Combined Document: Study Protocol, Statistical Analysis Plan (SAP), and Informed Consent Form (ICF)

Official Title of the study: Behavioral change communication intervention in menstrual disorder management among female university students in Bangladesh

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Study Protocol

Brief summery

Menstrual health is a neglected area of women's health research, especially in low- and middle-income countries, despite the high prevalence and impact of menstrual disorders on daily life. These issues are particularly common among young women in academic settings, yet few interventions address them holistically. In Bangladesh, female university students frequently experience dysmenorrhea, premenstrual syndrome (PMS), and menstrual irregularity (MI), conditions often worsened by modifiable lifestyle factors such as poor diet, physical inactivity, and food cravings. This study assessed the effectiveness of Behavior Change Communication (BCC) intervention promoting non-pharmacological strategies to improve menstrual health among female university students.

A quasi-experimental design included 498 participants (249 per group), aged 19–25, from three public universities. The intervention group received three interactive BCC sessions on menstrual disorders, diet, and physical activity (including yoga) between May and June 2023, followed by bi-monthly visits for six months. Post-intervention data were collected from February to March 2024. Outcomes (dysmenorrhea, PMS, MI) were measured using validated tools. Propensity score matching (1:1 nearest-neighbor, caliper = 0.01) yielded 98 matched participants per group. Covariates included physical activity, body mass index (BMI), dietary diversity, food cravings, breakfast skipping, sleep, bedtime, caffeine intake, and socio-demographic factors. Data were collected via validated Bengali questionnaires. Analyses included descriptive statistics, chi-square and t-tests, logistic regression, and sensitivity analyses. Ethical approval was granted by the Shahjalal University Ethics Board.

Detailed description of the study

Menstrual health is a significantly under-researched aspect of women's health, particularly among adolescents and young adults in low- and middle-income countries(1), even though menstrual disorders affect up to 75% of them and often interfere with daily functioning and overall well-being. (2). In Bangladesh, female university students frequently experience menstrual disorders such as dysmenorrhea, premenstrual syndrome (PMS), and menstrual irregularity (MI). These conditions are often aggravated by modifiable lifestyle factors including poor dietary intake, physical inactivity and food cravings for high fat and sweet food (3).

This study evaluated the effectiveness of a structured behavior change communication (BCC) intervention designed to improve menstrual health among female university students in Bangladesh. The intervention focused on three key menstrual health outcomes: dysmenorrhea, PMS, and MI. It promote a sustainable, non-pharmacological approach to managing common menstrual disorders through behavior and lifestyle changes including improved physical activity and dietary diversity.

The study employed a quasi-experimental design involved two groups: an intervention group that received BCC module and a control group that did not. Participants were female undergraduate students aged 19 to 25 years, residing in dormitories at three public universities in Bangladesh i.e. Patuakhali Science and Technology University (PSTU), Barishal University (BU), and Khulna University (KU). Ethical approval was obtained from the Shahjalal University of Science and Technology Research Ethics Board (Ref. No. AST/002/258), and all participants provided written informed consent. The BCC intervention comprised three interactive educational sessions

delivered between May 20 and June 30, 2023, by trained female facilitators. The first session addressed menstrual disorders and associated risk factors, the second focused on healthy dietary practices, and the third emphasized physical activity (including yoga) and other relevant lifestyle modifications. To reinforce the content, follow-up visits were conducted every two months over a six-month period. Post-intervention data collection was carried out between February and March 2024.

A total of 498 participants (249 in each group) were initially enrolled, based on power calculations designed to detect a 30% reduction in the prevalence of menstrual disorders, with 80% statistical power and 95% confidence level. After exclusions for missing data and loss to follow-up, 234 intervention and 238 control participants were included in the analysis of dysmenorrhea; and 228 participants per group were retained for PMS and MI outcomes. To reduce selection bias and ensure covariate balance, 1:1 nearest-neighbor propensity score matching (PSM) was applied using a logistic regression model with a caliper of 0.01 and no replacement. The final matched sample included 196 participants (98 per group) for each outcome.

Among all the primary outcomes, dysmenorrhea was assessed using the Andersch and Milsom (4) four-point scale and dichotomized as no pain (Grade 0) vs. any pain (Grades 1 – 3). PMS was evaluated by the premenstrual symptoms screening tool (PSST) and recoded into a binary variable: No/Mild PMS (code = 0) and Moderate to Severe PMS or premenstrual dysphoric disorder (PMDD) (code = 1) (5). Additionally, Menstrual irregularity was determined based on self-reported cycle length and coded as irregular (1) if <21 or >35 days, and not irregular (0) if within the 21–35 day range (6).

The treatment variable was exposure to the BCC intervention (yes/no). The covariates included physical activity, obesity, dietary habits, lifestyle factors, and socio-demographic characteristics. Physical activity was classified according to WHO guidelines (7) as: (i) sedentary: light-intensity activities; (ii) active: moderate-intensity activities for 150–300 minutes per week; and (iii) athlete: vigorous-intensity activities for 75–150 minutes per week. Obesity was assessed using body mass index (BMI, kg/m^2) and categorized according to WHO Asian-specific cut-offs (8): (i) underweight (<18.5), (ii) normal weight (18.5–22.9), (iii) overweight (23.0–27.5), and (iv) obese (>27.5). Dietary information was collected using a five-day 24-hour recall method, and dietary diversity score (DDS) was calculated following FAO guidelines (9) . Lifestyle-related covariates included food cravings for high-fat or sweet foods (10), skipping breakfast, sleep duration, bedtime and caffeine intake (11). Socio-demographic variables included family history of menstrual disorders, age at menarche, marital status, and participants' residence as well as parental educational and occupational status.

