



1 **Key words:** Bottle feeding, breastfeeding, supplemental feeding methods, neonatal  
2 intensive care unit, premature

### 3 **1. Introduction**

4 Independent oral feeding is an important issue for preterm infants, since it predicts  
5 hospital length of stay [1,2]. Among infants with a stable cardiopulmonary status oral  
6 feeding is usually started at postmenstrual age of 33 to 34 weeks. During this period, their  
7 sucking pattern is similar to the pattern of term infants when the two components of  
8 sucking (rhythmic alternation of suction and expression) are considered [1].

9 Any therapy or instrument, improving preterm infants' oral feeding skills, enables them  
10 to perform successful and safe oral feeding, reduces their length of hospital stay,  
11 accelerates the reunion between mother and infant, and reduces medical costs [2].

12 Alternative feeding devices include the use of bottles, supplemental feeding tube devices  
13 (SFTDs), finger feeding, cups, and syringes [3,4]. Many healthcare professionals and  
14 International Board Certified Lactation Consultants recommend supplemental feeding  
15 devices instead of the bottle [3]. The exclusive breast feeding rates and total breast feeding  
16 periods are not found to be in the expected level because of extensive bottle feeding [5].

17 Exclusive breastfeeding in full breastfeeding is defined as the baby not eating or drinking  
18 anything other than breast milk [6]. Breastfeeding is one of the most effective ways to  
19 ensure health and survival of an infant [5]. The World Health Organization (WHO)  
20 launched the "Baby Friendly Hospital Initiative" for support of breastfeeding and has  
21 published the "Ten Steps to Successful Breastfeeding" for facilities providing maternity  
22 and newborn services [7]. The ninth step of these steps is expressed as "Counsel Mothers

23 on the use and risks of feeding bottles, teats and pacifiers." [7]. SFTD is presented as an  
24 alternative for bottle use. There are many "baby-friendly" hospitals in the world and in

1 Turkey [5]. In a systematic review investigating 58 studies on birth and neonatal care, a  
2 correlation was found between giving birth in a baby friendly hospital and improvement  
3 possibility of breastfeeding outcomes and it was obviously indicated that adhering to "Ten  
4 Steps to Successful Breastfeeding" affected the breastfeeding rates [8].

5 In a previous study, it was reported that the bottle feeding rarely maintained a  
6 breastfeeding relationship in five geographic regions (Asia, Australia, Canada, South  
7 America, and the USA), and although it was rarely preferred, it was the most commonly  
8 used feeding method. The majority of the respondents reported that SFTD best preserved  
9 the breastfeeding relationship and it was preferred as reinforcement method [3].

10 Bottle feeding with artificial milk requires less work and the baby reaches milk more  
11 easily. Nevertheless, this intervention does not give the infant access to the beneficial  
12 elements of human milk and does not provide the breastfeeding bond desired by the  
13 mother [9]. SFTD refers to a tool used for supplemental nourishment of the infant during  
14 breastfeeding. This tool has a container containing human milk or artificial milk, being  
15 held by the mother or hung around the mother's neck. A thin tube is attached to the  
16 mother's breast using a tape extending slightly towards sides of the nipple [9].

17 Many lactation consultants have advocated the use of SFTD to maintain a breastfeeding  
18 relationship and to feed the infant in the breast [9]. Although there is insufficient number  
19 of evidence about the use of SFTD [3], the American Academy of Family Physicians, the  
20 United States Breastfeeding Committee, and many health departments like the States of  
21 Indiana and California suggest the use of supplemental feeding tube devices to  
22 supplement breastfeeding [4].

23 Currently, there are three commercially available SFTDs: Supplemental Nursing System  
24 (SNS) (Medela AC, Baar, Switzerland), the Lact-Aid Nursing Training System (Lact-Aid

1 International, Inc., Ponte Vedre Beach, USA), and the Jack Newman Lactation Aid and  
2 Feeding Tube (Lactation Connection, Bluff Dale, Texas) [4]. Despite suggestions for its  
3 use, evidences supporting the use of these devices have not been well described, yet [4,9].  
4 Since the SFTD method provides skin-to-skin contact of the mother with her infant and  
5 allows him/her to suck breast compared to the bottle feeding method, it may also have an  
6 effect on the bonding between the mother and her infant and human milk production. The  
7 purpose of this study was to determine the effects of the SFTD and bottle methods on  
8 weight gain, transition to full breastfeeding, breastfeeding success, and time between  
9 transition to full breastfeeding and discharge in preterm infants.

