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Vitamin E and Ginger Powder on Severity of Primary Dysmenorrhea among Students: A Non-Blinded Controlled Trial

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Abstract Introduction: Menstruation, frequently referred to as 'period', is a common phenomenon among women, in which the blood gets discharged from the uterus into cervix and then, passes via the vagina. Dysmenorrhea is one of the most common reasons for the occurrence of menstrual problems as well as pelvic discomfort while it causes painful uterine cramps during menstruation. It is also the most commonly found issue among women, particularly during their reproductive stage. Many research works have determined the effects of supplements containing vitamins E and ginger upon reducing the severity of primary dysmenorrhea. Aims & Objective: The current study is aimed at analyzing the impact of ginger and Vitamin E upon pain severity among adolescent girls enrolled in colleges with primary dysmenorrhea. Further, the study also aims at determining the association between pain scores among the students who consume additional pain relief medicine or therapy during the course of the study. **Methods:** This non-blinded randomized controlled experiment was carried out for four months in 2022 among the students aged between 18 and 25 years, residing in the hostels of Sikkim Manipal University, Sikkim and experienced moderate to severe dysmenorrhea during menstruation. For this study, a total of 102 students were selected and were randomly segregated into three groups such as control, Vitamin E and ginger power group. With the help of a background questionnaire as well as a pretested Visual Analogue Scale (VAS), the author analyzed the impact of ginger power and vit-E upon reducing the severity of primary dysmenorrhea for three successive cycles. The data collected using the questionnaire were analyzed using SPSS version 21. **Results:** At the beginning, a total of 187 participants were covered for the investigation among which 85 study participants were excluded from the study citing not meeting the inclusion criteria or dropping out from the study. Prior to the intervention, the mean VAS scores of the overall study population for dysmenorrhea were 7.03 (Control group), 7.15 (Ginger group) and 7.00 (Vitamin E group) respectively while after the third month of the trial, the mean VAS scores were calculated as 6.62 (Control group), 4.74 (Ginger group) and 4.47 (Vitamin E group) respectively. Among the groups, vitamin E group respondents mentioned that their pain intensity got heavily reduced (F=32.573, P<0.001), followed by the ginger powder group (F=25.868, P<0.001). Conclusion: The current study findings confirmed that it is possible to significantly reduce the impact of dysmenorrhea by administering ginger powder and vitamin E while the latter shows the maximum impact. Since administering these supplements carries a lower risk in comparison with analgesics, in-depth research is required to validate the findings and determine their effects.

Keywords Ginger, Primary Dysmenorrhea, Menstrual Cycle, Vitamin E, Students, Adolescents

1. Introduction

Menstruation, commonly known as 'period', is a common phenomenon among adolescent girls and women in which the cervical blood passes from the inner lining of the uterus into the cervix and drains into the vagina. Women menstruate in their lifetime after attaining puberty until they reach the menopause stage. The average menstrual cycle lasts for 28 days [1]. The adult cycles last for 21 to 35 days, compared to early adolescent periods that last for 21 to 45 days. Menstrual cramps begin at the initial stages of the menstrual period and it remains for around 12 to 48 hours. However, menstrual cramps cause extreme pain among women without any obvious pelvic pathology, a typical characteristic of primary dysmenorrhea [2]. Pelvic pain reduces the quality of life among menstruating women. The estimates of the prevalence of dysmenorrhea in various populations range from 50% to 90% [3]. Though the pathophysiology of primary dysmenorrhea is still unclear and vague, studies have established the relationship between prostaglandins and primary dysmenorrhea as well as contractions. So, prostaglandin inhibitors are used to relieve pain in about 80% of the affected women. The key objective of this medication is to reduce the prostaglandin level in women [4].

Some of the available treatments for dysmenorrhea include Transcutaneous Electrical Nerve Stimulation (TENS), psychotherapy, Oral Contraceptive Pills (OCPs) and prescription of vitamins and Nonsteroidal anti-inflammatory medicines (NSAIDs). In spite of these, there exists a few disadvantages in terms of prescribing NSAIDs and OCPs since at times, patients may not be responsive to these drugs (with a 15% effective failure rate) while a few tend to stop due to side effects or other types of drug interactions. So, in-depth research should be conducted for determining the optimal therapeutic method [5-7].

Acupressure, acupuncture, herbal medicine, reikki treatments, massage, therapeutic touch, and other complementary and alternative therapies are widely accepted and accessible to women in the recent years. Further, a few techniques such as biofeedback, hypnosis, relaxation, and sensitization are also employed in treating dysmenorrhea [8]. Ayurveda uses a variety of herbal remedies for the treatment of dysmenorrhea. Without causing any side effects, these herbal medications can treat dysmenorrhea. Further, herbs can also be used to nourish tissues and blood vessels, tone the organs, and combat physical symptoms in addition to promoting the body's natural ability to repair itself [8-9].

In order to alleviate dysmenorrhea and reduce the discomfort associated with painful menstrual cycles, home treatments are also employed such as massages, yoga, ginger tea, hot water bottles, warm baths, vitamins and physical activity to reduce the menstrual pain [9]. Ginger

(Zingiber officinale), an herb, is prevalently found in most of the Asian countries and is a common household herb. The rhizome i.e., underground stem, is used both as a spice as well as a medication. It is frequently used in various forms such as fresh, dried, powdered, as juice and as oil as well [10]. Since ancient times, ginger has been used safely in food preparation, traditional and home remedies for medicinal conditions. It has anti-inflammatory properties and is used as an analgesic while it further enhances the blood circulation. In addition to this, it helps in relaxation of muscular spasms and pain management at the time of ovulation and menstrual periods. On the other hand, Ginger tea is a useful concoction made from ginger to reduce the pain caused by menstrual cramps [9-12].

