Table S1. CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1–2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	2–3
	4b	Settings and locations where the data were collected	2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3–5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3–5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	3
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5

	11b	If relevant, description of the similarity of interventions	3
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5–6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6–7
	13b	For each group, losses and exclusions after randomisation, together with reasons	6–7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	2
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	6–7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8–12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12–14
Other information			
Registration	23	Registration number and name of trial registry	2, 14
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

Table S2. Mean MDQ scores during the premenstrual period (full analysis set).

Factors	Group	Baseline
Physical score	Placebo	9.8 ± 0.7
	OLL2809	10.3 ± 0.9
Psychological score	Placebo	8.4 ± 1.4
	OLL2809	8.2 ± 1.2
Subfactors		
Pain	Placebo	4.8 ± 0.5
	OLL2809	5.0 ± 0.5
Water retention	Placebo	4.0 ± 0.4
	OLL2809	4.1 ± 0.4
Autonomic reactions	Placebo	0.8 ± 0.2
	OLL2809	0.9 ± 0.2
Negative affect	Placebo	4.5 ± 0.7
	OLL2809	5.2 ± 0.7
Concentration	Placebo	3.3 ± 0.6
	OLL2809	2.8 ± 0.4
Behavioral change	Placebo	2.3 ± 0.4
	OLL2809	1.9 ± 0.3
Arousal (positive)	Placebo	1.7 ± 0.4
	OLL2809	1.7 ± 0.4
Control	Placebo	0.3 ± 0.1
	OLL2809	0.3 ± 0.1

Baseline (placebo, $n = 40$; OLL2809, $n = 40$). Data are shown as mean ± SE.

Table S3. Mean scores and changes during the study period, and estimated treatment differences for MDQ in the menstrual period (per-protocol set).

Factors	Group	Baseline	Cycle 2	Cycle 3	Score changes (Cycle 3 – Baseline)	Estimated treatment difference	
						β [95% CI]	*p*-value
Physical score	Placebo	11.1 ± 1.1	7.0 ± 1.0 †	6.9 ± 1.1 †	−4.1 ± 1.2	−1.19[−4.39 – 2.00]	0.459
	OLL2809	11.2 ± 0.9	7.6 ± 0.7 †	6.1 ± 0.8 †	−5.1 ± 1.0		
Psychological score	Placebo	9.4 ± 1.7	4.5 ± 1.2 †	5.0 ± 1.7 †	−4.4 ± 1.7	0.03[−4.75 – 4.81]	0.989
	OLL2809	8.3 ± 1.2	6.7 ± 2.1	4.5 ± 1.6 †	−3.9 ± 1.6		
Subfactors							
Pain	Placebo	6.9 ± 0.7	4.2 ± 0.6 †	4.2 ± 0.6 †	−2.7 ± 0.7	−0.07[−2.04 – 1.89]	0.941
	OLL2809	6.3 ± 0.5	4.3 ± 0.4 †	3.7 ± 0.5 †	−2.7 ± 0.6		
Water retention	Placebo	2.8 ± 0.3	2.0 ± 0.3 †	1.9 ± 0.4 †	−0.9 ± 0.3	−0.99[−2.11 –0.14]	0.086
	OLL2809	3.7 ± 0.5	2.5 ± 0.3 †	2.0 ± 0.3 †	−1.8 ± 0.4		
Autonomic reactions	Placebo	1.1 ± 0.3	0.6 ± 0.2 †	0.6 ± 0.2	−0.4 ± 0.3	−0.22[−0.89 – 0.45]	0.519
	OLL2809	0.9 ± 0.2	0.6 ± 0.2	0.3 ± 0.1 †	−0.6 ± 0.2		
Negative affect	Placebo	3.9 ± 0.8	2.5 ± 0.6	2.6 ± 0.8 †	−1.3 ± 0.6	−0.70[−2.86 – 1.46]	0.522
	OLL2809	4.7 ± 0.6	4.2 ± 1.0	2.8 ± 0.6 †	−1.8 ± 0.9		
Concentration	Placebo	3.9 ± 0.7	1.9 ± 0.5 †	2.1 ± 0.5 †	−1.9 ± 0.8	1.03[−0.88 – 2.94]	0.285
	OLL2809	3.1 ± 0.5	3.0 ± 0.7	2.6 ± 0.5	−0.6 ± 0.5		
Behavioral change	Placebo	2.8 ± 0.5	1.4 ± 0.4 †	2.1 ± 0.5	−0.7 ± 0.5	0.04[−1.26 – 1.34]	0.948
	OLL2809	2.3 ± 0.3	2.3 ± 0.4	1.9 ± 0.4	−0.4 ± 0.4		
Arousal (positive)	Placebo	1.3 ± 0.3	1.3 ± 0.3	1.8 ± 0.4	0.5 ± 0.4	0.35[−0.74 – 1.43]	0.527
	OLL2809	1.7 ± 0.4	2.7 ± 0.6 †	2.8 ± 0.6 †	1.0 ± 0.4		
Control	Placebo	0.3 ± 0.1	0.2 ± 0.1	0.3 ± 0.1	−0.1 ± 0.1	0.08[−0.31 – 0.48]	0.677
	OLL2809	0.3 ± 0.1	0.2 ± 0.1	0.2 ± 0.1	0.0 ± 0.2		

Baseline (placebo, n = 38; OLL2809, n = 39), cycle 2 (placebo, n = 38; OLL2809, n = 39), cycle 3 (placebo, n = 38; OLL2809, n = 38). Data are shown as mean ± SE. The estimates were driven by multiple regression analysis. β: standardized partial regression coefficient. † $p < 0.05$ vs Baseline.

