



Comparing the effects of auricular seed acupressure and foot reflexology on neonatal abstinence syndrome: A modified double blind clinical trial



Shimaalsadat Sajadi^a, Majid Kazemi^{b,*}, Babak Bakhtar^c, Hamid Ostadebrahimi^d

^a School of Nursing and Midwifery, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

^b Department of Medical Surgical Nursing, Faculty of Nursing and Midwifery, Non-Communicable Disease Research Center, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

^c Department of Management of Treatment, Iran Social Security Organization, Rafsanjan, Iran

^d Department of Pediatrics, Faculty of Medicine, Non-Communicable Disease Research Center, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

ARTICLE INFO

Keywords:

Neonatal abstinence syndrome

Foot reflexology

Auricular acupuncture

ABSTRACT

Background: The neonates of addicted women are at risk for neonatal abstinence syndrome. This study aimed to compare the effects of auricular seed acupressure and foot reflexology on neonatal abstinence syndrome among the neonates of addicted women.

Methods: Thirty one neonates of addicted women were purposively recruited and randomly allocated through coin flipping to receive either foot reflexology then seed acupressure or seed acupressure then foot reflexology. Interventions were performed in two successive days with a 12-h washout interval. Foot reflexology was applied for 15 min to the first horizontal zone of the sole while seed acupressure was applied for 24 h through attaching acupuncture-specific ear seeds to the posterior surface of the auricle on the SJ 17 acupoint. The symptoms of abstinence syndrome were assessed using Finnegan Neonatal Abstinence Scoring System before and after foot reflexology, and before, 15 min, and 24 h after the onset of the seed acupressure intervention. Symptom assessment was done by a research assistant who was blind to the study intervention.

Findings: The mean score of abstinence symptoms for the foot reflexology intervention significantly reduced from 10.32 ± 2.10 at pretest to 7.87 ± 2.04 at posttest ($P < 0.001$). Moreover, the mean score of abstinence symptoms for the seed acupressure intervention significantly reduced from 9.70 ± 2.10 to 8.70 ± 1.46 at the first posttest ($P = 0.007$) and 7.32 ± 1.42 at the second posttest ($P < 0.001$). The change in the mean score of the foot reflexology intervention was significantly greater than the change in the mean score at the first seed acupressure posttest ($P < 0.001$) but did not significantly differ from the change in the second seed acupressure posttest ($P = 0.880$).

Conclusion: Both foot reflexology and auricular seed acupressure has significant effects on abstinence symptoms. Of course, 15-min seed acupressure is less effective than 15-min foot reflexology, while 24-h seed acupressure is as effective as 15-min foot reflexology in alleviating abstinence symptoms.

1. Introduction

Drug abuse is among the most important concerns of the contemporary world. It can negatively affect the growth and development of societies and hence, is considered as a significant threat [1]. Statistics show that the number of drug addicts in Iran is almost three millions—3.7% of the total population [2].

Drug abuse among women of reproductive age is a more significant concern. The prevalence of addiction among women of reproductive age is increasing [3]. Addiction among these women can cause menstrual disturbances and unwanted pregnancy [4]. There is no reliable

statistics on the number of addicted women in Iran though a study showed that 9.6% of all addicts in Iran are women [5].

Drug addiction in pregnant women can have negative effects on their babies and cause them low weight gain, microcephaly, and prematurity [6]. Moreover, as these babies receive drug from their mothers during pregnancy, they will suffer from low blood drug level after delivery and hence, will develop neonatal abstinence syndrome (NAS) [7]. The manifestations of NAS include high-pitched cry, nasal stuffiness, sneezing, tremor, problematic sucking, inadequate feeding, fever, diarrhea, and convulsion [8].

Pharmacological treatment of NAS includes the use of medications

* Corresponding author.

E-mail addresses: shimasajjadi95@gmail.com (S. Sajadi), Maj_kaz@yahoo.com, Dr.kazemi.n@rums.ac.ir (M. Kazemi).