## 10 **2. Materials and methods**

### 11 **2.1. Study design**

12 This randomized controlled trial was conducted at the level III neonatal intensive care  
13 unit (NICU) with 30 beds in a tertiary hospital with 750 beds in Istanbul between August  
14 2016 and September 2017. The hospital included lactation counselling unit. Moreover,  
15 since it was a baby friendly hospital, a training including 16-hour theory and 4-hour  
16 practice was provided to all nurses working in the hospital. The content of the training  
17 included the subjects related to correct practices of breastfeeding such as the condition of  
18 breastfeeding, importance of human milk, physiology of breastfeeding, problems related  
19 to breastfeeding, baby friendly hospitals, communication, and counselling.

### 20 **2.2. Participants**

21 A power analysis was performed in this study using the LATCH Breastfeeding  
22 Assessment Tool score of a study [10]. The effect size was 1.09, the power was 0.95,  $\beta$   
23 was 0.05, and  $\alpha$  was 0.05. The sample size was determined as a total of 46 preterm infants  
24 including minimum 23 infants for each group. In the CONSORT diagram [11], the groups

1 were shown in Figure 1. Randomization was performed by randomly distributing the  
2 numbers 1-46 into two groups via a computer program without repetition.

3 The inclusion criteria of the study were determined as follows: being at the postmenstrual  
4 age (PMA) of 34 weeks; being  $\leq 1250$  g, having previous enteral feeding via orogastric  
5 tubes, having gavage-based feeding with the human milk, and the mother's willingness to  
6 breastfeed their infant; based on the cue-based feeding approach to readiness for feeding  
7 [12] tolerating enteral feeding, having a stable oxygen saturation and respiratory system  
8 during feeding, having the ability to lick, nuzzle or suck non-nutritive, being able to transit  
9 to the alert state, and rooting in response to touch around the mouth and lips. The  
10 exclusion criteria of the study included having congenital anomaly, sepsis, chromosomal  
11 disorder, and intracranial hemorrhage.

## 12 **2.3. Setting**

### 13 **2.3.1. The infant-mother information and follow-up forms**

14 The form included the items about the infant's gender, birth weight, birth length, and  
15 weight during the first oral feeding, feeding frequency, and weight gain follow-up as well  
16 as mother's age, education level, mode of delivery, number of living children, and  
17 breastfeeding experience.

### 18 **2.3.2. LATCH breastfeeding assessment instrument**

19 Breastfeeding success of the mothers was assessed by using LATCH. The instrument was  
20 developed by Jensen et al. [13] to evaluate mothers' breastfeeding success. This  
21 assessment instrument is comprised of 5 assessment criteria: Latch (L), Audible  
22 swallowing (A), Type of Nipple (T), Comfort [Breast / Nipple] (C), and Hold  
23 [Positioning] (H). Each item is rated between 0 and 2 and total score is 10 points. A high  
24 score signifies successful breastfeeding [13]. This scale was adapted into Turkish by

1 Yenil and Okumuş [13]. The Cronbach's alpha coefficient of the scale was 0.95 [14]. In  
2 this study, the Intraclass Correlation Coefficient (ICC) of the scale was found to be 0.81  
3 LATCH 1st measurement and 0.77 LATCH 2nd measurement. LATCH was routinely  
4 being used in the clinic. Latch assessment was recorded by two nurses independently and  
5 simultaneously during the study.

### 6 **2.3.3. Supplemental nursing system and bottle**

7 In this study, the SNS was used for feeding infants in the study group. The device has two  
8 probes enabling the mother to breastfeed (multiple infants) at the same time from both  
9 breasts. Two tubes in the device for right and left breasts were attached to the mother's  
10 nipple. When the mother breastfed her infant with a probe of the device fixed to her breast,  
11 the other probe of the device was clamped. The SNS is a sterile product with an adjustable  
12 human milk flow system and an adjustable neck strap. It is produced without bisphenol  
13 A (BPA) and all of its parts are directly contact with the human milk. Bottle which has a  
14 narrow mouth and is sterile and latex-free was used for the infants in the control group.  
15 The feeding bottle expands by means of suction-free air-duct feature, thus allowing the  
16 preterm infant to easily suck with low pressure.

