Innovations

Efficacy of Physiotherapy Intervention for Management of Primary Dysmenorrhoea- A Pilot Study

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Abstract:

Objectives: To evaluate preliminary effects of a structured physiotherapy program on pain and quality of life in women with primary dysmenorrhoea. To assess feasibility of methodological procedures and obtain preliminary data (effect size) to estimate the sample size for a future randomised control trial. Methods: Eighteen women aged 18-25 years were divided into two groups(experimental group and control group) by lottery method. Women assigned to experimental group performed a set of structured supervised exercises for 3 days a week for 8 weeks whereas women in control group were educated with verbal instructions on managing menstrual pain and they continue their own home management. Participants were assessed at the end of 0^{th} week, 4^{th} week and finally at 8^{th} week on the outcome measures of pain (NPRS) and quality of life (SF -36). Results: The study findings revealed that there was a significant difference in the numeric pain rating scale between groups (p=0.001), there was a significant difference in pvalue between all sub-scales of SF-36. Conclusion: A structured physiotherapy intervention helped young women with managingsymptoms of dysmenorrhoea which greatly impacted their quality of life. Their pain levels also came down after completion of the protocol.

Keywords: Primary dysmenorrhoea, pain, quality of life, physiotherapy.

Introduction:

Primary dysmenorrhoea is a a clinical manifestation of pain that is associated with menstruation without any aetiology which lasts for 8-72 hours. Pain is due to excessive production and release of prostaglandins which thereby increases

uterine muscle contraction. It's prevalence increases during adolescence and reaches to it's highest in 20-24 years and decreases after that¹.

PD clinical manifestation may include lower back pain, premenstrual irritability, nervousness, fatigue, depressed mood, headache, some of gastrointestinal symptoms such as; nausea, vomiting, bloated abdomen and difficulty in emptying the intestines with constipation or diarrhoea, an urge to urinate frequently that can be noticeable in women with PD at least a part or for the duration of the menstrual period². Approximately 45-95 % of women suffer from symptoms related to dysmenorrheawith every one in five cases being severe³. The menstrual pain affects almost threedecades of a women's life. Prevalence of menstrual pain in India specifically ranges from 50-87.8%⁴.In a cross-sectional study on Indian femalestudents in the age group of 11-28 years found that participants with moderate andsevere pain missed 2-2.5 days of education per month. Around 25.5% of them soughtpharmacological methods to deal with the pain and 83.2% depended on non-pharmacological methods where only 14.2% sought medical advice⁵.

While there have been studies which did mention that inclusion of regular physical activity helped in relieving women of painful menstrual cramps as the blood flow to the uterus increases thereby decreasing the ischemic uterine pain⁶ but a structured physiotherapy program involving multiple types of exercises in combination was yet to be studied.

Methodology:

- Study Design: Randomised control trial
- Sampling: Simple Random Sampling
- Randomisation: Lottery Method
- Source of data-Women from community level residing in Urban Bangalore
- Population- Women between age range 18-25 with menstrual pain (primarydysmenorrhoea)
- Inclusion Criteria:
- Women with normal menstrual cycle with dysmenorrhea (menstrual pain)
- Women in age between 18-25 years
- Menstrual pain higher than 4 according to NRS (Numeric Rating Scale)
- Have primary dysmenorrhoea (self-reported pain) during the majority of themenstrual cycles in the past three months.
- Womenwho are able to understand English.
- Exclusion Criteria:
- Mild or infrequent dysmenorrhoea (less than 1 out of 3 three cycles)
- Irregular or infrequent menstrual cycles (usually outside of the typical range of a 21 to 35 day cycle)

- Women with Gastrointestinal, urogynecological, autoimmune, psychiatric diseases, other chronic pain syndromes, childbirth, positive pregnancy test, those who useintrauterine devices, those who have had pelvic surgery.
- Women with hormonal therapy
- Women are physically active on a regular basis
- Women performing any other exercises &sports.
- Sampling Method-Simple random Sampling

Ethics approval and consent to participate:

Permission to conduct the study was obtained from Institutional Ethical Committee. Consent was obtained from the participants. The researchers were offered adequate information about the study purposes and its significance. Participation was voluntary. Participants were assured that their responses would be confidential and information that might reveal their identity would not be recorded, and only aggregated data would be communicated.

