

## Comparison of Clustered Care with Three and Four Procedures on Physiological Responses of Preterm Infants: Randomized Crossover Clinical Trial

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### ABSTRACT

**Introduction:** Preterm infants are under different procedures as a part of their care in the Neonatal Intensive Care Unit (NICU). Reduction of their stress and to provide rest opportunity for them is very important. In this regard, clustering of routine care is recommended. The aim of this study was to compare of physiological responses in preterm infants to clustered care with three and four noninvasive procedures (Respectively 7 and 10 point stressor).

**Methods:** A randomized crossover clinical trial performed in NICU of Al-Zahra teaching hospital, Tabriz, Iran in 2013. Thirty one preterm infants were studied at 32 weeks gestational age. The tool for data collection was a researcher-made data gathering sheet that personal information and measurement of primary outcomes (heart rate, respiratory rate and blood oxygen saturation) were recorded. The analysis of data was done with use of mixed model method at 0.05 significant level.

**Results:** Mean of oxygen saturation in before, during and after of clustered care with three procedures were respectively 97.52, 97.32, 97.84 and four procedures 97.29, 97.16, 97.35, heart rate of three procedures 146.26, 149.90, 149.97 and four procedures 146.45, 150.39, 151.13, respiratory rate of three procedures 51.68, 48.87, 47.71 and four procedures 51.71, 50.26, 52.35 that all of them were at normal range. Significant differences were not found between mean of physiological responses in two interventions.

**Conclusion:** There was no significant difference between clustered care with four and three procedures. Both of them could be recommended for preterm infants in 32 weeks.

## Introduction

Improvement on prenatal and neonatal care has reduced the mortality rate of preterm infants that they have high risk of developmental deficiency. The challenge that professional health care providers who caring from these infants and their families are facing is not only to ensure infant survival but is optimizing development process and developmental outcomes of infants.<sup>1</sup> Preterm infants necessarily are developing in environment that is stressful on different aspects for them.<sup>2</sup> Also for keeping on their

life, they need for intensive care and invasive procedures. The imposed stress on infants by these procedures may cause neurological damage and as a result abnormal development of infant.<sup>3</sup> Especially due to developing brain vulnerability in preterm infant, activities that may cause adverse outcomes are not limited to invasive or painful procedures, but may include routine care or normal handling.<sup>4,5</sup> Various studies showed that preterm infants receive a mean of 10 to 16 painful procedures per day at the first days of their life.<sup>6</sup> Also epidemiological

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investigations estimated that these infants receive 16 distressful procedures daily at first 14 days of hospitalization in NICU.<sup>7</sup>

The developmental care process has simulated of intrauterine environment and tries to reduce stressors of environment that preterm infant will be in it and create for him/her the environment similar to the uterus.<sup>8</sup> The Synactive theory and Newborn Individualised Developmental Care and Assessment Programme (NIDCAP) emphasize on promotion of clustered care.<sup>9</sup> Clustered care is clustering several routine or nursing care events together rather than spacing them out over time. The main goal of clustering care is allowing the infant to have longer periods of rest.<sup>10</sup> At the same time, clustering or scheduling of routine care in infants being born at lower gestational age, was associated with lower oxygen saturation, more behavioral responses related to stress and negative stress responses.<sup>4,11</sup> Others emphasize on cue-based care dependent on received feedback related to stress status of infant and his readiness for the care receiving.<sup>4</sup>

Little modifications to routine care practices such as swaddled bathing or swaddled weighing for reduction of infant stress is useful.<sup>10</sup> Also clustering care for provide longer periods of rest is recommended but this should not cause that preterm or patient infant falls to the challenge because of long-term care. In fact some studies showed that when is provided periods of rest for stable preterm infants, they sleep more, gain more weight and have rapid reduction in apnea incidence. These advantages may be greater.<sup>12</sup>

Holsti and coworkers found that mean heart rate of preterm infants increases significantly at clustered care after blood sampling compared to clustered care after rest, whereas sleep/wake state have not any difference at clustered care after blood sampling and clustered care after rest.<sup>11</sup> In other study has been shown that there is no difference at sleep/wake state between blood

sampling after rest and blood sampling after clustered care. Also no meaningful difference was found on heart rate changes between two above mentioned condition.<sup>12</sup>

