

Effect of premature infant oral motor intervention(PIOMI) combined with music therapy on feeding progression of premature infants: a randomized control trial

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Abstract

Background: To explore the clinical effect of premature infant oral motor intervention (PIOMI) combined with music therapy on feeding progression of premature infants.

Method: Premature infants with post-menstrual ages between 26-30 weeks were included in the study. 52 participants were random divided into the intervention and control groups. All infants received PIOMI, and the intervention group had additional music therapy. The participants of the two groups were compared based on weight gain, feeding progression, Preterm Oral Feeding Readiness Scale (POFRAS), milk volume and length of hospitalization.

Result: Intervention group reached independent oral feeding earlier, length of hospitalization was shorter, and POFRAS score was higher. There was no difference in weight gain between groups.

Conclusion: PIOMI combined with music therapy can improve feeding progression of premature infants by 8 days and reduce length of stay by 6 days.

Introduction

Every year, 15 million premature infants are born globally(1). A premature infant is that born before 37 weeks gestation. Prematurity produces long-term complications in physical and cognitive development for infants. The rate of premature birth has increased in the last decade, however, due to advancements in medical care the survival rate of preterm infants has also increased. Due to the lack of adequate care in developing countries, less neonates survive compared to developed countries (2).

On the other hand developmental complications such as lack of coordination of sucking, swallowing, and breathing deprive the premature infant of successful oral feeding (3). There is also a growing concern about the mental, cognitive, and quality of life of premature infants as the survival rate of younger post menstrual age infants increases. Premature infants may have poor sucking reflexes and therefore need feeding support. The use of feeding or breathing tubes deprives the infant of the sensation of taste and sucking experiences and causes subsequent sensory and motor problems in the infant(4). Therefore these problems increase the length of hospital stay and potential costs and increases the need for intervention to improve oral sensory and motor problems. In addition, the prolonged hospital stay due to inadequate development of feeding skills extends the mother-child separation in the neonatal intensive care unit (NICU) causing stress and can affect brain development(5, 6). There is a need for interventions that can improve feeding, reduce length of stay, and reduce the separation time between the infant and the mother.

In many studies, the effect of music therapy in preterm infants was investigated(7, 8). The widespread impact of music on brain function, including auditory perception, language processing, attention, memory, emotion, mood, and motor skills, has made music a therapeutic tool for infants at risk for neuro-developmental complications, including premature infants(9). Music therapy affects the regulation of senses, weight gain, feeding and also reduces hospitalization and infant stress(10, 11). Music triggers a sequence of cognitive, motor, and emotional processes unilaterally as well as bilaterally that involve a number of brain areas(12).

Studies on improving the feeding skills of infants introduce various strategies, such as pre-breastfeeding, and non-nutritive sucking (NNS) approaches (13). There are some protocols such as Beckman Oral Motor Intervention

(BOMI), that are not suitable for younger post-menstrual age premature infants due to the smaller oral cavity and longer duration of the treatment (14, 15) which is not tolerated by preterm infants. One of the treatment programs designed to facilitate the premature infants sucking and feeding is PIOMI(3), which is well established in the literature and is derived from the BOMI. The PIOMI method is specific to premature infants small oral cavity, tolerance, and limits the intervention time to five minutes. It makes treatment tolerable for premature infants due to less time and incorporates NNS into the program. PIOMI is designed to be done as early as 29 weeks post-menstrual age before attempts at oral feeding as pre-habilitation rather than later re-habilitation after poor feeding has been established. The results of PIOMI studies have shown that premature infants demonstrate earlier readiness to feed, acquire full oral feeding skills earlier and hospitalization time is reduced. Therefore, it should be included in the feeding program for premature infants(16, 17) as prehabilitation to prepare their brains for feeding.