<https://doi.org/10.1016/j.ctcp.2019.06.002>

Received 5 December 2018; Received in revised form 29 May 2019; Accepted 7 June 2019

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such as opioids chiefly morphine, Phenobarbital or clonidine. However, these medications have different side effects such as apnea, muscular flaccidity, and somnolence [9]. Therefore, non-pharmacological therapies are recommended for NAS management. These therapies include environmental modifications, swaddling, breastfeeding, kangaroo care, massage therapy, acupressure, and acupuncture [10,11].

With a five thousand year history, acupuncture is the traditional medicine of China [12]. Auricular acupuncture can reduce the pain significant, which is demonstrated by several investigations [13]. It is considered as a safe, simple, and easy method for reducing NAS-associated pain and symptoms [14]. Moreover, it is easily accepted by parents [15]. A study reported the effectiveness of acupuncture on the Yintang point in reducing procedural pain among premature infants [16]. However, further studies have been recommended to provide adequate evidence for the effects of auricular acupuncture [15].

Massage is another non-pharmacological therapy for health problems. It has a history of around 4700 years [17]. As a certain type of massage, reflexology or zone therapy is an easy non-invasive intervention which can enable healthcare providers to provide holistic care to patients [18]. The theory behind reflexology holds that the sole is related with all body organs and hence, massaging each point on the sole can affect its related organ or zone in the body. Reflexology can potentially relieve pain and bring calmness [19]. Previous studies reported the positive effects of reflexology on acute and chronic pain [20,21]. However, to the best of our knowledge, there is no information regarding its effects on NAS. Thus, the present study was designed and conducted to compare the effects of auricular seed acupressure and foot reflexology on NAS among neonates.

2. Methods

This modified double blind clinical trial was conducted in 2017–2018 using a crossover design. Study setting was the neonatal care unit of a teaching hospital affiliated to Rafsanjan University of Medical Sciences, Rafsanjan, Iran. Participants were 36 neonates of addicted women who were purposively recruited to the study in the first day of their hospital admission. They were included if they had a gestational age of 36–40 weeks, obtained a score of 8 or more for the Finnegan Neonatal Abstinence Scoring System, had no congenital anomalies, suffered from no birth injury, their mothers had abused drugs during pregnancy, and their parents consented to participate in the study. The clinical presentations were explored by the expert specialist in neonatology. The mothers were addicted to three distinct drugs, including heroin, opium and methadone. Two groups were matched regarding the drugs ($p > 0.1$). Exclusion criteria were hospital discharge, death, or life-threatening conditions during the study. Participants were randomly allocated through coin flipping to receive either foot reflexology then seed acupressure or seed acupressure then foot reflexology.

NAS was assessed before and after each study intervention using Finnegan Neonatal Abstinence Scoring System. This system included 28 items in four parts, namely central nervous system symptoms (thirteen items), vegetative symptoms (seven items), gastrointestinal symptoms (six items), and respiratory symptoms (two items). The total score of this system can range from 0 to 36. Scores 8 and more are indicative of NAS and highlight the need for NAS care [8].

Participants received either foot reflexology then seed acupressure or seed acupressure then foot reflexology. Foot reflexology was applied to the first horizontal zone of the sole for 15 min twice a day. The first horizontal zone encompasses the toes and is supposed to be related to the head and the neck and to opioid production in the body. For auricular acupuncture, acupuncture-specific earrings, called ear seeds, were attached using adhesive tape to the posterior surface of the auricle on the SJ 17 acupoint for 24 h. Each earring was made of a tiny 1-mm needle attached to a small plate. The time interval between the two interventions (i.e. the washout period) was 12 h. NAS symptoms were

assessed before and 20 min after the foot reflexology intervention, and before, 15 min, and 24 h after the onset of the seed acupressure intervention. The NAS scores for both assessments of reflexology were determined and their medians were used as the final unit NAS score. Symptom assessment was done by a research assistant who was blind to the study intervention. Due to the fact that the adhesive tape was used for all of the participants, hence the blind research assistant was unable to distinguish the infant groups. Due to the fact that the neonates were also unable to know the treatment and the procedures naturally, the protocol of our study was named modified double blind. During the study intervention, all participants received routine medical treatments which included the administration of morphine or Phenobarbital. Accordingly, Phenobarbital was administered 10–15 mg/kg in stat and 3–5 mg/kg in BID modes. In the cases of Phenobarbital was not effective, the infants was treated with 2 drops of 0.4 mg morphine. It should be noted that the reflexology and auricular acupuncture were performed 1 h before the routine medical treatment and then the NAS symptoms were assessed as described above.