In literature, Annesa Halder [13] compared and contrasted the impact of consuming oral ginger and progressive muscle relaxation (an alternative treatment method) upon the symptoms of dysmenorrhea. The study was conducted among 75 students enrolled in nursing programs in various colleges in the state of Maharashtra, India. After randomly segregating the students into three groups such as a control and two experimental groups, one gram of ginger was given to the second experimental group as an intervention. During the first three days of their period, they were instructed to consume ginger powder twice daily with warm water after a meal. The data was collected to determine the severity of a few specific dysmenorrhea symptoms using the daily symptom calendar in which a 5point Likert scale was used. The severity of a few chosen dysmenorrhea symptoms was the primary outcome measure, which was examined using MANOVA. The outcomes established the effectiveness of ginger powder compared to the other methods in the treatment of dysmenorrhea symptoms.

Complementary and Alternative Medicine (CAM) has recommended the consumption of vitamin E supplements as a novel treatment approach [14-16]. Dysmenorrhea can also be treated with vitamin E. During the menstrual cycle, various phases are involved among which in the luteal phase, the progesterone levels get reduced. This phenomenon results in the production of arachidonic acid and phospholipid peroxidation which in turn results in enzyme lysis. All of these alterations produce higher prostaglandin levels, which in turn triggers cramps and contractions in the uterus. The antioxidant qualities of vitamin E prevent the discharge of arachidonic acid, how it gets transformed into prostaglandins and reduce the levels of phospholipid peroxidation. This phenomenon has the potential to significantly lessen the severity dysmenorrhea [17].

NSAIDs are generally prescribed as a first-line treatment for women with menstrual cramps. Other medications including aspirin, ibuprofen, naproxen and mefenamic acid have been proven to be successful in treating dysmenorrhea. However, a few studies indicate that this medication had a 20–25% failure rate, and when administered for an extended period of time, it could also cause cardiovascular

problems and damage the kidneys and digestive issues. So, in order to treat dysmenorrhea, it is essential to start using alternative treatment options that are natural, cost-effective and without side effects [18].

1.1. Objectives

- To compare the effects of vitamin E and ginger powder upon duration as well as severity of pain caused by dysmenorrhea among college students.
- 2. To determine the association between pain score in students and taking additional pain relief medicine or therapy during the study.

1.2. Operational Definitions

- 1. **Vitamin E**: It refers to synthetic forms of vitamin E at a rate of 800 units per day after consuming food. The dosage is as follows; thrice a month during the first three days of menstruation.
- Ginger powder: It refers to dry ginger rhizome powder and the dosage is as follows; 500 mg of dry ginger powder dissolved in 200 ml of lukewarm water; thrice a month for the first three days of menstruation after consuming food.
- 3. **Primary dysmenorrhea**: This term denotes the menstrual cramps that induce pain among the study respondents after the beginning of menstruation to three successive months and the data was assessed on a recall basis.
- 4. **Severity of dysmenorrhea**: In this study, VAS was utilized to determine the pain severity and pain intensity. For the study, the researcher analyzed the severity of pain on the final day of menstrual bleeding during all the three study cycles. On a scale of 0-10, the respondents were asked to score their pain levels such as 0-no pain; 1-3=mild; 4-6=moderate and 7-10=severe.
- Students: It refers to the female students enrolled in nursing programs and residing in the nursing student hostel, SMIMS, Sikkim, India and who were regularly menstruating during the study period and suffered from primary dysmenorrhea.

1.3. Hypothesis

 H₁: There is a significant difference in severity and duration of pain scores among the students in vitamin E group, and in Ginger powder group at 0.05 level of significance.

2. Materials and Methods

2.1. Research Design

The current non-blinded Randomized Control Trial

(RCT) is aimed at comparing and contrasting the impact of vitamin E as well as ginger powder upon duration and the severity of pain in primary dysmenorrhea among the nursing students residing at Students' hostel, Sikkim Manipal University, Sikkim for a period of four months in the year 2022. The study intends to identify the association between pain score among the students treated with pain-relief medicines or alternative therapies during the course of the study. For this study, pre-test and post-test were conducted for all the three groups (one control and two experimental) for three days as soon as the menstruation began. A total of 102 students was allocated in a random manner to each one of the groups, thus each group had a total of 34 students.

2.2. Participants

The inclusion criteria of the current study are as follows; unmarried students of reproductive age between 18-25 years, have primary dysmenorrhea for the past three months on a recall basis and with a history of regular menstrual cycles (28 days \pm 7 days). For this study, the author collected the demographic information such as age. age of menarche, menstrual cycle and bleeding duration, a family history of dysmenorrhea, and the level of pain during the course of the study. Students diagnosed with secondary dysmenorrhea, urogenital, or coagulation disorders, gynecological diseases, history of severe gastrointestinal disorders, mild dysmenorrhea, history of abdominal or pelvic surgery, under herbal medications, anticoagulants, allergic to synthetic or herbal medications, and established deficiencies of minerals or vitamins were excluded from the study.

Sample size calculation:

$$n = \frac{2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2}{\Delta^2}$$

$$n = \frac{2 \times (1.96 + 0.84)^2}{0.8^2}$$

$$= \frac{2 \times 2.8^2}{0.64}$$

$$= \frac{2 \times 7.84}{0.64}$$

$$= \frac{15.68}{0.64}$$

By considering 20% of the sample drop outs, mortality and attrition extra sample, an optimal sample size of 34 was finalized for each group.

2.3. Intervention Protocols

After obtaining approval from the Institutional Ethical Committee, Sikkim Manipal University, the study

respondents with primary dysmenorrhea (n = 34) were selected as per the inclusion criteria. The respondents were provided with VAS scale to indicate the level of their discomfort during the study period. The scale starts with "no pain," and ends with "severe pain," correspondingly. Then, the respondents were segregated into four groups based on their pain intensity such as painless, mild, moderate and severe for which the respective scores were 0, 1-3, 4-7 and 8-10 during three menstrual cycles. The students in vitamin E group were advised to consume synthetic forms of vitamin E 800 units/day (Avion, 3 days in a month during the first three days of the menstrual cycle) after having food. On the other hand, the students in ginger powder group were advised to take 500 mg of ginger powder with 200 ml of Luke warm water (3 days a month during the first three days of menstrual cycle) after having food. The variations in the respondents' pain severity were assessed using a self-rated questionnaire administered among the study participants (see Figure 1).

