Appendix 1.

Quantitative information section

Domain 1: health concerns (12 items)

Before/after the lifestyle intervention, I was concerned about:

Choices:

1. This is not an issue for me
2. Not concerned
3. Indifferent
4. Somewhat concerned
5. Very concerned

Domain item	Pre-intervention scores* (n = 55)	Post-intervention scores* (n = 55)
1. Fertility and my ability to become pregnant in the future	4.1 ± 1.3	4.2 ± 1.1
2. Irregular menstrual bleeding	4.2 ± 0.8	3.8 ± 1.1
3. Unwanted male pattern hair growth (hirsutism)	4.1 ± 1.1	4.2 ± 0.8
4. High male hormone levels (hyperandrogenemia)	3.9 ± 1.1	4.3 ± 0.8
5. Acne	3.4 ± 1.4	4.0 ± 1.2
6. Scalp hair loss (alopecia)	3.3 ± 1.5	3.7 ± 1.3
7. A weight problem	4.6 ± 0.9	4.6 ± 0.8
8. High insulin levels and insulin resistance	4.1 ± 1.2	4.5 ± 0.8
9. My risk of developing cancer of the uterus or breast	4.4 ± 1.0	4.4 ± 0.7
10. My risk of developing diabetes	4.6 ± 0.8	4.6 ± 0.6
11. My risk of developing cardiovascular disease	4.3 ± 0.9	4.4 ± 0.6
12. My risk of developing the metabolic syndrome (a group of symptoms, including elevated levels of blood triglyceride, glucose, waist circumference, blood pressure, and decreased high-density lipoprotein cholesterol levels)	4.4 ± 0.9	4.7 ± 0.6

Domain 2: healthcare satisfaction (5 items)

Before/after the lifestyle intervention:

Choices:

1. I did not see a healthcare provider
2. Don't know
3. No
4. Yes somewhat
5. Yes to a large extent

Domain item	Pre-intervention scores* (n = 55)	Post-intervention scores* (n = 55)
13. I had discussed my symptoms with my primary healthcare providers	4.2 ± 1.0	4.7 ± 0.6
14. I felt satisfied with the explanation given to me about my symptoms by my healthcare providers	4.0 ± 1.0	4.6 ± 0.7
15. I felt satisfied with the treatment options offered to me by my healthcare providers	3.4 ± 1.0	4.3 ± 0.9
16. I felt satisfied with the treatment I was receiving (or had received) for my symptoms by my healthcare providers	3.3 ± 1.0	4.3 ± 0.9
17. I felt satisfied with the on-going care I was receiving for my symptoms by my healthcare providers	3.3 ± 1.0	4.3 ± 0.8

Domain 3: knowledge about PCOS (23 items)

Before/after the lifestyle intervention I understood [that]:

Choices:

1. I do not understand this information
2. I am unsure
3. Yes, I somewhat understand
4. Yes, I understand

Domain item	Pre-intervention scores* (n = 55)	Post-intervention scores* (n = 55)
18. A follicle is a small fluid-filled sac with a single egg inside and that follicles are often called cysts	3.5 ± 0.7	3.8 ± 0
19. How follicle growth and egg release occur	3.0 ± 0.8	3.7 ± 0.4
20. Polycystic ovaries contain more visible follicles than the average ovary	3.5 ± 0.7	3.9 ± 0.5
21. Polycystic ovaries tend to ovulate less frequently than the average ovary	3.5 ± 0.7	3.9 ± 0.2
22. Ovulating more frequently would improve my fertility	3.7 ± 0.7	3.9 ± 0.3
23. After egg release (ovulation), progesterone is released: progesterone would allow my uterine lining to shed and make me have a regular menstrual period (if I'm not pregnant)	3.3 ± 0.8	3.9 ± 0.3
24. Having monthly increases in progesterone and therefore, menstrual periods would decrease my risk of cancer of the uterus	3.1 ± 0.9	3.8 ± 0.6
25. Polycystic ovary tends to make more male hormones (like testosterone) than the average ovary	3.3 ± 0.9	4.0 ± 0.2
26. The amount of fat in the body affects the amount of free male hormone in my body	2.8 ± 0.9	3.7 ± 0.5
27. More free male hormone promotes unwanted hair growth, acne and scalp hair loss (alopecia)	3.1 ± 0.9	3.9 ± 0.4
28. Medications can stop the production of male hormone by the ovary (like hormonal contraception) or block the effects of the male hormone, and would help to prevent unwanted hair growth, acne or alopecia (male pattern balding)	3.0 ± 0.9	3.7 ± 0.6
29. Insulin helps the ovary make more male hormones (like testosterone)	2.9 ± 0.9	3.7 ± 0.5
30. High insulin levels are common in women with PCOS	3.3 ± 0.9	3.9 ± 0.2
31. High insulin levels promote weight gain and make it harder to lose weight	3.4 ± 0.8	4.0 ± 0.2
32. High insulin levels place individuals at high risk for developing diabetes	3.5 ± 0.8	4.0 ± 0.2
33. Lowering insulin levels may help to decrease male hormone levels, help with weight loss and help trigger ovulation	3.3 ± 0.8	3.9 ± 0.3
34. Insulin levels can be reduced by exercise and by certain changes in diet	3.5 ± 0.8	4.0 ± 0.2
35. Insulin levels can be lowered by medications (like metformin) that make the body more sensitive to insulin	3.3 ± 0.8	3.8 ± 0.5
36. Increasing the amount of muscle in my body will increase my body's metabolic rate, that is my body's ability to burn calories	3.5 ± 0.7	3.9 ± 0.4
37. The metabolic syndrome increases my risk of developing diabetes and cardiovascular disease.	3.2 ± 0.9	3.9 ± 0.3
38. The metabolic syndrome is common in women with PCOS	3.2 ± 0.9	3.9 ± 0.4
39. That exercise, appropriate changes in diet, and weight loss can decrease the risk of developing the metabolic syndrome	3.4 ± 0.9	4.0 ± 0.2
40. Enough about PCOS to explain to another person what PCOS is, and how it affects health parameters	3.1 ± 0.7	3.7 ± 0.6
Domain 4: healthy lifestyle behaviors including active living and healthy eating (14 items) Before/after the lifestyle intervention:		
Sub-domain of active living (6 items)		
Sub-domain item	**Pre-intervention scores* (n = 55)**	**Post-intervention scores* (n = 55)**
41. I led an active lifestyle *Choices:* 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree	3.0 ± 1.2	4.1 ± 1.0
42. Total number of times I exercised per week *Choices:* 1. No, I didn't really exercise 2. 1 to 2 days each week 3. 3 to 4 days each week 4. 5 to 6 days each week 5. Daily	2.2 ± 1.2	3.2 ± 1.1
43. The number of days per week of doing aerobic exercise (that is, an exercise that increases heart rate and makes you warm and sweaty) was	2.4 ± 1.4	3.7 ± 1.2

Choices: 1. Occasional 2. 1-2 times per week 3. 3-4 times per week 4. 5-6 times per week 5. Daily	3.1 ± 2.0	5.0 ± 1.2
44. The number of minutes per session of doing aerobic exercise was (examples of non-aerobic exercise include resistance bands, hand weights, Pilates or Yoga but not activities such as jogging or walking) *Choices:* 1. 2-5 minutes 2. 6-10 minutes 3. 11-15 minutes 4. 16-30 minutes 5. 31-44 minutes 6. greater than 45 minutes	2.1 ± 1.1	2.7 ± 1.2
45. The number of days per week of non-aerobic exercise was *Choices:* 1. Occasional 2. 1-2 times per week 3. 3-4 times per week 4. 5-6 times per week 5. Daily	2.7 ± 0.2	3.7 ± 1.5
46. The number of minutes per session of non-aerobic exercise was *Choices:* 1. 2-5 minutes 2. 6-10 minutes 3. 11-15 minutes 4. 16-30 minutes 5. 31-44 minutes 6. Greater than 45 minutes		
Sub-domain of healthy eating (8 items)		
Sub-domain item		
Before/after the lifestyle intervention: *Choices:* 1. Never 2. Hardly ever 3. Sometimes 4. Almost always 5. Always		
Domain item	**Pre-intervention scores* (n = 55)**	**Post-intervention scores* (n = 55)**
47. I thought about the types of food I was eating when planning every meal	3.0 ± 0.8	4.0 ± 0.8
48. I ate three meals per day	3.5 ± 1.2	4.0 ± 0.9
49. I ate protein with every meal	3.5 ± 0.9	3.9 ± 0.8
50. I ate a diet low in fat	2.8 ± 0.8	3.8 ± 0.8
51. I made healthy food choices for snacks	3.0 ± 0.7	3.9 ± 0.9
52. I ate a diet rich in fruits and vegetables	3.3 ± 0.8	4.2 ± 0.7
53. I knew which foods were high in protein	3.6 ± 1.0	4.3 ± 0.9
54. I knew the difference between simple and complex carbohydrate-containing foods	1.6 ± 1.2	4.2 ± 1.2