According to increase of preterm birth rate, adverse effects of stress on preterm infants at period of hospitalization in NICU and recommendation of clustered care as a strategy for reduction of their stress,<sup>2,12,13</sup> also since which one of special nursing interventions and how compose with each other in the clustered care is unknown<sup>1</sup> and has been emphasized on necessity of studies related to assessment of infants responses to clustered care,<sup>11</sup> study in this field seems necessary. With expanded review of local and foreign literature found only few studies related to clustered care, in all of these studies clustered care was included changing the diaper, measuring abdominal girth, taking the axillary temperature and mouth care.<sup>11,12,14,15</sup> Also there are no information about clustered care with different noninvasive procedures. Specially the objective assessment of preterm infants tolerance threshold are not addressed throughout mentioned studies. Therefore further examination of the specific effects of clustered care is vital. The aim of this study was to compare of physiological responses changes (heart rate, respiratory rate and blood oxygen saturation) of hospitalized preterm infants to clustered care with three and four noninvasive procedures respectively 7 points and 10 points stress level.

It assumed more than two procedures as clustered care and preferred to use newnham *et al.*, stressor scoring system as the base for determine the safe clustered care.

## Materials and methods

The present study was a randomized crossover clinical trial with allocated ratio of 1:1 that was conducted from May 2013 to July 2013 at the NICU of Al-Zahra teaching hospital affiliated to Tabriz University of Medical Sciences, Iran.

The study population includes all preterm infants that hospitalized in NICU of Al-Zahra teaching hospital, Tabriz. The study sample comprised preterm neonates who had the following inclusion criteria: 30 to 32 weeks gestational age at birth, 32 weeks gestational age during the study, minimum weight of 1000 g, consent form is signed by parents, absence of congenital anomalies, written order of related physician for gavage, without prohibited changing position, respiratory score lower than or equal to five and apgar of fifth minute 7 or greater.

The respiratory score is utilized for judging the severity of respiratory distress in infants who are breathing spontaneously. This score had presented by Downes and colleagues in 1970 and is a set of six components of the respiratory assessment; respiratory rate, oxygen requirement, retractions, grunting, breath sounds on auscultation and prematurity, each component is scored from 0 to 2. Respiratory score below 5 is acceptable.<sup>16</sup>

Infants with septicemia, significant intraventricular hemorrhage (grade 3 and 4) and/or periventricular leukomalacia, as well as infants, who had need for mechanical ventilation or steady decline in heart rate, oxygen saturation and respiratory rate of normal range, were excluded.

The convenience method was used to neonates sampling. Then allocation of samples to the groups performed with use of random blocks permutation method. The sample size estimated based on a pilot study. GPOWER software was used to calculate the sample size estimate, primary outcomes of study include mean and standard deviation of heart rate and blood oxygen saturation intra class changes according to pilot study samples from 6 infants was gathered. In order to obtain the greatest accuracy, minimum amount of effect size (0.27) was used. With considering confidence interval %95, power of 0.80, two type of clustering procedures and three repeated measurements

the minimum required sample size for each group estimated 31 cases.

The researcher after taking approval of ethics committee with code No. 9220 and registration of study in the Iranian Registry of Clinical Trials, corporation with Al-Zahra teaching hospital officials and taking written informed consent of parents, study subjects comprise infants were qualified for entering to study have studied at the evening shift. A single research nurse carried out clustered care of all samples. Infants were randomly divided into two groups, for each group was conducted at one day clustered care with three procedures and at other day clustered care with four procedures (Figure 1). First, infants' demographic information collected from infants' records then according to the crossover design of study and the group that infant was in it, clustered care times were performed. At each time; after devoting 30 minutes to rest, respiratory score was calculated and recorded for infants, two cameras, Canon PC1732 model, one of them was focused on the infant to examine the respiratory rate and the other was focused on monitor screen, Masimo S 1600 model, to evaluate other physiological measures including heart rate and blood oxygen saturation were installed, both cameras simultaneously were switched on two minutes before the clustered care, during clustered care and by two minutes after it had continue video recording. Data related to each infant were completed in two days.