Participants:

Recruitment and Study procedure:

Participants were recruited by simple random sampling and they were allocated into experimental group and control group by lottery method. Exercise protocol comprising of exercising 3 days per week on alternate days and continuance of theentire protocol for 8 weeks. Both the outcome measures (NPRS and QoL by SF36) were assessed on the day of maximum pain intensity (i.e., first/second day of menstruation) of the menstrual cycle on 0th week and reassessed on end of 4th week and at the end of 8thweek after completion of the interventions on the day of maximum pain intensity (i.e., first/second day of menstruation) of next menstrual cycle.

Because menstruation pain in primary dysmenorrhea starts from several hours before the beginning of bleeding up to 24 to 48 hours later, most individuals experience this pain on the first day. Therefore, the study participants were asked to contact the researcher at the peak of menstrual pain (usually on the first day).

Intervention:

The exercise protocol was led and monitored by trained physical therapistfor 8weeks which consisted of six categories of exercises. The duration of each exercise session was 50 minutes. Treatment was started after 4th dayof menstruation.

The protocol starts with a warmup which includes a group of stretching and flexibility exercises (neck, trapezius, shoulder girdle, forearm muscles, quadriceps, adductors, hamstrings) for about 10 minutes with a hold time of 5 seconds for each group of muscles.

The exercise program included a set of isometric exercises for 10 minutes which included exercises for pelvic floor, adductors, rectus and transverse abdominis, internal and external oblique muscle with the participant in lying down position is performed, each exercise was to be held for 5 seconds.

The next group of exercises were core strengthening exercises for 10 minutes, followed by aerobic exercises also performed for 10 minutes, at the end participants were instructed regarding pelvic floor exercises for 5 minutes. The exercises session was concluded with a cool down session comprising of relaxation exercises for last 5 minutes.

Outcome Measures:

The exercise program was given for 8 weeks and improvement of symptoms of primary dysmenorrhoea was assessed on basis of pain and quality of life.

Pain Intensity:

Pain being the primary and most important complaint among women with primary dysmenorrhoea. The pain score was assessed using Numeric pain rating scale (NPRS)

Quality of life:

Along with pain the quality of life of women also gets affected due to primary dysmenorrhoea. This parameter was assessed by using health related quality of life scale SF-36.

Statistical Analysis:

Analysis of data efficacy was accomplished on the intent to treat women with menstrual pain, defined as all randomised participants who met the inclusion criteria and completed the physiotherapy exercise protocol 3 times per week for 8 weeks. The data were entered into a computer database. The software package used was SPSS version 27.0 was used for the analysis with p <0.05 will be considered as significant.

Summarisation of descriptive data was done, normality of data checked using Kolmogorov -Smirnov test/ Shapriowilk . The mean and standard deviation with normal distribution was done. Data was collected at baseline / 0th week , at the end of 4 th week and finally at the end of 8 th week. Data will be analysed using repeated measures ANOVA.Numbers and percentages were used to express categorical data.

Results:

Sociodemographic and clinical characteristics of both groups:

A total of 20 patients were included for this pilot study where 10 were included in the experimental group and 10 were included in the control group.

The baseline demographic and clinical data of the participants of this pilot study of participants are shown in Table 1.

| Group Data: | | | | | |
|-------------|--------------|----|---------|----------------|---------|
| | Group | N | Mean | Std. Deviation | t |
| Age | Experimental | 10 | 23.700 | 1.252 | 3.055 |
| | Control | 10 | 22.200 | .919 | p=0.007 |
| Height | Experimental | 10 | 163.300 | 10.371 | 1.713 |
| | Control | 10 | 156.800 | 6.033 | p=0.104 |
| Weight | Experimental | 10 | 57.300 | 9.978 | .787 |
| | Control | 10 | 53.500 | 11.559 | p=0.442 |
| BMI | Experimental | 10 | 21.790 | 3.478 | .054 |
| | Control | 10 | 21.700 | 3.927 | p=0.957 |

