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Comparison of the Effect of Cumin Cyminum and Nettle Oral Drops on the Breast Milk Sufficiency Indicators in the New Mother

Fatemeh Farshad,[1] *Elahe Sadeghi Sahebzad,[2,3] Masoomeh Kheirkhah,[3] Mahnaz Shafikhani,[3] Elham Azmoude[4]

[1]School of Dentistry, Tehran University of Medical Sciences, Tehran, Iran; Departments of [2]Anatomy and [3]Midwifery & Reproductive Health, Iran University of Medical Sciences, Tehran, Iran; [4]Healthy Ageing Research Centre, Neyshabur University of Medical Sciences, Neyshabur, Iran.
**Corresponding Author's e-mail: sadeghi.se22@gmail.com*

Abstract

Objective: Due to the presence of phytoestrogens in the combinations of cumin and nettle, they may have milk increasing properties. The present study compared the effects of Cuminum cyminum and nettle oral drops on the indicators of breast milk adequacy in lactating mothers. ***Methods:*** A triple-blind, randomized, controlled clinical trial was conducted on 117 lactating mothers with healthy 10-15 days infants who received cumin oral drops (n = 39), nettle oral drops (n = 39), or placebo (n = 39) from August 2020 to March 2021. Three study groups received 15 drops three times a day for four weeks. Infant weight, breastfeeding frequency, number of wet diapers, diaper weight and frequency of infant defecation were evaluated before and after the intervention. ANOVA and chi-square tests were carried out with SPSS software version 22. ***Results:*** At the beginning of the trial, there were no statistically significant differences between the three groups in infant weight (p = 0.891) breastfeeding frequency (p = 0.921), number of wet diapers (p = 0.783), diaper weight (p = 0.841) and frequency of infant defecation (p = 0.898) However, following the intervention, the mean scores of all the indicators were significantly more in the

experimental groups than the placebo ($p < 0.001$). In addition, all the indicators in the cumin group increased significantly compared to the nettle group ($p < 0.001$).
Conclusion: Considering the effectiveness of cumin and nettle in increasing milk and the availability of these native plants in Iran, it is suggested that they, especially cumin, be used postpartum to increase breast milk production.
Keywords: Green Cumin, Nettle, Breastfeeding, Growth Parameters.

Advances in Knowledge

- This study highlights that green cumin is effective in improving the indicators of breast milk adequacy in lactating women, and green cumin is more effective than nettle in this respect.

Application to Patient Care

- This study shows that consumption of cumin or nettle oral drops increased infant weight, breastfeeding frequency, number of wet diapers, infant poop frequency, and diaper weight compared to the placebo group. These indicators were also significantly higher in the cumin group compared to the nettle group.

Introduction

Breastfeeding plays a major role in attaining the infants to optimal growth during the first year of their lives.[1] Breastfeeding is also one of the best ways to ensure child health and survival.[1] Its effects on maternal health are also well-documented.[2,3] In addition to beneficial effects on the physical health of mother and infant, exclusive breast-feeding promotes frequent interaction between mothers and infants, which is vital for a baby's brain development.[4]

Various studies have shown that the percentages of exclusive breastfeeding in their first six months differ across cultures.[5,6] According to research, the prevalence of exclusive breastfeeding is 25% in Africa, 31% in Latin America, 45% in Asia, 13.9% in USA and 13.8% in Canada.[5] One study that have been conducted in Iran, reported the prevalence of exclusive breastfeeding 90% in the first year and 57% in the second year after birth. The rates of exclusive breastfeeding in the rural and urban areas of

Iran are 5% and 31 %, respectively in another study. One of the most common reasons for discontinuing exclusive breastfeeding in the first six months in Iran that mentioned in this research was mother's perception from breast milk insufficiency.[6]

Many lactating women seek drugs or non-drug therapy to increase breast milk production.[7] Drugs that enhance breast milk production are metoclopramide, oxytocin, domperidone, and chlorpromazine. The side effects of these drugs include tremor, slow movement, acute dystonic reactions, and weight gain.[8,9] These medicines are not widely used due to these side effects.[10]

