Evaluation of the accuracy of wrist skin temperature measured using an infrared temperature sensor for prediction ovulation date

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Abstract

Background: Technological advancements have made it possible to measure vital signs through wearable devices.

Objective: This study aimed to evaluate accuracy of wrist skin temperature measurement using an infrared temperature sensor in a wearable device for predicting ovulation dates.

Methods: We recruited 106 women and measured data for a total of 318 cycles. All participants were required to measure their wrist skin temperature while sleeping, their oral temperature every day immediately after waking up, and perform an ovulation test several days before and after the expected ovulation date. We aimed to compare the accuracy of the expected ovulation date and actual ovulation date through wrist skin temperature measurement, accuracy comparison with the next menstrual date, and the correlation between oral temperature and wrist skin temperature.

Results: In the full analysis set (FAS), data of 225 cycles from 85 women were analyzed after excluding dropouts (21 of 106 women). In the per-protocol set, data of 52 women (156 cycles) were analyzed. When analyzing 225 cycles in FAS and comparing the actual ovulation date with the ovulation date predicted by wrist skin temperature, 64.0% had a difference of less than 2 days (95% CI, 57.7-70.3%). A comparison of differences within 3 days showed a significant value, with an accuracy of 77.8% (95% CI, 72.4-83.2%, P=.005). When analyzing 156 cycles in the PP set, the accuracy of the difference within 2 days was 64.1% (95% CI, 56.6-71.6%) while comparing the actual ovulation date with the ovulation date predicted by the wrist skin temperature. When comparing the differences within 3 days, the accuracy was 78.9% (95% CI, 72.4-85.3%, P=.008), showing significant prediction similar to FAS. The prediction of the next menstrual cycle was also analyzed. In FAS, the difference within 2 days was 68.2% (95% CI, 62.5-74.0%, P=.73), and the difference within 3 days was 78.8% (95% CI, 73.8-83.8%, P=.001). According to per-protocol analysis, 69.9% of cases showed a difference within 2 days (95% CI, 62.7-77.1%, P=.51), and 81.4% of cases showed a difference within 3 days (95% CI, 75.3-87.5%, P=.001). When evaluating the correlation between oral temperature and wrist skin temperature, the FAS showed r = 0.423 (95% CI, 0.403-0.443), and the per-protocol showed r = 0.448 (95% CI, 0.423-0.473).

Conclusions: Wrist skin temperature measured using an infrared temperature sensor did not show statistically significant results in predicting the actual ovulation date within 2 days, but showed significant results within 3 days, which is the original approval. Therefore, measuring wrist skin temperature during sleep using a wearable device may be helpful in predicting ovulation date and next expected menstruation date and may be another useful aspect of using wearable devices. Clinical Trial: not applicable

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Original research articles

Evaluation of the accuracy of wrist skin temperature measured using an infrared temperature sensor for prediction ovulation date

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Conclusions: Wrist skin temperature measured using an infrared temperature sensor did not show statistically significant results in predicting the actual ovulation date within 2 days, but showed significant results within 3 days, which is the original approval. Therefore, measuring wrist skin temperature during sleep using a wearable device may be helpful in predicting ovulation date and next expected menstruation date and may be another useful aspect of using wearable devices.

Keywords: wearable electronic devices; wrist skin temperature; infrared temperature sensor; ovulation detection; menstrual cycle

Introduction

Regular menstruation is important for the health of women. Irregular menstruation is synonymous with irregular ovulation and associated with infertility. Irregular menstruation is especially linked to endometrial cancer; therefore, it is necessary for menstruating women to regularly check their menstrual cycles[1].

An increase in luteinizing hormone (LH) induces ovulation, and the hormone progesterone produced in the ovulated corpus luteum plays a role in maintaining the endometrium and increasing basal body temperature. Therefore, in the past, to check for ovulation, the basal body temperature (BBT) method of measuring body temperature from the mouth has been widely used, and recently, tests using urine LH concentrations have also been used[2-4]. However, it is difficult to predict ovulation in advance because the body temperature rises after ovulation and does not correlate precisely with the ovulation date[2,5]. Furthermore, it was inconvenient for women to hold the thermometer in mouth for 5 minutes immediately after waking up in the morning. The ovulation test method, which has been widely used recently, also has the disadvantages of requiring measurements through a daily urine test[6] and missing the exact date of ovulation when missing the test by just one day.