Table 1:Group Statistics

Mean age of experimental and control group was almost identical $(23.7\pm1.25 \text{ vs } 22.2\pm0.91)$ respectively. 21.8 ± 3.47 and 21.7 ± 3.92 was the BMI of experimental and control groups respectively. 45% of the total participants had normal BMI. There was no statistically significant difference between the studied groups concerning age and BMI at baseline measurement (p>0.05).

The menarche age for 45 % of the participants was 12- 14 years and for 40 % of the participants it was between 15-17 years. All the participant in the pilot study did have regular menstrual cycles and all of them did have menstrual pain in the previous 3 cycles which was a part of their inclusion criteria as well. All the 20 participants were unmarried.

The cycle length of around 60% of the participants in the pilot study was 25-28 days. The number of days of flow for around 50% of the participants was 5 days where around 65% of women ideally used 2-3 sanitary pads in the initial 1-2 days of flow. Around 85% of the participants did not have any menorrhagia and only 10% of the participants did have clots during their cycle. 65% of the total participants in this pilot study had a family history of menstrual pain where their mother, sisters or aunts also had a similar history at their young age. The most common musculoskeletal complaints among these women were low back pain, led pain, thigh pain, abdominal cramps and fatigue. Few of them also had mood swings, irritability and nausea. 70% of the participants had at least 1 day getting missed due to menstrual pain and they found their efficiency at schools and colleges or at work getting affected due to pain.

At the initial assessment, there was no statistically significant differences between the studied groups in terms of menstrual characteristics(p>0.05).

Effects of Physiotherapy Protocol on dysmenorrhoea pain:

The mean baseline dysmenorrhoea pain intensity obtained with NPRS (Numeric Pain Rating Scale) in control group was 8.10±0.99; the mean baseline in experimental group was 8.30 ± 0.82 . The intensity of pain at the end of 4 th week was 7.10±0.56 in control group and 6.40±0.69 in control group which showed statistical significance. While the last measurement was done at the end of 8th week where the mean NPRS in control group was 5.80 ± 0.63 and in experimental group was 3.70±0.82; thereby suggesting a significant improvement in pain in experimental group.

The next outcome measure for the study was SF-36 Health Survey quality of life scale which consists of 8 sub-scales. (Physical functioning, Role limitation-Physical, RoleLimitation-Emotional, Energy/ Vitality, Emotional wellbeing, social functioning, Bodily Pain and General Health). There were significant differences in all the 8 sub-scales on performing repeated measures ANOVA (Analysis of variance) to understand the improvement of the protocol within group at different time frames. This can be seen from the tables given below Table 2: RM ANOVA.

| | | Experimental | Control Group | |
|--------|--------------------------|---------------|---------------|----------|
| S. No | Parameters | Group | | P- Value |
| | Mean ± Standard Deviatio | | | |
| SF-36 | | | | |
| DI -00 | | | | |
| 1 | PF | | | |
| | Physical | | | |
| | Functioning | | | |
| | O th | 49.90 ± 11.45 | 50.70 ± 12.17 | <0.001* |
| | 4 th | 62.20 ± 10.17 | 58.50 ± 14.08 | |
| | 8 th | 84.80 ± 11.44 | 66.60 ± 12.95 | |
| 2 | RL_P | | | |
| | (Role limitation- | | | |
| | Physical) | | | |
| | O th | 23.40 ± 12.31 | 22.40 ± 12.85 | <0.001* |
| | 4 th | 35.80 ± 11.67 | 29.10 ± 12.8 | |
| | 8 th | 67.4 ± 18.95 | 33 ± 12.79 | |
| 3 | RL_E | | | |
| | (Role Limitation- | | | |
| | Emotional) | | | |
| | O th | 68.30 ± 11.80 | 69.40 ± 10.52 | <0.001* |

