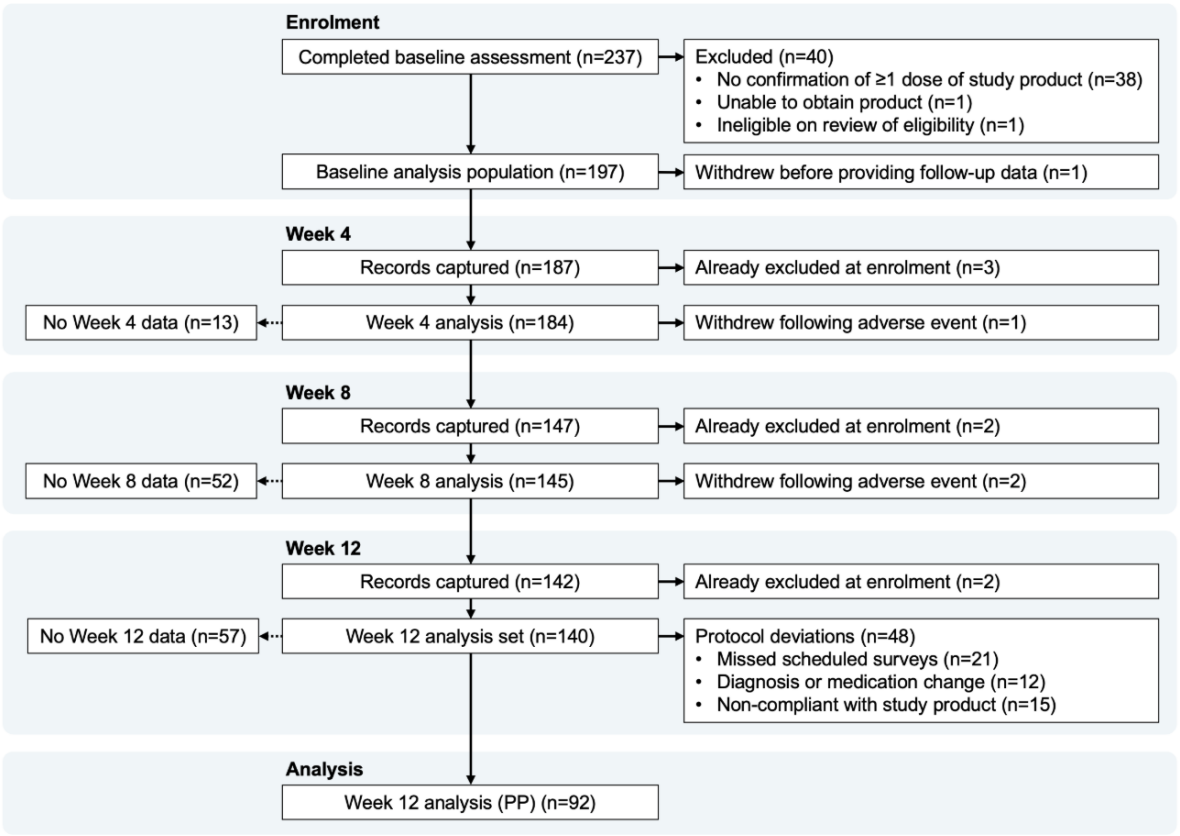
Participant Flow



Baseline Characteristics

Characteristic	All participants (n=197)	Week 12 data (n=140)	No Week 12 data (n=57)
Age, n (%)			
31–40 years	7 (3.6)	4 (2.9)	3 (5.3)
41–50 years	128 (65.0)	89 (63.6)	39 (68.4)
51–60 years	62 (31.5)	47 (33.6)	15 (26.3)
Ethnicity, n (%)			
White	164 (83.2)	116 (82.9)	48 (84.2)
Asian/Asian British	18 (9.1)	13 (9.3)	5 (8.8)
Black/African/Caribbean/ Black British	8 (4.1)	5 (3.6)	3 (5.3)
Mixed	6 (3.0)	5 (3.6)	1 (1.8)
Other	1 (0.5)	1 (0.7)	0 (0.0)
BMI, mean (kg/m2)*			
Mean (SD)	26.0 (5.4)	26.0 (5.4)	26.0 (5.5)
Baseline treatments, n (%)			
HRT	88 (44.7)	62 (44.3)	26 (45.6)
No HRT	109 (55.3)	78 (55.7)	31 (54.4)
Oral contraceptive	14 (7.1)	9 (6.4)	5 (8.8)
Antidepressants	23 (11.7)	12 (8.6)	11 (19.3)
Relevant conditions, n (%)			
None reported	168 (85.3)	121 (86.4)	47 (82.5)
IBS	17 (8.6)	12 (8.6)	5 (8.8)
Endometriosis	6 (3.0)	3 (2.1)	3 (5.3)
PCOS	6 (3.0)	4 (2.9)	2 (3.5)
Baseline symptom scores, mean			
MENQOL total	4.54	4.52	4.60
MSI total	73.24	72.14	75.95
MSI-GI	6.92	6.94	6.88
SRQ total	22.38	22.40	22.32

Table 1: Baseline demographic and clinical characteristics. Participants are shown for the baseline analysis set overall and according to whether Week 12 outcome data were available. No significance testing was performed for comparisons between these groups. *Available for 176 of the 197 participants. BMI, body mass index; HRT, hormone replacement therapy; IBS, irritable bowel syndrome; PCOS, polycystic ovary syndrome.

Outcome Measures

Symptom scores	Baseline mean (SD)	Week 12 mean (SD)	Mean change	% change from baseline	p value	Response rate (%)	MCID response rate (%)
MENQOL total	4.52 (1.11)	2.44 (0.94)	–2.07	–45.8	<0.001	98	84