Table S4. Mean MDQ scores during the menstrual period (full analysis set).

Factors	Group	Baseline
Physical score	Placebo	11.0 ± 1.0
	OLL2809	11.0 ± 0.9
Psychological score	Placebo	9.1 ± 1.7
	OLL2809	8.2 ± 1.2
Subfactors		
Pain	Placebo	6.9 ± 0.7
	OLL2809	6.3 ± 0.5
Water retention	Placebo	2.8 ± 0.3
	OLL2809	3.7 ± 0.4
Autonomic reactions	Placebo	1.0 ± 0.2
	OLL2809	0.9 ± 0.2
Negative affect	Placebo	3.8 ± 0.7
	OLL2809	4.6 ± 0.6
Concentration	Placebo	3.8 ± 0.7
	OLL2809	3.0 ± 0.5
Behavioral change	Placebo	2.7 ± 0.5
	OLL2809	2.2 ± 0.3
Arousal (positive)	Placebo	1.2 ± 0.3
	OLL2809	1.7 ± 0.4
Control	Placebo	0.3 ± 0.1
	OLL2809	0.3 ± 0.1

Baseline (placebo, $n = 40$; OLL2809, $n = 40$). Data are shown as mean ± SE.

Table S5. Mean scores and changes during the study period, and estimated treatment differences for SF-36 and VAS in the menstrual period (per-protocol set).

Factors	Group	Baseline	Cycle 2	Cycle 3	Score changes (Cycle 3 – Baseline)	Estimated treatment difference	
						β [95% CI]	*p*-value
SF-36							
PCS	Placebo	49.6 ± 1.3	53.6 ± 1.2 †	52.9 ± 0.9 †	3.3 ± 1.0	−2.65[−5.70 – 0.39]	0.087
	OLL2809	53.4 ± 1.0	54.2 ± 0.9	54.2 ± 1.0	0.8 ± 1.1		
MCS	Placebo	49.0 ± 1.4	52.3 ± 1.4 †	52.2 ± 1.5 †	3.1 ± 1.5	2.61[−1.47 – 6.68]	0.206
	OLL2809	48.5 ± 1.1	51.8 ± 1.5 †	53.6 ± 1.4 †	5.0 ± 1.4		
RCS	Placebo	45.8 ± 1.8	47.7 ± 1.7	45.2 ± 2.0	−0.6 ± 1.4	3.26[−1.28 – 7.80]	0.156
	OLL2809	46.1 ± 1.3	47.8 ± 1.4	48.9 ± 1.4	2.9 ± 1.7		
VAS							
Lower abdominal cramps	Placebo	45.1 ± 4.1	35.6 ± 4.3 †	27.9 ± 3.6 †	−16.6 ± 4.0	−1.35[−12.15 – 9.45]	0.804
	OLL2809	46.5 ± 3.7	31.6 ± 3.4 †	27.9 ± 3.9 †	−17.7 ± 3.4		
Skin disorders	Placebo	28.5 ± 3.3	17.4 ± 3.3 †	16.5 ± 2.8 †	−10.9 ± 3.2	−3.64[−14.56 – 7.27]	0.507
	OLL2809	39.8 ± 3.6	21.6 ± 3.1 †	21.9 ± 3.4 †	−16.8 ± 4.4		
Swelling	Placebo	31.8 ± 4.1	19.2 ± 3.5 †	19.4 ± 3.1 †	−11.9 ± 3.9	−0.73[−11.30 – 9.85]	0.891
	OLL2809	31.6 ± 4.0	18.5 ± 2.8 †	15.0 ± 2.8 †	−14.9 ± 3.6		
Irritability	Placebo	31.7 ± 4.0	22.8 ± 4.4	17.0 ± 3.6 †	−13.8 ± 3.6	−5.71[−18.05 – 6.62]	0.359
	OLL2809	40.6 ± 3.8	25.5 ± 3.7 †	19.2 ± 3.1 †	−20.2 ± 4.8		
Mood swings	Placebo	23.8 ± 3.7	15.6 ± 3.6	13.6 ± 3.1 †	−8.3 ± 2.9	−6.25[−17.42 – 4.92]	0.268
	OLL2809	28.8 ± 4.1	21.0 ± 3.4	15.8 ± 3.2 †	−14.3 ± 4.5		

Baseline (placebo, n = 38; OLL2809, n = 39), cycle 2 (SF-36: placebo, n = 38; OLL2809, n = 38; VAS: placebo, n = 35; OLL2809, n = 37), cycle 3 (SF-36: placebo, n = 38; OLL2809, n = 39; VAS: placebo, n = 35; OLL2809, n = 37). Data are shown as mean ± SE. The estimates were driven by multiple regression analysis. β: standardized partial regression coefficient. † $p < 0.05$ vs Baseline.

Abbreviations: PCS, physical component summary; MCS, mental component summary; RCS, role/social component summary.