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The effects of Aviva gymnastics on symptoms of premenstrual syndrome and primary painful menstruation, body awareness and uterine artery circulation—the value of incorporating integrative medicine into evidence-based medicine treatment

Ph.D. Thesis

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Introduction

The Aviva exercise was chosen as an intervention method for this research because of its associated positive empirical experiences. Records of the experiences were accumulated as observational data over 24 years of my gynaecological work. Our aim was to support this observation of Aviva gymnastics with scientific research regarding changes in menstrual pain levels and body awareness in women with primary dysmenorrhoea (PD) for the very first time. Premenstrual syndrome (PMS) and PD are often considered as separate entities despite the fact that their co-occurrence was already highlighted by Bancroft in 1995. Since then, numerous articles have investigated their co-occurrence and negative impact on quality of life. Therefore, we investigated changes in behavioural symptoms caused by PMS in participants who also suffered from PD. The complexity of the topic is reflected in the 268 citations listed in this thesis.

Integrative medicine

Integrative medicine (IM) combines complementary and alternative medicine with conventional medicine to prevent and treat chronic diseases. These treatments include acupuncture, hypnotherapy, massage therapy, exercise, nutrition, stress management and other non-pharmacological methods, among which includes physical activity (exercise), which is a central concept in integrative medicine to maintain health and fight diseases in the modern age. In contrast, physical inactivity (lack of exercise) is a major cause of chronic disease and is detrimental to physical and mental health and well-being.

Exercise Intervention Program

Upon entry, participants placed in the intervention group (IG) were given 4 h of training to learn the exercise intervention program. These exercises are different from general exercises, e.g., hiking, running or swimming. The intervention program consisted of a total of 19 exercises accompanied by music, performed twice a week in groups under the supervision of a qualified instructor in Budapest, Hungary. The exercises were a carefully structured, intense and

methodical series of movement sequences, including a 5 min warm-up exercise at the beginning and 5 min cooling-down exercises at the end of the intervention. The exercise intervention program lasted 30 min. There was no break between the 19 exercises—the participants exercised continuously.

The exercises were performed by the participants in the IG twice a week during the study period, regardless of the day and phase of the menstrual cycle. During the study period, women in the IG and control group (CG) were asked not to take any medication, including painkillers. CG subjects did not participate in any exercise intervention.

Registry and Ethics

The study was registered at clinicaltrials.gov: NCT04618172.The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Róbert Magán Kórház (RKM) and by the National Centre for Public Health and Pharmacy. The protocol codes were 2018/1/RKM and 12977-7/2020/EÜIG. Informed consent was obtained from all subjects involved in the study.

Objectives:

1. To summarize the epidemiology, aetiology, symptoms and therapeutic options of PMS and PD, respectively.

2. To present Aviva gymnastics, which is easy to learn, low-cost, and can be practiced alone at home.

3. To study the effects of Aviva gymnastics for the first time using objective (ultrasound flow measurement) and subjective (validated questionnaires) methods over several menstrual cycles in IG participants with PMS or PD who are willing to learn and practice gymnastics, and then compare the results of IG with the results of CG.

4. To monitor the intensity of Aviva gymnastics after exercise, on a self-report basis.

5. To analyse the psychological impact of Aviva gymnastics on body awareness.

6. To monitor adherence associated with the regular practice of Aviva gymnastics.

Our hypotheses were:

1) There would be a significant difference in the degree of PMS-induced behavioural status between IG and CG over two menstrual cycle periods.

2) There would be a significant increase in the PI of UAs in the mild-to-moderate exercise intervention group (IG) compared to the control group (CG).

3) There would be a significant difference between the IG and CG regarding the PI of UAs and menstrual pain measured by using the Numeric Rating Scale (NRS).

4) There would be a significant difference in the level of menstruation pain between the IG and CG and that this change would be more favorable in the IG

5) There would be a significant correlation between the degree of physical exertion recorded by IG participants on the Borg scale and the reduction in menstrual pain in menstrual cycles 2 and 3 following Aviva gymnastics.

6) There would be a significant difference between the IG and CG regarding the different subscales of the BAQ-H.

Common features of our clinical trials

We performed a prospective observational trials. At the start of the study period, entry criteria included age between 18 and 44 years, body mass index (BMI) between 17 and 35, regular menstrual cycle duration between 21 and 35 days and menstrual duration between 3 and 7 days. All IG patients were new to this exercise series.

Exclusion criteria included pregnancy, taking oral contraceptive pills, painkillers for PD, any case of secondary dysmenorrhoea (SD), (e.g., ovarian cysts, uterine malformations, endometrial polyps or endometriosis, pelvic inflammatory disease), regular medication for psychiatric neurological or endocrinological conditions, established professional or regular sports performance, and major traumatic life events (death in the family, etc.) within three months prior to the start of the study. We also excluded patients who became pregnant during the study and those who decided to discontinue participation before the end of the study. We also excluded participants who did not complete the questionnaire correctly for three consecutive days or attend the ultrasound flowmetry measurements. Women were allowed to volunteer to participate after being informed about the study and its requirements.