2.4. Pain Assessment

In this study, background proforma and pre-tested VAS scale were used to collect the data. The degree of pain prior to the intervention was assessed using VAS scale, categorized as a 4-level tool, to measure the severity of dysmenorrhea. The respondents with no history of painful menstruation were grouped under level 0 i.e., the absence of pain. Respondents with painful menstruation yet not requiring any analgesic were grouped under level 1 i.e., light discomfort. Afterwards, the investigation was discontinued for both the groups. Respondents with moderate dysmenorrhea, whose daily activities were impacted by the condition yet the symptoms got reduced with the intake of painkillers, were grouped under level 2. Those respondents with severe dysmenorrhea, whose daily activities were negatively impacted by the condition yet the painkillers rarely responded, were grouped under level 3. The final analysis included all the respondents with moderate to severe dysmenorrhea (see Figure 1).

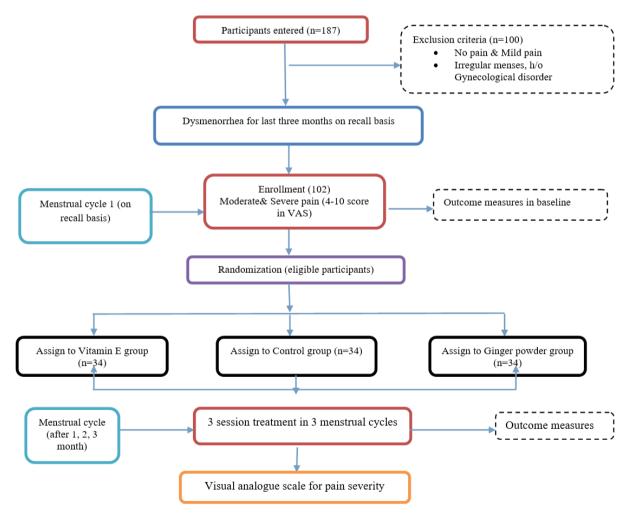


Figure 1. Schematic view of the study design

2.5. Statistical Analysis

The current study analyzed the collected data using SPSS software (version 21) for descriptive statistics in which the frequency, percentage, mean and standard deviation were calculated. Shapiro-Wilk normality test was conducted whereas the Levene test was utilized to conduct the homogeneity analysis. Once the assumption test was fulfilled (the cut off value for significance was set at 0.05 i.e., p>0.05), ANOVA was utilized to compare the pre- and post-test scores for both within and between the groups.

3. Results

3.1. Section 1: Findings Related to the Socio-Demographic Profile of the Students

A total of 102 students were found to be eligible for the

study among which the majority (Control group = 50%, Ginger group = 62% & vitamin E group = 62%) were between 18-23 years old. Further, the majority (Control group= 56%, Ginger group = 65% & vitamin E group = 59%) of the respondents attained menarche between the ages of 13-15. Also, most (Control group= 91%, Ginger group = 91% & vitamin E group = 94%) of the respondents had their menstrual cycle length in the range of 28 to 35 days. The duration of bleeding for most of the participants was 2-5 days (Control group = 79%, Ginger group = 77%& vitamin E group = 62%) (see Table 1). An interesting observation from the findings is that a significant number of nursing students mentioned that they have a family history of dysmenorrhea (Control group = 29%, Ginger group=32% & vitamin E group = 41%). The majority (Control group = 56%, Ginger group = 65% & vitamin E group= 59%) of the respondents, who had dysmenorrhea. were 13-15 years old (Control group = 44%, Ginger group = 53% & vitamin E group = 44%).

Table 1. Demographic and menstrual characteristics of the study participants

| Sl.No | Sample | Contro | l Group | Ginger Group | | Vitamin E Group | |
|-------|--|--------|---------|--------------|----|-----------------|----|
| | | f | % | f | % | f | % |
| 1 | Age of the students | | | | | | |
| a | 18-20 years | 17 | 50 | 21 | 62 | 10 | 29 |
| b | 21-23 years | 15 | 44 | 12 | 35 | 21 | 62 |
| c | >23 years | 2 | 6 | 1 | 3 | 3 | 9 |
| 2 | Age at menarche: | | | | | | |
| a | 10-12 years | 15 | 44 | 11 | 32 | 11 | 32 |
| b | 13-15 years | 19 | 56 | 22 | 65 | 20 | 59 |
| c | 16-19 years | 0 | 0 | 1 | 3 | 3 | 9 |
| 3 | Length of Menstrual cycle | | | | | | |
| a | 20-27 days | 2 | 6 | 2 | 6 | 2 | 6 |
| b | 28-35 days | 31 | 91 | 31 | 91 | 32 | 94 |
| c | 36-42 days | 0 | 0 | 1 | 3 | 0 | 0 |
| d | >43 days | 1 | 3 | 0 | 0 | 0 | 0 |
| 4 | Duration of bleeding | | | | | | |
| a | 2-5 days | 27 | 79 | 26 | 77 | 21 | 62 |
| b | 6-9 days | 6 | 18 | 8 | 23 | 13 | 38 |
| c | 10-13 days | 1 | 3 | 0 | 0 | 0 | 0 |
| 5 | Do you have the positive family history of dysmenorrhea in your immediate family members | | | | | | |
| a | Yes | 10 | 29 | 11 | 32 | 14 | 41 |
| b | No | 24 | 71 | 23 | 68 | 20 | 59 |
| 6 | Age of onset of dysmenorrhea | | | | | | |
| a | 10-12 years | 10 | 29 | 10 | 29 | 8 | 23 |
| b | 13-15 years | 15 | 44 | 18 | 53 | 15 | 44 |
| c | 16-19 years | 9 | 27 | 5 | 15 | 2 | 6 |
| d | >20 years | 0 | 0 | 1 | 3 | 9 | 27 |

N=102, n=34

Table 2 shows the percentage of students who were under additional pain relief medication during the study period while a few students were under medication during the course of the study along with other study interventions. Before the commencement of the study, the students were well-informed that if the pain was unbearable, then they were free to take their regular medicine while if they did so, they were advised to keep a note of it for analysis (see Table 2).