Yang Liu proposed that early combined rehabilitation intervention can improve the short-term clinical outcomes of premature infants(18). Due to widespread impact of music on brain function and oral motor intervention on improving the feeding skills of premature infants (corporation of sucking, swallowing, and breathing), we introduce music therapy combined with PIOMI in premature infants to explore the clinical effect of these interventions such as the duration of reaching eight oral feedings per day, weight gain, milk volume intake and the length of hospitalization on premature infants in NICU.

Methods

Study design and participants

This single-blind, parallel randomized clinical trial was conducted from September 2021 to February 2022 in two hospitals Vali-E-Asr(Imam Khomeini Complex) and Yas in Tehran, the capital city of Iran. We included 52 premature infants (26 infants in each of the control and intervention groups) with a post-menstrual age of 26 to 30 weeks at birth. Infants whose parents signed informed consent form and had inclusion criteria recruited in the study. Children who were eligible assigned randomly to each of control and intervention groups in form of convenience sampling and using random number table.

Inclusion criteria were: post-menstrual age between 26 to 30 weeks at birth, physiological respiratory and cardiovascular stability vital signs and lack of stress symptoms when presenting stimuli (by monitoring and behavioral symptoms), behavioral symptoms(stress signs) are skin color changes,excessive saliva, change in muscle tone, trembling of the tongue, hiccups, and cry.

Exclusion criteria were: Intubation or assisted ventilation like CPAP(continuous positive airways pressure), Apgar score less than seven at birth and five minutes after birth, any congenital anomalies and chronic medical problems such as asphyxia and seizures, broncho-pulmonary dysplasia, intraventricular hemorrhage, necrotizing entero-colitis (NEC) or hearing loss, lack of parental consent to continue the study and transfer the infant to other centers.

Intervention

At the post-menstrual age of 30 weeks we initiated intervention if the infants were physiologically stable and gavage feeding started. Two trained speech therapists who were familiar with NICU workplace and intervention performed required assessments and intervention. The therapists learned PIOMI through a tested training video and after approved training performed intervention. The eligibility of therapists was approved by a pediatrician and

speech therapist who were knowledgeable and experienced in caring for premature infants. The first author consulted with the founder of PIOMI and validated appropriate use.

The interventions were performed inside the incubator, individually, once a day for 10 days in both groups. In the intervention group, 5 minutes PIOMI and 10 minutes of Mozart music were performed daily, and in the control group only 5 minutes of PIOMI were administered.

In the PIOMI protocol facial and oral structures are stimulated, including rolling, curling and stretching of lips, stretch of cheeks, massage of lateral and middle borders of tongue, gums, palate and cheeks, elicit of sucking and NNS(19).

In the final phase of the PIOMI (non-nutritional sucking), music was played and continued for another 8 minutes, with a total of 10 minutes of music presentation. The selected music was specific Mozart music for pregnancy which played by a disinfected speaker inside the incubator. Speaker was placed at a distance of 30 cm from the infant's ear with an intensity of 45 ± 5 dB because "The American Academy of Pediatrics (AAP) has warned that high noise levels may adversely affect newborns' growth and development and environmental noise levels should not exceed 40–45 dB"(8, 20). During the intervention, environment temperature and noise were kept constant by thermometer and sound level meter. Before, during, and after stimulation of the infant, the researcher monitors vital signs. If any symptoms of intolerance occurred through infant respiration and heart rate, exchange facial expression, and gesture the stimulus stopped immediately. If there were no symptoms of stress, we provided stimuli.

Assessment tool

The Preterm Oral Feeding Readiness Scale (POFRAS) scale was used for assessment of behavioral organization, oral posture, oral reflexes and nonnutritive sucking which sum of the scores can vary from 0 to 36. The POFRAS psychometric properties were; interrater reliability (ICC: 0.84; 95% CI: 0.66–0.92), and intrarater reliability (ICC: 0.97; 95% CI: 0.94–0.98) (21). The assessor evaluated infants using the POFRAS on the first, fifth, and tenth days of the intervention.