Specific characteristics of our clinical trials

The Effect of Aviva gymnastics on behavioural symptoms of premenstrual syndrome

With respect to criteria of the American College of Obstetricians and Gynecologists (ACOG), the initial diagnosis for all patients presenting with PD included a medical, family, psychosocial, gynaecological and menstrual history to confirm whether a patient had PD or symptoms characteristic of secondary dysmenorrhea via outpatient gynaecological department. When a patient only presents with symptoms of PD, manual pelvic and vaginalultrasound examinations are not necessary. A detailed anamnesis was taken, taking into account the questionnaire filled in at the time of application, in an outpatient gynaecology clinic. Exclusion criteria included regular medication for PMS, a score above 40 on the Beck depression questionnaire completed at enrolment.

The Effect of Exercise on Pulsatility Index of Uterine Arteries and Pain in Primary Dysmenorrhea

With respect to the Committee Opinion No. 760 of the American College of Obstetricians and Gynecologists (ACOG), the initial diagnosis for all patients presenting with PD included a medical, family, psychosocial, gynaecological and menstrual history to confirm

whether a patient had PD or symptoms characteristic of secondary dysmenorrhea via outpatient gynaecological department. When a patient only presents with symptoms of PD, manual pelvic and vaginal ultrasound examinations are not necessary. Exclusion criteria included the use of pain medication for PD, any case of SD (e.g. ovarian cysts, uterine malformations, endometrial polyps or endometriosis, PID). We also excluded participants who did not participate in ultrasound flowmetry.

The Effect of Aviva Exercise Intervention on Pain Level and Body Awareness in Women with Primary Dysmenorrhea

The diagnosis and exclusion criteria were the same as described in the previous subsection, with the addition that ultrasound flowmetry was not used in this study.

Sample Size and Assignment

Convenience sampling was used because no preliminary or earlier data were available when examining the effects of exercise on the pulsatility index (PI) values of uterine arteries (UAs) in individuals with PD. The IG and CG were non-randomized as participants self-selected under real-world conditions to be included either in the exercise intervention or the control arms of the study. Selfselection included voluntary participation in learning a new set of exercises and willingness to regularly practice in a group afterwards. We also sought to make our research flexible and realistic, with women of all ages and from all parts of the country in the reproductive life stage who volunteered to participate in the research, even travelling from remote location to practice together. This volunteering was time-consuming, costly and not compatible with work or family commitments for all participants. In view of the above, as well as the ethical considerations, we did not want to deprive volunteers of the opportunity to make an effort to learn practice intervention.

Statistical methods

The Effect of Aviva gymnastics on behavioural symptoms of premenstrual syndrome

The chi-squared test was used to measure the association between qualitative variables in the analysis. An independent samples t-test was used for comparisons of two groups based on quantitative variables, the choice of which was made conditional on the fulfilment of normality. The assumption of homogeneity of variances was analysed using the Levene test. A Generalized Estimating Equations test was performed to assess the effect of Aviva gymnastics exercises on cognitive status at different phases of the menstrual cycle during two menstrual cycles. The Wald chi-squared test was used to determine the significance of the model coefficients. Participants with missing data were excluded during each study. The significance level was set uniformly at 0.05 in the analysis. Statistical calculations were performed using IBM SPSS 25 software.

The Effect of Exercise on Pulsatility Index of Uterine Arteries and Pain in Primary Dysmenorrhea

The chi-square test was used to measure the association between qualitative variables in the analysis. To compare the two groups using quantitative variables, an independentsamples test was used, the choice of which was conditional on normality being satisfied. Normality was tested using the Kolmogorov–Smirnov test, the result of which was used to decide whether normality could be assumed. The independent-samples t-test was used if the null hypothesis of normality was accepted, and the Mann–Whitney test was used if it was rejected. When the effect of several qualitative variables on quantity variables was investigated and an interaction term was included in the model, the ANCOVA was used. Exploratory data analysis was conducted on the Borg scale data, as this indicated that the scale scores weakly discriminated between subjects. A power analysis was performed to demonstrate the sample size needed for specific levels of power based on Cohen's d and partial eta-squared. In each test, subjects missing any

of the included data were excluded. The significance level was set at 0.05 for all tests and analyses were performed using IBM SPSS StatistIG version 25.

The Effect of Aviva Exercise Intervention on Pain Level and Body Awareness in Women with Primary Dysmenorrhea

The statistical methods were the same as described in the previous subsection. The relationship between the Borg scale scores and the degree of menstrual pain was assessed using Pearson correlation analysis.

The Effect of Aviva gymnastics on behavioural symptoms of premenstrual syndrome

Data collection

Recruitment and data collection took place continuously during the study period: 1 March 2019–30 June 2020. All consecutive participants were enrolled for a period of two consecutive menstrual cycles and the period of the next menstrual bleeding. No adverse effect information was observed when performing Aviva gymnastics exercises.