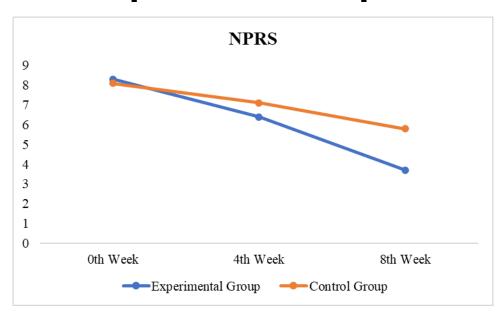
| 8th 87.8 ± 10.45 78.90 ± 10.10 | |
|--|--|
| 8^{th} 87.8 ± 10.45 78.90 ± 10.10 | |
| | |
| 4 E/V (Vitality) | |
| 0^{th} 48.90 ± 16.57 46.80 ± 10.24 $0.002*$ | |
| | |
| 4 th 63.50 ± 14.60 53.50 ± 10.48 | |
| 8 th 74.30 ± 10.72 60.10 ± 11.48 | |
| 5 Ewb | |
| (Emotional | |
| Wellbeing) | |
| 0^{th} 58 ± 12.43 56.10 ± 14.15 $0.009*$ | |
| 4 th 74.40 ± 11.24 63.30 ± 10.26 | |
| 85.60 ± 10.13 69.80 ± 11.43 | |
| 6 SF | |
| (Social | |
| Functioning) | |
| 0 th 57.7 ± 17.752 55.10 ± 10.214 <0.001* | |
| 4 th 75.90 ± 11.63 59.50 ± 9.83 | |
| 86.30 ± 13.32 67.20 ± 10 | |
| 7 BP | |
| (Bodily Pain) | |
| 0 th 57.90 ± 12.64 56 ± 10.31 0.001* | |
| 4 th 76.60 ± 11.15 61.90 ± 11.29 | |
| 84.20 ± 10.17 67.40 ± 13.71 | |
| 8 CH | |
| (General Health | |
| | |
| 0 th 52.60 ± 10.12 50.40 ± 10.82 0.001* | |
| 4 th 70.30 ± 10.71 62.70 ± 10.10 | |
| 86.10 ± 12.13 74.10 ± 10.09 | |
| 1 NPRS | |
| (Numeric Pain | |

| Rating Scale) | | | |
|-----------------|-----------------|-----------------|---------|
| O th | 8.30 ± 0.82 | 8.10 ± 0.99 | <0.001* |
| 4 th | 6.40 ± 0.69 | 7.10 ± 0.57 | |
| 8 th | 3.70 ± 0.82 | 5.80 ± 0.63 | |

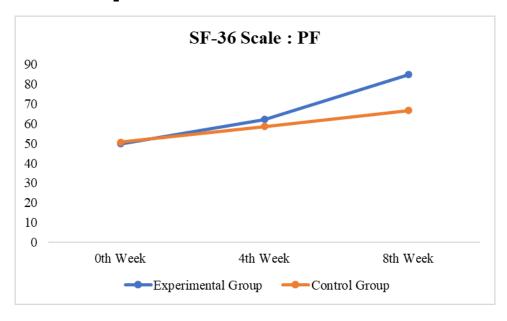
Statistical Software: SPSS Version 27; Statistical Test: Repeated Measures of ANOVA; P-Value < 0.05 - Significant*

(*- Significant difference, **-Highly Significant, ***- Very Highly significant)

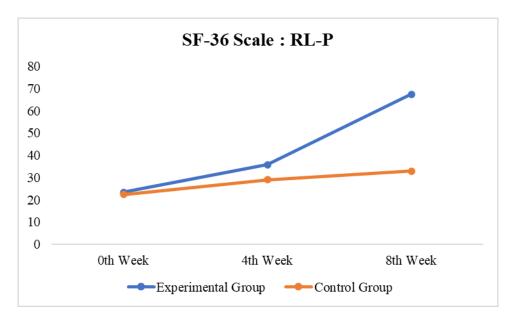
Repeated measures ANOVA Graphs:



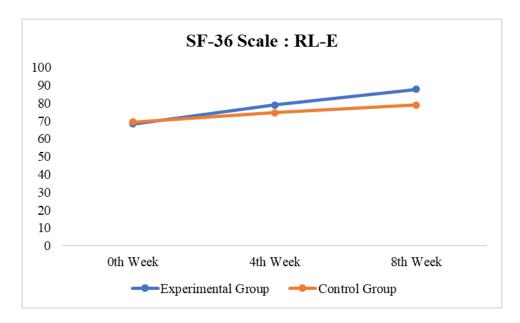
Graph 1: Decrease in Pain scores over time.



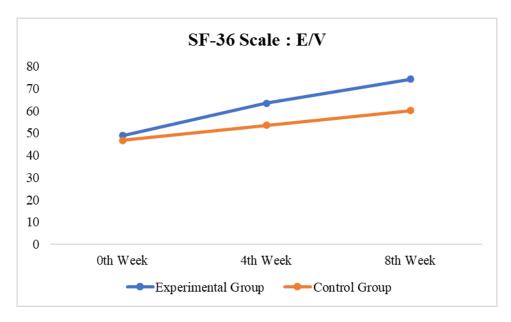
Graph 2: Improvement in Physical Functioning over time.



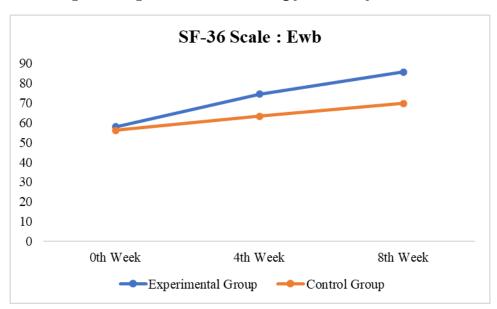
Graph 3: Improvement in Role Limitation – Physical over time.



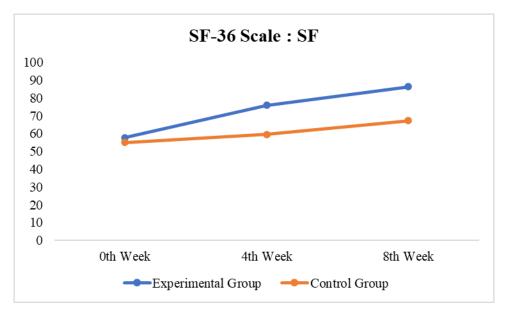
Graph 4: Improvement in Role Limitation- Emotional over time.



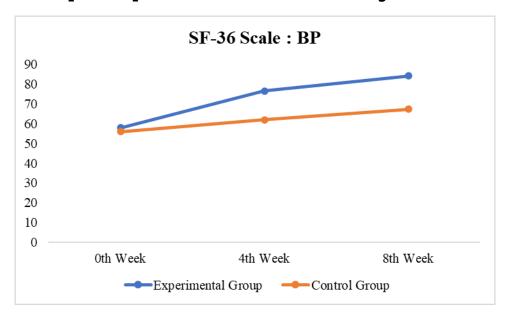
Graph 5: Improvement in Energy / Vitality over time.



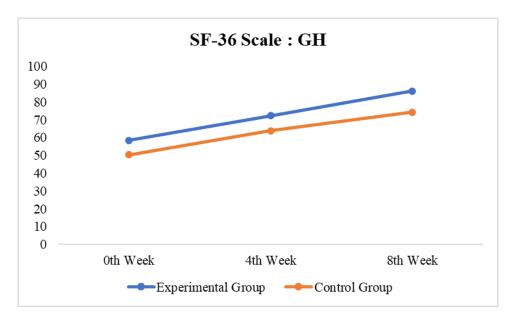
Graph 6: Improvement in Emotional Wellbeing over time.



Graph 7: Improvement in Social Functioning over time.