With the recent development of wearable devices, it has become possible to measure various vital parameters, such as heart rate and blood pressure[7-9]. In particular, with increasing ease in the measurement of body temperature, researchers have gained interest in various uses of this function. If continuous body temperature measurement is possible through a wearable device, there is no need to measure the BBT orally. The ovulation date can be predicted without using an ovulation tester, and changes in body temperature according to the menstrual cycle can be observed, making it easy to predict and manage menstruation[10].

Therefore, we planned this study to compare the accuracy of the measurement of wrist skin temperature and the prediction of the menstrual cycle using an infrared temperature sensor built in a wearable device with existing methods.

Methods

Recruitment

A total of 106 women were screened. To select the number of subjects, the minimum accuracy (P_0) for predicting the expected ovulation date was assumed to be 70%, and the expected accuracy (P_1) for predicting the expected ovulation date through wrist temperature was assumed to be 80%. To obtain 80% power with a one-sided type I error of 5%, 42 women were required, and 106 women were recruited for follow-up loss and unmeasured cycles. Power Analysis and Sample Size Software (2022) was used for the calculations.

The study protocol was approved by the Institutional Review Board of the Samsung Medical Center (IRB No. 2023-02-033). Written informed consent was obtained from all the participants.

We included women (1) with reproductive age over 18 years old; (2) whose menstrual cycle has been 28 ± 7 days for the past 3 months; (3) who do not plan to become pregnant within 6 months; and (4) using a Galaxy smartphone

Women were excluded if they (1) were pregnant or lactating, (2) worked as shift workers, (3) had sleep disorders or slept less than 4 hours a day, (4) were taking hormonal contraceptives, (5) were receiving hormonal treatment to suppress ovulation, or (6) had menopausal symptoms.

Subjects' sex, age, weight, height, blood pressure, past medical history, medication history, previous menstrual cycle information, pregnancy, and childbirth history were collected with consent.

Measurements

All participants were required to measure their wrist skin temperature while sleeping, their oral temperature every day immediately after waking up, and to perform an ovulation test several days before and after the expected ovulation date. The start and end dates of menstruation were recorded using an application on a Galaxy mobile phone. When the LH peak was observed through the ovulation tester, the expected ovulation date was designated and blood was collected within ±1 d.

The ovulation tester was the Smile Ovulation Test David (Runbio Biotech, China) and the oral thermometer was the MC-172L model (OMRON HEALTHCARE, Japan). Wrist skin temperature was measured using a Galaxy Watch 5 (Samsung Electronics, Korea). When subjects wore the Galaxy Watch 5 and were asleep for more than 4 hours, the wrist skin temperature was measured, and the wrist skin temperature was analyzed using Cycle Tracking software (Natural Cycles Nordic AB, Sweden) to predict the menstrual cycle.

Statistical analysis

A single-arm design was used to test whether the accuracy was > 0.7. We calculated that 126 cycles or 42 subjects (3 cycles per subject) would be required to give the trial 80% power to detect a difference of 10% at a one-sided α of .025. We assumed an anovulation rate of 20% and a loss to follow-up rate of 50% without collecting three cycles per subject. Finally, 106 participants were included in this study, resulting in 318 cycles (three cycles per participant). The sample size was computed using the PASS 2024 version 24.0.2. The results were confirmed using a one-sample Z-test to determine whether the lower limit of the 95% confidence interval (CI) for accuracy was greater than 70%. A repeated-measures correlation was performed to calculate the association between the two temperatures. All statistical analyses were performed using the SAS software (version 9.4) and R software (version 4.2.2).

The primary endpoint of this study was the prediction accuracy for the expected ovulation date. The secondary endpoint was to compare the prediction accuracy for the next expected menstrual date and the trends in changes in oral body temperature and wrist skin temperature. The prediction accuracy for the expected ovulation date was evaluated within 2 days by comparing the expected ovulation date between the LH and progesterone tests and the expected ovulation date according to changes in wrist skin temperature.

In the full analysis set (FAS), all subjects who completed the measurement of 3 cycle data were analyzed, excluding cases in which LH results were not measured or did not meet the criteria. Per protocol (PP) analysis was conducted excluding cases where data for all 3 cycles were not measured, when more than 70% of wrist skin temperature data for each cycle were not measured, and when blood tests for each cycle were not performed within ±1 of the expected ovulation date.