IG and CG participants completed the PRISM questionnaire electronically on a daily basis during the research period. The data obtained were evaluated retrospectively. It was first explained in detail when and how the PRISM questionnaire should be completed prior to its completion, which took approximately 5-10 minutes per day. We also reminded the subjects not to miss a day of Aviva gymnastics as much as possible; however, if that is unavoidable, the subjects had to indicate this in some way, including days when Aviva gymnastics was not performed. All subjects were informed that they were to start completing the questionnaire on the first day of the next cycle and were asked to indicate any days of bleeding. Each night during the two menstrual periods, the person completing the questionnaire had to rate whether they had experienced the symptom as well as its degree of severity for the corresponding symptoms.

The validated PRISM questionnaire has been used in previous research and it is used herein to describe menstrual cycle symptoms. The PRISM questionnaire asks about 26 symptoms in total, of which 15 are physical symptoms such as insomnia, breast tenderness, oedema, fatigue, abdominal distension, headache, gluttony, nausea and menstrual cramps, all scored between 0 and 3. The remaining five physical symptoms are scored 0 or 1 depending on whether they occur or not: constipation or diarrhoea, changes in appetite, sex drive, chills/colds or sweating and spotting. In addition, the following 11 items evaluate emotional symptoms: irritability, mood swings/labile mood crying, inner anger, depressed/depressed mood, anxiety, restlessness, feeling ugly, loss of control/abandonment, acting without a reason, low self-esteem and guilt. Emotional symptoms should also be scored between 0 and 3. Item 11 explores behavioural symptoms through the impact on daily life: being aggressive with others verbally or non-verbally, a desire to be alone, neglecting housework, reduced performance at work or not going to work, being distracted and inattentive, accident-prone or clumsy, having difficulty driving, suicidal thoughts, staying at home and increased alcohol consumption. Behavioural symptoms were rated 0 or 1 by all participants depending on whether the symptom was present or not. Current body weight was also recorded. Data were evaluated for all participants during both menstrual periods. Based on the diary, PMS symptoms on menstrual days were analysed and summarized separately for each menstrual cycle. In addition, based on the calendar, the cycle was divided into two parts (follicular and luteal phases) at the midpoint (e.g., day 14 of a 28-day cycle, as this is the presumed time of ovulation). The late follicular phase was obtained by summing the values of the symptoms reported on the 7 days before ovulation (days 8-14 of the cycle). The values of the cycle between days 22 and 28 (i.e., 7 days) were summed, which corresponds to the late luteal phase. The same principle was applied for cycles other than 28 days: 7 to 7 days of symptoms were counted for each cycle, i.e., 7 days from the half-cycle backwards and 7 days before menstruation. Menstrual pain was checked daily with the NRS. Beck's depression questionnaire was completed by all study participants to isolate PMS/PMDD and exclude depressive status. The Borg scale was used to subjectively rate physical activity and was completed by participants after a single exercise session. The same questionnaires were used in the CG as in the IG and the method of completion was the same. However, the CG participants did not perform Aviva gymnastics, unlike the IG group members. We kept in contact with participants in both groups. Participants were able to ask questions to the research supervisor at any time, and IG participants were also able to ask questions to the Aviva trainers. We used a non-stretchable fibreglass tape for the perimeter measurements.

The Effect of Exercise on Pulsatility Index of Uterine Arteries and Pain in Primary Dysmenorrhea

Doppler ultrasound flowmetry assessment

The non-invasive and easy-to-use Doppler ultrasound equipment has become a mainstay in the assessment of such properties. Using Doppler ultrasound, different impedance parameters can be estimated. Of these, PI has been given more importance as it seems to more accurately describe the blood velocity waveform. The reference ranges for the PI values of UA during menstrual cycles in healthy patients were examined in different studies.The relationship between menstrual pain and PI values of UAs during different phases of the menstrual cycle in healthy patients and those with PD was also examined in other studies. To our knowledge, our study is the first in the literature investigating the effects of mild-to-moderate twice-weekly thirty-minute exercise as a non-pharmaceutical lifestyle intervention on the PI values of UAs in individuals with PD. The ultrasound examination was performed with the woman in the supine position and in the morning. Uterine artery Doppler flowmetry assessment was performed using a Voluson E6 (GE Healthcare Technologies, Chicago, IL, USA) ultrasound machine with multi-frequency transvaginal transducers. a Voluson E6 (GE Healthcare Technologies, Chicago, IL, USA) ultrasound machine with multi-frequency transvaginal transducers. The evaluations were performed by a single operator with extensive experience in performing a Doppler ultrasound, using a transvaginal transducer to avoid inter-observer variation. After excluding uterine, Fallopian tube and ovarian pathology with the conventional ultrasound, a sagittal image of the uterus was taken, including the cervical canal and the internal cervical canal. The transducer was then gently tilted to the side and a colour flow mapping was used to identify the right and left uterine artery at the level of the internal uterine orifice. Pulsed-wave Doppler was used, with a 2 mm sampling gate being used to image the entire vessel and ensure that the angle of insonation was less than 30.

