Protocol for Prevalence of Menstrual Pain and Menstrual Symptoms Among Japanese Women and Their Association with Age and BMI

Introduction

Menstruation is a normal physiological process for women and has a significant and undeniable impact on their overall health[1]. During menstruation, many women experience a range of symptoms, including physical pain and discomfort, as well as emotional symptoms such as anxiety, depression, and irritability[2, 3]. These symptoms can greatly reduce women's quality of life. As a critical women's health issue, menstrual symptoms not only affect attention but also decrease productivity at school and work, and impact attendance, leading to a series of social and economic consequences[3-6].

There are multiple potential factors influencing menstrual pain and related symptoms. Obesity may contribute to menstrual disorders by interfering with endometrial repair and affecting hormonal balance, which increases the likelihood of menstrual irregularities and polycystic ovary syndrome (PCOS)[7]. Although research results vary, existing studies suggest that being underweight, overweight, or obese may be associated with dysmenorrhea and other menstruation-related symptoms[8, 9]. Moreover, research has shown that age is also related to the occurrence and distribution of menstrual pain and symptoms[10].

Despite the high prevalence and significant impact of menstrual pain and symptoms, societal norms and stigma have long caused women to conceal their menstrual-related discomfort[11]. However, mobile health applications offer anonymous platforms that help reduce stigma and normalize the discussion of menstrual symptoms[12, 13]. This enables participants to more accurately and authentically report their symptoms. Thus, this study will utilize data collected through the Sofy and Sofy Girl apps. The Sofy Girl app is designed for young girls who have just begun menstruating and their mothers, providing tools for menstrual cycle management, while the Sofy app offers additional support for menstrual pain and premenstrual syndrome (PMS). As of September 1, 2021, these two apps have collectively garnered over one million users in Japan[14].

The objectives of this study are as follows: (1) To investigate and describe the prevalence of menstrual pain and other menstruation-related symptoms in the Japanese population. (2) To analyze the distribution characteristics of menstruation-related symptoms, including physical and emotional symptoms, across different age groups and BMI categories. (3) To analyze the distribution characteristics of the total number of menstruation symptoms, physical symptoms, and emotional symptoms among Japanese women, as well as their distribution across different age groups and BMI categories. (4) To analyze the correlation between BMI and age with menstrual pain, the total number of menstruation-related symptoms, physical symptoms, and emotional symptoms.

Methods

Setting and participants

All data for this study will be collected via the Sofy app. Variables such as menstrual pain, menstrual symptoms, and additional information including height, weight, BMI (calculated by dividing weight in kilograms by the square of height in meters), age, contraceptive use, and painkiller use, will be gathered through a self-reported mandatory sign-up questionnaire. After data collection, all information will be imported into Excel, and entries that did not meet the inclusion and exclusion criteria will be removed. The inclusion and exclusion criteria are as follows: Inclusion criteria: (1) Japanese-speaking; (2) Resides in Japan; (3) Aged between 12 and

51 years. This age range is based on the median ages of menarche and menopause in Japan, which are 12.19 years[15] and 50.54 years[16], respectively. Exclusion criteria: (1) Taking contraceptive pills; (2) Taking painkillers. The use of painkillers and contraceptives is included in the exclusion criteria due to their potential relationship with menstrual pain and related symptoms[17, 18]; (3) Duplicate user IDs; (4) Incomplete responses; (5) Responses with BMI values outside the overall mean ± 1.96 standard deviation (SD).

Data collection

Menstrual pain will be measured using a self-reported four-point Likert scale, with severity levels ranging from 1 (no pain) to 4 (severe pain). Other menstruation-related symptoms will be divided into physical and emotional categories. Participants will report these symptoms by selecting them from a checklist. The physical symptoms will consist of 13 items: short-term and long-term fatigue, abdominal ache, rough skin, sleepiness, breast pain, headache, lower back pain, chills, edema, increased appetite, nausea, and dizziness. Emotional symptoms will include irritation, easily angered feelings, depression, anxiety, and emotional fluctuations. The total number of symptoms, as well as the number of physical and emotional symptoms, will also be calculated for data analysis (with totals of 18, 13, and 5, respectively). The use of contraceptives and painkillers will be assessed by asking participants two questions: "Do you use contraceptives?" and "Do you use painkillers?" Participants who respond "yes" will be classified as using contraceptives or painkillers and will be excluded from the analysis.

Statistical methods

The basic characteristics of BMI categories, menstrual pain severity, and the number of symptoms for the overall population and each age group will be summarized in a table using N (%) and mean (SD). The prevalence of menstrual pain and the mean values of menstrual symptoms—including the total number of symptoms, physical symptoms, and emotional symptoms—will be calculated across different age groups and BMI categories, along with their 95% confidence intervals (CIs) to observe overall trends. The prevalence of individual symptoms within the total population will also be determined, and radar charts will be employed to visualize the symptom distribution across various age groups and BMI categories. Generalized Additive Models (GAM) will be used to estimate the nonlinear and interactive relationships between age, BMI, and menstrual pain, as well as the total number of symptoms, physical symptoms, and emotional symptoms. These models will utilize nonparametric tensor product smoothing functions with cubic basis functions to capture high-dimensional interactions among these variables. Menstrual pain will be treated as a binary outcome and analyzed using a logistic link function, while the total number of symptoms, physical symptoms, and emotional symptoms will be modeled as positive integer variables using a quasi-Poisson distribution to address overdispersion. Model parameters, including smoothing and scaling, will be optimized using the Restricted Maximum Likelihood Estimation (REML) method. All analyses will be conducted using R version 4.3.3, with the *fmsb* package for radar charts and *mgcv* for the GAM analysis.

Ethical considerations

The study protocol is planned to obtain ethical approval from Shiba Palace Clinic Ethics Review Committee, ensuring compliance with ethical guidelines, including obtaining informed consent from all participants prior to data collection.

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