Results

A total of 106 women were enrolled, and the FAS was conducted on 85 women, excluding 21 who dropped out of the study. A total of 255 data cycles were measured from 85 women (three cycles each). A total of 225 cycles were analyzed, excluding cases in which data values were missing. In PP analysis, only 52 women were analyzed excluding if the skin temperature per cycle is less than 70% (n = 4), if a blood test was not performed within ± 1 d of the expected ovulation date (n = 10), or if data for all 3 cycles have not been measured (n = 19)(Figure 1).

When analyzing 225 cycles with FAS and comparing the actual ovulation date with the ovulation date predicted by wrist skin temperature, 64.0% had a difference of less than 2 days (95% CI, 57.7-70.3%) (Table 1). A comparison of differences within 3 days showed a significant value, with an accuracy of 77.8% (95% CI, 72.4-83.2%, P=.005). Comparing the accuracy of the actual ovulation date and the ovulation tester, the difference within 2 days showed an accuracy of 89.4% (95% CI, 85.6-93.2%, P<.001).

Table 1. Difference between ovulation date and ovulation date predicted by wrist skin temperature (full analysis set)

Difference date	Number of cycles	%	Cumulative number of cycles	Cumulative percent (%)
0	40	17.8	40	17.8
1	40	17.8	80	35.6
2	64	28.4	144	64
3	31	13.8	175	77.8
4	18	8	193	85.8
5	16	7.1	209	92.9
6	5	2.2	214	95.1
7	6	2.7	220	97.8
8	4	1.8	224	99.6
11	1	0.4	225	100

*Difference date represents the absolute value calculated from the difference between the ovulation date and the ovulation date estimated by the application

When analyzing 156 cycles in the PP set, the accuracy of the difference within 2 days was 64.1% (95% CI, 56.6-71.6%) when comparing the actual ovulation date with the ovulation date predicted by the wrist skin temperature (Table 2). When comparing the differences within 3 days, the accuracy was 78.9% (95% CI, 72.4-85.3%, P=.008), showing significant prediction similar to FAS.

Table 2. Difference between ovulation date and ovulation date predicted by wrist skin temperature (per protocol)

Difference date	Number of cycles	%	Cumulative number of cycles	Cumulative percent (%)
0	30	19.2	30	19.2
1	26	16.7	56	35.9
2	44	28.2	100	64.1
3	23	14.7	123	78.9
4	9	5.8	132	84.6
5	13	8.3	145	93.0
6	2	1.3	147	94.2
7	5	3.2	152	97.4
8	3	1.9	155	99.4
11	1	0.6	156	100

*Difference date represents the absolute value calculated from the difference between the ovulation date and the ovulation date estimated by the application

The prediction of the next menstrual date, which was the secondary endpoint, was also compared. In FAS, the difference within 2 days was 68.2% (95% CI, 62.5-74.0%, P=.73), and the difference within 3 days was 78.8% (95% CI, 73.8-83.8%, P=.001). Per-protocol analysis showed that 69.9% of cases showed a difference within 2 days (95% CI, 62.7-77.1%, P=.51), and 81.4% of cases showed a difference within 3 days (95% CI, 75.3-87.5%, P=.001).

When evaluating the correlation between oral temperature and wrist skin temperature, the FAS showed r = 0.423 (95% CI, 0.403-0.443), and the per-protocol showed r = 0.448 (95% CI, 0.423-0.473).

Discussion

Through our study, wrist skin temperature measurement did not show a significant difference in accuracy from the actual ovulation date within 2 days, but showed significant results in prediction within 3 days, which is the original approval for the Galaxy Watch 5.

Several methods are available for predicting ovulation. Measuring BBT using the classical method has the advantage of low cost; however, it is associated with disadvantages such as the requirement of body temperature measurement on a daily basis, measurement before waking up[11], measurement is inconvenient[12], and non-prediction of the exact date of ovulation as the body temperature rises only after the process. Ovulation prediction using the urine LH test, which has been widely used recently, is a highly accurate method[4,5]; however, it has disadvantages such as the need of continuous payment for the LH kit and daily measurement around the expected ovulation date. Furthermore, the method is not suitable for women with irregular periods. Therefore, concerns remain regarding the determination of the date of ovulation by continuous measurement method without inconvenience.