The participants of the two groups were compared based on POFRAS score and feeding progression(reaching eight oral feedings per day) which were the primary outcomes and weightgain, length of hospitalization, and milk volume which were the secondary outcomes. The neonatologist makes all decisions about neonatal discharge.

Sample size

Sample size with a power of 95% and using information from similar studies according to the following formula, was obtained for each group.

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2/k) (z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_1 = \frac{(2.1^2 + 2.1^2/1)(1.96 + 1.64)^2}{2^2}$$

$$n_1 = 29$$

$$n_2 = k * n_1 = 29$$

Random allocation was done based on the sequence created by the computer using the site, the second step was to hide the random allocation, which was done using opaque and sealed envelopes, and sequences will be recorded on the cards. At the time of registration, the envelopes are opened according to the order of entry of the envelopes and the allocation group is determined. People who were in random allocation and the person who assigned participants were different.

Blinding

This study is a single blind randomized control trial. The intervention is presented by the researcher and the outcome assessment is performed by a trained speech therapist using the POFRAS.

Statistical analysis

The data were analyzed using the following statistical tests: independent sample t-test and covariance test. All analyses were performed using SPSS version 18.

Result

58 infants received intended treatment. After randomization two infants were excluded from the intervention group, one infant due to seizure and the other infant was discharged from the hospital. In the control group, four infants were excluded, one baby due to seizure, two babies due to lack of physiological stability, and one baby died. So 26 infants were included to each group. (Fig. 1)

Table 1 demonstrate the demographic characteristics of participants. There was no statistically significant difference in post-menstrual age, birth weight, postmenstrual age, first day POFRAS score, and first day milk volume between the intervention and control groups.

Primary outcomes: POFRAS scores

The mean score of POFRAS scale on the 5th and 10th days were 22.88 ± 3.1 and 28.65 ± 3.0 in the intervention groups; and 17.38 ± 3.4 and 20.96 ± 3.3 in the control groups retrospectively (p .value < 0.05). (Fig. 2)

Feeding progression

The mean time to achieve 8 independent feedings was 31.54 ± 8.6 and 39.19 ± 13.3 days in the intervention and control groups respectively (p value < 0.05).

Secondary outcomes:

Milk volume Consumption

The mean volume of milk on the 5th and 10th days were 184.31 ± 50.9 and 215.38 ± 56.4 in the intervention group; and 141.85 ± 65.7 and 155.69 ± 68.9 in the control group respectively, (p .value < 0.05). (Fig. 3)

length of hospitalization

The mean length of hospitalization days in the intervention group was 44.96 ± 16.2 days and in the control group was 50.65 ± 17.1 . The intervention group discharged about 5 days earlier but the difference between the two groups was not statistically significant (p value=0.224) .(Table 2)

Weightgain

The mean weight gain were 1388.54 ± 171.3 and 1350.96 ± 243.2 gr, in intervention and control groups respectively. The difference between the mean weight gain in the two groups was not statistically significant (p value > 0.05). (Table 2)

There was no harm or unintended effects in each group. Table 3 shows 95% Confidence Interval of the Differences.

Table 1
The Demographic characteristics of the participants

Groups	Number	Sex		Birth weight(gr) (Mean \pm SD)	Gestational age (week) (Mean \pm SD)	Post menstrual age(week) (Mean \pm SD)	First day POFRAS	First day milk volume(cc)
		Male	Female					
intervention	26	17	9	1252.42 \pm 207.2	28.69 \pm 0.8	31.50 \pm 1.6	16.69 \pm 2.1	113.23 \pm 51.9
Control	26	17	9	1237.31 \pm 285.2	29.31 \pm 0.9	31.46 \pm 1.2	15.69 \pm 3.3	91.69 \pm 56.1
P-value	1.000	1.000	1.000	0.522	0.051	0.923	0.204	0.157

Table 2
Comparison of clinical characteristics on intervention and control groups