In this study, Chi square test was conducted to validate whether a relationship exists between the pain scores of the students in control group and the use of additional painkillers or therapy. Since there was no intervention, no such relationship was found from any of the time points (pre-test, after one month, after two months, and after three months) (p > .05). This indicates that the pain reduction occurred only in the intervention for a prolonged period (see Table 3).

In order to find the association between the pain score in students and taking additional pain relief medicine or therapy during the course of the study in ginger group, chi square test was conducted. The outcomes revealed the absence of an association between the pain scores with the intake of additional medicine or therapy during pre-test, after the 1st, 2nd and 3rd months of the study (p> .05). This finding infers that the pain can be reduced only if the ginger powder is consumed for a long period (see Table 4).

In order to find the association between pain score in students and taking additional pain relief medicine or therapy during the course of the study in vitamin E group, chi square test was conducted. The researcher found no association between the pain scores with the intake of additional medicine or therapy during pre-test and after the 1^{st} , 2^{nd} and 3^{rd} months of the study (p > .05). This finding infers that the pain gets reduced only after administering vitamin E for a longer period (see Table 5).

Table 2. Distribution of the respondents in terms of taking additional pain relief medicine during the course of the study

| Sl.No. | Question/Sample | Control Group | | Ginger Group | | Vitamin E Group | |
|--------|--|---------------|----|--------------|----|-----------------|----|
| | | f | % | f | % | f | % |
| A | Additional Pain Medication or therapy you used to reduce dysmenorrhea during the study | | | | | | |
| a | 1 Month | 9 | 26 | 7 | 21 | 5 | 15 |
| b | 2 Months | 8 | 24 | 6 | 18 | 7 | 21 |
| c | 3 Months | 5 | 15 | 7 | 21 | 4 | 12 |

N=102, n=34

Table 3. Association between pain score in students and taking additional pain relief medicine or therapy during the study in control group

| Sl.No. | Control Group | Additional Pa | Additional Pain Medication or therapy | | df | P-value |
|--------|----------------------------|---------------|---------------------------------------|--------------------|----|---------|
| 1 | Time of assessment of pain | Yes | No | | | |
| a | 1 Month | 9 | 25 | 6.178 ^a | 4 | .186 |
| b | 2 Months | 8 | 26 | 5.616 ^a | 4 | .230 |
| c | 3 Months | 5 | 29 | 1.867ª | 3 | .601 |

N=102, n=34

Table 4. Association between pain scale in students and taking additional pain relief medicine or therapy during the study in ginger group

| Sl.No. | Ginger Group | Additional Pain M | Additional Pain Medication or therapy | | df | P-value |
|--------|----------------------------|-------------------|---------------------------------------|--------------------|----|---------|
| 1 | Time of assessment of pain | Yes | No | | | |
| a | 1 Month | 7 | 29 | 3.371 ^a | 4 | .498 |
| b | 2 Months | 6 | 28 | 2.422ª | 2 | .298 |
| c | 3 Months | 7 | 29 | 1.335 ^a | 3 | .721 |

N=102, n=34

^{*} p > .05

^{*} p > .05

| Sl.No. | Vitamin E | Additional Pain Medication or therapy | | Chi Sq | df | P-value | |
|--------|----------------------------|---------------------------------------|----|--------------------|----|---------|--|
| 1 | Time of assessment of pain | Yes | No | | | | |
| a | 1 Month | 5 | 29 | 1.575 ^a | 2 | .455 | |
| b | 2 Months | 7 | 27 | .455a | 2 | .796 | |
| c | 3 Months | 4 | 30 | .455a | 2 | .796 | |

Table 5. Association between pain scale in students and taking additional pain relief medicine or therapy during the course of the study in Vitamin E group

N=102, n=34

3.2. Section 2: Frequency Distribution of Students in Terms of their Initial Pain Score

Table 6 represents the descriptive statistics for pain score in pre-test across the study groups. The mean pain score and standard deviation at the time of segregating the participants into three groups were similar (Control group = 7.03 ± 1.7 , Ginger group= 7.15 ± 1.7 & vitamin E group = 7 ± 1.4).

The descriptive statistics for the pain score after the 1st, 2nd and 3rd months of all the three groups are shown in table 7. The mean pain score and standard deviation, when assessing the participants for the first time, were different across the three groups (Control group= 7.29 ±1.5, Ginger group = 6.21 ± 1.2 & vitamin E group = 6.21 ± 1) (see Table 7). Table 7 also shows that the standard deviation and the mean of pain score secured by the study participants, during the second assessment, were dissimilar across the three groups (Control group = 6.94 ± 1.3 , Ginger group = 5.21 ± 1 & vitamin E group = 4.85 ± 1). It was also found that after three months, the mean pain score and standard deviation values, attained by the participants during second assessed were different across the three groups (Control group = 62 ± 1.1 , Ginger group = 4.74 ± 0.9 & vitamin E group = 4.47 ± 0.8).

3.3. Section 3: ANOVA for Pain Score Difference between Pre-test Pain Score and Pain Score after 1 Month, Pain Score after 2 Months, and Pain Score after 3 Months

Table 8 shows the results attained through ANOVA analysis which infers whether an outcome of group means is statistically significant or not. The pain scores, across the three groups, before the administration of the supplements (pre-test) was validated with the help of one-way ANOVA tests (among the groups). The outcomes infer that prior to administration, no significant difference was observed in all the three groups in terms of pain scores (F [2, 99] = .074, p>.05). This finding infers that the group was homogeneous in terms of the severity of pain level.

The results from the ANOVA analysis infer whether the group mean difference is statistically significant or not. The pain scores across the three groups after the administration of supplements (after one month) were determined with the help of one-way ANOVA tests (among the groups) (see Table 9). According to the findings, all the three groups

experienced varied levels of pain following the administration of supplements and this variation was found to be statistically significant (F [2, 99] = 8.193, p < 0.001).