Therefore, women are looking for alternative non-chemical treatments to increase milk production. There are some herbal medicines or substances that initiate, maintain and enhance breast milk production.[11] Asparagus, dill, parsley, black cumin,[12,13] alfalfa,[14] galega fenugreek,[15] fennel (*Foeniculum vuglare*),[16] and nettle are among these herbal medicines.[17]

Green cumin (*Cuminum cyminum*) has effective terpenes called karven, myrcene, limonene, and alpha- and beta-pinene.[18] It probably enhances breast milk production through the mechanism of increasing prolactin in serum of lactating women. In addition to increasing breast milk production, green cumin is considered a pain killer and an anti-spasmodic agent. This herb is used to treat flatulence in today's medicine.[19]

Another common herbal medicine that increases breast milk production is nettle. The active ingredients of this plant include polysaccharides, phytosterols, flavonoids and triterpenic acids, which increase prolactin and thus enhance milk production. This herb contains tannin, mucilage and formic acid, a type of waxy substance, a phytosterol, potassium and calcium nitrates, iron compounds, and a glucoside that causes skin redness.[18]The effect of this herb in the enhancement of breast milk production may be related to increasing of estrogen level. Estrogen apparently increases prolactin receptors, raises prolactin levels, and leads to increased milk production by acting directly on the mammary glands.[20]

Limited studies have been conducted to investigate the effects of these two medicinal plants in increasing breast milk production.[9,21-23] In this regard, the results of a randomized clinical trial conducted by Ozalkaya at el. (2018) in Iran showed that consumption of commercially available herbal mixture tea containing nettle and five other herbs significantly increases breast milk production in mothers with preterm infants.[21]

In addition to the few studies in this field, a study comparing the breastfeeding outcomes of these two herbal medicines is not available. Therefore, this paper was written with the aim of comparing the effects of green cumin and nettle on the indicators of breast milk adequacy in lactating mothers.

Methods

The current study was a triple-blind clinical trial with two experimental and one control groups. The study was held during August 2020 to March 2021. The participants were selected through convenience sampling and were lactating women with healthy 10–15-day old infants that were recruited from a regional public health care center affiliated with Iran university of Medical Sciences of Tehran, Iran. This center is one of the largest centers in the south of Tehran with a large population that provides a range of maternal and child health services.

A pilot study was done to determine the sample size. Assuming α=0.05, β=0.2, a confidence level of 95%, a test power of 80%, and an attrition rate of 10%, the sample size was determined to be 39 in each group.

$$n = \frac{2\sigma^2 \left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2}{(\mu_1 - \mu_2)^2}$$

$$\sigma^2 = \frac{S_1^2 + S_2^2}{2}$$

The participants were considered eligible for participation if they were multigravida and had healthy 10-15-day old term born infants (37-42 weeks gestation), multigravida (with 2 or 3 baby) and have exclusively breast feeding and agreed the study procedures. Women who used other drugs for increasing milk supply or did not exclusively breastfeed their infants were not included in the research. In addition,

women with underlying diseases (untreated active tuberculosis or HIV/AIDS), drug or alcohol addiction, or those who took special medications such as phenobarbital and ergotamine and those with breast problems such as abscess, nipple indentation, breast cancer and underlying diseases such as asthma, coagulation disorders, cardiovascular disease and diabetes, hypertension, and gastrointestinal diseases were not involved in the study.

Two questionnaires were used for data collection. 1) A maternal-infant information questionnaire: This scale included questions about demographic questions including age, mother's Weight, education levels of mother and father, economic status, parity, type of delivery. 2) Breast milk sufficiency indicators form: This form is taken from Ghasemi et al.'s study.[24] This form evaluates the adequacy of breast milk by measuring the indicators of the feeding frequency, number of wet diapers, frequency of defecation and diaper weight. In the present study, this form was completed daily by mothers

In addition, growth parameters included weight, height and head circumference of the infants were measured with the weighting scale (Seca, Hamburg, Germany), tall-meter table and tape measure by researcher, respectively. At the beginning of the study and after a detailed explanation about the study, informed consent was obtained from the participants. Then they were randomly assigned to two experimental groups (receiving cumin or nettle oral drops) and a control group (placebo drop) using Excel software.