Recently, as temperature measurements using wearable devices have become possible, many studies have been conducted using this technology[13,14]. With the development of a watch that can be used on a daily basis, measurement of basic vital signs such as heart rate and blood pressure is possible[7-9]. The technology is suitable not only for healthy people but also for people who need to measure vital signs periodically. Particularly, the feasibility of body temperature measurement has widened the development range of healthcare systems. Many studies have shown that body temperature measurement can be helpful in predicting ovulation date[10]. However, the existing prediction devices do not accurately predict the ovulation dates and use multiple apps; therefore, research on new wearable devices is necessary.

Thus, to determine whether the new Galaxy Watch 5 helps predict ovulation date, we decided to set up a study by referring to existing papers and determining whether the difference between the actual ovulation date and the difference within two days is accurate. However, there was a difference from our results because in the case of the Galaxy watch 5, the difference permitted by the cycle tracking app was within 3 days[15]. In FAS, the actual ovulation date and the ovulation date predicted by the wrist skin temperature showed a difference of within 2 days in 64.0% (95% CI, 57.7-70.3%). When analyzed by PP, 64.1% (95% CI, 56.6-71.6%) also showed a difference of within 2 days. However, when calculated as a difference of within 3 days as initially permitted by the cycle tracking app, the accuracy was 77.8% (95% CI, 72.4-83.2%, P=.005) in FAS and 78.9% (95% CI, 72.4-85.3%, P=.008) in PP. In other words, this study did not show significant results because the primary endpoint was set to within two days; however, if the standards at the time of app development were applied, it can be said that the ovulation date can be significantly predicted using wrist skin temperature.

In predicting the next menstruation date, which was intended to be viewed as a secondary outcome, the difference within two days did not show significant accuracy results, but the difference within three days, which was the standard set by the app itself, showed significant accuracy. It is highly likely that the prediction range was set too strictly in the research setting.

To exam whether the wrist skin temperature measurement during sleep using an infrared temperature sensor was accurate, we also checked the correlation with BBT, which is highly correlated with the menstrual cycle. Our study showed a relationship of r = 0.423 for the FAS and r = 0.448 for each protocol. In another study, the correlation between wrist skin temperature and BBT in the follicular phase was 0.294 (P=.001), and in the luteal phase, the correlation was 0.124 (P=.19) [16], whereas the correlation in our study was confirmed to be higher. However, the correlation value itself is not very strong, at the level of moderate. Perhaps the reason is that oral body temperature was measured within a short period of 5 minutes and at regular times, whereas wrist skin temperature is measured during sleep, so it is influenced by the surroundings and the measurement time is long, which may have led to the results above. Therefore, it can be said that the wrist skin temperature measurement was not inaccurate.

The advantage of this study is that ovulation was confirmed by measuring progesterone levels. In other studies that predicted fertile days using wrist-worn medical devices, ovulation was mainly predicted using urine LH tests or body temperature [13,14,16-18]. However, in our study, only cycles that normally ovulated, excluding luteal phase defects, were confirmed by measuring progesterone levels, so it can be said that ovulation was measured with stricter criteria than in other studies.

This study has several limitations. Initially, owing to an error caused by an app update, the data measuring the wrist skin temperature were not connected to the app server; therefore, the data from that period were not available, resulting in a dropout. It should also be noted that infectious diseases that could affect body temperature could not be ruled out. However, in the real world, it is difficult to exclude and record the cycle every time an infection occurs; therefore, these data can be considered more appropriate for real-world applications. In addition, the wrist skin temperature measurement can be affected by the temperature of the surrounding environment and has limitations in that it must be worn properly on the wrist during measurement. Therefore, if a wearable device with enhanced skin contact is developed, it would be more advantageous for measuring skin temperature.

The prediction of ovulation date by measuring wrist skin temperature using an infrared temperature sensor had limitations within 2 days. However, it gave significant results in showing accuracy within 3 days of the actual ovulation date, which was originally approved by the Galaxy Watch 5, and this study once again proved the results. Therefore, measuring wrist skin temperature during sleep using a wearable device may be helpful in predicting ovulation date and next expected menstruation date and may be another useful aspect of using wearable devices.