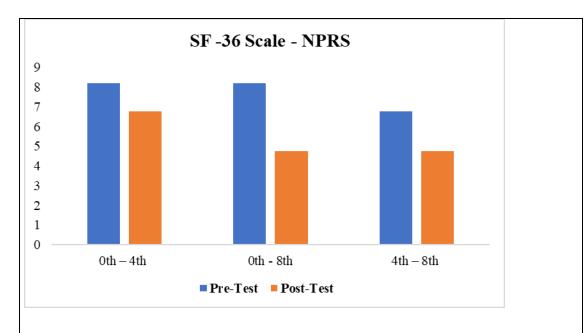
Graph 8: Improvement in Bodily Pain over time.



Graph 9: Improvement in General Health over time.

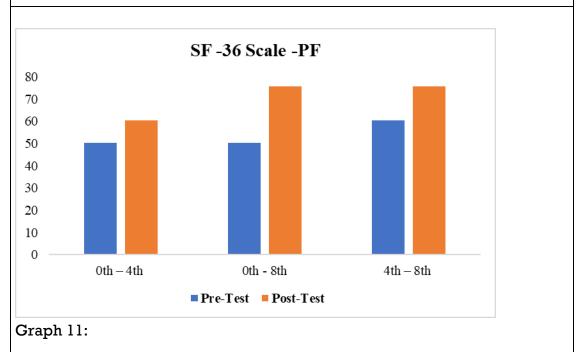
Student's unpaired t- test was performed to understand improvement in pain and quality of life outcome measures between experimental and control group at 0^{th} week, 4^{th} week and 8^{th} week as presented in table 3: Independent t-test between the groups.

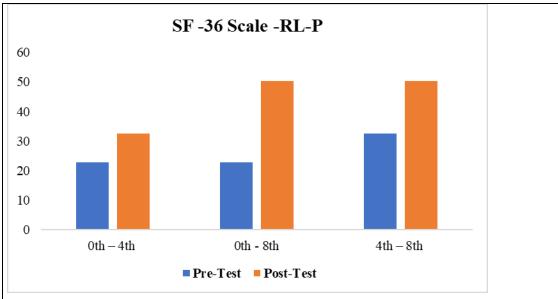
| NPRS | | | | | | |
|--------|--|------------|----|-------|-----------|----------|
| | | | | | Std. | |
| Period | | group | N | Mean | Deviation | P value |
| 0 th | | Experiment | 10 | 8.300 | .823 | |
| | | al | | | | |
| | | Control | 10 | 8.100 | .994 | 0.63 |
| 4th | | Experiment | 10 | 6.400 | .699 | |
| | | al | | | | |
| | | Control | 10 | 7.100 | .568 | 0.024* |
| 8th | | Experiment | 10 | 3.700 | .823 | |
| | | al | | | | |
| | | Control | 10 | 5.800 | .632 | 0.001*** |



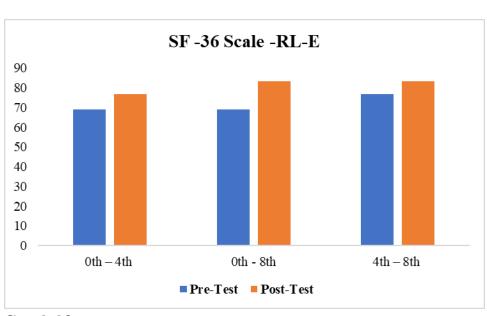
Graph 10:

PF

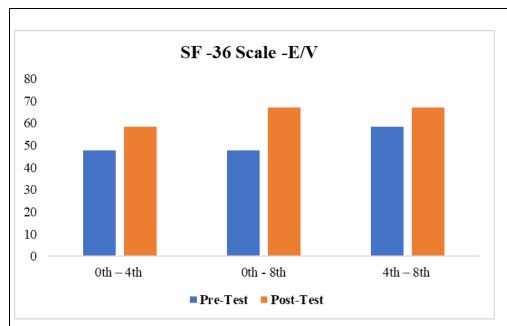




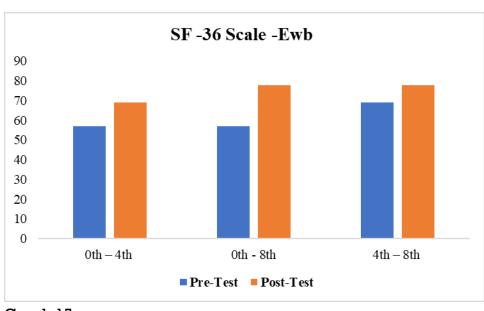
Graph 12:



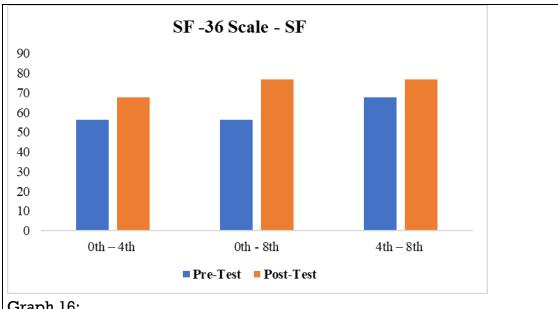
Graph 13:



Graph 14:

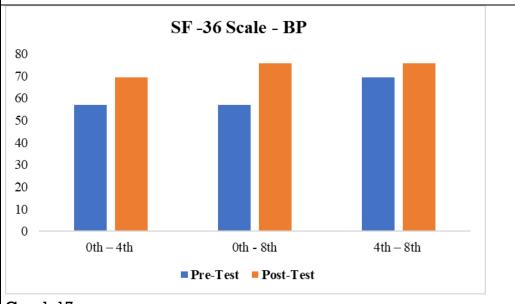


Graph 15:



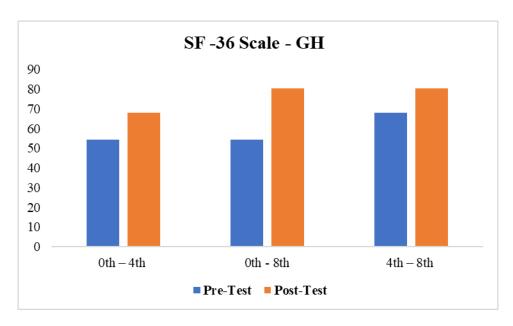
Graph 16:

ΒP



Graph 17:

GH



Graph 18:

It can be comprehended from the statistical analysis that NPRS (pain) scores decreased significantly at 4^{th} week and also at the end of 8^{th} week in the experimental group as compared to control group.

Almost in all the sub-scales of SF-36 there was an improvement in the experimental group. The improvement was significant at 8th week in the experimental group, whereas significant changes were also seen in few of the subscales like Emotional well-being, Social Functioning and Bodily pain even at the end of 4th week. The sample size being small an all-conclusive answer could not be obtained, which can be found out in a large-scalestudy, but the protocol definitely helps in decreasing pain due to dysmenorrhoea and improvement of quality of life, which thus solves the purpose of this pilot study.

Discussion:

Primary dysmenorrhoea (PD) ismenstrual pain without any pelvic pathology that usually develops 1 or 2 years after menarche, where the pain is often described as cramping, spasmodic located at the lower abdomen and radiating to front and medial thigh. This pain usually starts 48-72 hours before or after menstruation⁷. PD does impact the lives of young women drastically, with literatures which states thatPD causes work or school absenteeism, limitations in participation social activities^{8,9,10}, psychological disorders such as depression and anxiety¹¹, increased rates of self medication to manage symptoms of PD. Previous literature also suggests the prevalence of dysmenorrhoea generally around 67-90% among women aged 17-24 years^{12,13}.

Pain is the most common symptom, which is localised to lower abdomen, which may spread to suprapubic region, thighs, lumbar region and lower back. There could be other symptoms like headache, nausea, constipation, diarrhoea, incontinence and vomiting¹⁴.