At one time; clustered care was included three noninvasive procedures (stressor score seven) consists of taking the axillary temperature (2 points), change location of pulse oximeter probe (2 points) and changing position (3 points) and in other time; four noninvasive procedures (stressor score ten) consists of taking the axillary temperature (2 points), change location of pulse oximeter probe (2 points), gavage (3 points) and changing position (3 points) were performed. After completion of work, the recorded films were reviewed and physiological responses

(heart rate, blood oxygen saturation and respiratory rate) were evaluated, all the information was recorded in researcher-made data gathering sheet that had same code with the movie. Mean HR, O<sub>2</sub>sat and RR were calculated in total length of two minutes before, during and after two minutes of clustered care. Imposed stress of clustered care with three and four procedures was calculated based on their procedures according to Newnham developed (2009) Neonatal Infant Stressor Scale (NISS). The flowchart of study shows in figure 1.

Data gathering sheet developed by researchers and the validity was evaluated according to content and face validity with obtaining comments of ten academic members of Tabriz University of medical sciences then required reformations was applied. Evaluating of reliability was done with kappa Cohen observers' agreement via same time observation of six infants' videos by two observers. The value of inter-observers correlation was 0.98 which shows an excellent agreement. Also, calibration of digital devices include monitor before implementing the study was approved by the engineer.

The data were summarized with use of mean (standard deviation). In addition, K-S test was used to normality assessment.

At present crossover design the group effect, time effect and carry over effect were analyzed using mixed model with choose of covariance structure AR1 (AIC criterion) and restricted maximum likelihood method (REML). There was no interaction between time and clustered care with three and four procedures (carry over effect) hence no results were reported. The confounding variables including age, weight, respiratory status, respiratory score and duration of clustered care were entered to the model and their effects were adjusted. Logarithmic transformation was applied to non-normal variables include duration of clustered care. The evaluation and analysis of data was done

with use of STATA 10 software at 0.05 significant level.<sup>17-19</sup>

## Results

Total of 31 preterm infants (15 males, 16 females) were studied at two time, one time clustered care with three procedures (7 stressor score) and other time clustered care with four procedures (10 stressor score). All infants were born at same center that they were hospitalized. Mean and standard deviation of infants gestational age at birth was 31.3(0.8) weeks and their weight at birth was 1476.8(317.2) gram. In addition, mean and standard deviation of infants' primary hemoglobin was 16.7(2). Most infants who participated in the study were born by cesarean section and were singleton, also the most common cause of hospitalization was prematurity & R/O RDS (According to ICD10; P07: prematurity and short length of pregnancy period). All the infants had negative primary blood culture, but most of them blood culture at hospitalization period was unknown and not checked (Table 1).

About respiratory status and respiratory score, most infants (80.6%) were without supplemental oxygen before clustered care with three and four procedures and 67.7% of them had respiratory score one. Mean and standard deviation of infants age on study day of clustered care with three procedures was 32.36 (0.18) weeks and for clustered care with four procedures 32.36 (0.19) weeks. Mean and standard deviation of their weight on study day of clustered care with three procedures was 1391.3 (257.9) gram and for clustered care with four procedures 1398.7 (273.3) gram. Also mean and standard deviation of clustered care duration in clustered care with three procedures was estimated 1.12 (0.23) minutes and for clustered care with four procedures 1.79 (0.43) minutes. Age, weight, respiratory status, respiratory score and duration of clustered care variables as confounding variables statistically were tested that were

not significant, only the duration of clustered care was significant ( $P < 0.001$ ).

**Table 1.** Infants characteristics (demographic and health related) (n=31)

Variables	Frequency N (%)
<b>Delivery type</b>	
Vaginal	9(29)
Cesarean	22(71)
<b>Number of concurrent fetus</b>	
Singleton	21(67.8)
Twin	9(29)
Triplet	1(3.2)
<b>Cause of hospitalization</b>	
Prematurity	8(25.8)
Prematurity & R/ORDS	18(58.1)
Prematurity & RDS	5(16.1)
<b>Apgar of first minute</b>	
4	1(3.2)
5	2(6.5)
6	4(12.9)
7	4(12.9)
8	14(45.2)
9	6(19.3)
<b>Apgar of fifth minute</b>	
7	5(16.1)
8	3(9.7)
9	16(51.6)
10	7(22.6)
<b>Primary blood culture</b>	
Negative	31(100)
Positive	0(0)
<b>Blood culture at hospitalization period</b>	
Unknown	29(93.5)
Negative	2(6.5)
Positive	0(0)