Data were collected through interviewer-administered, culturally adapted, and validated Bengali-questionnaires. Descriptive statistics summarized baseline characteristics. Group differences were tested using chi-square and t-tests. Propensity scores were estimated using logistic regression, and covariate balance post-matching was evaluated using standardized mean differences (SMD <10%). Intervention effects were analyzed using conditional logistic regression on the matched sample, and logistic regression (bivariate/multivariate) on the unmatched sample. Sensitivity analyses included covariate balance diagnostics, estimation of average treatment effects (ATE/ATT), and Bayesian logistic regression with log Bayes factor.

This study complies with U.S. regulatory requirements for clinical trial registration and reporting under 42 CFR Part 11. The responsible party confirms that all submitted information is complete and accurate, and that the study protocol, statistical analysis plan (SAP), and informed consent form (ICF) reflect the approved trial objectives and design.

Participant flow

Recruitment details

Female students were recruited from three public universities in Bangladesh: Patuakhali Science and Technology University (PSTU), Barisal University (BU), and Khulna University (KU) for a BCC module on menstrual health from May 20 to June 30, 2023. Recruitment occurred via campus outreach and voluntary registration. University-approved session dates were held in campus venues. Follow-up occurred from July 15, 2023, to January 15, 2024. A post-intervention assessment was conducted from February to March 2024 through comparing the intervention group to the control group.

Pre-assignment details

Initially 498 participants (249/group) were recruited. Seven intervention participants were excluded before assignment for missing sessions/protocol violation, leaving 242. At six-month follow-up, 480 participants (239 intervention, 241 control) completed assessments as because 3 intervention and 8 control participants were excluded due to missed follow-up or withdrawal. After data checks, 8 were excluded for invalid dysmenorrhea data, leaving 234 intervention and 238 control (total 472 participants) for that outcome. For PMS and MI, 24 more were excluded (10

intervention and 14 control group), yielding 456 participants (228 per group). Propensity score matching (PSM) identified 196 matched participants (98 per group) for each of outcomes.

Group information

Two groups were assigned: an intervention group receiving the BCC module on menstrual health, and a control group with no intervention. Participants were female university students from PSTU, BU, and KU, Bangladesh, with group assignment based on attending at the BCC sessions.

Group title

1. Intervention Group
2. Control Group

Group description

The Intervention group comprised female university students from PSTU, BU, and KU who participated in a structured BCC module designed to enhance awareness and promote effective management of menstrual disorders through lifestyle and behavioral modifications. The module consisted of three interactive sessions that included educational presentations, yoga demonstrations, informational pamphlet distribution, quiz competitions, and small gift incentives to boost engagement. Sessions were facilitated by trained female educators under the guidance of a public health expert and a gynecologist. Participants were selected through voluntary registration and received follow-up support at every two months to reinforce behavioral changes, address challenges, and ensure continued adherence to healthy practices.

The Control group consisted of female students from the same universities who were not exposed to the BCC intervention. They were selected using student dormitory records and matched to the intervention group through propensity score matching to ensure comparability. As they did not receive any form of menstrual health education or BCC intervention, this group served as the baseline comparator for evaluating the effectiveness of the BCC module on menstrual health outcomes.

Period(s)

This study was organized into three distinct periods to reflect the logical progression of the intervention and its evaluation: (1) implementation of the intervention, (2) follow-up phase to monitor and support behavior change, and (3) post-intervention evaluation to assess outcomes. Each period captured critical milestones and participant flow to assess the feasibility, adherence, and effectiveness of the intervention.

Period 1: Implementation of the intervention

The first period of the study involved the implementation of a structured BCC intervention among female university students to enhance awareness and promote effective management of menstrual disorders. Three structured sessions were conducted covering menstrual disorders, dietary behaviors, and physical activity. Two trained female educators facilitated these sessions. The details of participation status of this period is presented in Table 1.

Table 1. Summary of participation status and key milestones in intervention implementation

Participation status	Data (number of participants)	Comments	Milestone title	Milestone data (number of participants)
Started	249 (Intervention Group) 249 (Control group)	Intervention: participants who registered after informed consent and attended the first session of BCC module Control: Participant from the same universities were selected and listed after providing consent for the assessment study.	Intervention: first session attendance Control: Not exposed to the BCC intervention	249 (Intervention Group) 249 (Control group)
Completed	242 (Intervention Group)	Participants who attended all three intervention sessions.	Completed all sessions	242
Not completed	7 (Intervention Group)	Participants dropped out before completing the 2nd and/or 3rd session.	Protocol violation	7

Period 2: Follow-up phase

This was a six-month post-intervention follow-up period, during which participants in the intervention group received periodic support visits to reinforce behavioral changes and sustain the practices introduced during the BCC sessions (Table 2).

Table 2. Overview of participation status and milestone achievements in follow-up phase

Participation status	Data (number of participants)	Comments	Milestone title	Milestone data (number of participants)
Started	242 (Intervention Group)	Participants who completed all the sessions of the intervention and entered follow-up phase.	Follow-up initiated and available at first follow-up visit	242

Completed	239 (Intervention Group)	Participants available at 6-month follow-up assessment.	Follow-up completed	239
Not completed	3 (Intervention Group)	Participants lost to follow-up during the periodic monitoring visits conducted every two months.	Lost to follow-up	3

Period 3: Post-intervention evaluation

This period represents the final stage of the study to assess the effectiveness of the BCC module on key menstrual health outcomes through a quasi-experimental design using matched control and intervention participants (1:1 PSM) (Table 3, Table 4A and 4B). Outcome assessments were done for dysmenorrhea, PMS and MI.