Acknowledgement

We thank Hyoujoo Kwon (Samsung Electronics) for technical assistance with the Galaxy Watch device instructions.

This study was funded by Samsung Electronics.

Conflict of interest

None declared.

Data Availability

Some or all datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author upon reasonable request.

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Observational Study. J Med Internet Res 2019;21:e13404.

Figure Legends

Figure 1. Flow chart of the study

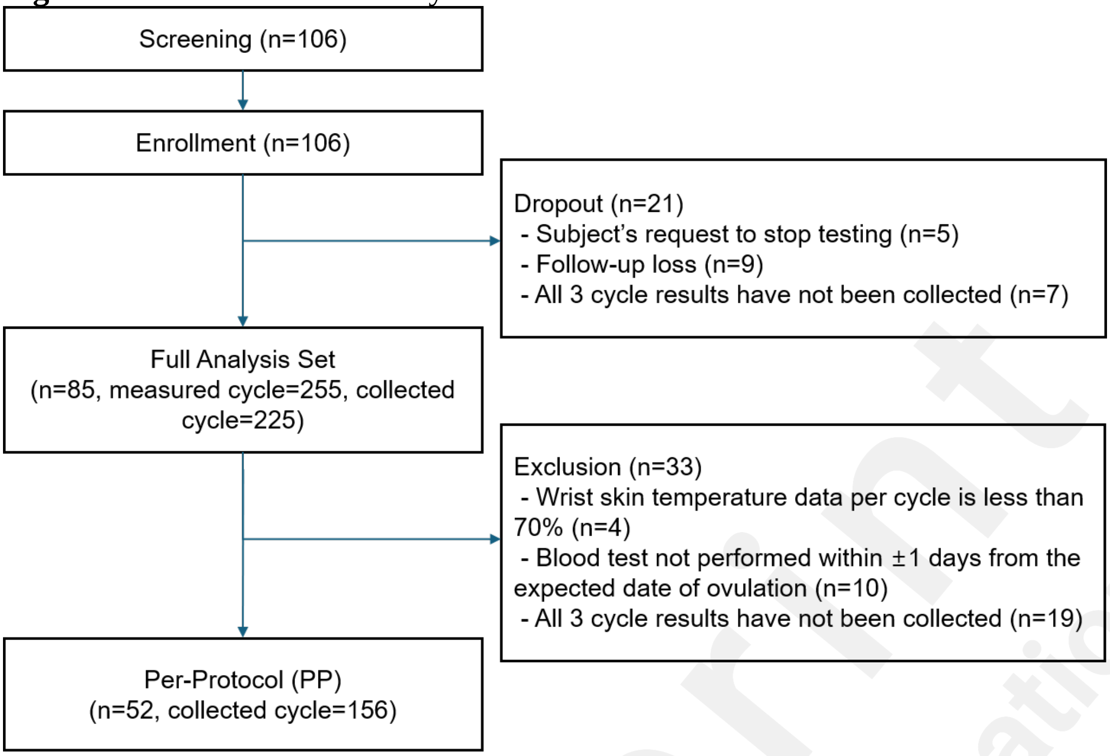
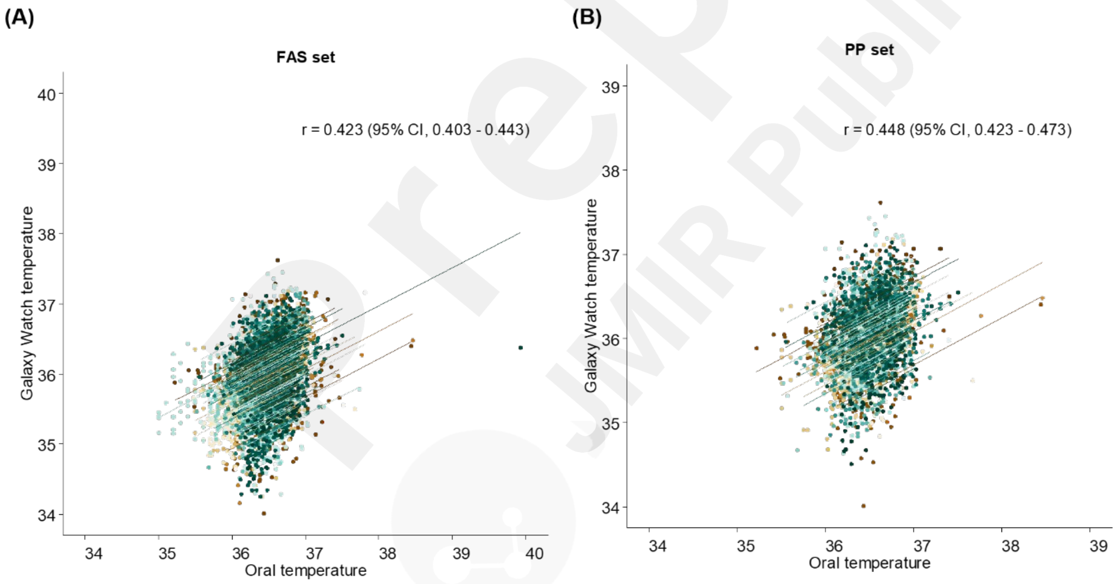