The mean and standard deviation of heart rate on clustered care with three procedures, increased from 146.26 (13.15) during two minutes before clustered care to 149.90 (13.24) during the clustered care and to 149.97 (13.01) during two minutes after clustered care. During clustered care with four procedures, it increased from 146.45 (11.93) during two minutes before clustered care to 150.39 (15.15) during the clustered care and to 151.13 (15.68) during two minutes after clustered care. Significant statistical difference was observed

across the three phases of clustered care with 7 points stressor [ $F(2,60)=4.31$ ;  $P= 0.018$ ] and three phases of clustered care with 10 points stressor [ $F(2,60)=5.93$ ;  $P= 0.004$ ] (Figure 2). There was statistical difference between before and during phases of clustered care with three procedures. Statistical difference was between before and during, also before and after phases of clustered care with four procedures. About between groups difference, significant statistical difference was not observed between before, during and after clustered care with three procedures compared to four procedures (respectively  $P= 1.00, 0.99, 0.96$ ).

The mean and standard deviation of blood oxygen saturation on clustered care with three procedures decreased a little from 97.52(1.43) during two minutes before clustered care to 97.32 (1.70) during the clustered care and returned to 97.84 (1.29) during two minutes after clustered care. During clustered care with four procedures, decreased from 97.29(1.37) during two minutes before clustered care to 97.16 (1.71) during the clustered care and increased to 97.35(1.78) during two minutes after clustered care. There was not significant statistical difference across the three phases of clustered care with 7 stressor score [ $F(2, 51) =2.93$ ;  $P= 0.071$ ] and three phases of clustered care with 10 stressor score [ $F(2, 51) =0.24$ ;  $P= 0.742$ ] (Figure 3). Related to between groups difference; significant statistical difference was not found between the mean of blood oxygen saturation on before, during and after clustered care with three procedures compared to four procedures (respectively  $P= 0.811, 0.957, 0.501$ ).

The mean and standard deviation of respiratory rate on clustered care with three procedures, decreased from 51.68 (10.27) during two minutes before clustered care to 48.87 (7.77) during the clustered care and to 47.71 (6.83) during two minutes after clustered care. During clustered care with four procedures, decreased from 51.71 (9.51)

during two minutes before clustered care to 50.26(8.44) during the clustered care and increased to 52.35(9.56) during two minutes after clustered care. There was significant statistical difference across the three phases of clustered care with three procedures [ $F(2,40)=8.29$ ;  $P= 0.003$ ] and three phases of clustered care with four procedures [ $F(2,46)=4.49$ ;  $P= 0.024$ ] (Figure 4). Statistical difference was between before and during, also before and after phases of clustered care with three procedures. There was statistical difference between before and during, also during and after phases of clustered care with four procedures. The mean of respiratory rate showed statistical difference between clustered care with three procedures compared to four procedures (respectively  $P= 1.00, 0.830, 0.045$ ), only on after phase of clustered care was significant.