Table 3. Participant flow and milestone completion in post-intervention outcome evaluation before matching

Participation status	**Outcomes**	**Data (number of participants)**	**Comments**	**Milestone title**	**Milestone data (number of participants)**
Started	Dysmenorrhea, PMS and MI	239 (Intervention), 241 (Control)	Participants agreed to join and assessed for final evaluation of outcomes	Assessment initiated	480
Completed	Dysmenorrhea	234 (Intervention), 238 (Control)	Participants included after cleaning for dysmenorrhea outcomes.	Valid responses	472
	PMS and MI	228 (Intervention), 228 (Control)	Final sample included participants with valid PMS and IMC outcome data	Appropriate responses	456
Not completed	Dysmenorrhea	8 (5 intervention and 3 control)	Omitted from the final dataset due to	Incomplete response	8

			data quality issues, including missing or invalid responses		
	PMS and MI	24 (11 intervention and 13 control)	Removed from analysis because of incomplete or inaccurate data.	Invalid response/ missed data	24

Table 4A. Participation flow of matched sample for post-intervention dysmenorrhea analysis

Participation status	**Groups**	**Data (number of participants)**	**Comments**	**Milestone title**	**Milestone data (number of participants)**
Started	Intervention	234	Out of 234 eligible participants, 98 were selected using PSM and individually matched in a 1:1 ratio with control participants within the common support region.	Enrollment	472
	Control	238	All participants initially eligible; matched pool was drawn from this group		
Completed	Intervention	98	All 98 matched completed the post-intervention evaluation	Matching completion and final outcome analysis	196
	Control	98	98 matched controls completed the evaluation and the remaining controls not matched due to 1:1, no-replacement rule		
Not completed	Intervention	136	The participants were excluded from the analysis because they could not be matched with any control participants within the specified caliper of 0.01	Excluded due to fall outside the region of common support	276
	Control	140	Even though these participants fell within the common support region, they were excluded because of the 1:1 matching requirement and the no-replacement rule.	Not selected due to 1:1 matching without replacement	

Table 4B. Matched sample of participants for post-intervention assessment of PMS and MI outcomes

Participation status	Groups	Data (number of participants)	Comments	Milestone title	Milestone data (number of participants)
Started	Intervention	228	From the pool of 228 eligible participants, 98 were chosen using PSM and matched one-to-one with control participants within the common support region.	Enrollment	456
	Control	228	A subset of matched participants was selected from all 228 initially eligible control individuals		
Completed	Intervention	98	All 98 participants in the matched group successfully completed the post-intervention assessment.	Matching completion and final outcome analysis	196
	Control	98	The evaluation was completed by 98 matched control participants while the rest were excluded in accordance with the 1:1 matching and no-replacement criteria.		
Not completed	Intervention	130	As no matches within the caliper of 0.01 could be identified, the participants were excluded from the analysis	Participants were excluded as they did not fall within the region of common support.	260
	Control	130	Despite being within the common support region, these participants were excluded to maintain the 1:1 matching ratio and adhere to the no-replacement rule.	Excluded because of 1:1 matching without replacement.	

Baseline characteristics

Group information

Group title

1. Intervention Group
2. Control Group

Group description

The intervention group included participants who attended all three sessions of the BCC module on menstrual health management. Initially, 249 participants were recruited, and 242 completed all sessions. At the six-month follow-up, 239 participants completed the outcome assessment. After data cleaning, 234 participants were eligible for the final analysis of the dysmenorrhea outcome, while 228 participants had valid data and were included in the analyses of PMS and MI.

Participants in the control group did not receive the BCC intervention but were matched in number and characteristics to the intervention group. Initially, 249 participants were listed for the control arm, and 241 completed the outcome assessment interview. Following data quality verification, 238 participants were included in the final analysis for the dysmenorrhea outcome. For the PMS and MI outcomes, 228 participants had valid and complete data and were included in the respective analyses.

After propensity score matching, 98 matched participants from each group (n=196) were used for the final analysis of each outcome variable, ensuring balance between the groups on key covariates.

Baseline analysis population information

The baseline analysis populations differ slightly from the initial recruitment numbers due to participant withdrawal, non-response, absence during sessions or protocol violation, and exclusion based on data quality checks for outcome variables (Table 5).

Table 5. Baseline Profile of Participants by Study Group: Intervention vs. Control

Outcome	Group	Overall number of baseline participants	Baseline analysis population description
Dysmenorrhea	Intervention	234	After recruitment and data quality checks, 234 participants were included in the initial analysis. After propensity score matching, 98 were retained.
	Control	238	From 238 eligible controls, 98 matched participants were used in the final matched analysis.
	Total	472	The final matched sample included 196 participants (98 per group), selected through 1:1 propensity score matching without replacement using a caliper of 0.01.
PMS and MI	Intervention	228	228 participants provided valid and complete responses and were included in the baseline analysis. After matching, 98 were included in the final matched analysis.
	Control	228	228 participants were eligible for baseline analysis. After matching, 98 were used for final analysis.
	Total	456	A total of 196 participants (98 in each group) were retained after 1:1 matching with a 0.01 caliper and no replacement.

Baseline Measure Information

The baseline characteristics of study participants were assessed using a combination of study-specific and standard measures to comprehensively capture their lifestyle, nutritional, reproductive, and socio-demographic profiles (Table 6). Study-specific measures included

physical activity level (categorized according to WHO guidelines), body mass index (BMI) using Asian-specific cut-offs, and minimum dietary diversity (MDD) based on a 5-day food diary aligned with FAO recommendations. Additional lifestyle factors assessed included food cravings, skipping breakfast, sleep duration, caffeine intake frequency, and bedtime. Reproductive health and demographic factors such as age, age at menarche, marital status, and participant's residence, family history of menstrual disorders, as well as parental education and occupation were also recorded. These baseline measures were used to describe the participant population and to adjust for potential confounding in subsequent analyses.