Three drops were manufactured by a pharmaceutical company that provided the oral drops that were labeled only with the randomization codes (A, B, C labels). All drops were in the same form in sterile containers. The placebo drop was tasteless, odorless, green and had no milk-enhancing properties. Additionally, it has an identical appearance with herbal drops. Also, placebo containing sterile water. Cumin drops had the registration number 1624 and nettle edible drops had the registration number 1228018596 of the Iran Food and Drug Organization. All participants were administered 15 drops three times per day for four weeks. The researcher, evaluator and participants in the three study groups were unaware of the type of drops used.

The study variables were measured two days before the intervention. At first, the weight of all infants was measured with Seca scale by a trained researcher after changing the diaper, before breastfeeding and without any clothes on the infants. Then, the number and weight of wet diapers per day, the frequency of defecation and feeding frequency were recorded by the participants at home during 2 days using breast milk sufficiency indicators form. The participants were encouraged to fill out a study form accurately.

Further, according to the assigned group, each participant was provided with a drop, three packs of diapers and a study form to record indicators of breast milk sufficiency for the first two weeks. According to the checklist form, the mother should change the diaper every six hours and record the number of feedings, the frequency of defecation, the number and weight of wet diapers daily. Wet diapers were collected daily and weighted using a scale at the end of each day.

Follow-up phone calls were made every three days to ensure the accuracy of data collection and any possible complications. The researcher strongly recommended to the participants to complete the forms accurately. In addition, the contact number of the researcher was given to all the participants to contact if needed.

After the first two weeks, the participants had referred to the health center and the study form were taken and assessed by the trained researcher. Then drop, three packs of diapers and a study form were given to the participants for the second two weeks again.

After the end of the fourth week, the participants and their infants had returned to the health center and the study forms were received and the weight of the infants was measured by the previous scale after changing the diapers by the researcher.
SPSS software version 22 (Inc., Chicago, IL, USA) was used to analyze the data, the Kolmogorov–Smirnov test to determine the variable distributions and the chi-square test and the one-way and ANOVA to evaluate demographic and clinical characteristics among the study groups. Additionally, the one-way ANOVA was used to compare changes in the parameters at baseline and at the end of the treatment between the study groups. P values < 0.05 were considered as a significant.

The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences. Written informed consent was obtained from all couple's participants before and after the study enrolment in accordance with the Declaration of Helsinki. Additionally, the participants were free to withdraw from the research at any time during the research without giving a reason. All the participants were given the researcher's phone number to report any side effects for mothers and babies. This study registered in the Clinical Trials Registration Center of Iran.

Results

The study was conducted on 117 lactating women in three groups of intervention and placebo with 39 people in each group (Figure 1). Throughout the research, the flow diagram depicted the inclusion and exclusion criteria for the participants according to the CONSORT statement. During the study, 3 out of 117 participants were excluded from the study including one woman from each group.

Participant characteristics are presented in the Table 1. The average maternal age was 25.8±7.06, 27.3±4.48 and 29.05±6.73 in Cumin Cyminum, Nettle and placebo groups ($p=0.293$). The majority of participants in three groups have high school education ($p=343$). No significant differences were observed between the three groups in terms of other demographic and clinical characteristics ($p>0.05$) (Table 1).

Before the intervention, no significant differences were observed between there groups in infant weight ($p=0.891$) (Table 2). However, at the end of the intervention there were significant differences between three groups in the terms of infant weight ($p<0.001$). So that, infant weight was significantly more in the green cumin group compared to the nettle and the placebo groups ($p<0.001$). Infant weight was also significantly higher in the nettle group than in the placebo group ($p<0.001$) (Table 3).