Tukey post hoc test is utilized to find whether there is a significant difference in the mean pain scores of all the three groups after one month. Table 10 shows that the mean pain scores of the ginger group (p<.002) and vitamin e group (p<.002) got reduced than the control group (p>0.05) as per the 'Mean Difference (1.088)'. Thus, it can be established that both ginger and vitamin E groups created a difference and reduced the pain scores after one month of study. But, no statistically-significant difference was found between ginger (p>.05) and vitamin e groups (p>0.05) in terms of reduction of pain scores after one month (see Table 10).

The ANOVA analysis result infers whether the group means difference is statistically significant or not. The pain scores across the three groups after two months of administering supplements were determined with the help of one-way ANOVA tests (among the groups) (see Table 11). According to the findings, all the three groups experienced varied levels of pain following the administration of supplements and this variation was found to have a statistically-significant difference (F [2,99] = 30.990, p<0.000).

After two months, a remarkable difference was found in terms of pain scores among the groups, according to the outcomes from Tukey post hoc test. Table 12 shows a decline in the mean pain score in both ginger (p<.000) and Vitamin E (p<.000) groups than the control group (p>0.05) as per the 'Mean Difference'. Thus, it can be stated that after two months of trial, both ginger and vitamin E groups made a significant difference and reduced the pain scores in a uniform manner. However, no statistically significant difference was found between the intervention groups after two months (p>.05 and p>0.05, respectively) in terms of reduced pain scores after two months (see Table 12).

The pain scores across the three groups after three months of administering the supplements were determined with the help of one-way ANOVA tests (among groups) (see Table 13). The findings indicate that the three groups experienced varied levels of pain following the administration of supplements and this variation had a statistical significance (F [2,99] = 47.501, p<0.001).

All the three groups showed remarkable differences with regard to pain scores after three months, according to the

p > .05

Tukey post hoc test. This finding allowed the researcher to identify the specific groups with differences. As per table 14, the mean pain score got reduced in both ginger as well as vitamin E groups than the control group (p>0.05) as per 'Mean Difference'. It may be inferred that, after three months of investigation, both ginger and vitamin E groups

made a significant difference and reduced the pain scores uniformly across the board. In terms of three-month pain reduction levels (see Table 14), no statistically significant difference was achieved between ginger (p>.05) and the vitamin E (p>0.05) groups.

Table 6. Distribution of students in terms of pre-test pain score in control group, ginger group and vitamin e groups

| Assessment of pain score | | Pretest | | | | | |
|--------------------------|---------------|--------------|-----------------|--|--|--|--|
| | Control group | Ginger group | Vitamin E group | | | | |
| Mean | 7.03 | 7.15 | 7.00 | | | | |
| Std. Error of Mean | 303 | 302 | 250 | | | | |
| Median | 6.00 | 8.00 | 8.00 | | | | |
| Std. Deviation | 1.766 | 1.760 | 1.456 | | | | |
| Sum | 239 | 243 | 238 | | | | |

N=102, n=34

Table 7. Distribution of students in terms of pain score after one month, two months and three months in control group, ginger group and vitamin e groups

| Assessment of | After one month | | | After two months | | | After three months | | |
|-----------------------|-----------------|-----------------|--------------------|------------------|-----------------|--------------------|--------------------|-----------------|--------------------|
| pain score | Control group | Ginger group | Vitamin E group | Control group | Ginger group | Vitamin E group | Control group | Ginger group | Vitamin E group |
| Mean | 7.29 | 6.21 | 6.21 | 6.94 | 5.21 | 4.85 | 6.62 | 4.74 | 4.47 |
| Std. Error of Mean | 259 | 206 | 188 | 235 | 173 | 189 | 189 | 165 | 154 |
| Median | 7.00 | 6.00 | 6.00 | 7.00 | 5.00 | 4.50 | 7.00 | 4.50 | 4.00 |
| Std. Deviation | 1.508 | 1.200 | 1.095 | 1.369 | 1.008 | 1.105 | 1.101 | 963 | 896 |
| Sum | 248 | 211 | 211 | 236 | 177 | 165 | 225 | 161 | 152 |

N=102, n=34

 Table 8.
 ANOVA for pre-test pain score difference among control group, ginger group and vitamin e groups

| Pretest pain score | Sum of Squares | Df | Mean Square | F | Sig. | |
|--------------------|----------------|-----|-------------|-----|------|--|
| Between Groups | 412 | 2 | 206 | 074 | 929 | |
| Within Groups | 275.235 | 99 | 2.780 | | | |
| Total | 275.647 | 101 | | | | |

N=102, n=34

p > .05

Table 9. ANOVA for pain score difference after 1 month among control group, ginger group and vitamin e groups

| After one month | Sum of Squares | df | Mean Square | F | Sig. |
|-----------------|----------------|-----|-------------|-------|------|
| Between Groups | 26.843 | 2 | 13.422 | 8.193 | 001 |
| Within Groups | 162.176 | 99 | 1.638 | | |
| Total | 189.020 | 101 | | | |

N=102, n=34

p < .05

Table 10. LSD post hoc test for multiple comparisons among the groups to see the specific groups differed in pain scores after 1 month

| | Multiple Comparisons | | | | | | | | | |
|---------------------|----------------------|---------------------|--------------------------------------|-------|-------------|-------------|--|--|--|--|
| | one month ey HSD | | | | | | | | | |
| (I) Group | (J) Group | Mean Difference | Std. Error Sig. 95% Confidence Inter | | e Interval | | | | | |
| | | (I-J) | | | Lower Bound | Upper Bound | | | | |
| Control group | Ginger powder group | 1.088^{*} | 310 | 002 | 35 | 1.83 | | | | |
| | Vitamin E group | 1.088^{*} | 310 | 002 | 35 | 1.83 | | | | |
| Ginger powder group | Control group | -1.088 [*] | 310 | 002 | -1.83 | 35 | | | | |
| | Vitamin E group | 000 | 310 | 1.000 | 74 | 74 | | | | |
| Vitamin E group | Control group | -1.088 [*] | 310 | 002 | -1.83 | 35 | | | | |
| | Ginger powder group | .000 | 310 | 1.000 | 74 | 74 | | | | |

^{*.} The mean difference is significant at the 0.05 level.