To evaluate the impact of the BCC intervention on reducing dysmenorrhea, key covariates were balanced between groups using propensity score matching. These included physical activity level, BMI, minimum dietary diversity (MDD score ≥ 5), food cravings for high-fat and sweet foods, breakfast skipping, sleep duration, caffeine intake frequency, family history of menstrual disorders, age at menarche, marital status, father's and mother's educational status, and mother's occupation. These balanced covariates (13 covariates) were included in the regression models and in the estimation of both the average treatment effect (ATE) and the average treatment effect on the treated (ATT).

Additionally, to assess the effectiveness of the intervention on PMS and MI outcomes, propensity score matching was used to achieve balance in key baseline covariates between the intervention and control groups. The matched covariates included physical activity level, BMI (kg/m^2), minimum dietary diversity (MDD score ≥ 5), food cravings for high-fat and sweet foods, breakfast skipping, sleep duration, age at menarche, and participants' residence. These variables (8 covariates) were subsequently adjusted for in the estimation of treatment effects.

Table 6. Baseline characteristics of participants by defined study measures

Baseline measure title (Study-specific measure)	Study-specific baseline measure title(s)	Baseline measure description	Measure type	Measure of dispersion	Category title	Unit of measure
Physical activity	Physical activity level	Categorized per WHO recommendations based on weekly activity intensity: sedentary (with little or no activity), active (moderate, 150–300 min/week) and athlete (vigorous, 75–150 min/week). Active and athlete were merged during analysis	Count of participants	Not applicable	Sedentary/ Active and athlete	Participants
Body mass index (BMI)	BMI (Kg/m^2)	Classified using WHO cut-offs for Asian populations, such as underweight (<18.5), normal (18.5–22.9) and overweight/obese (≥23.0). Overweight and obese categories were merged.	Count of Participants	Not applicable	Underweight / Normal / Overweight and obese	Participants
Dietary diversity Score (DDS)	MDD (scoring ≥ 5)	Dietary diversity was assessed using a 5-day food diary based on the 24-hour recall method, following FAO guidelines. Food items were classified into 10 predefined groups, and scores ranged from 0 to 10. Minimum dietary diversity (MDD) was defined as achieving a score of 5 or more.	Count of participants	Not applicable	Yes / No	Participants
Food Craving	Food craving for high-fat and sweet food	Self-reported craving for high-fat and sweet food.	Count of participants	Not applicable	Yes / No	Participants
Skipping breakfast	Skipping breakfast	Reported skipping breakfast one or more times during the last week.	Count of participants	Not applicable	Yes / No	Participants
Sleep duration	Sleep hours per night	Based on self-reported average nightly sleep duration	Count of participants	Not applicable	<7 hrs / ≥7 hrs	Participants
Caffeine consumption	Frequency of caffeine Intake	Based on frequency of caffeine intake per week; categorized as infrequent (<3 times/week) or frequent (≥3 times/week)	Count of participants	Not applicable	Infrequent / Frequent	Participants

Bedtime	Bedtime (hours)	Bedtime was classified into two groups: ≤23:00 hours and >23:00 hours, based on a 24-hour clock format	Count of participants	Not applicable	Before or at 23:00 / After 23:00	Participants
Family history of menstrual disorders	Family history of menstrual disorders	Participants reported whether they had family history of any kind of menstrual disorders viz. dysmenorrhea, PMS, or IMC.	Count of participants	Not applicable	Yes / No	Participants
Age (Not study-specific measure)	Age	Treated as continuous variable	Mean	Standard deviation	Not applicable	Participants
Menarche age	Age at menarche	Reported age at first menstruation in years and treated as continuous variable.	Mean	Standard deviation	Not applicable	Participants
Marital status	Marital status	Marital status was self-reported. Participants categorized as divorced, separated, or recently married were grouped under ever married. All others were classified as never married.	Count of participants	Not applicable	Never married / Ever married	Years
Residence	Participant's residence	Living arrangement of the participants during the study time.	Count of participants	Not applicable	With Family / at student dormitory	Participants
Father's Education	Father's educational status	Education levels were categorized as: "Below secondary education" (no formal education, primary, or incomplete secondary schooling) and "Secondary or higher education" (completed secondary school, higher secondary, college, or university)	Count of participants	Not applicable	Below Secondary (0-5 y schooling) / Secondary and above(> 5 y schooling)	Participants
Mother's Education	Mother's educational status					
Father's Occupation	Father's occupational status	Occupational status was self-reported as either Formal (salaried or secure jobs) or Informal (homemaking, daily wage, or insecure work)	Count of participants	Not applicable	Formal / Informal	Participants
Mother's Occupation	Mother's occupational status					

Number of baseline participants

The number of baseline participants is the same as the overall number of baseline participants, as it includes all individuals who completed baseline data collection and met the data quality criteria. Although PSM was later used to create comparable groups for outcome analysis, the baseline measures reflect the entire recruited sample before matching. Therefore, no separate or reduced sample size is reported in this section.

Baseline Measure Data

Baseline characteristics were assessed at the time of outcome evaluation for both the intervention and control groups. Although data were collected post-intervention, propensity score matching was applied to balance pre-existing covariates and reduce selection bias in estimating the treatment effect. The Table 7(A and B) present the baseline values for each measure across the intervention and control groups, as well as for the total study population.