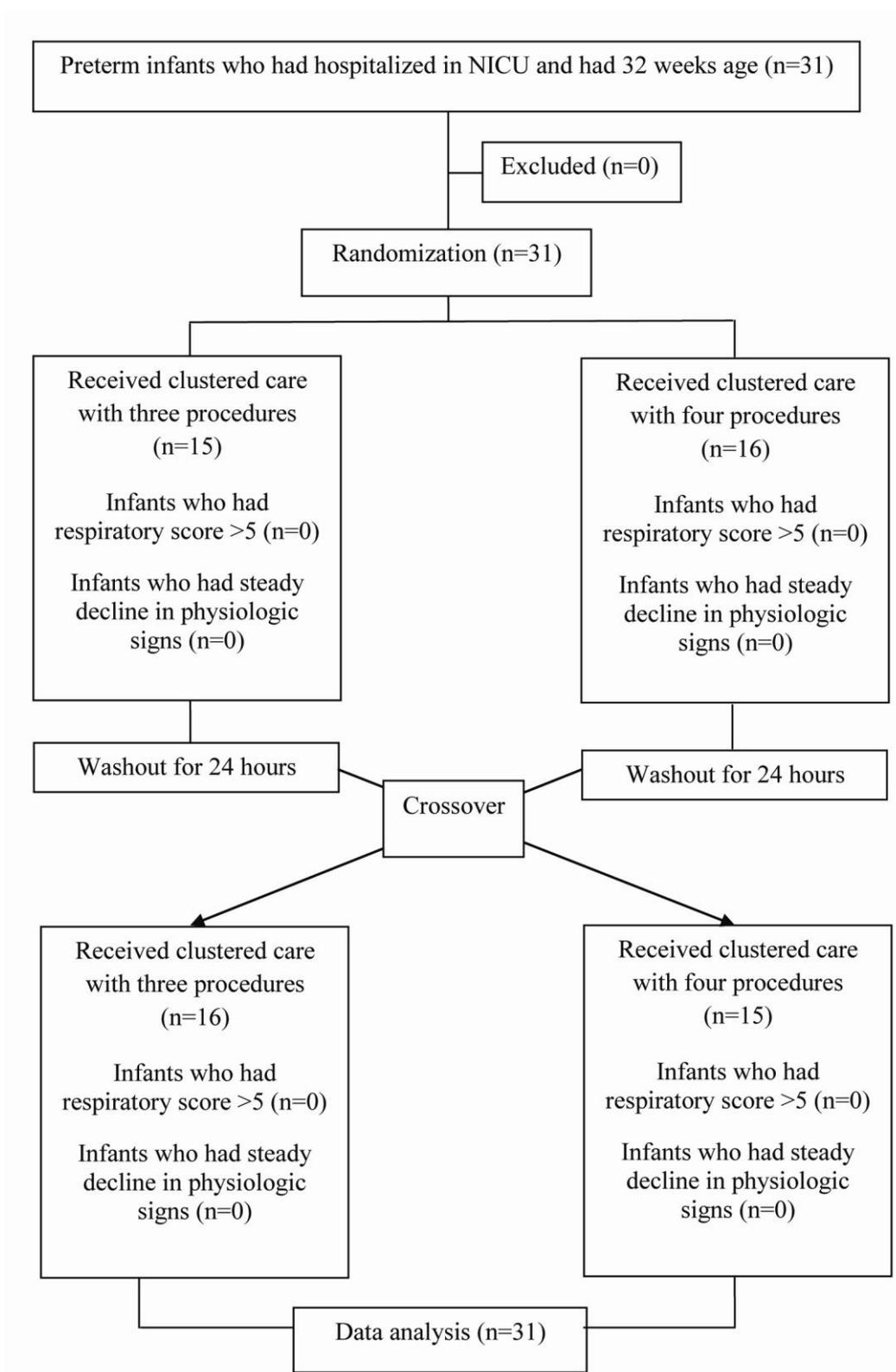
In total can be stated that revealed no significant differences in physiological responses changes on clustered care with three procedures compared to four procedures, therefore both of clustered care can be assumed the same and acceptable which did not alter generally the heart rate, blood oxygen saturation and respiratory rate.

## Discussion

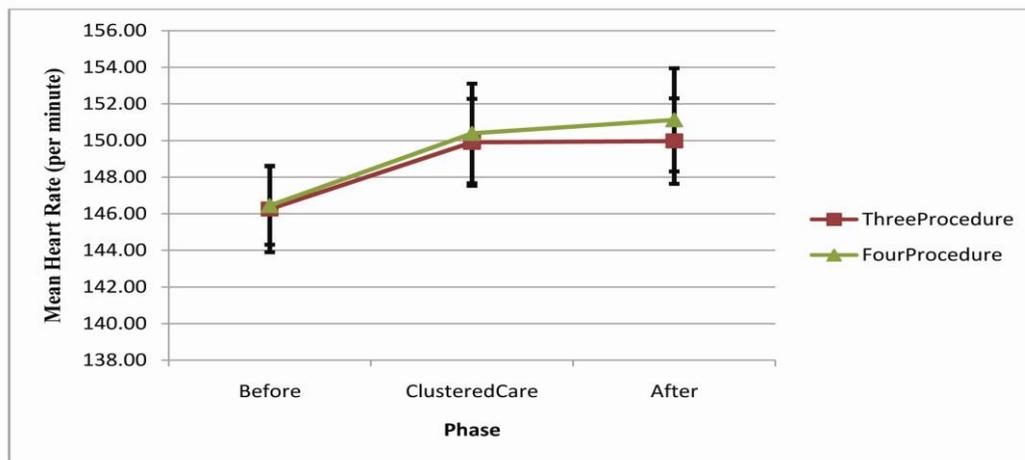
This study is the first research that has included several noninvasive procedures in clustered care to examine the effects on physiological responses in preterm infants. The included procedures in clustered care are performed many times in day routinely and are different from previous studies clustered care. More importantly, for classification of different procedures was used Newnham developed neonatal infant stressor scale<sup>2</sup> and imposed stress on infant was scored by each of clustered care.