2.1. Statistical data analysis

Analysis of the data was made via the SPSS for Windows program (v. 18.0). The results of the Kolmogorov-Smirnov test illustrated that all study variables had normal distribution ($P > 0.05$). Thus, between- and within-sample analyses were conducted using the paired-sample *t*-test at a significance level of less than 0.05.

3. Ethical considerations

This study was approved by the Ethics Committee of Rafsanjan University of Medical Sciences, Rafsanjan, Iran, (approval code: IR.RUMS.REC.1396.72) and was registered in the Iranian Registry of Clinical Trials (registration code: IRCT20161126155965N9). Participants' mothers were well informed about the aim and the methods of the study and were ensured that their refusal to participate or their withdrawal from the study would have no negative effects on the quality of care services provided to their neonates. Written consent for participation was obtained from all of them.

4. Findings

Initially, 36 neonates were recruited to the study. However, five infants were excluded due to early discharge from hospital with parental consent to another therapeutic center. Thus, the study was ended with 31 neonates (Fig. 1). Neonates aged 8.10 ± 6.4 h on average, and 51.6% of them (sixteen ones) were female. The age mean of neonates' mothers was 33.77 ± 4.34 years in the range of 20–43. The most commonly used drugs among mothers were opium and its derivatives (71%), methadone (19.3%), and heroin (9.7%), respectively. Thirteen neonates (41.9%) had meconium excretion during foot reflexology.

The mean score of NAS before foot reflexology did not significantly differ from the mean score of NAS before seed acupressure ($P = 0.116$). Moreover, the post-foot reflexology mean score of NAS did not significantly differ from the mean score of NAS at 15 min and 24 h after the onset of the seed acupressure intervention ($P = 0.065$ and 0.224 , respectively; Table 1).

The post-foot reflexology mean score of NAS was significantly less than the pre-foot reflexology mean score ($P = < 0.001$). Similarly, the pre-seed acupressure mean score of NAS was significantly greater than the mean score of NAS at 15 min and 24 h after the seed acupressure onset ($P = 0.007$ and < 0.001 ; Table 1).

Pretest posttest mean difference analysis was employed to compare the changes brought about by seed acupressure and foot reflexology in the mean scores of NAS. The results showed that the posttest mean difference of NAS for the foot reflexology intervention was significantly greater than the mean difference between the pretest and the first