Three similar successive waveforms were obtained, and the average PI of the left and right UAs was calculated. To determine the average intraobserver error, a single operator repeated the transvaginal ultrasound examination for five patients each, five consecutive times. The intraobserver variation coefficient was found to be 7–9% for the PI of UAs.

Data collection

Recruitment and data collection took place continuously during the study period: 1 March 2019–30 June 2020. All participants were enrolled for a period of one spontaneous menstrual cycle and the consecutive time of the next menstruation. All women in the IG and CG were examined via ultrasound Doppler flowmetry once during one spontaneous menstrual cycle. The date of the vaginal ultrasound scan for each participant in the IG and CG depended on the appointment, as well as what suited the participant and the ultrasound operator. Therefore, some of the ultrasound assessments took place in the follicular phase (but not the days of menses), while some of them took place during the ovulation period and some during the luteal phase according to the length of the participants' cycle and predicted ovulation period. In the IG, each participant took part in the first ultrasound assessment of the PI of UAs before the 30-min exercise training. The second ultrasound assessment of the PI of the left and right UAs took place after the 30-min exercise training. In the CG, each participant took part in the first and the second ultrasound assessment of the PI of the UAs, with each occurring 30 min apart. During the 30-min break, they did not practice any exercise and sat in a calm place.

After one spontaneous menstrual cycle of the participants in the IG and CG, the degree of pain in the next menstrual period was assessed daily by all IG and CG participants during consecutive menstruation by completing the NRS electronically, where 0 means no pain and 10 means unbearable pain. The Borg scale is generally accepted as a tool for assessing perception of exercise intensity and has been used for many years as a self-report method for physical training participants. The Borg scale scores were self-reported by the IG participants immediately after the exercise intervention, indicating how exhausting they found the exercise.

No data on the adverse effects of the practices were collected.

The Effect of Aviva Exercise Intervention on Pain Level and Body Awareness in Women with Primary Dysmenorrhea

Body awareness

According to Mehling, body awareness is an attentional focus on and awareness of internal body sensations. It refers to the subjective, phenomenological aspect of proprioception and interoception that enters conscious awareness, which can be modified by mental processes, including attention, attitudes and effects, appraisal, beliefs, memories, and conditioning. In psychological and medical scientific articles, definitions of body awareness have traditionally been dominated by the concern that heightened body awareness must lead to somatosensory amplification and is maladaptive for clinical outcomes such as pain. However, when body awareness is defined as the ability to recognize subtle body cues, findings from numerous studies seem to contradict this traditional understanding of body awareness and suggest that body cues may be useful in the management of chronic diseases. There are various publications on the relationship between body awareness, measured by the Body Awareness Questionnaire (BAQ), and pain. Koteles developed the Hungarian version of the Body Awareness Questionnaire (BAQ-H) and evaluated it from a psychometric point of view among yoga practitioners and young adult controls.

The results supported the validity and reliability of the BAQ-H.

Data collection

Recruitment and data collection were continuously performed throughout the study period: 1 March 2019–30 June 2020.All consecutive participants were enrolled for a period of two consecutive menstrualcycles and the period of the next menstrual bleeding.The extent of menstrual pain was evaluated daily during menstruation by all participantsof the IG and CG by completing the numeric rating scale (NRS) electronically,where 0 means no pain and 10 means unbearable pain. In a clinometric study, the NRS wasevaluated and validated as a good scale to rate PD pain. There was a difference between the beginning of the data collection with questionnairesand the start of the Aviva exercises. No exercise was performed in the IG during