Groups	Weight gain (gr)(Mean \pm SD)	Hospitalization (days) (Mean \pm SD)	Feeding progression (days) (Mean \pm SD)	Fifth day POFRAS (Mean \pm SD)	Tenth day POFRAS (Mean \pm SD)	Fifth DAY milk volume (cc) (Mean \pm SD)	Tenth day milk volume (cc) (Mean \pm SD)
intervention	1388.54 \pm 171.3	44.96 \pm 16.2	31.54 \pm 8.6	22.88 \pm 3.1	28.65 \pm 3.0	184.31 \pm 50.9	215.38 \pm 56.4
control	1350.96 \pm 243.2	50.65 \pm 17.1	39.19 \pm 13.3	17.38 \pm 3.4	20.96 \pm 3.3	141.85 \pm 65.7	155.69 \pm 68.9
P-value	0.522	0.224	0.018	0.000	0.000	0.012	0.001

Table 3
95% Confidence Interval of the Differences

Variables	95% Confidence Interval of the Differences			
	Equal variances assumed		Equal variances not assumed	
	lower	upper	lower	upper
Weight gain	-79.606	154.760	-79.936	155.090
Hospitalization	-14.984	3.600	-14.984	3.600
Feeding progression	-12.936	0.090	-12.936	0.105
Fifth day POFRAS	4.386	8.307	4.386	8.307
Tenth day POFRAS	5.922	9.462	5.922	9.463
Fifth DAY milk volume	9.700	75.223	9.649	75.274
Tenth day milk volume	24.611	94.774	24.577	94.808

Discussion

In this study, we aimed to evaluate feeding progression as a result of the combination of PIOMI and music therapy for premature infants with a birth post-menstrual age between 26–30 weeks. The results showed that PIOMI and music therapy intervention was effective in improving feeding progression, milk intake, and reduction of the duration of hospitalization, even over PIOMI alone.

Because the premature infants have little control on oral movement, which is associated with lower muscle tone around the mouth, less sensation, and lower tongue strength, PIOMI was selected as oral stimulation in this study because it designed specifically for premature infants and has demonstrated overwhelming evidence of effectiveness(22–32).

In this study the infants in the intervention group received independent feeding 8 days earlier and were discharged 6 days earlier from the NICU.

In Xiao-Li Li et al.'s study (2020), PIOMI was given once per day for 14 days (33). In their study POFRAS score in the intervention group, increased by 6 points and in the control group by 3 points within 10 days. In our study, POFRAS score increased by 12 points in the intervention group and 5 points in the control group within the same time (10 days).

In the Ghomi et al.'s study (2019), infants who received PIOMI at 29 weeks were discharged 9 days earlier and achieved independent feeding 14 days earlier than a control group with routine care, and there was no significant difference between the two groups in weight gain(19). In the present study, both groups received PIOMI, but in Ghomi's study, the control group did not receive intervention, this means that the intervention group was compared to the non-intervention group, so the difference in the results of the two groups in their study was more significant.

Lyu (2014) used the longer Fucile's method in infants with a post-menstrual age of 29–34 weeks at birth(34) and older at time of intervention. In line with our study, between the intervention and control groups in weight gain and

length of hospitalization was no significant difference. In Lyu's study, the duration of feeding progression in the intervention group was 4 days and in our study was 8 days less than control group.

Asadollahpour et al (2013) who studied the effect of Beckman prefeeding oral stimulation program on the feeding performance of preterm infants showed that the experimental group was discharged 5.85 days sooner from the hospital(35). In Asadollahpour's study, the infant's post-menstrual ages ranged from 26 to 32 weeks at birth which it means that their participants were older than our study at birth and at the time of intervention. Even though the infants in our study were younger, they achieved the same results as the 15 days Beckman intervention but we achieved this result by 10 days.