N=102, n=34

Table 11. ANOVA for pain score difference after two months among control group, ginger group and vitamin e groups

| ANOVA | | | | | | | | |
|------------------|----------------|-----|-------------|--------|------|--|--|--|
| After two months | Sum of Squares | Df | Mean Square | F | Sig. | | | |
| Between Groups | 84.961 | 2 | 42.480 | 30.990 | 000 | | | |
| Within Groups | 135.706 | 99 | 1.371 | | | | | |
| Total | 220.667 | 101 | | | | | | |

N=102, n=34

p < .05

Table 12. LSD post hoc test for multiple comparisons among the groups to see the specific groups differed after two months

| | Multiple Comparisons | | | | | | | | | |
|---------------------|----------------------|------------------|------------|------|-------------------------|-------------|--|--|--|--|
| After to | wo months | | | | | | | | | |
| Tuk | ey HSD | | | | | | | | | |
| (I) Group | (J) Group | Mean | Std. Error | Sig. | 95% Confidence Interval | | | | | |
| | | Difference (I-J) | | | Lower Bound | Upper Bound | | | | |
| Control group | Ginger powder group | 1.735* | .284 | .000 | 1.06 | 2.41 | | | | |
| | Vitamin E group | 2.088* | .284 | .000 | 1.41 | 2.76 | | | | |
| Ginger powder group | Control group | -1.735* | .284 | .000 | -2.41 | -1.06 | | | | |
| | Vitamin E group | .353 | .284 | .431 | 32 | 1.03 | | | | |
| Vitamin E group | Control group | -2.088* | .284 | .000 | -2.76 | -1.41 | | | | |
| | Ginger powder group | 353 | .284 | .431 | -1.03 | .32 | | | | |

st. The mean difference is significant at the 0.05 level.

N=102, n=34

p < .05

^{**} p < .05

| After three months | Sum of Squares | df | Mean Square | F | Sig. |
|--------------------|----------------|----|-------------|--------|------|
| Between Groups | 93.196 | 2 | 46.598 | 47.501 | .000 |
| Within Groups | 97.118 | 99 | .981 | | |

101

Table 13. ANOVA for pain score difference after three months among control group, ginger group and vitamin e groups

N=102, n=34

p < .05

Total

Table 14. LSD post hoc test for multiple comparisons among the groups to see the specific groups differed after three months

| Multiple Comparisons | | | | | | | | |
|----------------------|---------------------|--------------------------|------------|------|-------------------------|-------------|--|--|
| After thi | ree months | | | | | | | |
| Tuke | y HSD | | | | | | | |
| (I) Group | (J) Group | Mean Difference (I-J) | Std. Error | Sig. | 95% Confidence Interval | | | |
| | | | | | Lower Bound | Upper Bound | | |
| Control group | Ginger powder group | 1.882* | .240 | .000 | 1.31 | 2.45 | | |
| | Vitamin E group | 2.147* | .240 | .000 | 1.58 | 2.72 | | |
| Ginger powder group | Control group | -1.882* | .240 | .000 | -2.45 | -1.31 | | |
| | Vitamin E group | .265 | .240 | .515 | 31 | .84 | | |
| Vitamin E group | Control group | -2.147* | .240 | .000 | -2.72 | -1.58 | | |
| | Ginger powder group | 265 | .240 | .515 | 84 | .31 | | |

N=102, n=34

3.4. Section 4: Findings Related to the Repeated Measures ANOVA to See the Long-Term Effectiveness of Pain Intensity Score

190.314

Table 15 shows the overall significant difference between the means at varying time points. It also shows the F value that corresponds to the 'time' component, its associated level of significance, and the effect size ('Partial Eta Squared'). As already assumed, the repeated measures ANOVA mandate tests such as sphericity and Mauchly's tests should be conducted in the above-mentioned scenario. With p>.05, the data meets the demands of sphericity. So, there is no need to correct the data as in Greenhouse-Geisser of Huynh-Feldt. The data from table 15 report that in the case of utilizing ANOVA with repeated measures, the mean scores for the pain remain unchanged (F (3, 99) = 1.350, P>.05) within the control group (see Table 15).

Figure 2 shows that most of the students had pain scores in the range of 6.62 to 7.29 and it further helps in understanding the tabular results (see Figure 2). Based on the results from ANOVA repeated measures, it can be understood that no statistically significant difference was found in the mean pain scores among the time points (F (3, 99) = 1.350, P>.05).

Table 16 shows the F value for time, related significance level and the impact size (partial eta squared). Since the current study data defied the sphericity assumption, the numbers in the "Greenhouse-Geisser" row were examined further (see Table 16). The mean pain scores were found to

have statistically-significant difference within the ginger group during ANOVA with repeated measures and Greenhouse-Geisser correction (F(2.013, 11.663) = 25.868, p < .000).

Figure 3 shows that most of the students had pain scores in the range of 4.47 to 7, which further helps in understanding the tabulated results. The mean pain scores were determined to have statistically-significant difference among the time points (F(2.013, 11.663) = 25.868, p < .000) in repeated measures ANOVA. With the implementation of Bonferroni correction in post hoc tests, it was revealed that the Ginger powder administration reduced the severity of pain soon after one month, two months, and three months of the study period i.e., statistically significant (P<.000). Therefore, it can be concluded that consuming ginger powder daily after food steadily 3 months reduces the severity of pain within the group throughout the study period and for a long term too (see Figure 3).