### 17 **2.4. Procedure**

18 In the unit, preterm infants were fed with the bottle method. The SFTD method was a  
19 new method for the unit in the supplemental feeding method. Therefore, the SFTD  
20 method was determined as the study group and the bottle method was determined as the  
21 control group. The study was conducted in an empty, quiet room where mothers  
22 breastfeed their infants comfortably between 8:00 am and 4:00 pm on weekdays, at 10:00  
23 am, 1:00 pm and 4:00 pm feeding hours. In the first stage of the study, a breastfeeding  
24 consultant nurse of the unit provided the mothers in both groups with training on

1 breastfeeding. The content of the training included the subjects of importance of human  
2 milk, feeding with breastfeeding, increasing techniques of feeding with human milk, and  
3 providing feeding with quality human milk.

4 During the initial breastfeeding, all the mothers' breastfeeding was independently  
5 assessed by two nurses in the research team at the same time (LATCH, measurement 1).

6 Due to the fact that the preterm infants in the study and control groups experienced  
7 sucking the breast of their mothers and skin-to-skin contact was achieved, mothers tried  
8 to breastfeed their infants for the first 10 minutes. The mothers in the study group  
9 breastfed their infants for 20 minutes using the SNS device (Figure 2). The preterm infants  
10 in the control group were fed by their mothers for 20 minutes with a bottle containing  
11 human milk in their mothers' arms and in the breastfeeding position (Figure 3). The  
12 preterm infants in the study and control groups were fed with human milk using orogastric  
13 tube between 4:00 pm and 8:00 am and at all feeding times on weekends. Until all preterm  
14 infants' transition to full breastfeeding is achieved, 4.4 gr human milk fortifier was added  
15 to 100 ml human milk. The human milk fortification product used in our NICU is  
16 Eoprotin (Milupa AG, Friedrichsdorf, Germany) 4.4 gr of which contain 1.1 gr protein  
17 and 15 kcal energy. Weights of all preterm infants were measured and recorded at 8:00  
18 am every day until they were transition to full breastfeeding.

19 The preterm infants in the study and control groups were breastfed by their mothers  
20 between 8 am and 12 midnight on weekdays and weekends after transition to full  
21 breastfeeding. All preterm infants were fed with human milk using an orogastric tube  
22 from 1:00 am to 8:00 am. During this period, weights of all infants were measured and  
23 recorded every day at 8:00 until discharge. At the last breastfeeding of all preterm infants  
24 before discharge, in order to evaluate the breastfeeding success of their mothers,

1 breastfeeding of the mothers was independently and simultaneously evaluated by two  
2 nurses in the research team using a measuring tool (LATCH, measurement 2).

### 3 **2.5. Ethical considerations**

4 The ethical approval from the Clinical Trials Ethics Committee of the Kartal Dr. Lütfi  
5 Kırdar Training and Research Hospital (IRB: 2016/514/86/4) and institutional permission  
6 from the same hospital were obtained. While informed written consent from the families  
7 were obtained, written permission was received from the author of the scale via-email for  
8 the use of the scale.

### 9 **2.6. Data analysis**

10 The IBM SPSS Statistics 22 (IBM SPSS, Turkey) was used for statistical analysis of the  
11 results of the study. The Shapiro Wilks test was used to evaluate the compatibility of the  
12 variables to normal distribution. The data of the study were evaluated using descriptive  
13 statistical methods (percentage, mean, standard deviation, median). The Student t-test for  
14 assessment of the normally distributed quantitative data between two groups and the  
15 Mann Whitney U test for assessment of non-normally distributed quantitative data were  
16 used. The Wilcoxon Signed Ranks test was used to evaluate the scale scores before and  
17 after STFD in study group. Intraclass Correlation Coefficient (ICC) was used to assess  
18 the interobserver agreement. The Chi-square and Fisher's exact Chi-square tests were  
19 used to assess the qualitative data. Significance was evaluated at the level of  $p < 0.05$ .

## 20 **3. Results**

### 21 **3.1. Descriptive characteristics**

22 There was not any significant difference between both groups in terms of the descriptive  
23 characteristics of the infants and their mothers ( $p > 0.05$ ) (Table 1).



