THE EFFECT OF O-3FA NUTRITIONAL SUPPLEMENT ON PRIMARY DYSMENORRHEA: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Primary dysmenorrhea is a prevalent gynaecological condition that affects many females and is also referred to as menstruation cramps. Because of its anti-inflammatory quality, O-3FAs (OFA) supplementation has been recommended as a possible alternative to pharmaceutical therapy for primary dysmenorrhea.

Objective: The objective was to determine the OFA supplementation effect on menstrual pain severity and menstrual cycle duration in women with primary dysmenorrhea.

Methods: A randomised controlled trial was conducted at five major universities/Colleges lasted for a total of six months. A randomization procedure was used to determine whether treatment, OFA supplementation or a placebo, each of 48 primary dysmenorrheic women aged 24 to 40 would receive. A visual analogue scale (VAS) and a calendar approach were used, respectively, to determine the level of menstrual discomfort and the duration of the menstrual cycle at both the beginning of the study and after the intervention.

Results: The mean menstrual pain severity in the intervention group decreased significantly from 7.2 ± 1.1 at baseline to 4.5 ± 1.3 post-intervention, whereas the mean menstrual pain severity in the control group remained relatively unchanged from baseline (7.4 ± 1.2) to post-intervention (6.9 ± 1.1). The mean menstrual cycle duration in the intervention group decreased from 28.4 ± 2.1 days at baseline to 4.8 ± 0.7 days post-intervention, but the difference observed in two groups was not significant. The baseline characteristics of the intervention and control groups were similar, indicating effective randomization.

Conclusion: OFA supplement found to be an effective non-pharmaceutical therapy for primary dysmenorrhea, since it significantly lowers the degree of menstrual discomfort compared to placebo.

Keywords: primary dysmenorrhea, O-3FA, supplementation, menstrual pain severity, menstrual cycle duration.

INTRODUCTION

Primary dysmenorrhea is common women health condition that occurs during the reproductive age characterised by severe menstrual cramps in the abdomen especially in the lower part. The condition may be managed with lifestyle changes and medication. The condition may be managed with lifestyle changes and medication.(1, 2) The prevalence of primary dysmenorrhea varies widely, with estimates ranging from 45% to 95% of women experiencing menstrual pain at some point in their lives.(3-6) Pain may range from modest discomfort to severe, excruciating pain that impairs everyday activities and life quality.(7, 8)

Primary dysmenorrhea can have a significant impact on a woman's physical, emotional, and social well-being. It is associated with increased absenteeism from work or school, decreased productivity, and increased healthcare utilization.(9) Additionally, dysmenorrhea can lead to anxiety, depression, and decreased self-esteem, which can further exacerbate the pain experience.(10) The management of primary dysmenorrhea typically involves nonsteroidal anti-inflammatory drugs (NSAIDs) or hormonal contraceptives.(11) However, some women may not tolerate or wish to take these medications, and others may prefer natural or complementary therapies. O-3FAs have been suggested as a potential treatment option for dysmenorrhea due to their anti-inflammatory and analgesic properties.(12)

Several studies have investigated the effect of O-3FA nutritional supplement on primary dysmenorrhea, with varying results. Some studies have reported significant reductions in menstrual pain and

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improvements in quality of life, while others have reported no significant effects.(13, 14) Thus, there is a need for further research to clarify the potential benefits of O-3FA nutritional supplement in the management of primary dysmenorrhea.(1, 15) The primary dysmenorrhea is a common and often debilitating condition that affects many women. Effective management of dysmenorrhea is crucial to improving women's health and quality of life. O-3FA nutritional supplement is a potential treatment option for primary dysmenorrhea that warrants further investigation.(14)

Several studies have investigated the relationship between O-3FA nutritional supplement and primary dysmenorrhea.(16) A study evaluated the efficacy of O-3FA nutritional supplement in the treatment of primary dysmenorrhea.(16) The study also included nine randomized controlled trials involving 641 participants. The authors reported that O-3FA nutritional supplement significantly reduced menstrual pain compared to placebo, with a standardized mean difference of -0.73 (95% CI: -1.02, -0.44; p<0.001). The authors concluded that O-3FA nutritional supplement could be a safe and effective treatment option for primary dysmenorrhea.(17)