Furthermore, there were no significant differences in breastfeeding frequency, number of wet diapers, infant poop frequency, and diaper weight before the intervention between the three study groups ($p=0.921$, $p=0.783$, $p=0.898$ and $p=0.841$, respectively) (Table 2). After the intervention, there were significant differences between the three groups in all the parameters ($p<0.001$). The highest score belonged to the green cumin drop group (Table 3).

The post-hoc analysis showed that there were significant differences between the green cumin and the nettle groups (p=0.001, p=0.001, p=0.041, and p=0.021). In addition, the post- hoc analysis in both experimental groups indicated that there were significant differences between them and the control group in all the variables (p<0.001). It is noteworthy that no side effects were reported during the intervention.

Discussion

To the best of our knowledge, this was the first study to compare the effects of cumin and nettle oral drops on the indicators of breast milk adequacy. In present study, consumption of cumin or nettle oral drops increased infant weight, breastfeeding frequency, number of wet diapers, infant defecation frequency, and diaper weight compared to the placebo group. It is important to note these indicators were also significantly higher in the cumin group compared to the nettle group after intervention.

Based on evidence, green cumin has estrogenic properties. The active ingredients of this herb include a type of terpene called carvone or myrcene, limonene and alpha- and beta-pinene that increases milk production. Actually, green cumin increases milk production possibly by increasing estrogen and prolactin levels.[25,26]

However based on many studies, despite no increasing of prolactin levels, herbal galactogogues has effect on increasing milk production.[27-29] This shows that there are alternative mechanisms affected by galactogogues. Such as, in a study was done by Liu et al., herbal galactogogues were shown to regulate expression and function of the aquaporins receptors of mammary glands and increase milk secretion on rats.[29] Consequently, there may be other mechanisms for the effectiveness of nettle and cumin on increasing milk production.

However, the results of Humphries's study (2014), are consistent with the present study. They showed that nettle increased milk production and estrogen and prolactin.[22] The result of Zuppa et al. (2010) that investigated the effect of milk supplements (fennel, cumin and dill) on milk production, showed that the increases in milk volume, the frequency of and the weight of infants were more in the group receiving this galactogogues composition than the placebo group.[9] Similarly,

Ozalkaya et al. (2018) evaluated the effect of a herbal tea mixture containing stinging nettle on increasing milk production and serum prolactin levels in lactating women with preterm infants. Their result show that Increase of the milk production was more in herbal tea mixture group from the first to the seventh day. However, infant weight in the group receiving this galactogogues mixture was not significantly more than those in the galactogogues group compare with after seven days. It is important to note that this composition has not any effect on the serum prolactin levels of mothers.[21] The differences between these results and the present research can be due to the shorter duration of the intervention and the use of a combination of plants in the Ozalkaya study.[21] In an animal study, Nobahar et al (2013) also investigated the effect of the medicinal plant nettle on the growth indicators of young beluga fish. The growth indicators of the fish fed with the diet containing nettle increased significantly compared to fish in the control treatment.[23]

Generally, based on the results of the present study, and given the availability, low prices and the minor side effects of these two herbal medicines, it is recommended to use them as an aid to increase milk secretion in breastfeeding woman. However, due to the limited number of trials in this area, it seems further researches with larger sample sizes and longer intervention durations are needed to validate the effectiveness of these herbs.

Limitations and Strength

The limitations of this study include the differences in diet and psychological and mental states of the participants at the time of answering questions, which was out of the researcher's control. In addition, it is important that to consider the environmental and genetic factors may have an effect on infant weight gain, which was tried to be adjusted by randomization.

One of its strengths was the recommendation to use the herbal medicines that cause no complications, increase milk supply in lactating women and reduce the incidence of diseases in infants. Being a triple-blind study was another strong point of this study because this feature probably improved the accuracy of the findings.

Conclusion

Based on our results, green cumin is effective in improving the indicators of breast milk adequacy in lactating women, and green cumin is more effective than nettle in this respect. So, it is suggested that the authorities of the Ministry of Health in the areas of the health of mothers and their infants and midwifery recommend the use of green cumin drop as a galactogogue to mothers, midwives and specialists.