Table 7A. Comparison of baseline characteristics between study groups for dysmenorrhea outcome

Variables	**Control (n = 238)**	**Intervention (n = 234)**	**Total (N = 472)**
Physical activity level			
Sedentary	206 (43.6)	114 (24.2)	320 (67.8)
Active and Athlete	32 (6.6)	120 (25.6)	152 (32.2)
BMI (kg/m^2)			
Normal weight (18.5-22.9)	83 (17.6)	171 (36.2)	254 (53.8)
Underweight (<18.5)	44 (9.3)	37 (7.8)	81 (17.2)
Overweight and obese (>22.9)	111 (23.5)	26 (5.5)	137 (29.0)
MDD (scoring ≥ 5)			
No	153 (32.4)	96 (20.3)	249 (52.8)
Yes	85 (18.01)	138 (29.2)	223 (47.2)
Food craving for high fat and sweet food			
No	77 (16.3)	164 (34.8)	241 (51.1)

Yes	161 (34.1)	70 (14.8)	231 (48.9)
Skipping breakfast			
No	72 (15.5)	169 (35.8)	241 (51.1)
Yes	166 (35.2)	65 (13.8)	231 (48.9)
Sleep hours per night			
≥ 7 hours	75 (15.9)	155 (32.8)	230 (48.7)
< 7 hours	163 (34.5)	79 (16.7)	242 (51.3)
Frequency of caffeine Intake			
Infrequent (< 3 times per week)	65 (13.8)	157 (33.3)	222 (47.0)
Frequent ≥ 3 times per week)	173 (36.7)	77 (16.3)	250 (53.0)
Bedtime (hours)			
Before or at 23:00	26 (5.5)	139 (29.5)	165 (35.0)
After 23:00	212 (44.9)	95 (20.1)	307 (65.0)
Family history of menstrual disorders			
No	160 (33.9)	197 (41.7)	357 (75.6)
Yes	78 (16.5)	37 (7.8)	115 (24.4)
Age (years)			
Mean (SD)	21.9 (1.4)	21.0 (1.5)	21.5 (1.5)
Age at menarche (years)			
Mean (SD)	12.1 (1.5)	13.4 (1.7)	12.7 (1.7)
Marital status			
Never Married	216 (45.8)	226 (47.9)	442 (93.6)
Ever married	22 (4.7)	8 (1.7)	30 (6.4)
Place of residence			
With Family	18 (3.8)	46 (9.8)	64 (13.6)
At student dormitory	220 (46.6)	188 (39.8)	408 (86.4)
Father's educational status			
Secondary and above (> 5 y schooling)	188 (39.9)	217 (46.0)	405 (85.8)
Below secondary (0-5 y schooling)	50 (10.6)	17 (3.6)	67 (14.2)
Mother's educational status			
Secondary and above (>5 y schooling)	176 (37.3)	195 (41.3)	371 (78.6)
Below secondary (0-5 y schooling)	62 (13.1)	39 (8.3)	101 (21.4)
Father's occupational status			
Formal occupation	138 (29.2)	144 (30.5)	282 (59.8)
Informal occupation	100 (21.2)	90 (19.0)	190 (40.2)
Mother's occupational status			
Formal occupation	66 (14.0)	44 (9.3)	110 (23.3)
Informal occupation	172 (36.4)	190 (40.3)	362 (76.7)

Table 7B. Distribution of baseline characteristics among intervention and control groups for PMS and MI outcomes

Variables	Control (n = 228)	Intervention (n = 228)	Total (N = 456)
Physical activity level			
Sedentary	197 (43.3)	112 (24.6)	309 (67.8)
Active and Athlete	31 (6.8)	116 (25.4)	147 (32.2)
BMI (kg/m^2)			
Normal weight (18.5 – 22.9)	80 (17.5)	167 (36.6)	247 (54.2)
Underweight (< 18.5)	42 (9.2)	37 (8.1)	79 (17.3)
Overweight/obese (> 22.9)	106 (23.2)	24 (5.2)	130 (28.5)
MDD (scoring ≥ 5)			
No	145 (31.8)	93 (20.4)	238 (52.2)
Yes	83 (18.2)	135 (29.6)	218 (47.8)
Food craving for high fat and sweet food			
No	75 (16.5)	159 (34.9)	234 (51.3)
Yes	153 (33.5)	69 (15.1)	222 (48.7)
Skipping breakfast			
No	67 (14.7)	165 (36.0)	232 (50.9)
Yes	161 (35.3)	63 (14.0)	224 (49.1)
Sleep hours per night			
≥ 7 hours	71 (15.6)	151 (33.1)	222 (48.7)
< 7 hours	157 (34.4)	77 (16.9)	234 (51.3)
Frequency of caffeine Intake			
Infrequent (< 3 times per week)	60 (13.1)	152 (33.3)	212 (46.5)
Frequent (≥ 3 times per week)	168 (36.9)	76 (16.7)	244 (53.5)
Bedtime (hours)			
23:00 and before	24 (5.3)	137 (30.0)	161 (35.3)
After 23:00	204 (44.7)	91 (20.0)	295 (64.7)
Family history of menstrual disorders			
No	151 (33.1)	191 (41.9)	342 (75.0)
Yes	77 (16.9)	37 (8.1)	114 (25.0)
Age (years)			
Mean (SD)	22.0 (1.4)	21.0 (1.5)	21.5 (1.5)
Age at menarche (years)			
Mean (SD)	12.2 (1.5)	13.4 (1.7)	12.8 (1.7)
Marital status			
Never Married	206 (45.2)	221 (48.5)	427 (93.6)
Ever married	22 (4.8)	7 (1.5)	29 (6.4)
Place of participant's residence			

With family	17 (3.7)	44 (9.87)	61 (13.4)
At student dormitory	211 (46.3)	184 (40.3)	395 (86.6)
Father's educational status			
Secondary and above (> 5 y schooling)	180 (39.5)	212 (46.5)	392 (86.0)
Below secondary (0 – 5 y schooling)	48 (10.5)	16 (3.5)	64 (14.0)
Mother's educational status			
Secondary and above (> 5 y schooling)	168 (36.8)	191 (41.9)	359 (78.7)
Below secondary (0 – 5 y schooling)	60 (13.2)	37 (8.1)	97 (21.3)
Father's occupational status			
Formal occupation	130 (28.5)	142 (31.1)	272 (59.6)
Informal occupation	98 (21.5)	86 (18.9)	184 (40.4)
Mother's occupational status			
Formal occupation	65 (14.3)	44 (9.3)	109 (23.9)
Informal occupation	163 (35.7)	185 (40.6)	348 (76.1)

Outcome measures

Outcome measure information

In accordance with the study protocol, this section (Table 8) details the predefined primary outcomes used to evaluate intervention efficacy. The study focused on three key outcomes: dysmenorrhea, PMS and MI. Each was measured during the post-intervention period using standardized assessment tools. To support the study's quasi-experimental design and statistical analysis, all outcome variables were recoded as binary indicators.