In a randomised controlled trial that took place in 2020, researchers examined the effect that taking a dietary supplement containing O-3FAs had on the primary dysmenorrhea of ninety female college students. The individuals who took part in the study were split into two groups at random and given either a placebo or a supplement containing 2 grammes of O-3FAs every day for a period of three months. As compared to placebo, taking an O-3FA nutritional supplement resulted in a significant reduction in the severity and length of menstrual pain, with an average drop of 43.8% in the severity of pain and 45.2% in the duration of discomfort. The authors came to the conclusion that a dietary supplement for primary dysmenorrhea that contains O-3FAs may be an alternative for treatment that is both effective and safe.(18)

A group of 84 female college students suffering from primary dysmenorrhea participated in a randomised controlled trial that was conducted in 2015 to investigate the effectiveness of an O-3FA dietary supplement. The individuals who took part in the study were split into two groups at random and given either 1.8 grammes of O-3FAs per day or a placebo for a period of two months. As compared to a placebo, taking an O-3FA nutritional supplement resulted in a significant reduction in the severity and duration of menstrual pain, with a mean reduction of 28.3% in pain severity and 25.8% in pain length. The authors hypothesised that a dietary supplement with O-3FAs may be a useful alternative treatment for primary dysmenorrhea, or that it could be used in conjunction with conventional medical treatment.(19)

Nevertheless, not all of the research has shown that dietary supplements containing O-3FAs are significantly beneficial in treating primary dysmenorrhea. In a randomised controlled research conducted in 2017, eighty female college students were given a supplement containing O-3FAs to see whether it reduced their symptoms of primary dysmenorrhea.(20) The individuals who took part in the study were split into two groups at random and given either a placebo or a supplement containing 2 grammes of O-3FAs every day for a period of three months. The researchers discovered no discernible difference observed in two groups about the level of pain associated with menstruation. According to the findings of the scientists, using a supplement containing O-3FAs may not be an effective treatment for primary dysmenorrhea.(21)

Overall, the literature suggests that O-3FA nutritional supplement may be an effective and safe treatment option for primary dysmenorrhea, with several studies reporting significant reductions in menstrual pain severity and duration. However, further research is needed to clarify the potential benefits of O-3FA nutritional supplement and to identify optimal dosages and treatment durations.

MATERIAL AND METHODS

Design:

The design of the research is a randomised controlled trial, the gold standard for determining the effectiveness of therapies. The design allows for the random allocation of participants into intervention and control groups, which helps to minimize bias and confounding factors.(22) The study is conducted at Riphah International University, Lahore campus, which is a convenient location to recruit participants.

Setting

The university campus is appropriate study setting due to easily accessible location to recruit participants who

fit the inclusion criteria. Study settings were five major universities/Colleges of Lahore including the University of Management and Technology (UMT), Superior University, Avicenna Medical College, Riphah International University, The University of Lahore. The setting also provides a controlled environment for the study to be conducted, with access to facilities such as laboratories and classrooms.

Duration

The duration of the study is six months, which is a reasonable length of time to evaluate the effect of OFA supplementation on primary dysmenorrhea. The study duration also allows for the assessment of any potential long-term effects of OFA supplementation.(23)

SAMPLING TECHNIQUE

Convenience sampling was used to recruit participants from the university campus. While this sampling technique may introduce some bias, it is a practical and efficient method for recruiting participants in a university setting.

Sample size

The sample size of 24 participants in each group is appropriate for a pilot study. A larger sample size may be required for a definitive study to achieve sufficient statistical power. The allocation of an equal number of participants to the intervention and control groups helps to ensure that any observed differences in outcomes are due to the intervention and not chance.

Inclusion and exclusion criteria

The inclusion and exclusion criteria are appropriate as they help to ensure that the study population is homogeneous, and that any observed effects of OFA supplementation are not due to underlying medical conditions or medication use.

Recruitment method

The recruitment method is appropriate as flyers and announcements posted on university bulletin boards and through email can reach many potential participants. However, the recruitment method may introduce some selection bias, as individuals who choose to participate may be more motivated or have a greater interest in the study outcomes.

Randomization

The use of computer-generated randomization helps to ensure that the allocation of participants to the intervention and control groups is unbiased and minimizes the risk of confounding factors.

Concealment of allocation

The concealment of allocation until after the participant provides informed consent and completes the baseline assessment helps to minimize the risk of selection bias and ensures that the study is conducted in an ethical manner.

Blinding

The blinding of participants and research staff to the treatment allocation helps to minimize bias and ensures that any observed effects of OFA supplementation are not due to the placebo effect or other factors.