the firstmenstrual bleeding period, which was the time of the first measurement (T1). At T1,the data collection of the NRS started on the first day of the menses regarding the levelof menstrual pain in both groups. The pain scores of NRS were given daily during themenstrual bleeding period and averaged in the statistIG. After T1 measurement, theparticipants of the IG performed 30 min long Aviva exercises twice a week until the end ofthis study, including the second and third menstrual bleeding periods. This study endedon the last day of the third menstrual bleeding period. The second menstrual bleedingperiod was the second measurement time (T2), and the third menstrual bleeding periodwas the third measurement time (T3). The NRS scale was completed daily by participantsat T1, T2, and T3 in both the IG and CG. The scores of the BAQ-H were once completed bythe participants of both groups at T1, T2, and T3. The Borg scale is generally considered an accepted tool for assessing the perceptionof exercise intensity and has been used for many years as a self-reported method forparticipants in physical exercise training. The Borg scale scores were self-reported bythe IG participants immediately after the exercise intervention, indicating how exhaustingthey found the exercise. The scores of the Borg scale were completed by the participants ofthe IG on the first day of the T2. In the IG, the pulse was measured before and after 30 minof Aviva exercise. In the CG, pulse was also measured 30 min apart while sitting in a chairreading a book in a pleasant environment. Based on the slightly different durations of thefirst and second menstrual cycles and the duration of the third menstrual bleeding period,the number of exercising days slightly differed among the participants.If the participants in the IG skipped questionnaires or exercise sessions on any day,these were marked as skipped days. If the participants in the CG skipped questionnaireson any day, these were also marked as skipped days. There were no data on the adverseeffects of Aviva exercises during data collection. The primary endpoint was the change in the level of menstrual pain according to theNRS questionnaire between the IG and the CG at T1, T2, and T3. The secondaryoutcomes were as follows: The first was the difference between the IG and CG regardingthe different scales of the BAQ-H at T1, T2, and T3. The BAQ measures attentiveness tonormal, non-emotive internal bodily processes and sensations, specifically sensitivity tobodily cycles and rhythms, small changes in normal functioning, and the anticipation ofbodily reactions, using 18 items scored on a 7-point Likert scale ranging from 1 (not at alltrue about me) to 7 (very true about me). The original version of the BAQ has four scales:“note responses or changes in body process”; “predict bodily reaction”; “sleep-wake cycle”;and “onset of illness”. The BAQ-H contains the same 4 four scales as the original BAQ.After a minimal change, the BAQ-H contains 17 items of the original BAQ. In the BAQ-H,item number 10 of the original English BAQ (“I do not experience seasonal changes inmy

bodily functions".) was deleted, which was the only reverse item. The secondsecondary outcome was adherence to the intervention. The third was the Borg scale resultsfor the IG.

Results

The Effect of Aviva gymnastics on behavioural symptoms of premenstrual syndrome

A total of 93 people responded to the survey, of whom 55 were enrolled in the IG and 38 in the CG. Eight participants were excluded from the IG: four due to an incorrect completion of the questionnaire, two due to pregnancy, and the remaining two decided to withdraw from the study. Eight participants of the IG spontaneously reclassified themselves into the CG. Despite signing up for the IG and agreeing to take part in the Aviva exercise intervention twice a week, they did not fulfill this condition. Data from a total of 39 participants in the IG were analysed and evaluated. In the CG, nine participants were excluded: five due to an incorrect completion of the questionnaire, one due to pregnancy, and three decided to withdraw from the study. In the CG, data from a total of 37 people were analysed and evaluated.

A sample of 93 women was used to study the effect of Aviva gymnastics on the behavioural status of women at different stages of their menstrual cycle, which was divided into two groups: IG and CG. Initial comparisons between the two groups were made using chi-squared independence tests for sociodemographic variables and habits. The variables tested included smoking habits, alcohol consumption, the presence of PMS and/or PD in the participants' mother, coffee consumption, exposure to second-hand smoke, fast food consumption habits and occupational status (sedentary or non-sedentary). IG and CG did not differ significantly when comparing the aforementioned qualitative variables. The study also examined differences between groups on three scale variables for quantitative variables: hip circumference, waist circumference and number of hours of sleep the previous night. Data were analysed using an independent samples t-test, and the assumption of homogeneity of variances was analysed using Levene's test. A statistically significant difference between CG ($M = 97.59$, $SD = 10.507$) and IG ($M = 90.6$, $SD = 21.234$) was seen only for hip circumference ($t(101) = 2.186$, $p = 0.031$). A Generalized Estimating Equations analysis was performed to assess the effect of Aviva gymnastics exercises on PMS-induced behavioural status at different cycle phases during two menstrual cycles. The Wald chi-squared test was used to determine the

significance of the model coefficients. The Generalized Estimating Equations (GEAs) of the effects of Aviva gymnastics on women's behavioural status were used to calculate the estimated marginal means for each participant during each of the two menstrual cycles (follicular and luteal phases). These averages were adjusted for other variables in the model and represent the expected behavioural status of the CG and IG in each phase and cycle. Changes in behavioural status due to PMS were found in the two menstrual cycles along with their phases between IG and CG as a result of Aviva gymnastics. In the menstrual phase of the first cycle, the estimated marginal mean in the CG was 0.15589, compared to 0.11309 in the IG. In the second cycle, the mean CG was 0.12611 and the mean IG was 0.08733. These means suggest that the behavioural status was worse (higher scores) in CG during the menstrual phase, but the difference decreased in the second cycle. During the follicular phase, the marginal mean of the first cycle was 0.07822 in CG and 0.07487 in IG. In the second cycle, these means were 0.08244 and 0.07637. These results suggest a slight difference between the groups in the follicular phase, with a slight increase in the second cycle. In the luteal phase, the marginal mean of the first cycle was 0.10621 in CG and 0.10098 in IG. The mean for the second cycle was 0.11291 in CG and 0.10205 in IG, indicating a consistent difference between groups between cycles during the luteal phase. Wald chi-squared tests for the analysis of the significant main effects of the control and menstrual phase as well as the non-significant interactions indicate that these differences were generally consistent between menstrual phases and cycles even though there were differences in behavioural status between CG and IG.