Lessen (2011) who used PIOMI versus controls in a pilot study, found the intervention group achieved 8 independent feedings 5 days earlier and was discharged 3 days earlier(3). Osman (2016) conducted a dose-response study on PIOMI and found that the more days PIOMI was given, the more positive impact on feeding transition and reduced hospital stay(30). Arora (2018) gave PIOMI at 32 weeks and still found a decreased transition time to full oral feeds and shorter length of stay over controls(22). Thakker et al (2018) did PIOMI starting at 33 weeks during feedings, as opposed to before feedings, with similar results(32). Lessen Knoll, Daramas & Drake (2019) also tested PIOMI starting at 33 weeks versus controls and found higher volume of milk intake and faster transition to full oral feedings, and noted an exponential improvement in feeding over each day in the PIOMI group(27). As in our study, feeding readiness after PIOMI was also tested by Mahmoodi et al (2019) and Sumarni (2021) with similar positive effects on feeding and length of stay(28, 31).

Other studies have also tested PIOMI combined with other interventions. Jaywant, Dandavate & Kale (2020) and Jaywant & Kale (2020) found that adding infant massage to PIOMI decreased time to full oral feedings compared to PIOMI alone(24, 25). Chailangka et al (2018) and Le et al (2021) found that adding expressed breastmilk to the NNS step of PIOMI resulted in higher feeding efficiency than PIOMI alone(23). Kamitsuka et al (2017) combined PIOMI with infant driven feeding and NNS as a total protocol and found earlier readiness to feed and full oral feedings as well as shorter length of stay over controls(26). And finally, Majoli et al (2021) found that parents could perform PIOMI with equally positive improvement in feeding outcomes as if professionals performed it(29).

In the first 6 months after birth, the highest rate of brain growth and plasticity are detected(36). Music therapy is the use of musical interventions for therapeutic purposes. From neuroscience point of view, music is effective in creating a richly sensory environment. Brain imaging studies have shown that the neural activity associated with listening to music extends beyond the auditory cortex and includes extensive networks of frontal, temporal, parietal and subcortical areas that are related to motor function and memory(5, 18, 37, 38). The results of present study, showed that music will improve the infants feeding progression.

Loewy (2003) reported in their study infants' sucking and caloric intake increased with the presentation of music(39). The Standley's study (2003) which music was a selection of recorded lullabies sung by female vocalists showed that the combination of NNS and music improves the feeding rate(40). In the Yildiz's study (2012), infants received total oral feeding for a shorter period of time by receiving music and spent less time in hospital. The infants in the intervention group achieved total oral feeding 37 hours earlier and were discharged 25 hours earlier(41). Yue (2021) showed music therapy had a significant influence on preterm infant's heart rate, oral feeding volume, and stress level(18) also our study is in line with O'Toole, Alexa(42), Mohan, Arvind(43), van der Heijden(8) and Chorna, Olena D. (44).

According to the results of this study, it seems that PIOMI and music therapy intervention is effective on feeding progression in infants born between post-menstrual age of 26 to 30 weeks who receive the therapy between 30 and 34 weeks.

PIOMI and musical stimulation improved the feeding progression of premature infants, reduced time of achieving independent oral feeding, increased infant daily milk volume, and decreased length of hospitalization.

This protocol can also reduce costs for the family and the community. Because with the early acquisition of sucking and the earlier discharge from the hospital, infants spend fewer days in the hospital, which means a reduction in financial costs. Additionally, a shorter length of stay reduces the psychological burden of a prolonged hospitalization of the infant. These issues are important for the baby's family as well as the community.

This study had some limitations. Coronavirus (COVID-19) Pandemic led to prolongation of the sampling process.

In subsequent studies, it is suggested that the study be performed with a higher sample size and expand to infants with various post-menstrual ages, and also that the PIOMI protocol be evaluated in contrast to the exclusive stimulation of music therapy.

Conclusion

PIOMI in combination with music therapy can reduce time to transition to full oral feedings, and reduce the length of hospital stay, thus reducing not only the separation time between a mother and infant, but also reducing the economic burden of a prolonged hospitalization for both families and the country.