1 **3.2. Weight gain, duration of full breastfeeding, breastfeeding success, and time**  
2 **between transition to full breastfeeding and discharge**

3 The daily weight gain of the infants was  $24.09 \pm 15.21$  gr in the study group and  $27.17 \pm$   
4  $17.63$  gr in the control group. No significant statistical difference was found between the  
5 groups in terms of weight gain ( $p > 0.05$ ). The infants in the study group ( $4.70 \pm 2.44$   
6 days) transitioned to full breastfeeding earlier than the infants in the control group ( $6.00$   
7  $\pm 4.10$  days). No significant statistical difference was found between the groups in terms  
8 of transition time to full breastfeeding ( $p > 0.05$ ). The second LATCH measurement  
9 scores were significantly higher in both groups than 1st LATCH measurement scores ( $p$   
10  $< 0.01$ ). The infants in the study group ( $10.22 \pm 5.20$  days) were discharged earlier than  
11 those in the control group ( $13.48 \pm 8.78$  days). No significant statistical difference was  
12 found between the groups in terms of discharge period ( $p > 0.05$ ) (Table 2).

13 **4. Discussion**

14 A preterm infant's poor sucking capability and irregular sucking rhythm may discourage  
15 the mother from breastfeeding. Hence, mothers may require support and breastfeeding  
16 counselling to breastfeed and/or provide human milk during this period [15,16]. It may  
17 be necessary to support both the newborn, who struggles with grasping the nipple, and  
18 the mother, utilizing the necessary means (i.e. supplementary feeding/supplementation  
19 tools, etc.), in order to ensure a compatible breastfeeding period [17]. Breastfeeding, then,  
20 is primarily recommended when the preterm infants are thought to be ready to be fed  
21 orally [18]. However, given that preterm infants are generally unsuccessful at terms of  
22 sucking and taking the human milk during their initial breastfeeding experienced in their  
23 mothers' breast, it is required to support sucking behaviours with different feeding  
24 methods [19].

1 Cups, bottles, syringes, finger feeding, and the use of SFTDs are recommended as  
2 supplementary feeding methods in the literature [4]. The bottle method is not  
3 recommended since it reduces the intake of human milk in the long term [20,21], even  
4 though this method was used in some previous studies [10,22-25]. Based on the results  
5 of the 2018 Turkey Demographic and Health Survey, it was found that 59% of infants  
6 aged between 0-1 months were fed exclusively with human milk [26]. This rate decreased  
7 to 10% in infants aged between 4-5 months due to the use of bottle [27]. It has been  
8 reported that the SFTDs can help protect the breastfeeding relationship and contribute to  
9 the WHO's goal of increasing specific breastfeeding rates [3].

10 The infants in the study group transitioned to full breastfeeding within a shorter time and  
11 were discharged from the hospital earlier; however, their weight gain was less than the  
12 control group. Higher weight gain in the control group may be associated with the fact  
13 that it is easier for the infants to access the human milk from the bottle and they can also  
14 suck it more. In a randomized controlled trial conducted in Australia, it was reported that  
15 the novel feeding system (SFTD) and bottle fed groups were similar in terms of the period  
16 of transition to full breastfeeding and those in the novel system group stayed in the  
17 hospital for a shorter time [28]. In a systematic review, SFTD method was found to be  
18 beneficial for breastfeeding mothers as a supporting breastfeeding method [4].

19 In this sense, the strength of the present study is that all of the infants reaching full  
20 breastfeeding were breastfed by their mothers and thus discharged. 91.3% (n = 21) of the  
21 mothers in the study group were satisfied with the SFTD method. On the other hand, two  
22 mothers were unsatisfied with the device since they thought that the device only made  
23 breastfeeding more difficult, the rate of flow was high, and the probe tip was stiff. In a  
24 study conducted in America, the opinions of 22 mothers who used SFTDs, were taken. It

1 was reported that many mothers liked the device, but some others did not; likewise,  
2 several stated that even though they disliked the device, it helped them. It was determined  
3 that the mothers liked the device because the SFTD allowed them to successfully  
4 breastfeed their infants, to continue breastfeeding, and to have the desired breastfeeding  
5 relationships. The mothers who disliked the device described it as “bulky”, “time-  
6 consuming”, “artificial”, “complex”, “difficult to use”, and “untidy”. In conclusion, it was  
7 reported that SFTD was an acceptable valuable alternative in terms of helping mothers  
8 achieve their breastfeeding goals [9].

