weeks after the intervention by ASQ-2 in 12 months old. The intervention period was 8 weeks, but measuring after 4 weeks was merely to diagnose developmental changes.

2-3. Measuring tools

The tool used in this study was demographic and obstetric information form whose content validity was confirmed based on the ideas of 10 experts in infants and reproductive health. The next tool was ASQ-2. This screening test identified the developmental status of 4 to 60 month-old infants in 19 different age groups (4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 27, 30, 33, 36, 42, 48, 54 and 60 months old) divided into five developmental fields including gross motor, fine motor, communication, problem solving and personal-social developments and assessed and compared them with determined cut-off points. Each developmental field contained 6 questions and totally, the questionnaire contained 30 questions. This questionnaire was filled out by parents with at least elementary school education and was scored by the researcher. There were three choices for each question. Ten scores were assigned for "Yes", 5 scores for "Sometimes" and 0 score for "Not yet" choices. The highest possible score was 10 for each question and 60 for each developmental field.

The sum of scores of each field was separately assessed with each cut-off point appropriate to the age and infants with scores equal to or less than the cut-off point were referred to a specialist for more precise inspection of developmental delay. The simple and straight-forward language of the test, use of pictures with questions and being simple enough so as no special training was needed to complete the questionnaire were the advantages of this test. It took about 10-15 days to implement the test (35); of this study gross motor and fine motor were used and the research team decided to design the intervention

based on motor fields. Sajedi et al. (2012) confirmed the construct validity of the questionnaire with factor analysis method. In this study, by subtracting two standard deviations from the mean scores of Tehrani children, the cut-off points of child development were considered as the standardized criterion to compare the developmental status of other Tehrani children (36). Furthermore, the same researchers did a research on 555 Tehrani children of 4 to 60 months old in 2006 and Cronbach's alpha coefficient was calculated as 0.79 for the questionnaires. In a larger study on 11,000 Iranian infants of 4 to 60 months old, Cronbach's alpha was reported as 0.76 to 0.86 and inter-rater reliability (parents) was 0.93 (37).

2-4. Intervention

The care package provided by Iran's Ministry of Health and Medical Education, the proposed intervention by ASQ (Ages and Stages learning activities 0-5 years), written by Twombly and Fink (38) and translated by Zarkesh et al. (2011) (39), and derived from other interventions was taught in training sessions. The required teachings on the type of interventions were provided under the guidance of supervisor and advisor professor expert in the field. The teachings to intervention group were also provided by the researcher as MSc Student of Midwifery.

2-5. Ethical Considerations

This study was approved by the ethics committee of Shahid Beheshti University with code of ethics IR.SBMU.PHNM.1394.275. It is worth mentioning that mothers of the infants signed written informed consents and they were given the possibility to leave the study whenever they wanted. It was emphasized that their leaving of the study wouldn't create any obstacle to them for provision of other healthcare services by the center.

2-6. Inclusion and exclusion criteria

The criteria were as follows: infants must be born in singleton pregnancy with gestational age of more than 37 weeks, with birth weight of more than 2,500 grams, with no obvious abnormalities at birth, with no history of hospitalization (except for physiological jaundice), and no growth retardation (according to growth-monitoring card), with no history of central nervous system disorders such as convulsions, epilepsy, traumatic brain injury, meningitis, encephalitis, etc. and finally with score of -1 Standard deviation lower than the mean or more from Ages and Stages Questionnaire (ASQ). It is worth mentioning that the cut-off points for gross and fine motors were 32.3 and 45.4, respectively. Those with scores higher than this value could enter the study. Moreover, Iranian mothers with at least elementary school education were mentally and physically healthy and had no history of smoking and/or drinking alcohol or using other addictive drugs could enter the study. The criteria to exclude from the study were not filling out the questionnaires and not participating in two training sessions out of four.

2-7. Data Analyses

Data were analyzed using SPSS version 20.0 software. In order to investigate data, Chi-square test, independent t- test and repeated measures were employed. Chi-square test was applied for qualitative variables like demographic information, t-test was used to show the mean difference of motor skill scores before the intervention and repeated measures test was to indicate the mean difference of motor skill scores after the intervention.