MENQOL vasomotor	4.09 (1.92)	1.96 (1.32)	–2.13	–52.1	<0.001	83	76
MENQOL psychosocial	4.82 (1.41)	2.80 (1.33)	–2.01	–41.7	<0.001	93	76
MENQOL physical	4.52 (1.28)	2.42 (1.05)	–2.10	–46.5	<0.001	95	84
MENQOL sexual	4.23 (2.18)	2.23 (1.70)	–2.00	–47.3	<0.001	73	65
MSI total	72.14 (36.94)	34.86 (25.29)	–37.28	–51.7	<0.001	90	NE
MSI-GI	6.94 (5.03)	2.59 (3.12)	–4.36	–62.8	<0.001	78	NE
SRQ total	22.40 (7.45)	25.77 (8.46)	+3.37	+15.0	<0.001	66	NE

Table 2: Summary of changes in key clinical outcomes from baseline to Week 12 (Week 12 analysis set; n=140). Percentage changes calculated as mean change divided by baseline mean. Response rate defined as proportion of participants demonstrating improvement from baseline at Week 12. MCID shown where published thresholds are available; for MENQOL, a ≥1-point improvement was used as conservative threshold for clinically meaningful change. Response and MCID response rates are calculated among participants with paired baseline and Week 12 data and therefore exclude participants who did not complete Week 12 assessment. The term "response" denotes improvement from baseline. MCID, minimum clinically important difference; MENQOL, Menopause-Specific Quality of Life questionnaire; MSI, Midlife Women's Symptom Index; MSI-GI, gastrointestinal subscale of the MSI; NE, not established; SD, standard deviation; SRQ, Sleep Regularity Questionnaire.

Harms/Adverse Events

Adverse event	All participants (n=197) n (%)
All-cause mortality	0 (0.0%)
Serious adverse event	0 (0.0%)
Other adverse event	3 (1.5%)
GI upset	1 (0.5%)
Cystic acne	1 (0.5%)
Poorly tolerated response	1 (0.5%)

Table 3. Summary of adverse events. n = number of subjects with adverse event.