9 The fact that majority of the mothers using SFTD were satisfied with the method was a  
10 very important motivation for the present study. This method moreover helped mothers  
11 and their infants to spend 30 minutes together in a safe environment, which in turn  
12 resulted in skin-to-skin contact between the mother and infant via the breastfeeding.

#### 13 **4.1. Study limitations**

14 Limitation of the study was that SFTD was applied only between 8:00 am and 4:00 pm  
15 on weekdays. Therefore, the infants were given human milk via an orogastric tube  
16 between 4:00 pm and 8:00 am. In addition to, after transition to full breastfeeding, the  
17 mothers were in the hospital between 8:00 am and 12:00 midnight. These limitations may  
18 have an effect on the preterm infant's transition to full breastfeeding and the duration of  
19 hospitalization. Although the infants in the SFTD group had skin to skin contact with  
20 their mothers for 30 minutes and the infants in the bottle group for 10 minutes, the effect  
21 of skin-to-skin contact was not evaluated due to the time difference between the groups.

#### 22 **5. Conclusion**

23 The SFTD and bottle feeding methods were determined to be similar in terms of daily  
24 weight gain, transition to full breastfeeding, breastfeeding success, and duration of

1 hospitalization. The SFTD method can be used as an alternative method in the process of  
2 transition to full breastfeeding of preterm infants. It was concluded that the SFTD was an  
3 effective feeding method among systems supporting the breastfeeding for feeding of the  
4 preterm infants in NICU and the mothers were satisfied with this method. It is important  
5 for lactation consultants, nurses and caregivers to have the knowledge and skills for  
6 providing the best supplemental feeding method to a mother and her infant in order to  
7 maintain a breastfeeding bonding. It may be recommended to conduct future studies with  
8 large sample groups to compare SFTD and other feeding methods and to examine with  
9 parameters such as physiological variables, anthropometric measurements, feeding  
10 tolerance and bonding during the transition of the preterm infant to full breastfeeding.

#### 11 **Acknowledgement and/or disclaimers, if any**

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4 **Table 1.** Characteristics of infants and mothers (n=46).

<b>Preterm infants</b>		<b>Study group (n=23)</b>	<b>Control group (n=23)</b>	<b>p</b>
		<b>Median (Min-Max)</b>	<b>Median (Min-Max)</b>	
Birth weight (gr)		1730 (600-2480)	1585 (680-2200)	<sup>1</sup> 0.560
Birth length (cm)		40 (30-49)	40 (31-45)	<sup>1</sup> 0.965
Weight in the first oral feeding		1750 (1300-2450)	1705 (1330-2670)	<sup>1</sup> 0.684
		<b>n (%)</b>	<b>n (%)</b>	<b>p</b>
Gender	Female	9 (39.1)	11 (47.8)	<sup>3</sup> 0.767
	Male	14 (60.9)	12 (52.2)	
<b>Mothers</b>		<b>Median (Min-Max)</b>	<b>Median (Min-Max)</b>	<b>p</b>
Age (year)		28 (18-44)	30 (20-41)	<sup>2</sup> 0.259
Gravida		2 (1-4)	2 (1-5)	<sup>1</sup> 0.966
Previous experience breastfeeding (month)		14 (2-30)	12 (1-24)	<sup>1</sup> 0.334
		<b>n (%)</b>	<b>n (%)</b>	<b>p</b>



Level of education	Elementary	12 (52.2)	14 (60.9)	<sup>3</sup> 0.766
	≥ High school	11 (47.8)	9 (39.1)	

1 Note = The values are presented as median (min-max).

2 <sup>1</sup>Z: Mann Whitney U Test    <sup>2</sup>Student t Test

3 <sup>3</sup> $\chi^2$ : Chi-square and Fisher's exact Chi-square tests

4 **Table 2.** Distribution of infants with weight gain, full breastfeeding, breastfeeding  
5 success, and duration of discharge (n=46).