Study by Izzo and Labriola¹⁵ proposed that performing exercise caused an increase in blood flow and metabolism of uterus which helps in reduction of dysmenorrhoea symptoms. Improved metabolism also helps in reduction of symptoms. Increased menstrual pain due to uterine contraction is due hyperactivity of sympathetic nerve system via increased contractility of uterine muscles. It is also suggested that exercise helps in secretion of endorphins from brainand these materials in turn raise pain threshold of the body 16. Daley A J also proposed that the contracted ligamentous bands in abdominal region were the causative factor for physical compression of nerve pathways and thus stretching exercises were effective in relieving symptoms¹⁷.In a study by Golomb et al¹⁸ where they concluded that exercise is widely accepted as a means of moderating stressand biochemical changes in immune system, which helps in improving symptoms of dysmenorrhoea (by reducing stress).

In previous studies conducted by Zainab et al¹⁹, Tanmahasamut et al²⁰ and Kannan. P²¹ et all, all suggested that the first major complaint that women with dysmenorrhoea face was pain and because of the pain the quality of life of these women were affected to a greater extent among these young women.in yet another study by KaranthS et al²² which was also in sync with the previous studies that quality of life reduced in women with dysmenorrhoea. In yet another recent review article in 2022 by S Dash etal²³ where it was concluded that most women in southeast Asia did not seek any medical help or advise regarding any menstrual issues and preferred self management to deal with the symptoms. Preference for non-pharmacological management was found in 83% of these women. There was also an absence of holistic exercise protocol which would benefit in managing menstrual pain. It was also found from previous literature that most of the women were still not aware about the scope and prospects of physiotherapy and itsrole for dealing with such issues. Though few studies compared and contrasted with a single category of exercise, there was a need for a complete and comprehensive exercise protocol for dealing with pain due to dysmenorrhoea which is so common among young girls²⁴.

There have been few studies which have compared individually various exercise program to manage symptoms among dysmenorrhoeic women, but a proper planned and constructed exercise protocol was not done earlier. This pilot study wasaimed to assess the applicability, clarity, simplicity of tools and manoeuvres of interventions and estimate the time needed for administration and to evaluate the efficacy exercise protocol for pain and quality of life.

In this current pilot study, participants performed the set of structured exercises and they were evaluated at the end of 4th week where the participants reported a significant drop in pain scores with a mean of 8.30±0.82 to 6.40±0.69, while the mean score came down to 3.70 ±0.82 at the end of 8th week in the experimental group. There was significant difference in most of the sub-scales of SF-36.

Based on the above results, the final versions of the tools will be prepared. This pilot study helped in planning the schedule for field work and for executing it on larger sample size in future.

Limitation:

The study being a pilot study the sample size is considerably minimal. No long term follow up of subjects was done. The study was only conducted between the age group of 18-25 years.

Recommendations of the Study:

- Different age group can be selected as the group category,
- Sample size can be increased, and the study can be done in large population across varied geographical locations in India.
- In futurestudy long term follow up can be done, and also understand any waning effect of exercise.
- Including much more questionnaire is advised for further research study.

Conclusion:

According to the findings and discussion of this pilot study it can be concluded that majority of the participants were unmarried, who recorded absenteeism and decreased efficiency. Most of the participants did have a family history of dysmenorrhoea. Participants on performing the exercise protocol had a significant drop in pain scores (NPRS) and also improvement in great majority of domains quality of life scores (SF-36) at the end of 8 weeks.

Declarations:

Ethics approval and consent to participate.

Ethics approval for the study was obtained from the institutional review board of Garden City University. Written informed consent was obtained from all study participants. Participants were free to withdraw from the study at any time. Personal and health information and raw data collected in the study are stored securely on the password-protected personal computer of the primary investigator.

Consent for publication.

Written informed consent to publish study data was obtained from all participants.

Availability of data

The data used to support the findings of this study are available from the corresponding author upon reasonable request.

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Author's contributions

SSD contributed towards design and conduct of the study; study supervision, collection of data, supervision of intervention; and drafting and revision of the manuscript. AT and GD contributed tocontributed towardssupervision of intervention, statistical analysis and interpretation of data. All authors read and approved the final manuscript.

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