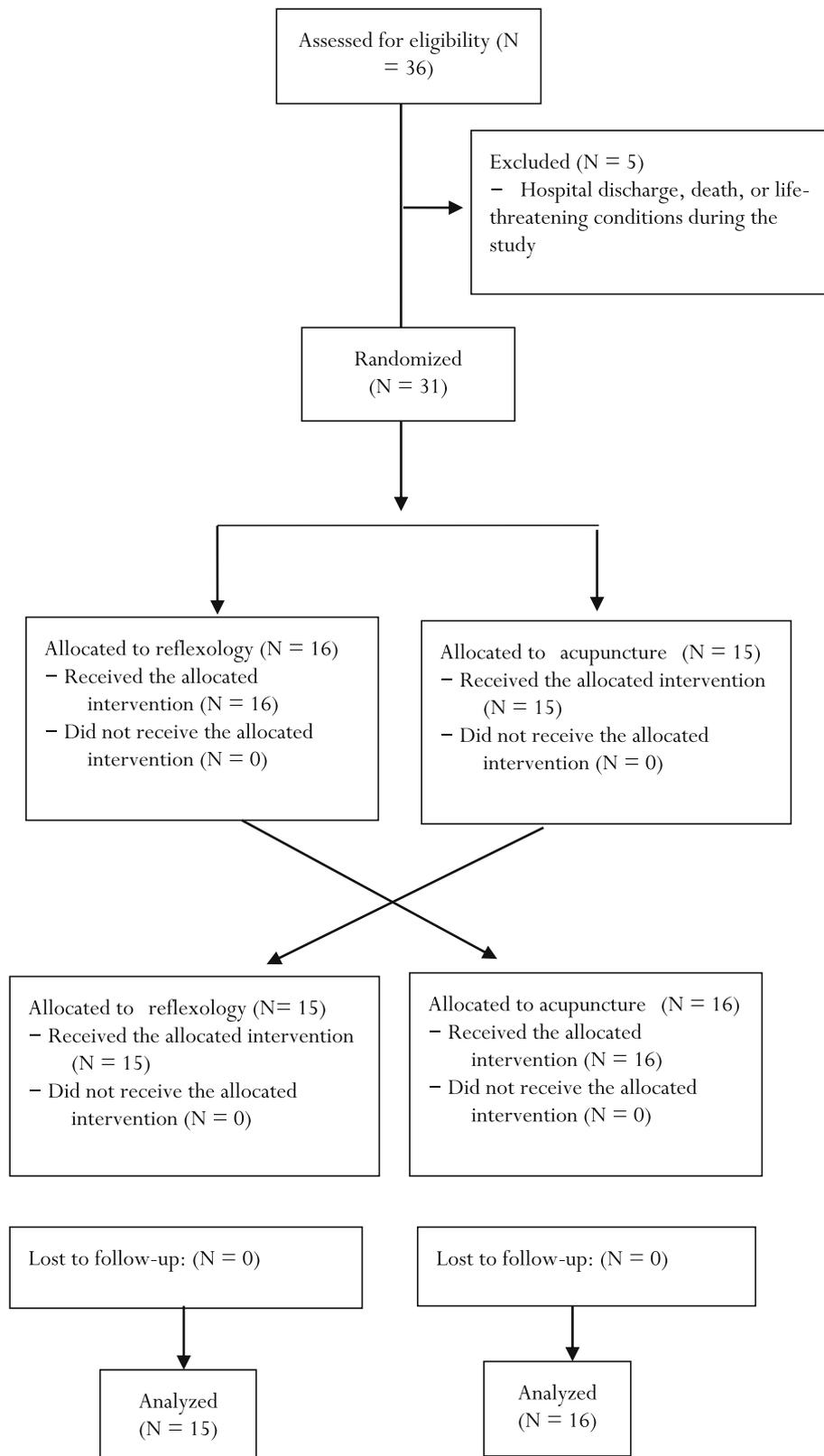


Fig. 1. The flow diagram of the study.

posttest scores of NAS for the seed acupressure intervention ($P < 0.001$). However, the pretest posttest mean difference of NAS for the foot reflexology intervention did not significantly differ from the mean difference between the pretest and the second posttest scores of NAS for the seed acupressure intervention ($P = 0.880$; Table 1).

Additionally, in order to show no effects of time on natural improvement of NAS symptoms, the baseline data of the foot reflexology at four times have analyzed using One-Way ANOVA test. The results demonstrated that no significant differences among the groups regarding the values ($P = 0.637$).

Table 1
Between- and within-sample comparisons respecting NAS mean score and its pretest posttest mean difference.

Group		Reflexology	Acupuncture	P value (Paired-sample t-test)	
Score and Time		Mean ± SD	Mean ± SD		
NAS mean score	Before	10.32 ± 2.10	9.70 ± 2.10		
	After	7.87 ± 2.04	15-min after 24-h after	8.70 ± 1.46 7.32 ± 1.42	0.116 0.065 0.224
P value (Paired-sample t-test)		< 0.001	< 0.007 ^a < 0.001 ^b	—	
NAS pretest posttest mean difference		2.45 ± 1.85	15-min after 24-h after	1.00 ± 1.91 2.38 ± 2.07	< 0.001 0.880

^a Comparison between pretest and the first posttest.