Feeding Methods	Study group (n=23)	Control group (n=23)	p
	Median (Min-Max)	Median (Min-Max)	
Weight gain (day)	23 (3-54)	24 (1-65)	<sup>1</sup> 0.605
Transition to full breastfeeding (day)	4 (1-11)	4 (1-14)	<sup>1</sup> 0.490
<b>Breastfeeding success (LATCH)</b>			
LATCH 1st measurement score	8 (6-10)	8 (6-9)	0.135
LATCH 2nd measurement score	10 (9-10)	10 (8-10)	0.413
p	<sup>4</sup> 0.001*	<sup>4</sup> 0.001*	

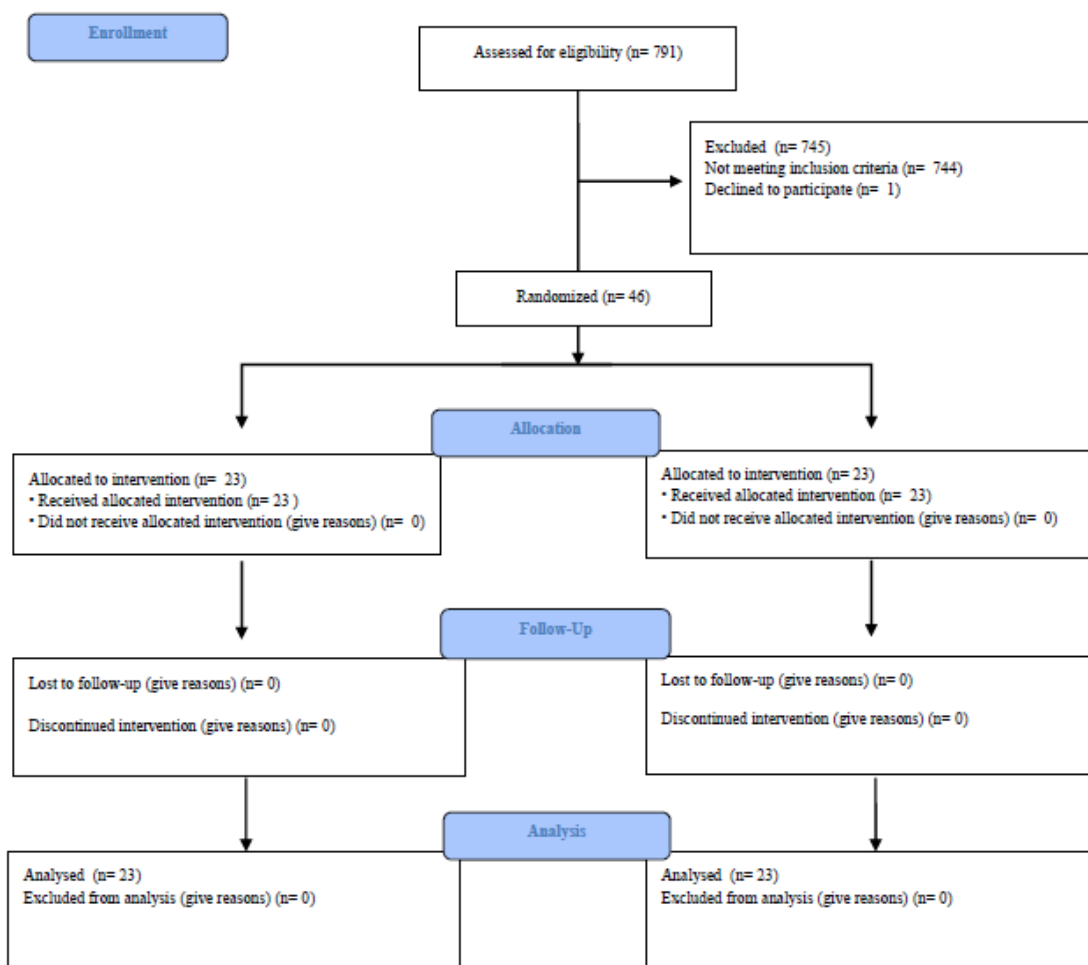
Time between transition to full breastfeeding and discharge (day)	10 (2-27)	11 (2-38)	<sup>1</sup> 0.321
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1 Note = The values are presented as median (min-max).

2 <sup>1</sup>Z: Mann Whitney U Test

<sup>4</sup>Z: Wilcoxon Signed Ranks test

3 \**p* < 0.01



4

5 **Figure 1.** CONSORT flow diagram.



1

2 **Figure 2.** The study group.





1

2 **Figure 3.** The control group.