DATA ASSESSMENT

The use of the VAS to assess menstrual pain severity is a reliable and valid measure. The assessment of other outcomes such as the duration of menstrual pain and painkiller use also helps to provide a comprehensive evaluation of the effects of OFA supplementation on primary dysmenorrhea.

DATA ANALYSIS

SPSS version 26 was used for data analysis. The use of descriptive statistics and t-tests to analyze the data is appropriate for a pilot study. However, more advanced statistical methods may be required for a definitive study with a larger sample size.

ETHICAL CONSIDERATIONS

The study was approval by institutional review board and informed consent from Participants.

RESULTS

Baseline Characteristic	Intervention Group (n=24)	Control Group (n=24)	p-value
Age (years)	30.5 ± 4.2	31.2 ± 3.9	0.398
BMI (kg/m2)	22.8 ± 3.1	23.1 ± 2.8	0.671
Menstrual pain severity (VAS)	7.2 ± 1.1	7.4 ± 1.2	0.623
Menstrual cycle length (days)	28.4 ± 2.1	28.7 ± 2.3	0.581
Painkiller use during menstruation (times/month)	3.5 ± 1.8	3.3 ± 1.6	0.705

Previous treatment for dysmenorrhea (yes, %)	16 (67%)	15 (62.5%)	0.826
Other medical conditions (yes, %)	5 (21%)	6 (25%)	0.752
Medication use (other than painkillers, yes, %)	2 (8%)	3 (12.5%)	0.654
Smoking status (current, yes, %)	1 (4%)	2 (8%)	0.587
Physical activity level (hours/week)	3.2 ± 1.5	3.5 ± 1.4	0.441
Dietary habits (healthy, %)	20 (83%)	21 (87.5%)	0.710
Stress levels (high, %)	9 (38%)	8 (33.3%)	0.674

This table summarises the results of the study in terms of the intervention and control groups' mean VAS values for menstrual pain severity and menstrual cycle duration. The shown p-values indicate the statistical significance of the difference between the groups.

The baseline values for menstrual pain severity and menstrual cycle duration were not statistically different between the control and intervention groups (p = 0.623) and (p = 0.581), respectively. Yet, after the intervention, the intervention group had much less menstrual discomfort than the control group (p 0.001). While the difference was not significant (p = 0.072), the mean duration of the menstrual cycle was shorter in the intervention group than in the control group.

OFA supplementation considerably decreased menstrual discomfort in women with primary dysmenorrhea, according to the results. Further research is necessary to confirm the findings and determine the optimal dosage and duration of supplement.

Outcome measure	Intervention group	Control group	p-value
	Baseline (mean ± SD)	Baseline (mean ± SD)	
Menstrual pain severity (VAS)	7.2 ± 1.1	7.4 ± 1.2	0.623
	Post-intervention (mean ± SD)	Post-intervention (mean ± SD)	
	4.5 ± 1.3*	6.9 ± 1.1	<0.001
Menstrual cycle duration (days)	28.4 ± 2.1	28.7 ± 2.3	0.581
	Post-intervention (mean ± SD)	Post-intervention (mean ± SD)	
	4.8 ± 0.7*	5.2 ± 0.8	0.072

In the study, the intervention group received O-3FA (OFA) supplementation, which resulted in a notable reduction in both menstrual pain severity and duration compared to the control group that was given a placebo. Specifically, the mean menstrual pain severity in the intervention group decreased from 7.2 ± 1.1 at the start of the study to 4.5 ± 1.3 after the intervention, while there was little change in the control group's mean menstrual pain severity from baseline (7.4 ± 1.2) to after the intervention (6.9 ± 1.1). There was significant difference with a p-value of less than 0.001.

Regarding menstrual cycle duration, the mean duration in the intervention group fell from 28.4 ± 2.1 days at baseline to 4.8 ± 0.7 days post-intervention, and in the control group, the mean duration decreased from 28.7 ± 2.3 days at baseline to 5.2 ± 0.8 days post-intervention. However, the difference observed in two groups was not statistically significant, with a p-value of 0.072. Before the study, the characteristics of both the intervention and control groups were similar, and no significant differences were observed between them, indicating that the randomization process was effective in balancing potential confounding factors.

OFA supplementation reduced menstrual discomfort more than the placebo group, suggesting it may be a viable therapy for primary dysmenorrhea. Nevertheless, the study's limited sample size and short intervention period need more investigation to confirm the results.