Declarations

Ethics approval and consent to participate

Ethical Approval of all procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This study was reviewed and approved by the ethics committee at the University of Social Welfare and Rehabilitation Sciences (IR.USWR.REC.1400.106). Registration of the trial protocol has been approved in Iranian Registry of Clinical Trials at 18/9/2021 (IRCT20210502051155N1), and the written informed consent was obtained from the parents of all children, the ethics committee approved this procedure. We confirm that all experiments were performed in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analysed during the current study is available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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None.

Authors' contributions

The authors confirm contribution to the paper as follows:

study conceptualization and drafting: ESH, TZ, FS

study conception and design: ESH, TZ, FS, BLK, ZM;

data collection: ESH, KGH ;

analysis and interpretation of results: ESH, TZ, FS, MN;

draft manuscript preparation: ESH, TZ, FS, BLK.

All authors reviewed the results and approved the final version of the manuscript.

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Figures

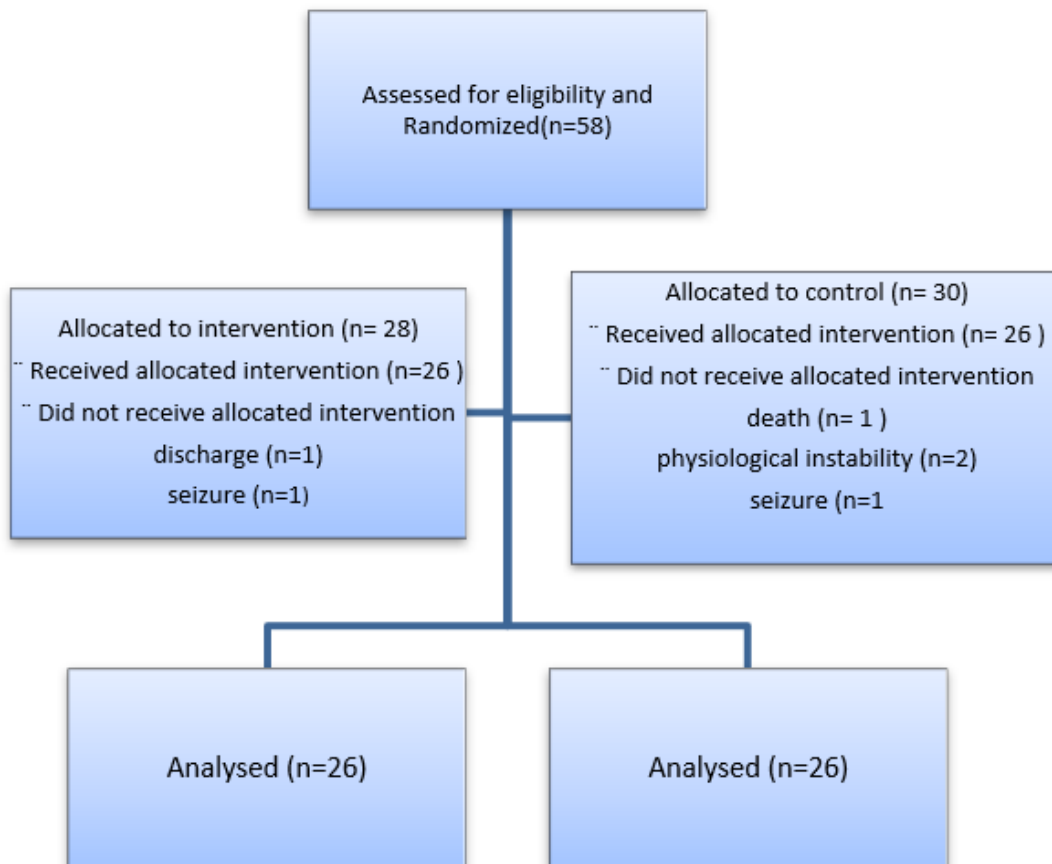


Figure 1

Participants flowchart

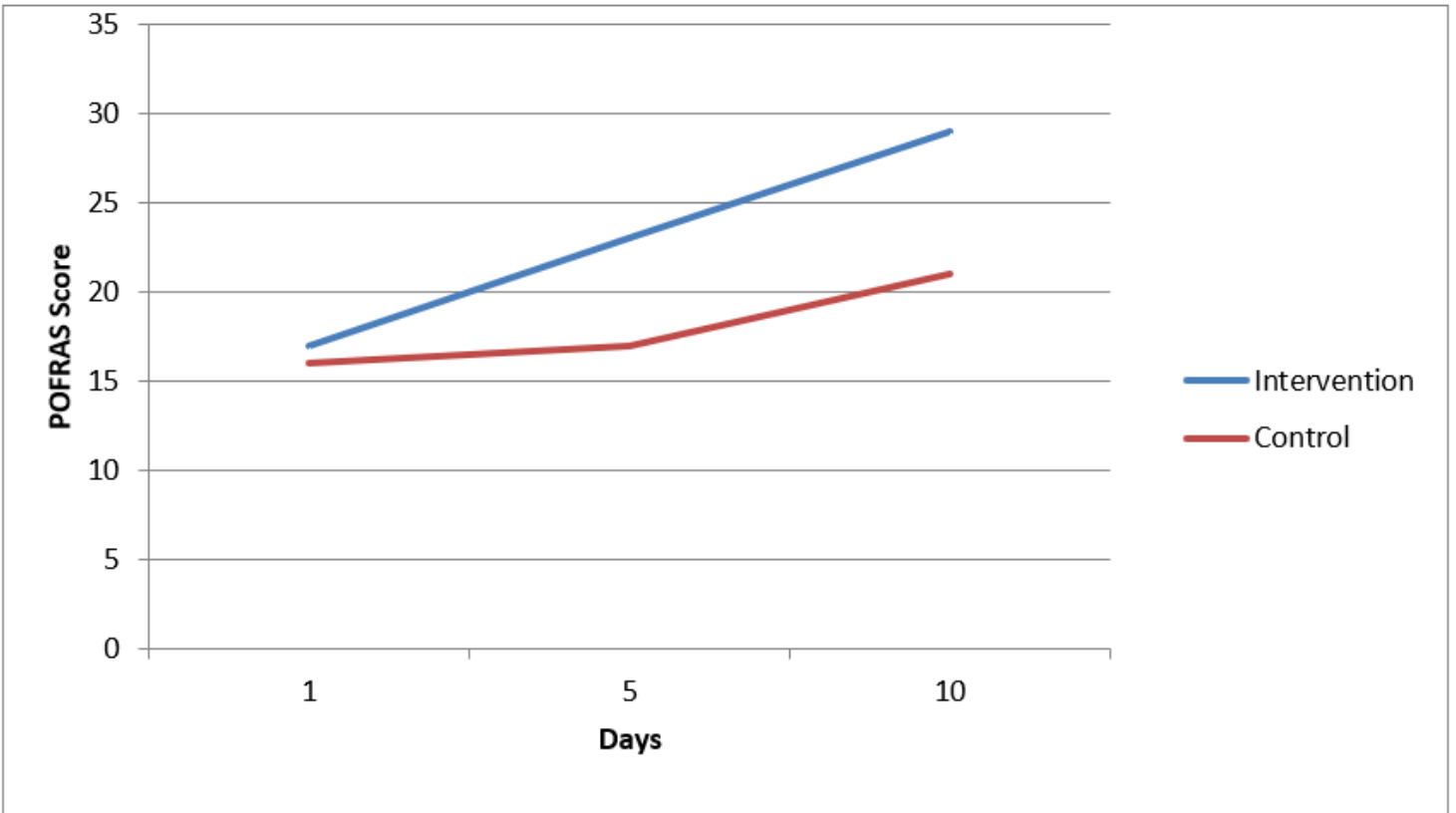


Figure 2

POFRAS Score progression chart on intervention and control groups

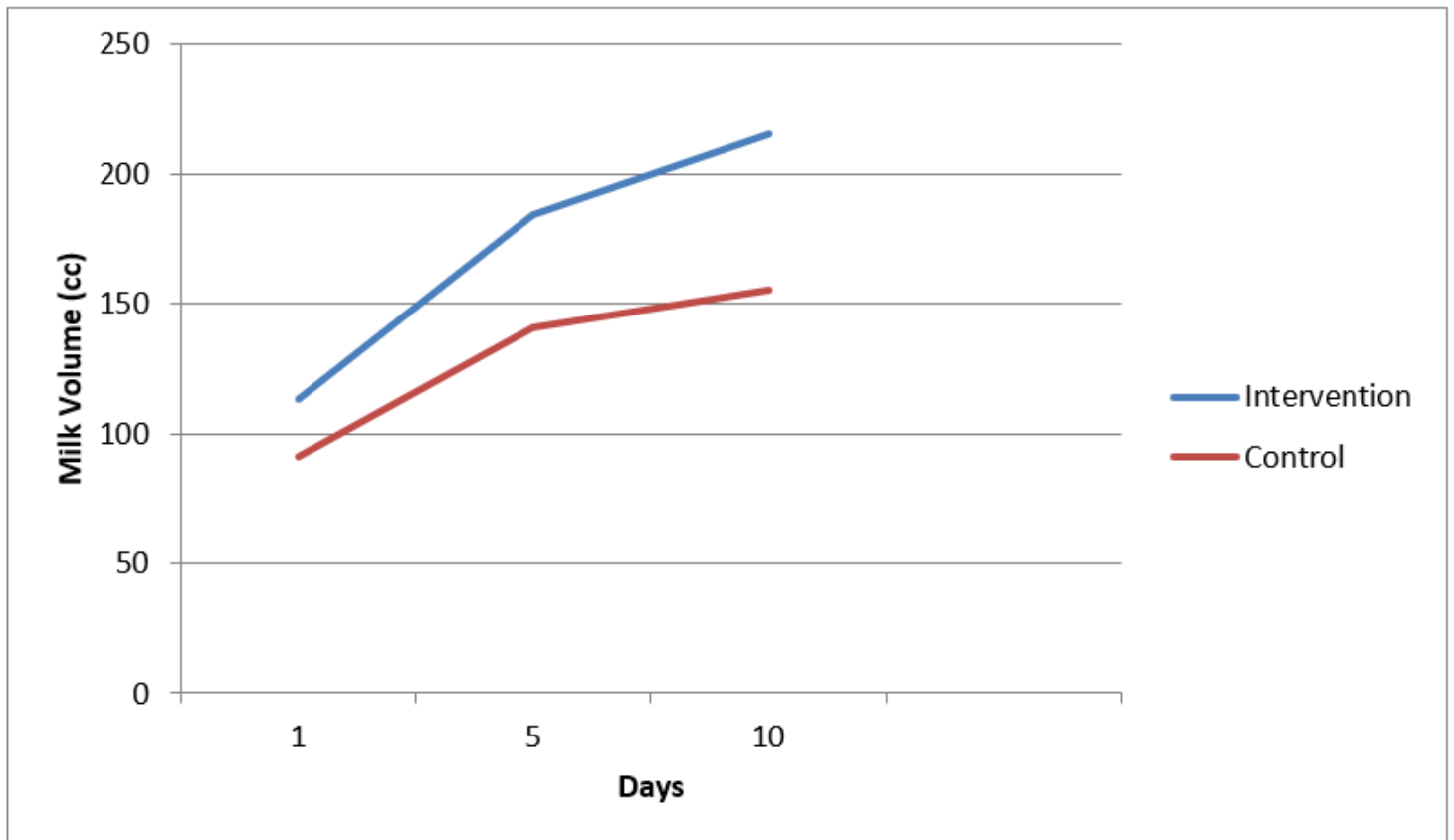


Figure 3

Milk volume progression chart on intervention and control groups