Authors' Contribution

ESS and FF conducted the research. MK collected the data. MSK and EA analyzed the data. ESS drafted the manuscript. All authors approved the final version of the manuscript.

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Conflicts of Interest

The authors declare no conflict of interests.

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418 **Table 1:** Demographic and Clinical Characteristics and their Comparison Between
419 the Two Groups.

Variable	experimental group Cumin Cyminum	experimental grou Nettle	placebo group	P value
Age	25.8±7.06	27.3±4.48	29.05±6.73	0.293[b]
Weight	77.15±9.63	78.05±9.38	81.38±12.39	0.170[b]
Height	166.2±3.32	165.4±3.37	163.06±17.3	0.397[b]
Infant weight	3323.78±337.4	3301.78±377.05	3281.92±302.41	0.606[b]
infant height	49.77±1.33	5.06±1.93	49.046±1.75	0.224[b]
Around the infant's head	34.75±1.24	34.87±1.25	34.67±1.19	0.617[b]
Mother's education level				
Illiterate	1(2.6)	4(10.3)	2(5.1)	
Elementary	2(5.1)	0	2(7.7)	
Guidance	6(15.3)	4(10.3)	13(33.33)	
Diploma	26(66.7)	20(51.3)	13(33.33)	
University	4(10.3)	11(28.1)	8(20.6)	
P value				0.343[c]

father's education level				
Illiterate	1(2.6)	3(7.7)	1(2.6)	
Elementary	5(12.8)	0	5(12.8)	
Guidance	10(25.6)	6(15.4)	10(25.6)	
Diploma	16(41)	19(48.7)	16(41)	
University	7(18)	11(28.2)	7(18)	
P value				0.392[c]
The economic situation				
Weak	6(15.4)	7(17.9)	2(5.1)	
Medium	28(71.7)	25(64.2)	28(71.7)	
Strong	5(12.9)	7(77.9)	9(23.2)	
				0.237[c]
Number of deliveries				
Zero	26(66.6)		16(41)	
One	5(12.8)		12(30.7)	
Two	7(17/9)		6(15.5)	
More than two	1(2.7)		5(12.8)	
P-value				0.382[c]
Voluntary delivery				
Yes	32(82)	35(89.7)	25(64.1)	
No	7(18)	4(10.3)	14(35.9)	
P-value				0.071[c]
Type of delivery				
NVD	28(71.8)	26(33.3)	26(66/6)	
Cs	11(28.2)	13(66.7)	13(33.4)	
P-value				0.087[c]

All data are presented as mean ± SD or N (%)

[b]*One Way ANOVA test*

[c]*Chi-square-test*

Table 2: Comparison of feeding frequency, number of wet diapers, frequency of infant defecation and diaper weight in different group before intervention.

variable / group	infant weight	feeding frequency	number of wet diapers	frequency of defecation	diaper weight
Placebo	3289.6000±64.30409	7.1262±1.18185	3.2500±1.03155	0.4750±0.50637	1091.2858±127.33911
Cumin cyminum	3229.6234±75.30209	7.8002±1.10082	3.4532±1.03280	0.5000±0.50574	1103.5253±126.44142
Nettle	3301.6234±45.30908	7.8376±1.16152	3.4000±1.18185	0.5250±0.50574	1107.0975±.58562
P value	0.891[b]	0.921[b]	0.783[b]	0.898[b]	0.841[b]

All data are presented as mean ± SD or N (%)