Table 17 shows the F value for the time factor, effect size (partial ETA squared) and the associated significance level. Since the current study data abrupted the sphericity assumptions, the 'Greenhouse-Geisser' is applied as shown in table 17. When ANOVA with repeated measures was utilized with Greenhouse-Geisser correction, a statistically-significant difference (F(2.739, 90.399) = 32.573, p < .000) was achieved for mean pain scores within the vitamin E group.

Figure 4 shows that most of the students had pain scores

^{**} p < .05

in the range of 4.47 to 7, which further helps in understanding the tabulated results. The mean pain scores were determined to have statistically-significant differences among the time points (F(2.013, 11.663) = 25.868, p < .000) by repeated measures ANOVA. With the implementation of Bonferroni correction in post hoc tests, it was revealed that Vitamin E capsule administration

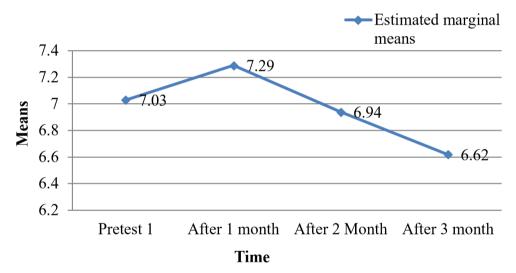
reduced the severity of pain soon after one month, two months, and three months of menstruation i.e., statistically significant (P<.000). Therefore, it can be concluded that the consumption of vitamin E capsule (three months) steadily reduced the severity of pain within the group throughout three months of administration and when used for a long term too (see Figure 4).

Table 15. Tests of within-subject's effects to see the overall remarkable difference in the mean pain score at varying time points within the control group

| Tests of Within-Subjects Effects | | | | | | | | |
|----------------------------------|--------------------|-------------------------|----|----------------|-------|------|------------------------|--|
| Measure: pair | 1 | | | | | | | |
| Source | | Type III Sum of Squares | df | Mean Square | F | Sig. | Partial Eta Squared | |
| time | Sphericity Assumed | 7.941 | 3 | 2.647 | 1.350 | .262 | .039 | |
| Error (time) | Sphericity Assumed | 194.059 | 99 | 1.960 | | | | |

N-34

p > .05



N-34

Figure 2. Estimated marginal means of pain score in Control group

Table 16. Tests of within-subject's effects to see overall significant difference among the mean pain scores at various time points within the ginger group

| Within-Subjects Effects Test | | | | | | | | | |
|------------------------------|--------------------|-------------------------|--------|-------------|--------|------|------------------------|--|--|
| Pain | | | | | | | | | |
| Test | | Type III Sum of Squares | df | Mean Square | F | Sig. | Partial Eta Squared | | |
| Time | Greenhouse-Geisser | 117.765 | 2.013 | 58.508 | 25.868 | 000 | 439 | | |
| Error (Time) | Greenhouse-Geisser | 150.235 | 66.423 | 2.262 | | | | | |

N-34

p<.05

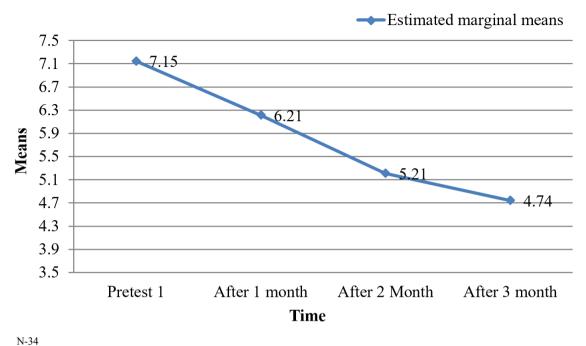


Figure 3. Estimated marginal means of pain score in Ginger group

Table 17. Tests of within-subject's effects to see overall significant difference among the mean pain scores at different time points within vitamin e

| Within-Subjects Effects Tests | | | | | | | | |
|-------------------------------|--------------------|----------------------------|-------|-------------|--------|------|------------------------|--|
| Pain | | | | | | | | |
| Test | | Type III Sum of Squares | df | Mean Square | F | Sig. | Partial Eta Squared | |
| Time | Greenhouse-Geisser | 141.324 | 2.739 | 51.590 | 32.573 | .000 | .497 | |
| Error (Time) | Greenhouse-Geisser | 143.176 | 90.39 | 1.584 | | | | |

N-34 p < .05

group

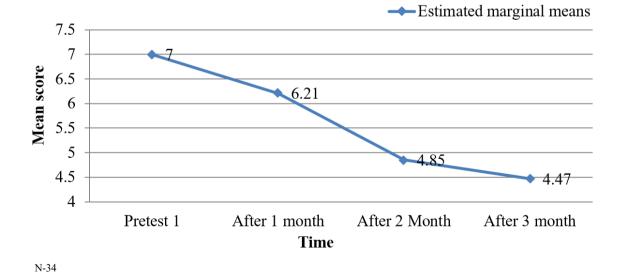


Figure 4. Estimated marginal means of pain score in vitamin E group

4. Discussion

The purpose of this study is to compare the effects of ginger and vitamin E upon students with primary dysmenorrhea and find whether an association exists between the additional medicine intake during the course of the study with that of the pain score in all the three groups. After identifying and comparing the effect on pain severity, the author also made an attempt to create an awareness initiative regarding the use of ginger and vitamin E to mitigate the ill-effects of dysmenorrhea. Thus, the burden of this disease in the society can be reduced and the quality of life of the students can also be improved.

The present study found that the mean pain scores for all the three groups before the administration of the supplements (pre-test) use one-way ANOVA (among the groups). The outcomes infer that prior to administration, no significant difference was obtained in terms of mean pain scores in the three groups (F [2, 99] = .074, p>.05). This finding infers that groups were homogeneous in terms of severity of pain level. The pain scores, across the three groups, were determined after the administration of supplements (after one month) using one-way ANOVA (among the groups). The results suggest that after the administration of supplements, all the three groups achieved different pain scores and this difference was found to be statistically significant (F [2, 99] = 8.193, p<0.001), after two months (F [2,99] = 30.990, p<0.000) and after three months (F [2,99] = 47.501, p<0.001). The results suggest that after the administration of supplements, all the three groups achieved different pain scores with statistically significant differences.