Domain 5: feelings and experiences about participating in lifestyle intervention (13 items) Before/after participating in the study, I felt: *Choices:* 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree		
55. Comfortable about asking questions [from the study researchers]	4.4 ± 0.6	4.7 ± 0.5
56. Comfortable about discussing personal or sensitive subjects [with the study researchers]	4.2 ± 0.7	4.5 ± 0.7
57. My information would remain confidential (unless I agreed to have my information sent to my family doctor)	4.5 ± 0.6	4.7 ± 0.5
58. The [study] researchers were knowledgeable about PCOS	4.7 ± 0.6	4.7 ± 0.6
59. The [study] researchers would gain helpful information about PCOS	4.6 ± 0.6	4.6 ± 0.6
60. The [study] researchers would be able to provide answers regarding my concerns about PCOS	4.6 ± 0.6	4.76 ± 0.5
61. It was helpful to look at the ultrasound images of my ovaries. Now it is now easier for me to understand what it means to have polycystic ovaries	4.4 ± 0.8	4.67 ± 0.5
Before/after participating in the study, my level of comfort with:	4.1 ± 0.2	4.2 ± 0.9
62. The idea of having blood tests was Choices: 1. Painful 2. Very uncomfortable 3. Uncomfortable 4. Slightly uncomfortable 5. Comfortable 6. Very comfortable	3.1 ± 0.2	4.0 ± 0.8
63. The idea of having physical examinations, including having my height, weight, and waist circumference measured, hair growth assessed, and body composition scans done was Choices: 1. Painful 2. Very uncomfortable 3. Uncomfortable 4. Slightly uncomfortable 5. Comfortable 6. Very comfortable	2.7 ± 1.2	2.9 ± 1.1
64. The idea of having a transvaginal ultrasound was Choices: 1. Uncomfortable 2. Slightly uncomfortable 3. Neutral 4. Comfortable 5. Very comfortable	3.5 ± 1.2	3.6 ± 1.4
65. The experience of doing blood tests was Choices: 1. Too painful 2. Painful and I wanted to quit but didn't say so 3. Painful but I didn't want to quit 4. Not overly painful 5. Not at all painful/no discomfort	3.6 ± 1.1	4.4 ± 0.6
66. The experience of doing physical examination tests was		

Choices: 1. Painful 2. Very uncomfortable 3. Uncomfortable 4. Slightly uncomfortable 5. Comfortable 6. Very comfortable	3.9 ± 0.7	4.1 ± 0.8
67. The experience of doing transvaginal ultrasound was Choices: 1. Too painful 2. Painful and I wanted to quit but didn't say so 3. Painful but I didn't want to quit 4. Not overly painful 5. Not at all painful/no discomfort		
Domain 6: feelings and experiences about PCOS diagnosis (7 items) Choose the response that best describes your feelings: 1. Don't know 2. No 3. Yes		
Domain item	**Pre-intervention scores* (n = 55)**	**Post-intervention scores* (n = 55)**
68. I was first diagnosed with PCOS as a result of	2.6 ± 0.5	-
69. I had an ultrasound in the last three years	2.4 ± 0.5	-
70. The type of ultrasound was transvaginal [In case of positive response to the last question]	2.2 ± 0.6	-
71. I suspect that other women in my family (like mother, sisters) or extended family (like aunts, cousins, grandmothers) have PCOS	2.5 ± 0.8	-
72. Excess weight (being overweight or obese) runs in my family	2.7 ± 0.5	-
73. I feel I need to lose weight for health reasons	2.7 ± 0.5	-
74. I didn't know that I had hirsutism (male pattern hair growth) until I was told during the pre-study diagnosis	2.1 ± 0.9	-
Qualitative information section Questions asked from participants after completing the lifestyle intervention study 75. If you have been advised to lose weight, how does this make you feel? 76. We are interested in learning more about how women experience the physical examination. Please tell us anything about your experience that you think we should know 77. We are interested in learning more about how women experience the transvaginal ultrasound, which was part of the PCOS study. Please tell us anything about your experience that you think we should know 78. Is there any topic that you think we should have asked you about? 79. Is there any comment you would like to make about the topic of PCOS or the topic of being involved in a study? 80. Is there anything that you would like to add, ask or comment about? 81. If you learned something about PCOS during the study, what ONE thing did you learn that is most helpful to you? 82. If you learned something about PCOS over the course of the study, what ONE thing came as a surprise to you?		

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	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 2
	2b	Specific objectives or hypotheses	Page 3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	Pages 3 and 4
	4b	Settings and locations where the data were collected	Page 3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 3 – 6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 3 – 6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	Page 6 and reference 18
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 4 and reference 14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Reference 14
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	Reference 14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Reference 14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Reference 14
	11b	If relevant, description of the similarity of interventions	Page 5, Reference 14
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 5 – 6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable
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	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 3
	14b	Why the trial ended or was stopped	Figure 1
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 16 – 17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1, Figure 1, and pages 6 – 8
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)	Pages 6 – 8, and Figures 2 – 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 10 – 11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 10 – 11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pages 8 – 11
Other information			
Registration	23	Registration number and name of trial registry	Pages 1 and 3
Protocol	24	Where the full trial protocol can be accessed, if available	Reference 18
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title Page

*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.