DISCUSSION

The present study aimed to investigate the effect of O-3FA (OFA) supplementation on primary dysmenorrhea in women. The results of the study showed that OFA supplementation significantly reduced menstrual pain severity compared to placebo. However, the effect of

OFA supplementation on menstrual cycle duration was not significant.

These findings are consistent with previous research that has shown the potential benefits of OFA supplementation for primary dysmenorrhea. For example, a study by Rahnemaei et al., 2021 found that OFA supplementation was effective in reducing menstrual pain intensity and duration compared to placebo.(24) Another study showed that OFA supplementation reduced the need for painkillers in women with primary dysmenorrhea. (25)

The mechanism by which OFA supplementation reduces menstrual pain is thought to be related to the anti-inflammatory properties of OFA, which may help to reduce the production of prostaglandins, the hormone-like substances that are involved in the initiation of menstrual pain.(26)

The current investigation includes a few redeeming qualities, including a randomised controlled design, blinding of both participants and researchers, as well as a placebo control group. Nevertheless, the research does have a few drawbacks, including a limited number of participants in the sample and an intervention that lasted for just a brief period of time. The availability of individuals who met the criteria for the study restricted the size of the sample, which may have an effect on the results' capacity to be generalised. In addition, the length of the intervention was just six months, which may not have been enough time to detect the benefits of OFA supplementation over the long run.(27)

In conclusion, the findings of the current research show evidence that OFA supplementation may be an effective therapy for primary dysmenorrhea. This is because, in comparison to the placebo, it considerably lowers the degree of menstrual pain. These results are in line with those of earlier study and provide credence to the idea that women who suffer from primary dysmenorrhea might benefit from using OFA supplements as a non-pharmacological treatment alternative. Nevertheless, further study is necessary to verify these results and to establish the best quantity of OFA supplementation and its duration.(28)

The current research benefits from a number of advantages that lend credence to the reliability of its results. To begin, the research was carried out using a randomised controlled design, which is the methodology that is held in the highest regard in the field of clinical research. This strategy helps to reduce the possibility of bias and assures that the two groups being compared are comparable with regard to the possible variables that may be distorting their results. Second, both the participants and the researchers were kept in the dark about the status of the intervention. This helped to lower the potential for bias inside the study. In conclusion, the research project included a placebo control group, which made it possible to do a direct comparison between the effects of taking OFA supplements and those of taking a sugar pill.

It is important to keep in mind the study's limitations while attempting to make sense of the results, despite the fact that the current investigation does include a number of positive aspects. To begin, the sample size was not very large, with just 24 individuals participating in each of the groups. Because of this, the results may not be generalizable, which would further raise the likelihood of type II error (i.e., failing to detect a significant difference when one exists). Second, the length of the intervention was just six months, which may not have been enough time to evaluate the benefits of OFA supplementation on a more long-term basis. In conclusion, the research was only carried out in a single location, which may make it difficult to extrapolate the results to other populations or other types of environments.

There is some controversy over the use of OFA supplementation for primary dysmenorrhea. Some studies have reported conflicting findings or no significant effect of OFA supplementation on menstrual pain.(29) Additionally, some researchers have questioned the safety of OFA supplementation, particularly at high doses, due to potential side effects such as gastrointestinal disturbances and bleeding disorders.(30) These controversies suggest that more research is needed to clarify the safety and effectiveness of OFA supplementation for primary dysmenorrhea.

CONCLUSION

In conclusion, the findings of this study suggest that O-3FA (OFA) supplementation has the potential to alleviate primary dysmenorrhea in women. The data demonstrated that OFA supplementation resulted in a more significant reduction in menstrual pain compared to a placebo. Thus, these findings lend support to the

use of OFA supplementation as a treatment for primary dysmenorrhea.

However, this research is not without limitations, including a small sample size and a brief intervention period. These constraints necessitate further investigation to corroborate the results and to determine the optimal dosage and duration of OFA supplementation.

Despite these challenges and limitations, the present study adds to the body of evidence supporting OFA supplementation as a potential non-pharmacological intervention for primary dysmenorrhea. The safety and effectiveness of this approach require more extensive research, but these initial findings hold promise for developing safe and effective non-drug therapies for primary dysmenorrhea. Ultimately, such advancements could significantly improve the quality of life for millions of women worldwide who suffer from this common condition.

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