3- RESULTS

There were 32 persons in intervention (the group tested in two time periods) of which 56.2 percent were girls and from 35 persons in control group, 51.4 percent were girls. Statistically and according to Chi-square, between the two groups in

terms of gender were not significantly different. Regarding the level of education, in intervention group, most subjects (31.2 percent) had high school diploma and in control group, 28.6 percent had elementary and middle school education; 78.1 percent of mothers in intervention group and 71.4 percent of them in control group were housewives; 31.2 percent of subjects in intervention group and 31.4 percent in control group had an income of 10 to 15 million Rials; these two groups were the same concerning the variables and revealed no significant difference. The fathers of most research units in both intervention (53.1%) and control groups (60%) were self-employed. Also, 56.2% of subjects in intervention group and 51.4% in control group were tenants. The studied groups were identical concerning these variables (**Table.1**). In **Table.2** The mean of scores for gross motor before intervention was 52.50±8.32 and 50.57±6.94 in intervention group and control group, respectively and the mean of scores for fine motor was 51.72± 8.29 and 49.57± 8.07 in control and intervention groups; independent t- test revealed no statistically significant difference for gross motor (P=0.30) and fine motor (P=0.28).The ANOVA test results with repeated measures demonstrated that for gross motor, 4 and 8 weeks after the intervention, the mean of scores in intervention group was higher than in control group (P=0.02) and the mean of scores in three periods (before intervention, 4 and 8 weeks after the intervention) was significantly different (P=0.002) (**Table.3 and Figure.1**). Similarly, for fine motor, ANOVA test results with repeated measures showed that the mean of scores in intervention group, 4 and 8 weeks after the intervention, was more than in control group (P=0.02) and the mean of scores in three periods (before intervention, 4 and 8 weeks after the intervention) was significantly different (P=0.01) (**Table.3 and Figure.2**). The results revealed that in this study, the scores of gross motor skills (P=0.02) and fine motor skills (P=0.02) four and eight weeks after the intervention in the group which received the teachings was better than those in control group (**Table.3**).

Table-1: The frequency distribution of characteristics of families of 12 month old infants under study

Variables	Sub-group	Intervention group	Control group	P-value
Mother's level of education	Elementary	25	28.6	0.90
	Middle School	25.1	28.6	
	High School Diploma	31.2	28.4	
	Associate Degree	9.4	8.6	
	Bachelor	6.2	8.6	
	Master Degree and PhD	3.1	0	
Father's level of education	Elementary	12.5	14.3	0.92
	Middle School	18.8	17.1	
	High School Diploma	40.6	34.3	
	Associate Degree	15.6	20	
	Bachelor	6.3	11.4	
	Master Degree and PhD	6.2	2.9	
Mother's job	House Wife	78.1	74.4	0.62
	Employee	12.5	14.4	
	Self-employed	9.4	14.2	
Father's job	Unemployed	3.1	0	0.62
	Self-employed	53.1	60	
	Employer	9.4	2.9	
	Employee	15.6	20	
	Worker	18.8	17.1	

Housing status	Private house Rented house Organized house Non-rented house	40.6 56.2 3.2 0	40 51.4 2.9 5.7	0.59
Monthly income (Rial)	Less than 10 million 10-15 million 15-20 million More than 20 million	31.1 31.3 18.8 18.8	28.6 31.4 20 20	0.99

Table-2: The comparison of mean of scores for gross and fine motor skills in intervention and control groups before intervention

Variables	Intervention Group	Control Group	P-value (t-test)
Scores for gross motor skills	52.50± 8.32	50.57± 6.94	0.30
Scores for fine motor skills	51.72± 8.29	49.57± 8.07	0.28

Table-3: The comparison of mean of scores for gross and fine motor skills in intervention and control groups during intervention

Variables	Sub-group	Before intervention	4 weeks after intervention	8 weeks after intervention
Scores for gross motor skills	Intervention group	52.50± 8.32	48.91± 6.68	53.91± 5.78
	Control group	50.57± 6.94	47.43± 7.41	48.57± 7.62
Comparison of two groups		0.02		
Comparison of time periods*		0.002		
Scores for fine motor skills	Intervention group	51.72± 8.29	51.41± 6.50	55.31± 5.67
	Control group	49.57± 8.07	46.86± 8.32	49.47± 8.16
Comparison of two groups		0.02		
Comparison of time periods*		0.01		

* ANOVA test. Repeated measures test results to indicate inter-group effects.