Shirvani et al [18] also obtained similar outcomes, as the researcher analyzed the influence of mefenamic acid and ginger in treating primary dysmenorrhea-induced pain. In this study, VAS was utilized to measure the pain intensity and the obtained data was analyzed for descriptive statistics and other correlation and regression analyses. A statistically significant difference was found among the groups in terms of pain scores at different times while no such relation was found between the groups. The study concluded the effectiveness of ginger alike mefenamic acid in mitigating the pain induced by dysmenorrhea.

Further, the current study results were in accordance with the research outcomes, obtained by Kashefi et al. [19] on the severity of primary dysmenorrhea. In this study, ginger, zinc sulphate, and a placebo were compared for their effectiveness. The results demonstrated that both zinc sulphate and ginger reduced the pain caused by primary dysmenorrhea among younger women. Pakniat et al. [20] compared vitamins E and D along with ginger for its effectiveness in reducing the severity of primary dysmenorrhea. In this study, the authors used VAS scale and a questionnaire to collect the data for two successive time periods. The equivalent outcomes were obtained which inferred the effectiveness of all the three elements

(vitamins E and D, ginger) in reducing the prevalence of dysmenorrhea, while ginger was found to be the most important contributor.

In the comparative analysis conducted by Ozgoli et al. [21], the impact of mefenamic acid, ibuprofen and ginger was compared in terms of pain severity reduction from dysmenorrhea. The data was collected among 150 students and the outcomes confirmed the superiority of ginger in mitigating the disease symptoms alike ibuprofen and mefenamic acid, though no significant difference was obtained. In [22], Rahnama et al. found that ginger supplements to students suffering from moderate to severe dysmenorrhea significantly mitigated the disease in two groups (with each group containing 60 students). In this study, two different protocols were used with 500 mg capsules for 5 and 3 days respectively. In spite of the decline in dysmenorrhea symptoms in both groups, the first group explicitly experienced lesser pain. Hamideh et al. [23] found that the supplementation of ginger is the most beneficial method against the disease. Further, ginger was called an effective herb against dysmenorrhea and its symptoms, as opined by Sana et al. [24]. So, the hypothesis "Ginger has more ability to reduce the pain, symptoms and problems of primary dysmenorrhea as compared to peppermint", was found to be true.

In spite of using NSAIDs in treating dysmenorrhea, it was found that the drug has a significant impact on both mortality and morbidity. So, ginger remains the optimal solution for mitigating the disease. The current study outcomes also found that the mean pain scores had statistically-significant differences in the ginger group (F(2.013, 11.663) = 25.868, p < .000) and in the vitamin E group (F(2.739, 90.399) = 32.573, p < .000), when using ANOVA with repeated measures and a Greenhouse-Geisser correction. In addition to this, the author also used chi-square method to determine the existence of a relationship between the student's pain scores and the use of additional painkillers or therapy, while they were studying under a control group. No such relationship was found at the pre-test, one month, two months, or three months into the study (p > .05), thus indicating the fact that only intervention can reduce the pain.

Nayeban et al. [25] found that 400 units of vitamin E every day for about five days can significantly reduce the pain intensity (p - 0.046 < 0.05). According to Safari et al. [26], vitamin E and mefenamic acid, common medicines used to treat dysmenorrhea, have an identical impact on the condition. A quasi-experimental study by Akhlaghi et al. [27] on 200 students from Mashhad Medical University revealed that the pre-intervention pain level reduced from 5.18 to 3.40 after the administration of vitamin E. When Khlaghi et al. [28] looked at the impact of vitamin E on the severity of dysmenorrhea, it was found that the intervention significantly affected both the intensity and duration of the condition.

Maryam et al. [29] stated that both control and vitamin

E groups have the potential to mitigate the pelvic pain of dysmenorrhea. However, vitamin E significantly reduces the pain. In terms of safety, it is better and safer to treat dysmenorrhea. Previous research has shown that after receiving a vitamin E injection, the discomfort associated with dysmenorrhea got significantly reduced, along with an increase in the molecules that resemble endorphins. The usage of vitamin E is thought to boost the levels of endorphins, which may contribute to pain reduction mechanism in dysmenorrhea [30-31]. Sadeghi et al. [32] revealed that Omega-3 inhibits prostaglandin synthesis, which in turn reduces the severity of dysmenorrhea. The results established that vitamin E in combination with omega-3 remarkably mitigates the pain in all the groups while the current study utilized merely vitamin E. Vilvapriya et al. [33] concluded that vitamin E reduces the pain severity and is a safer option compared to NSAIDs. The study findings infer that both vitamin E and ginger powder forms can be used as substitutes for NSAIDs to lessen the severity of dysmenorrhea, despite the fact that NSAIDs are a frequent medication used to treat the condition. Therefore, more in-depth research must be conducted to support this conclusion.

4.1. Limitations

- One of the study's biggest limitations was that some of the students were unwilling, which led to their elimination.
- The student taking additional pain medication is a confounding variable that makes it challenging to interpret and understand how the treatment medications treated the pain among young women. However, since these medications were not linked to pain levels over the course of three consecutive periods, the author was able to compare only how each group's effects affected the severity of pain experienced by students.

5. Conclusions and Suggestions

In conclusion, ginger powder and vitamin E have been proven to be the most helpful natural resources and when used frequently, they can reduce the intensity of discomfort. Being a natural alternative to synthetic medicines, ginger can treat primary dysmenorrhea with no side-effects. The consequences of dysmenorrhea can be greatly reduced by the widely-used vitamin E. However, in terms of treating primary dysmenorrhea, vitamin E seemed to be more effective than the ginger powder. Since the administration of these supplements carries a lower risk than the analgesics, more research is needed to determine their effects. Since the sample size (102) used to compare all the three groups for treatment was very small, the future research should be conducted with a large sample size to draw in-depth conclusions.

Patient Consent

Informed consent was obtained from all students.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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