Figure 2. Correlation between oral temperature and wrist skin temperature



*FAS; Full analysis set, PP; per protocol

Supplementary Files

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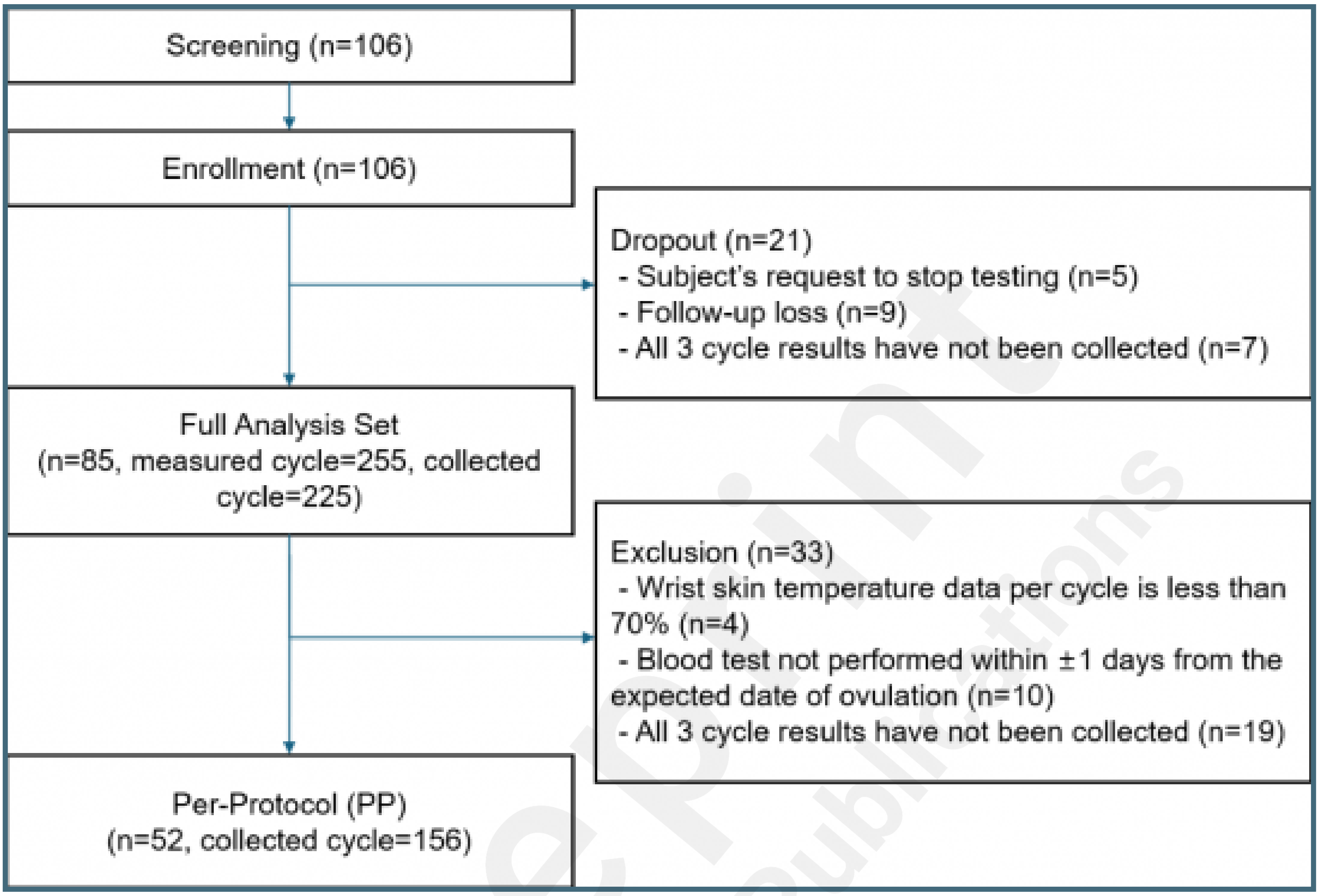
Figures