The Effect of Exercise on Pulsatility Index of Uterine Arteries and Pain in Primary Dysmenorrhea

A total of 93 people responded to the survey, of whom 55 were enrolled in the IG and 38 in the CG. Nine participants were excluded from the IG: three due to an incorrect completion of the questionnaire, two due to pregnancy, two decided to withdraw from the study and the remaining two did not participate in the ultrasound measurement. Eight participants of the IG spontaneously reclassified themselves into the CG. Despite signing up for the IG and agreeing to take part in the Aviva exercise intervention twice a week, they did not fulfill this condition. Data from a total of 38 participants in the IG were analysed and evaluated. In the CG, eleven participants were excluded: five due to an incorrect completion of the questionnaire, one due to

pregnancy, three decided to withdraw from the study and the remaining three did not participate in the ultrasound measurement. In the CG, data from a total of 35 people were analysed and evaluated.No significant difference was detected between the IG and the CG by using anydemographic variable. The Kolmogorov–Smirnov normality test concluded that for thevariables selected to confirm homogeneity, the two groups did not differ for any of thevariables (age (year), weight (kg), Body Mass Index (BMI), duration of menstrual cycle,age at onset of menstruation (year), age at the first dysmenorrhea (year), number ofdeliveries). Since normality could not be assumed for any of the variables, the comparisonwas performed by using the non-parametric Mann–Whitney test.There was no significant difference between IG and the CG regarding the phase of the menstrual cycle during vaginal US (χ^2 (2) = 2.653; p = 0.265).Examining the mean of the PI of UAs in the IG and the CG during the 1st and the2nd measurement, a significant difference was found in the change in the measured value(Z=-2,545; p=0,011). The IG showed a significantly higher increase in the mean of the PI(Median = 0.825) compared to the CG (Me = 0.130).

Sample Size Calculations

Mean PI in UAs during the 1st US measurement of the IG and the CG (PI UAs 1st US): Despite the medium effect size (Cohen's d = 0.433), the relationship is not significant (p = 0.066); however, with a sample size of 84 (n(IG) = 44, n(CG) = 40), the difference would be significant, i.e., with no change in means, and variances in thesignificance value would be below 5%. If the power of the test was to be increased from thecurrent 50% to 95%, a sample of 146 + 134 = 280 would be required for a significant result.Mean PI in UAs during the 2nd US measurement of the IG and the CG (PI UAs 2nd US): Due to the relatively small effect size (Cohen's d = 0.211), the differencebetween the two groups is not significant. If the power of the test was to be increased from14% to 95%, a sample of 635 + 585 = 1220 would be needed for a significant result.Difference between the means of the PI UAs 2nd US and PI UAs 1st US (PI UAs D): The result is significant, and the effect size ismedium-strong (Cohen's d = 0.640)with a power of 76.8%, which if increased to 95%, would require a sample of 130 (n(IG) = 68, n(CG) = 62) to obtain a significant result at the 5% level.When the change in the mean PI of UAs and the correlation between menstrual painare examined, the fitted ANCOVA model does not show a significant correlation betweenthe two variables. The model included participants' age (F(1.66) = 0.165, p = 0.686), weight(F(1.66) = 0.283, p = 0.596) and BMI

(F(1.66) = 1.316, p = 0.255) as control variables, noneof which have a significant effect in the model. The outcome variable was the level ofmenstrual pain, as self-reported by using the NRS at the end of the study period, and theexplanatory variables included PI UAs D (F(1.66) = 3.090, p = 0.083) in addition to thedummy variable group (F(1.66) = 0.872, p = 0.354) and the interaction between these two variables: Group _ PI UAs D (F(1.66) = 0.940, p = 0.336). No significant effects were found

Sample Size Calculation

The relatively small effect size (η^2= 0.045) of the PI UAs D means that there is nosignificant difference between the means of the PI UAs 2nd US and PI UAs 1st US of the IGand CG. The power analysis demonstrated that, assuming no change in trends, a samplesize of 143 would be required to confirm the significance of the present results.

Adherence to the Intervention

In the IG, eight participants reported not performing the exercises twice weekly on aregular basis. Eight participants of the IG spontaneously reclassified themselves into the CG.

The Effect of Aviva Exercise Intervention on Pain Level and Body Awareness in Women with Primary Dysmenorrhea