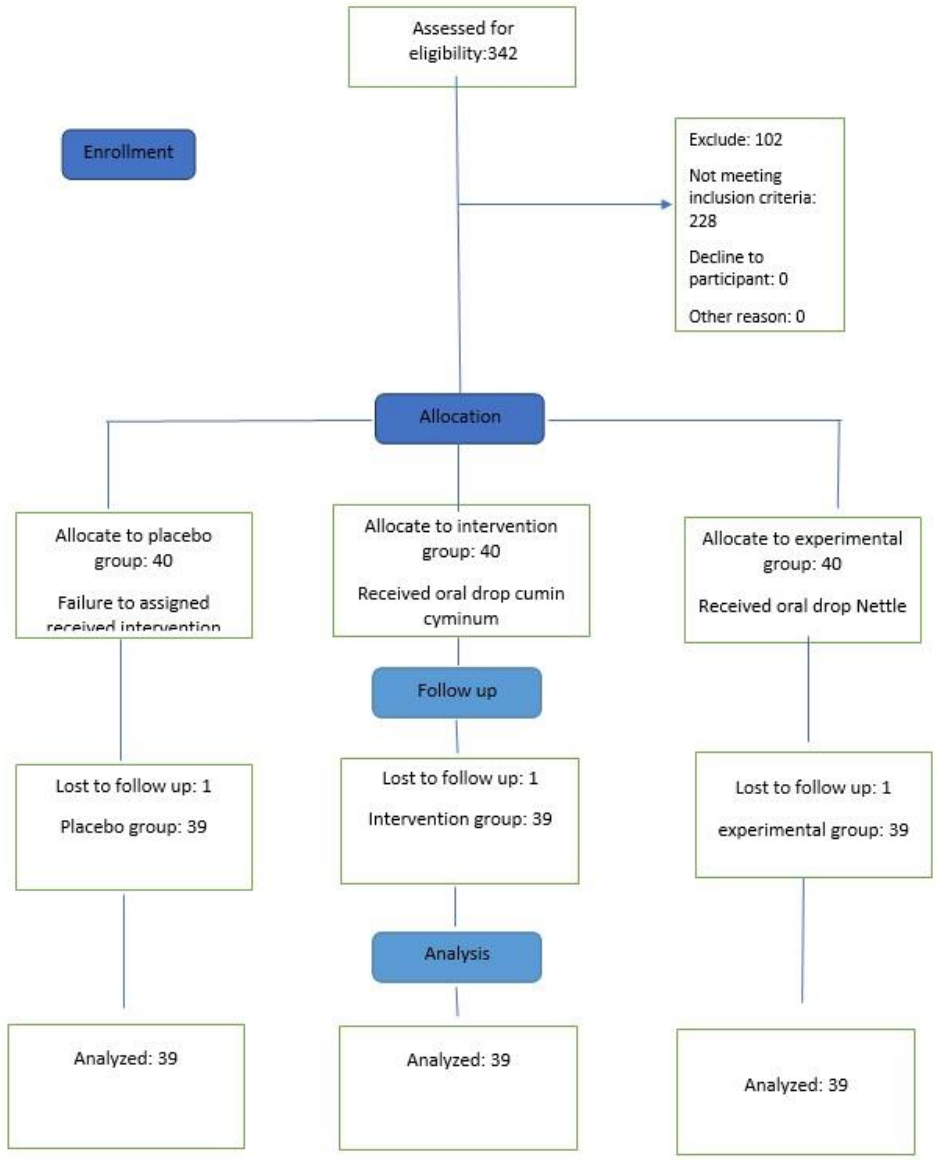
[b]*One Way ANOVA test*

Table 3: Comparison of feeding frequency, number of wet diapers, frequency of defecation and diaper weight in different group after intervention.

variable / group	Infant weight	feeding frequency	number of wet diapers	frequency of defecation	diaper weight
Placebo	3519.9750±64.95106	10.6410±0.95936	6.8000±0.68687	2.0000±0.78446	1140.7540±151.61849
Cumin cyminum	4031.5500±103.39988	13.7949±0.86388	13.6750±0.85896	3.1500±0.66216	1445.0600±148.99657
Nettle	3863.6750±94.76757	12.8974±0.68036	10.7000±1.06699	2.3750±0.58562	1352.1133±157.50329
P value	<0.001[b]	<0.001[b]	<0.001[b]	<0.001[b]	<0.001[b]

All data are presented as mean ± SD or N (%)

[b]*One Way ANOVA test*



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447 **Figure 1:** Flowchart