^b Comparison between pretest and the second posttest.

Table 2
The correlation between the pregnancy period, neonate age, mother age and the Finnegan Neonatal Abstinence scores.

			Gestational age	Neonate age	Mother age
Reflexology group	Finnegan Neonatal Abstinence scores	Pearson Correlation	− 0.206	0.317	−.075
		P value	0.443	0.232	0.782
Seed acupressure group	Finnegan Neonatal Abstinence scores	Pearson Correlation	0.34	0.41	0.599
		P value	0.20	0.12	0.018

The results showed that mother age has negative effects on the treatment to reduce Finnegan Neonatal Abstinence scores in the seed acupressure group (Table 2).

5. Discussion

The present study aimed to compare the effects of auricular seed acupressure and foot reflexology on NAS among neonates. Findings revealed the effectiveness of foot reflexology in alleviating the symptoms of NAS among the neonates of addicted women. In line with this finding, a review study reported massage therapy as one of the techniques for pain alleviation among neonates [22]. An earlier study also reported the same finding and attributed it to the stimulation of the vagus nerve [23]. Such stimulation might also have contributed to the alleviation of NAS symptoms after foot reflexology application in the present study.

The findings of this study also highlighted that auricular seed acupressure had significant positive effects on NAS symptoms. Similarly, two earlier studies indicated that acupuncture for more than 24 h can significantly alleviate NAS symptoms among neonates [15,24]. Consequently, acupuncture was recommended as another strategy for the alleviation of NAS symptoms [15]. The positive effects of acupuncture are probably related to reduce pain in the body [25]. Contrary to our findings, a study noted that as an invasive intervention, acupuncture can cause clients fear and stress and thereby, stimulates the sympathetic nervous system and negatively affects calmness [26]. Of course, we used ear seeds with tiny 1-mm needles and hence, our intervention can be considered as non-invasive or minimally invasive.

Our findings showed that the short-term application of seed acupressure for 15 min was less effective than 15-min foot reflexology in alleviating NAS symptoms. However, 24-h seed acupressure produced the same results as foot reflexology. These findings imply that in order to achieve desirable outcomes, seed acupressure needs to be applied in longer periods compared with foot reflexology. Of course, the effects of foot reflexology may disappear quickly and hence, its periodical application may be needed. Additionally, based on the results (Table 2) it appears that mother age can affect the NAS symptoms, because it has a positive correlate with Finnegan Neonatal Abstinence scores in the seed acupressure group. Although, the mother age was matched between groups, it needs to consider as an interventional factor for seed acupressure.

One study limitation was the short-term courses of its interventions. Future studies can apply foot reflexology and seed acupressure in longer periods of time. Moreover, frequent outcome assessments after both foot reflexology and seed acupressure are needed to determine their half-lives. Another limitation of our investigation was the low frequencies of the NAS, hence, the control group was not added to the study. To remove the natural effects of time on the improvement of NAS symptoms the baseline data regarding foot reflexology were compared. The result showed that there were not significant differences among the groups, hence, it appears that the improved symptoms were regarding the interventions.

6. Conclusion

This study concludes that both foot reflexology and auricular seed acupressure have significant positive effects on NAS symptoms. Of course, 15-min seed acupressure is less effective than 15-min foot reflexology, while 24-h seed acupressure is as effective as 15-min foot reflexology in alleviating NAS symptoms. Therefore, as simple and safe interventions, 15-min foot reflexology and 24-h auricular foot reflexology are recommended for NAS symptom management among the neonates of addicted women.

Acknowledgement

We are thankful to the Research Administration of Rafsanjan University of Medical Sciences, Rafsanjan, Iran, for approving and financially supporting the present study. Moreover, we thank the staff of the study setting and the family members of participants who helped us conduct this study. This project was founded by Rafsanjan University of Medical Sciences.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ctcp.2019.06.002>.

The results demonstrated that mother age has negative effects on the treatment to reduce Finnegan Neonatal Abstinence scores in the seed acupressure group.

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