A total of 93 people responded to the survey, of whom 55 were enrolled in the IG and 38 in the CG. Seven participants were excluded from the IG: three due to an incorrect completion of the questionnaire, two due to pregnancy, and the remaining two decided to withdraw from the study. Eight participants of the IG spontaneously reclassified themselves into the CG. Despite signing up for the IG and agreeing to take part in the Aviva exercise intervention twice a week, they did not fulfill this condition. Data from a total of 38 participants in the IG were analysed and evaluated. In the CG, eight participants were excluded: four due to an incorrect completion of the questionnaire, one due to pregnancy, and three decided to withdraw from the study. In the CG, data from a total of 37 people were analysed and evaluated.At baseline, there were non-

significant differences between the IG and CG in dysmenorrhea scores (NRS), age, BMI, duration of the first and second menstrual cycles, age at onset of menstruation, age at the first dysmenorrhea, and number of deliveries.A repeated-measure ANCOVA at T1, T2, and T3 was used to test whether the Avivaexercise had a significant effect on the change in the level of menstruation pain. In themodel, in addition to the dummy variable of the Aviva exercise, participants' age and BMIwere included too. The results show a significant difference in the level of menstrual pain according to the NRS questionnaire between the CG and IG ($F(1.607, 118.907) = 12.743$, $p < 0.001$,($\eta 2 = 0.147$).Based on the estimated marginal means of the menstrual pain of the IG and the CG at T1, T2, and T3, there was a significant decrease in pain reported in the sample among those who participated in the IG as opposed to CG ($F(1.607, 118.907) = 12.743$, $p < 0.001$, ($\eta 2 = 0.147$).

The Difference between the IG and CG Regarding the Different Scales of the BAQ-H at T1, T2 and T3

The means of the four subscales of the BAQ-H at T1, T2, and T3 were compared by usingrepeated measures ANCOVA with age and BMI as control variables and whether therespondent exercised twice a week using Aviva exercises. The analysis was based on theresults of the repeated-measure ANCOVA of BAQ-H. No significant differences were found between the IG and CG groups for any of the subscales of the BAQ-H in terms of how their scores changed over the T1, T2, and T3 measurements. Only one trend-like difference can be observed for the "Note responses or changes in body process" scale: the IG group is more likely to experience a stronger increase than the CG group ($F(1.823, 129.401) = 2569$, $p = 0.086$, $\eta 2 = 0.035$).

Adherence to the Intervention

Eight participants (20%) of the IG spontaneously reclassified themselves into the CG.Despite signing up for the IG and agreeing to take part in the Aviva exercise interventiontwice a week, they did not fulfill this condition.

Results of the Borg Scale

According to the Borg scale, 86% of IG participants reported having experienced mild to-moderate exertion (Borg scale: 11–14; equal to 60–75% of maximum target pulse rate) after the Aviva exercise intervention. Thus, there is no significant correlation between thelevel of physical exertion measured on the Borg scale and the level of pain during the secondmenstrual period measured at T2 (Pearson's r: 0.192, $p = 0.202$) and the level of pain duringthe third menstrual period measured at T3 (Pearson's r: 0.245, $p = 0.101$).

Discussion

There was no significant difference between IG and CG group members in our sociodemographic statistical analysis. Participation in IG was associated with significantly lower hip circumference compared to CG, but neither significant difference in waist circumference was found nor hours of sleep per day between the two groups. The first hypothesis was confirmed: Aviva gymnastics in IG may have a stabilizing effect on the fluctuations in behavioural status caused by PMS. Our second hypothesis was confirmed: after Aviva gymnastics in IG, the mean of the level of circulation (AU PI) was significantly higher than that in CG participants. The third hypothesis was not confirmed: the level of menstrual pain experienced by PD participants was independent of the AU PI. Our fourth hypothesis was confirmed: the level of menstrual pain according to the NRS questionnaire was significantly different between IG and CG. This change was more favourable in the IG, which became evident at time T3. However, similarly with the third hypothesis, our fifth and sixth hypotheses were not confirmed: it was observed that the more strenuous the performance of Aviva gymnastics, the greater the analgesic effect on PD in the IG; moreover, there was no significant difference between the IG and the CG for different subscales of the BAQ-H at times T1, T2 and T3.

Conclusions

The consistent pattern of differences between cycles and phases in behavioural symptoms of premenstrual syndrome, combined with the results of the Wald chi-squared test, suggests that Aviva gymnastics in the intervention group may have a stabilizing effect on the fluctuations in behavioural status caused by premenstrual syndrome. Our study is the first to document a significant effect of mild-to-moderate-intensity Aviva gymnastics on changes in pulsatility index values in the uterine artery of individuals with primary dysmenorrhea, based on the Borg scale. The intervention group had a significant increase in the pulsatility index of the uterine arteries after 30 minutes of Aviva exercise compared to the control group. This result indicated reduced blood flow due to circulatory redistribution in the intervention group. The degree of menstrual pain in patients with primary dysmenorrhoea is independent of the degree of blood flow in the pulsatility index values of the uterine arteries. Furthermore, our study is the first to document the effect of a mild-to-moderate-intensity Aviva gymnastics intervention on consecutive menstrual cycle pain levels and body awareness in women with primary dysmenorrhoea. We found that Aviva exercises may contribute to pain relief from primary dysmenorrhoea. However, we have not determined whether the more strenuous the performance of Aviva exercises, the greater the analgesic effect on PD in IG. Finally, no significant difference was found between the intervention group and the control group in terms of body awareness, although a trend-like effect was found for the practice of Aviva gymnastics.