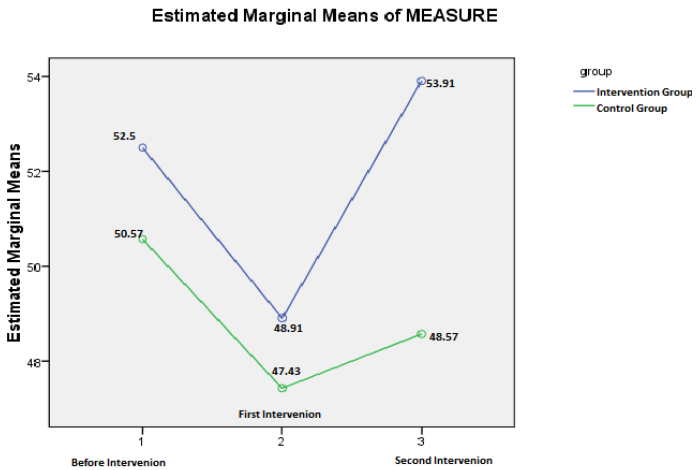

Fig.1: ANOVA test results with repeated measures revealed that for gross motor, the mean of scores in intervention group was more than in control group (p-value=0.02) and the mean of scores in three time periods was significantly different (p=0.002). Bonferroni test results showed that the mean of scores in period 2 (4 weeks after the intervention), was reduced in comparison with that of period 1 (before the intervention) (p-value=0.001). However, in period 3 (8 weeks after the intervention), the mean of scores was increased as compared with that of period 2 (p-value= 0.003).

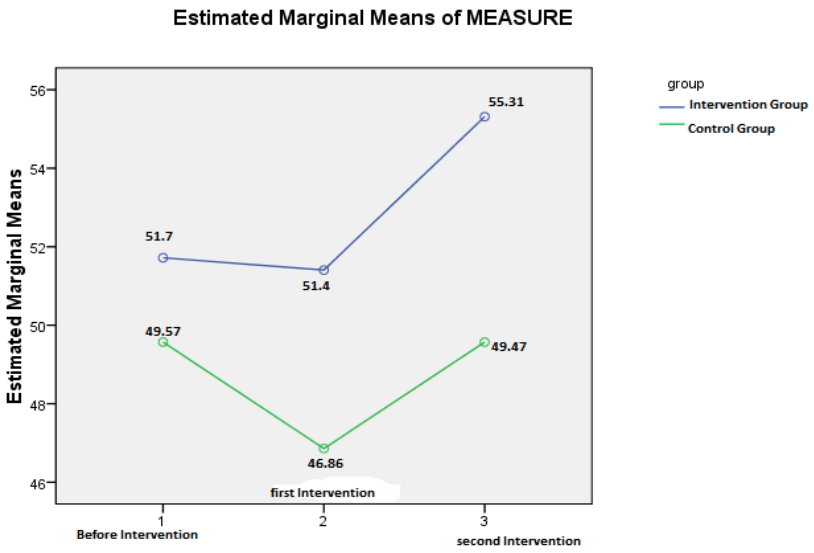

Fig.2: ANOVA test results with repeated measures indicated that for fine motor, the mean of scores in intervention group was more than in control group (p-value=0.02) and the mean of scores in three time periods was significantly different (p=0.01). Bonferroni test results demonstrated that the mean of scores in period 2 (4 weeks after the intervention) was not significantly different from that of period 1 (before the intervention) (p-value=0.11). However, in period 3 (8 weeks after the intervention), the mean of scores was increased as compared with that of period 2 (p-value= 0.001).

4- DISCUSSION

The research results revealed that there was no statistically significant difference between the mean of scores for fine and gross motor skills in intervention group and control group before the intervention; this can be due to identical social and cultural conditions and biological behavior (6). Four and 8 weeks after the intervention, a significant difference was observed in the scores of both fine and gross motor skills in intervention group. It sounds logical that training and interventions after a determined period led to results different from those of the first month. This was compatible with the results of the study by Rezaeian et al. (2013) entitled "An investigation of the effect of implementation of evidence-based care package on the gross motor development of the foster care infants" on 1-12 months old infants (2). One of the most important sections of interventions in the present study was the role of games played to improve fine and gross motor skills. The results indicated that the games parents play with their children at home can improve motor activities of children. In this regard, Miquelote et al. (12) whose study was on the effect of the home environment on motor and cognitive behavior of infants in Brazil, confirmed this and demonstrated that the role of games, physical activities and available physical environment is significant in general improvement of motor performance and cognitive development of infants (P<0.05).