Table 8. Summary of outcome measures information

Data elements	**Dysmenorrhea**	**Premenstrual Syndrome (PMS)**	**Menstrual Irregularity (MI)**
Outcome measure type	Primary	Primary	Primary
Outcome measure title	Prevalence of Dysmenorrhea	Prevalence of PMS	Prevalence of MI
Outcome measure description	Assessed according to Andersch and Milsom	Premenstrual symptoms were assessed using premenstrual	Menstrual irregularity was assessed based on

	scale (Grades 0 – 3) which evaluated the pain intensity and its impact on daily activities. The scale of pain intensity was recoded into binary: 0 = No (no pain), 1 = Yes (any pain: mild/moderate/severe).	symptoms screening tool (PSST) and categorized into three groups: No/Mild PMS, Moderate to Severe PMS, and premenstrual dysphoric disorder (PMDD). For analysis, these were combined into a binary variable: 0 = No/Mild PMS and 1 = Moderate to Severe PMS or PMDD	participants' self-reported cycle lengths. A cycle was considered irregular (coded 1 = Yes) if it was shorter than 21 days or longer than 35 days. Cycles within the 21–35 day range were classified as not irregular (coded 0 = No)
Outcome measure time frame	Participants received three BCC sessions over approximately 6 weeks, followed by regular support to encourage behavior change for up to 6 months, with monitoring every two months. Final outcomes were assessed about 8 months after enrollment.		
Outcome measure data type	Count of participants	Count of participants	Count of participants
Measure of dispersion/precision	Not applicable	Not applicable	Not applicable
Category title	Yes (Dysmenorrhea = 1)/ No (Dysmenorrhea = 0)	Yes (Moderate to Severe PMS/PMDD = 1)/ No (No/mild PMS = 0)	Yes (MI = 1)/ No (MI = 0)
Unit of Measure	Participants	Participants	Participants

Group information

Group title

1. Intervention Group
2. Control Group

Group description

The intervention group comprised female university students who attended all BCC sessions conducted between May 20 and June 30, 2023, followed by a six-month monitoring period that included scheduled follow-ups every two months through January 15, 2024. The sessions focused on menstrual health education, dietary improvements, and physical activity. At the end of the

follow-up, 239 participants completed the outcome assessment. After data cleaning, 234 participants were included in the final analysis for dysmenorrhea, while 228 with valid and complete data were analyzed for PMS and MI outcomes.

Participants in the control group did not receive the BCC intervention or any related educational sessions but were matched with the intervention group based on number and baseline characteristics. Of the 249 participants initially enrolled in the control arm, 241 completed the outcome assessment interview. After data quality checks, 238 participants were retained for the final dysmenorrhea analysis. For the PMS and MI outcomes, 228 participants with complete and valid data were included in their respective analyses.

After propensity score matching, 98 matched participants from each group (n=196) were used for the final analysis of each outcome variable, ensuring balance between the groups on key covariates.

Analysis population information

This section provides (Table 9) an overview of the analysis populations for each outcome measure, including the number of participants at baseline and after propensity score matching. It also outlines the methods used to define the final samples included in the analyses.

Table 9. Overview of analysis population by groups for outcome measures

Outcomes	Group	Overall number of participants analyzed	Analysis population description
Dysmenorrhea	Intervention	234	Following initial recruitment and data quality verification, 234 participants in the intervention group and 238 in the control group were eligible for analysis. However, Final analyses were conducted using 1:1 propensity score matching without replacement and a caliper of 0.01, yielding a matched sample of 196 participants (98 from each group).
	Control	238	
	Total	472	
PMS and MI	Intervention	228	For both PMS and IMC outcome measures, 228 participants from each group provided valid and complete responses for the baseline analysis. Following 1:1 propensity score matching without replacement (caliper = 0.01), 98 participants per group were retained, yielding a final matched sample of 196.
	Control	228	
	Total	456	

Outcome measure data

Table 10 represents the outcome measure data for all participants who completed the follow-up assessment. Results are shown separately for the intervention and control groups, with each outcome reported as the number and percentage of participants. The data reflect the prevalence of each specified condition at follow-up, according to group assignment.

Table 10. Prevalence of key menstrual disorders among participants in control and intervention groups

Outcome variables	**Control (n = 238)**	**Intervention (n = 234)**	**Total (N = 472)**
Prevalence of Dysmenorrhea			
No	29 (6.1)	159 (33.7)	188 (39.8)
Yes	209 (44.3)	75 (15.9)	284 (60.2)
Outcome variables	**Control (n = 228)**	**Intervention (n = 228)**	**Total (N = 456)**
Prevalence of premenstrual syndrome (PMS)			
No/Mild PMS	83 (18.2)	205 (45.0)	288 (63.2)
Moderate to Severe PMS/PMDD	145 (31.8)	23 (5.0)	168 (36.8)
Prevalence of Menstrual Irregularity (MI)			
No (regular)	118 (25.8)	93 (20.4)	323 (70.8)
Yes (Irregular)	205 (45.0)	23 (5.0)	218 (29.2)

Adverse event information

1. **All-cause mortality**

   No deaths occurred during the intervention or follow-up period. The intervention was non-invasive and behavioral in nature.