In our study, the mean of infant's heart rate increased a little during and after of both the clustered care with three procedures and four procedures compared to before phase that these were in the normal range of heart rate.

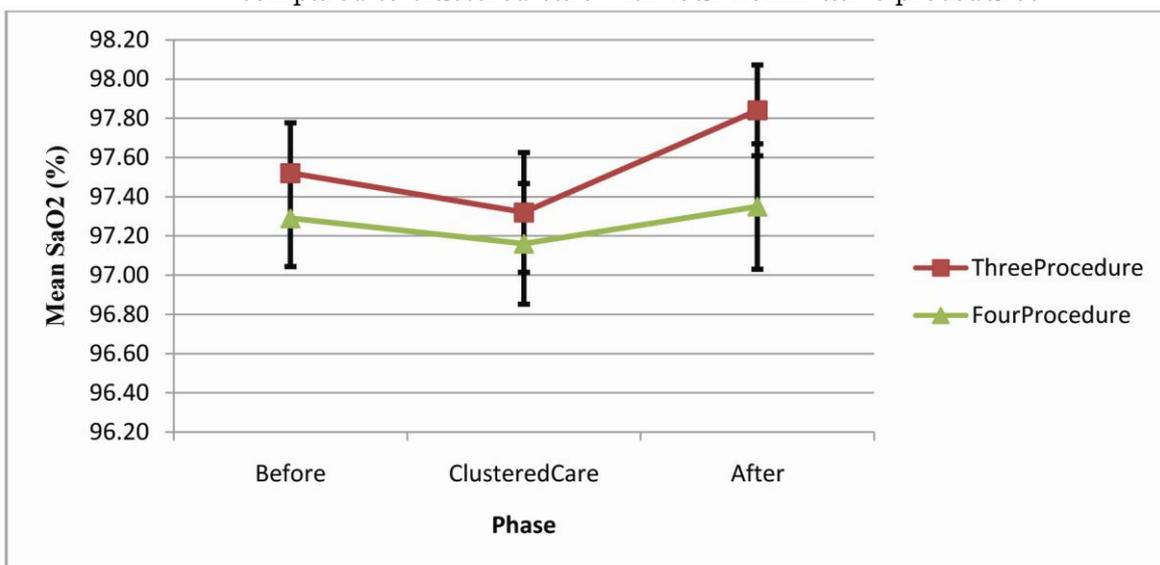
This increase was slightly more on clustered care with four procedures that is negligible. The findings of this study may be in contrast to previous studies which show that mean of heart rate increase during clustered care compared to before phase then decrease on after phase. This may be related to different types of time measurements. The time of each phases were 4 minute versus current study of 2 minute.<sup>11,14</sup> But significant statistical difference was observed across the three phases of clustered care with three procedures and four procedures in our study is in agreement with findings of Holsti et al. which showed significant statistical difference across the three phases of clustered care ( $p<0.001$ ).<sup>11,14</sup> The mean of blood oxygen saturation decreased a very little during both the clustered care with three procedures and four procedures compared to before phase then increased on after phase that overall these were in the normal range of blood oxygen saturation. Our findings are supported by Holsti et al., who have reported decrease of oxygen saturation during clustered care compared to before phase then increase on after phase.<sup>14</sup> There was not significant statistical difference across the three phases of clustered care with three and four procedures while Holsti et al., showed significant statistical difference across the three phases of clustered care.<sup>14</sup> In this regard type of procedures that has included in their clustered care can be involved. In addition, the mean of infant's respiratory rate decreased during and after clustered care with three procedures compared to before phase while it decreased during clustered care with four procedures compared to before phase and increased on after phase, totally were not outside the normal range of respiratory rate. Previous studies had not examined infant's respiratory rate as one of physiological responses. There was significant statistical difference across the three phases of clustered care with three procedures and four procedures.