In fact, since the age group they studied was of a range wider than 3 to 18 months and they also took cognitive development beside motor development into consideration, their intervention period was 6 months. The study carried out by Kosari et al. (2012) also showed that doing physical activities appropriate for children would result in improving their motor skills (40). Mombarg et al. (2013)

conducted a study on effect of Wii-intervention (a kind of game) on balance of children with poor motor performance in northern regions of the Netherlands. This study was a clinical trial with 30 children of 7-12 years of age. Tools used in this study were Movement Assessment Battery for children (M-ABC-2) and Bruininks-Oseretsky test of motor proficiency (BOT2) (28). ABC-2 investigated three components including manual dexterity, ball skills and balance. BOT-2 test consisted of weight fine and gross motor items. In this study, nine gross motor items for balance (walking forward on a line, Standing on one leg, etc.), and five items for running speed and agility (shuttle run, one-legged side hop), were used. The intervention group was trained for 6 weeks. The results indicated a significant statistical relationship in all balance and motor skills evaluated through two tests in intervention group as compared with control group. This was compatible with the results of the present study and results were obtained after 6 weeks which can be justified with accordance to the higher age of children in this study.

Fitzgerald et al. (2014) (41) conducted an intervention on 3-5 years old children in 24-lesson interventions. The 30-45 minute lessons included weekly trainings (age-appropriate songs, dances and games) to parents. Finally, the results of t-test indicated that gross motor skill in intervention group was better than in control group ($P<0.05$). In their quasi-experimental study, Sajedi and Barati (2014) (42), investigated the effect of perceptual motor training on motor skills of 60 preschool children of 4-6 years of age in Isfahan. After 15 one-hour training sessions over 2 months, a significant statistical improvement was observed in motor skill ($P=0.000$) as well as in gross ($P=0.000$) and fine motor skills ($P=0.000$).

Senturk et al. (2015) (43), also conducted a study entitled "Motor skills in pre-school education and affects to 5 year old children's psychomotor development". They demonstrated that training games which facilitate motor skills would develop motor performances (including balance, speed and capture). Novotna and Slovakova (2016) (44), showed that trainings like folk dances, modern dances and aerobic gymnastics spheres in early school age improved the results of motor tests in intervention group ($P<0.01$). Campbell (2017) (45), also supported the influence of teaching gymnastics (incorporating strength, flexibility, speed, balance, coordination, power and discipline) on gross motor skills in 1-6 years age group. In the study by Khodakarami et al. (2010) whose purpose was to study the effect of massage on the development and growth of 2-4 month-old infants during 2 months of intervention, there was detected a significant difference for gross motor ($P=0.03$), while there was no significant difference for fine motor (46). The above mentioned study was carried out in different age ranges and infants showed less skill in applying fine motor skills.

Therefore, the results were justified since the interventions of researcher in this study were specially designed to improve fine motor and gross motor leading to the enhancement of motor skills. Alidoosti Shahraki et al. (2003) conducted a research to determine the effect of training mothers about complementary feeding and developmental skills on the growth and development of 5-7 month-old infants taken to healthcare centers in Shiraz (34). The research results revealed that training gross motor developmental skills had no impact on the improvement of developmental performance. The reasons of such difference might be different age range (5-7 months old) and the nature of

interventions since no explanation was given about their nature.

4-1. Limitations of the study

In this study, the houses of samples under the study were not visited, so as to check the house environment and the way mothers played with their infants. The researcher also didn't practice and play with the samples in the intervention.

5- CONCLUSION

The results of the present study demonstrated that care package improved fine and gross motor skills and these changes occurred after 4 weeks which is justifiable since infants of 12 months of age are more skilled in hand, finger and foot performance, and recommended that the interventions in these healthcare centers be taught to parents of infants in other age ranges. Moreover, the results of this study can be utilized as an appropriate basis for other similar studies in Iran. Since the number of samples was limited, the results couldn't be generalized to the society. It is, therefore, recommended that further studies be carried out with more samples and other developmental fields like problem solving, personal-social and communication be taken into consideration in the investigations.

6- CONFLICT OF INTEREST: None.

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