2. **Serious adverse events**

   No serious adverse events were reported or observed. Participants were university students who voluntarily enrolled after providing informed consent. The intervention consisted of a non-invasive BCC module focused on menstrual health education. Given the educational nature and low-risk profile of the study population, no medical or psychological harm was expected or detected.

3. **Other (non-serious) adverse events**

   No non-serious adverse events exceeding the 5% frequency threshold were reported. Participants were monitored regularly throughout the study.

Time frame

Adverse events were monitored throughout the 6-month follow-up phase of the intervention.

Adverse event reporting description

Adverse events were not estimated due to the non-invasive nature of the behavioral intervention. No events were observed or self-reported during the periods of follow-up or impact assessment.

Collection approach for table default

Non-Systematic Assessment

Adverse events were self-reported if any occurred, but no systematic daily assessment was employed.

Group information

Group title

1. Intervention Group (participants who received BCC intervention)
2. Control Group (Participant s who did not received BCC intervention)

Group description

The intervention group attended BCC sessions on menstrual health, diet, and physical activity from May to June 2023, with bi-monthly follow-ups through January 2024. The control group did not receive any educational intervention. The dysmenorrhea outcome analysis included 234 participants from the intervention group and 238 from the control group. In the case of PMS and MI, 228 participants with complete and valid data were analyzed per group. To ensure baseline comparability, final analyses included 98 matched participants per group (n=196) after propensity score matching.

Total number affected by all-cause mortality

- Not applicable as the participants received the non-invasive nature of the behavioral intervention.

Total number at risk for all-cause mortality

- Not applicable as the participants received the non-invasive nature of the behavioral intervention.

Total number at risk for serious adverse events

- Not applicable as the participants received the non-invasive nature of the behavioral intervention.

Total number affected by any serious adverse event

- Not applicable as the participants received the non-invasive nature of the behavioral intervention.

Limitation and caveats

This quasi-experimental study lacked randomization, which may have introduced residual confounding and limited causal inference. About 4% of intervention participants missed sessions or follow-up, possibly underestimating the true effect. While the study aimed to reflect real-world settings by conducting sessions in academic institutions, potential confounding factors related to control group characteristics were not assessed. Dietary intake quantity was not measured, and 24-hour recalls may have been impacted by recall bias, affecting data accuracy.

Certain Agreements

Are all PIs employees of sponsor?

- Yes: The principal investigator (PI) is an employee of the sponsor

There were no agreements restricting the principal investigators from discussing, presenting or publishing the study results. The study was self-financed without external sponsorship.

Results point of contact

Name or official title: Professor Dr. GM Rabiul Islam, principal investigator (PI) of the study

Organization name: Shahjalal University of Science and Technology, Sylhet, Bangladesh

Phone: +8801787323944

Email: rabiat14@yahoo.com

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Statistical Analysis Plan (SAP)

Statistical analysis overview

Statistical analyses were conducted to evaluate the impact of the BCC intervention on three binary outcomes: dysmenorrhea, PMS, and IMC. Categorical variables were summarized as frequencies and percentages and analyzed using the chi-square (χ^2) test. Continuous variables were presented as means with standard deviations and compared using independent t-tests. To adjust for potential baseline imbalances between the intervention and control groups, propensity score matching (PSM) was carried out using logistic regression. A 1:1 nearest-neighbor matching algorithm was applied with a caliper width of 0.01 and without replacement. Post-matching covariate balance was assessed using standardized mean differences (with a bias threshold of <10%) and chi-square tests. The primary analysis of intervention effects was conducted using conditional logistic regression on the matched sample. To validate the findings, bivariate and multivariate logistic regression analyses were also performed on the unmatched dataset. Additionally, sensitivity analyses were conducted to ensure the robustness and consistency of the results, including covariate balance diagnostics, estimation of the average treatment effect (ATE) and the average treatment effect on the treated (ATT), and Bayesian logistic regression on the matched sample.

Comparison group selection

1. Intervention Group (received BCC module)

2. Control Group (did not receive BCC module)

Type of statistical test: Superiority

- Comments: The analyses were designed to assess whether the BCC intervention group had superior outcomes compared to the control group using fixed-effect models on matched pairs. Power calculations were based on expected reductions in outcome prevalence.

Statistical test of hypothesis

Conditional logistic regression was used to estimate the odds of binary outcomes between intervention and control groups after matching.

- P-Value: < 0.05
- Comments (P-Value): A p-value < 0.05 was considered statistically significant. No adjustments for multiple comparisons were made. Results were considered statistically significant at $p < 0.05$.
- Method: Chi-squared, t-test, regression (logistic), conditional logistic regression
- Comments (Method)**:** Pre- and post-PSM tests used Pearson's chi-square; conditional logistic regression applied to matched data; bivariate and multivariate logistic regression used for robustness checks

Method of Estimation

- Estimation Parameter: Odds Ratio (OR)
- Estimated Values: Reported as crude odds ratios (COR) and adjusted odds ratios (AOR). Coefficient value was used to estimate ATE and ATT (Table 11).
- Confidence Interval Level: 95%
- Number of Sides: 2-sided
- Lower and upper limit: Reported per outcome (see Table 11)

- Parameter Dispersion Type: Standard error of the mean
- Estimation Comments: Odds ratios compared the intervention group (numerator) to the control group (reference) for menstrual outcomes. Odds ratios reflect the likelihood of menstrual outcomes in the intervention group relative to the control group. ATE and ATT were also estimated using PSM.