Flow chart of the study.



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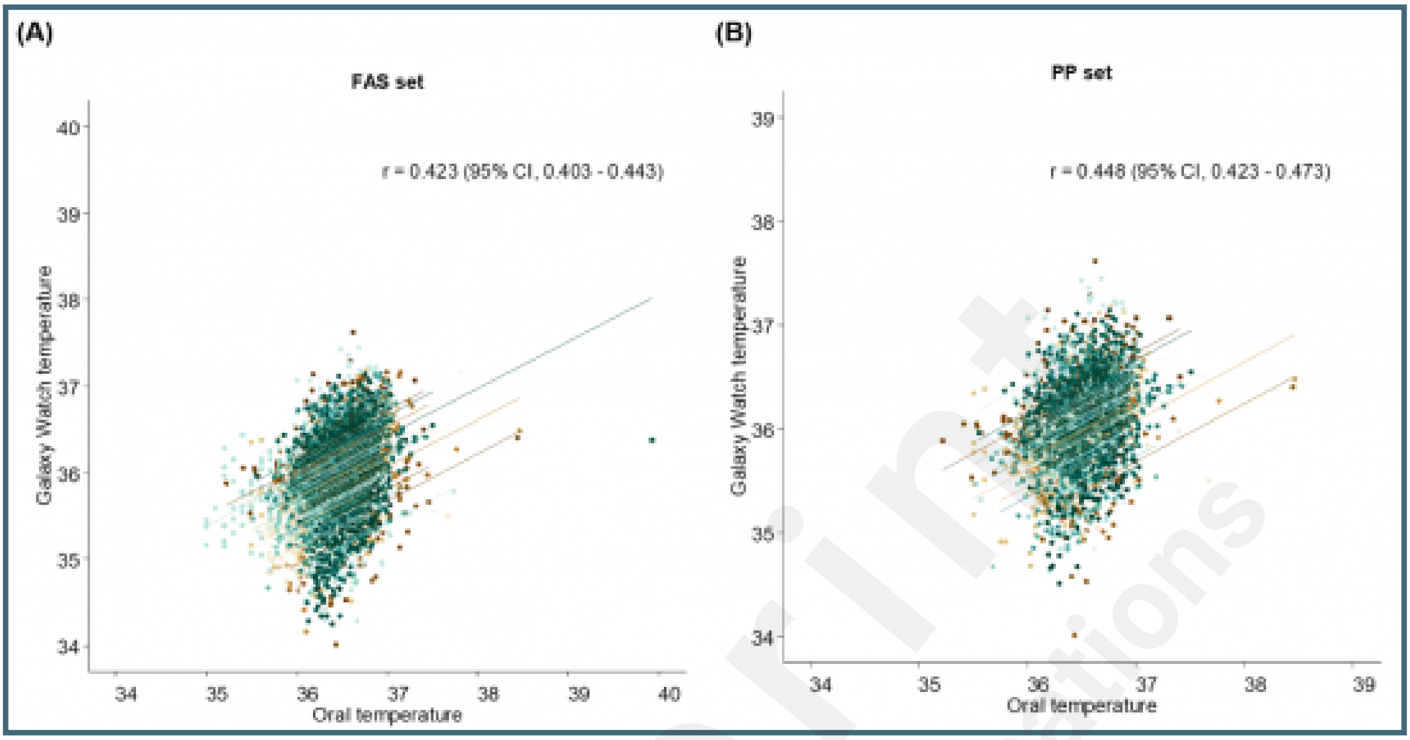

CONSORT (or other) checklists

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