Further research is recommended so as to determine the pulsatile index of the uterine arteries, not only immediately after Aviva gymnastics, but also one or two hours afterwards. In addition, it would be worthwhile to determine the pulsatile index values of the uterine arteries of the follicular and luteal phases of the menstrual cycle separately in both groups and to investigate the effect of Aviva gymnastics at different stages of the cycle. With a larger number of cases and a longer study duration, it would be advisable in the future to analyse data from patients with different ages, body weight, waist-to-hip ratio and cycle length, possibly including other objective markers (e.g., hormones, inflammatory markers).

The strength of our study is that we are the first group in Hungary to analyse the change in behavioural symptoms of PMS after regular mild-to-moderate-intensity exercise compared to CG using Aviva gymnastics. Moreover, we also mapped in detail sociodemographic factors and lifestyle habits in addition to behavioural symptom changes.

The limitations of our study were the relatively small number of participants, the duration of ultrasound assessment of each cycle, the short study period, the prospective observational study method and the multidimensional complexity of the human subject. Self-selection was another limitation, as it eliminated all the advantages of randomization, such as balancing confounders. We also had limited financial resources for our clinical trials as the COVID-19 pandemic resulted in numerous difficulties during our research period. Due to this, our study did not compare our data (in particular, AU PI values) with similar data from healthy CG participants. Additionally, we were not able to determine the AU PI values of the follicular and luteal phases of the menstrual cycle separately in both groups and investigate the effect of Aviva gymnastics at different phases of the menstrual cycle. Lastly, as a perception bias, only PD patients with mild-to-moderate menstrual pain who were not taking analgesIG were included in this study. For ethical reasons, we did not want to discourage women with mild, moderate, or severe menstrual pain from taking painkillers for the sake of the study. Therefore, further investigations are needed to evaluate Aviva gymnastics as a form of exercise that supports the female reproductive system and improves premenstrual syndrome and primary dysmenorrhoea.

Strengths and Limitations

The strength of our study is that we are the first group in Hungary to analyse the change in behavioural symptoms of PMS after regular mild-to-moderate-intensity exercise compared to CG using Aviva gymnastics. Moreover, we also mapped in detail sociodemographic factors and lifestyle habits in addition to behavioural symptom changes.

A strength of the study is the assessment of the significant effects of exercise trainingon the change in the PI of the UAs in individuals with PD for the first time. Anotherstrength is the flexible and realistic research, not only with adolescents but also women ofall ages in the reproductive life stage who volunteered to participate in the study. Mostresearch on PD only focuses on teenagers and young women. This study made the assessment of the effects of the mild-to-moderate Aviva exercise intervention on consecutive menstrual pain in women with PD and body awareness for the first time. Another strength of this study is that the Aviva exercise program is achievable even by individuals with a lack of free time, which is generally a characteristic of the modern lifestyle.

The limitations of our study were the relatively small number of participants, the duration of ultrasound assessment of each cycle, the short study period, the prospective observational study method and the multidimensional complexity of the human subject. Self-selection was another limitation, as it eliminated all the advantages of randomization, such as balancing confounders. We also had limited financial resources for our clinical trials as the COVID-19 pandemic resulted in numerous difficulties during our research period. Due to this, our study did not compare our data (in particular, AU PI values) with similar data from healthy CG participants. Additionally, we were not able to determine the AU PI values of the follicular and luteal phases of the menstrual cycle separately in both groups and investigate the effect of Aviva gymnastics at different phases of the menstrual cycle. Lastly, as a perception bias, only PD patients with mild-to-moderate menstrual pain who were not taking analgesics were included in this study. For ethical reasons, we did not want to discourage women with mild, moderate, or severe menstrual pain from taking painkillers for the sake of the study. Therefore, further investigations are needed to evaluate Aviva gymnastics as a form of exercise that supports the female reproductive system and improves premenstrual syndrome and primary dysmenorrhoea.

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List of Publications

In extenso publications

Articles related to the thesis

1. Z, Kovács; E, Atombosiye; G, Hegyi; H, Szőke
The Effect of Aviva Exercise Intervention on Pain Level and Body Awareness in Women with Primary Dysmenorrhea
MEDICINA-LITHUANIA 60 : 1 Paper: 184 , 15 p. (2024) (IF: 2,6)

2. Z, Kovács; G, Hegyi; H, Szőke
The Effect of Exercise on Pulsatility Index of Uterine Arteries and Pain in Primary Dysmenorrhea
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3. Z, Kovács; G, Hegyi; H, Szőke
Premenstruális szindróma és premenstruális dysphoriás zavar: I. Epidemiológia és etiológia [Premenstrual syndrome and premenstrual dysphoric disorder I. Epidemiology and etiology]
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4. Z, Kovács; G, Hegyi; H, Szőke
Premenstruális szindróma és premenstruális dysphoriás zavar: II. Diagnózis, kezelés. [Premenstrual syndrome and premenstrual dysphoric disorder II. Diagnosis and treatment]
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Total IF: 6,8

Additional articles

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