Table 11. Estimated odds ratios from bivariate and multivariable (before matching) as well as conditional (after matching) and logistic regression models assessing the impact of the BCC module on menstrual health outcomes

Outcomes	**Before matching**		**After matching**
	COR (95% CI)	**AOR (95% CI)**	**AOR (95% CI)**
Dysmenorrhea	0.07 (0.04, 0.11)***	0.13 (0.06, 0.26)***	0.13 (0.05, 0.34)***
Premenstrual syndrome	0.07 (0.04, 0.11)***	0.13 (0.07, 0.23)***	0.12 (0.06, 0.27)***
Menstrual Irregularity	0.12 (0.07, 0.20)***	0.26 (0.14, 0.48)***	0.21 (0.09, 0.45)***

** Indicated chi square value define the level of significance i.e. * p < 0.05, ** p < 0.01, *** p < 0.001*

Other statistical analysis

Additional scientifically appropriate analyses were conducted to ensure robustness and validity of the findings:

1. **Propensity Score Matching (PSM)**: PSM was used to control for baseline differences between the intervention and control groups. Participants were matched 1:1 using nearest-neighbor matching with a caliper width of 0.01 and without replacement. Covariate balance was assessed using standardized mean differences (bias <10%) and post-matching chi-square tests.

2. **Sensitivity Analyses**: To confirm the quality of matching and reduce potential bias, covariate balance diagnostics were conducted, including checks for percentage bias (<10%), variance ratios (acceptable range: 0.5–2.0), and visual inspection via kernel density plots to ensure common support. Bayesian logistic regression was also applied to estimate the Log Bayes Factor, comparing models with and without the intervention to assess the strength and consistency of effects.
3. **Alternative Estimates of Treatment Effect**: In addition to logistic regression models, the ATE an ATT were calculated (Table 12). These estimates served as supplementary measures and supported the stability of intervention effects across multiple analytical approaches.

Table 12. Estimated treatment effect of the BCC intervention on menstrual health outcomes via propensity score matching technique

Outcomes	Average treatment effect (ATE)		Average treatment effect on the treated (ATT)	
	Coefficient (95% CI)	p-value	Coefficient (95% CI)	p-value
Dysmenorrhea	−0.23 (−0.35, −0.11)	p < 0.001***	−0.27 (−0.40, −0.13)	p < 0.001***
Premenstrual syndrome (PMS)	−0.39 (−0.52, −0.25)	p < 0.001***	−0.42 (−0.57, −0.26)	p < 0.001***
Menstrual irregularity (MI)	−0.30 (−0.41, −0.18)	p < 0.001***	−0.31 (−0.45, −0.16)	p < 0.001***

** Indicated chi square value define the level of significance i.e. * p < 0.05, ** p < 0.01, *** p < 0.001*

Informed Consent Form (ICF)

Research project title: Behavioral change communication intervention in menstrual disorder management among female university students in Bangladesh

Objective of the study: to evaluate the effectiveness of a structured behavior change communication intervention designed to improve menstrual health among female university students in Bangladesh.

(The interviewer will introduce herself and take consent of the interviewee before commencing the session)

Introductory statement

My name is……. I am currently working for Mr. Liton Chandra Sen, Associate Professor at the Faculty of Nutrition and Food Science, Patuakhali Science and Technology University. I have been assigned as an interviewer for the aforementioned PhD project, conducted under the Department of Food Engineering and Tea Technology at Shahjalal University of Science and Technology. Therefore, I kindly request your permission to conduct the interview, which typically takes about 15–20 minutes. We assure you that your identity will not be disclosed in any reports derived from this interview. Your confidentiality will be strictly maintained. You may skip any question or stop the interview at any time. With your consent, I would like to take written notes during the interview.

What will you need to do if you agree to participate?

As a selected respondent, your valuable input on a few key issues is requested. If any question makes you feel uncomfortable, you are free to skip it or not respond.

Risks, Benefits, confidentiality and compensation for participating

There are no risks to participating. Your input will support Mr. Sen's PhD research and help improve national reproductive health programs for young adults. All information will remain strictly confidential and used only for research by authorized personnel. Your participation in this study is completely voluntary and offers no financial compensation. There is no pressure or obligation to take part.

Right to refuse or withdraw

This study has been approved by the Ethical Approval Committee at Shahjalal University of Science and Technology. Participation is voluntary, and you can skip questions or withdraw at any time.

Who do I contact if I have a question or problem?

If you wish to know more about your rights as a participant in this study you may write Mr. Liton Chadra Sen, Associate Professor, Department of Community Health and Hygiene, Patuakhali Science and Technology University, Dumki, patuakhali-8602, email- liton.sen@pstu.ac.bd, mobile no. +8801717504808. If you have further questions regarding the nature of this study you may also contact Professor Dr. G.M. Rabiul Islam, Department of Food Engineering and Tea Technology, Shahajalal University of Science and Technology, Sylhet, email- rabiat14@yahoo.com, phone: 880 821 713 850 extn.242 (office); Cell: +88 01787323944.

Do you have any questions about the interview?

May we begin now? If so, please read and sign the consent form, and keep a copy for your records.

Consent to publication

This is to state that I give my full permission for the publication, reproduction, broadcast and other use of identifiable details, which can include case history and/or details within the questionnaires to be published in any Journal and Article. I confirm that I have seen and been given the opportunity to read the methodology to be published by any journal.

I understand that the published article may be available in both print and on the internet, and will be available to a broader audience through marketing channels and other third parties. Therefore, anyone can read material published in the Journal. I understand that readers may include not only public health professionals and scholarly researchers but also journalists and general members of the public. I also understand that the information will be published without my personal details and every attempt will be made to ensure anonymity.

I declare, in consequence of granting this permission, that I have no claim on ground of breach of confidence or any other ground in any legal system against the authors and its agents, publishers, successors and assigns in respect of such use of the collected information.

Participant's Name: …… Signature …….. Date: ……

Name of person obtaining consent: …… Signature: …… Date: ……..

(Individual who has been designated to obtain consent)

To be counter-signed and dated electronically for telephone interviews or in the presence of the participant for face to face interviews.