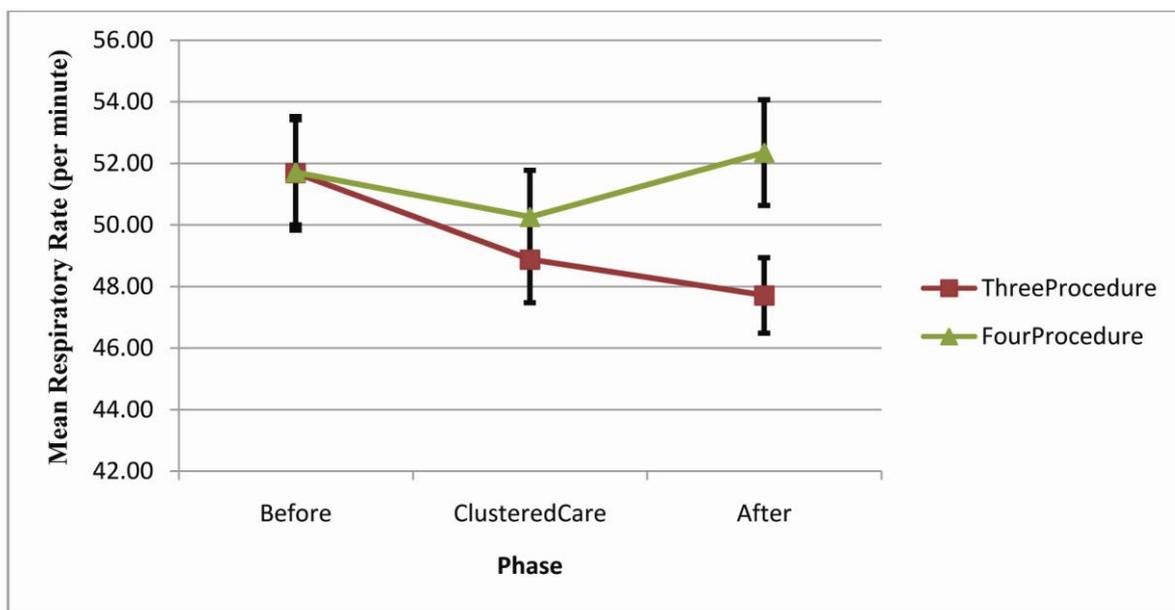
**Figure 1.** Flow chart of the study



**Figure 2.** 95%CI for mean of heart rate during clustered care with three noninvasive procedures compared to clustered care with four noninvasive procedures



**Figure 3.** 95% CI for mean of blood oxygen saturation during clustered care with three noninvasive procedures compared to clustered care with four noninvasive procedures



**Figure 4.** 95% CI for Mean of respiratory rate during clustered care with three noninvasive procedures compared to clustered care with four noninvasive procedures

Some factors such as loud noises of unit include staff speaking, unnecessary traffic and alarms of different machines could not be controlled that may be changed physiological responses. Also infants who had some medical and

congenital problems were not entered to study, so results of present study may not be generalized for such infants.

## Conclusion

Findings of this study show that the physiological signs of clustered care with four noninvasive procedures as no significant difference with three noninvasive procedures; both of them could not cause considerable changes on physiological responses of infants with 32 weeks age, so there are acceptable for clustering in 32 weeks. Stress scores of performed clustered care in present study were seven and ten, so the amount of stress can be assumed acceptable for such infants. Examine the effects of clustered care with noninvasive procedures different from previous studies, created some new information; we hope that

results of present study will be used for promotion of developmental care in order to reduce the development possible complications of hospitalized preterm infants in neonatal intensive care unit.

According to findings of this study we recommend that clustered care will be considered as an essential caring method in NICUs, policies be done in order to further implementation of it and all nurses should be aware of information in this field.

We suggest that further studies examine clusters of other noninvasive procedures, be studied sleep/wake state and behavioral responses of preterm infants together with physiological responses; also clustering of more than four procedures seems necessary.

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## Ethical issues

None to be declared.

## Conflict of interest

There is not any conflict of interest to disclose in this study.

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