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To predict the fertile window and menstrual cycles with the bracelet

Submission date 17/08/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/09/2024	**Overall study status** Completed	
Last Edited 09/09/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
In the field of reproductive health, many women are also using applications (apps) to track menstrual cycles and identify fertile days, during which the chance of getting pregnant is the biggest. However, the accuracy of these apps is far from satisfactory. Many parameters such as basal body temperature, cervical mucus status, and hormone levels will be input by the users themselves, and it largely increases the inconvenience. Nowadays, advances in digital health have made it possible for people to invasively monitor their health. This study aims to use the wearable device, Huawei Band 6 pro, to continuously record women's physiological data including wrist skin temperature (WST), heart rate (HR), heart rate variability, and respiratory rate. This will aid in developing fertile window and menstruation prediction algorithms through machine learning based on women's physiological parameters data collected by Huawei Band 6 pro. These algorithms will be applied among both regular and irregular menstruators.

Who can participate?
Healthy non-pregnant women aged 18-45 years old

What does the study involve?
In this study, there is no invasive intervention for the participants' health. Each participant will wear the Huawei Band 6 pro to record their WST, HR, heart rate variability, and respiratory rate. These data will be recorded for at least two menstrual cycles. To determine the ovulatory day, blood tests will be done to measure the hormone levels (E2, FSH, LH, etc.) and serial ultrasonography will be done to monitor the follicular development. After these physiological data are collected, algorithms will be developed to predict the fertile window and menstrual cycle based on WST and HR among both regular and irregular menstruators.

What are the possible benefits and risks of participating?
Since sexual hormone levels will be tested and ultrasonography will be done to follow the follicle development, women enrolled in this study will have a detailed understanding of their reproductive endocrine status. There will be a low risk when participating in this study since there is no intervention.

Where is the study run from?
Obstetrics and Gynecology Hospital of Fudan University in Shanghai, China.

When is the study starting and how long is it expected to run for?
October 2021 to April 2023

Who is funding the study?
Huawei Device (Shenzhen) Co., Ltd will mainly support this study.

Who is the main contact?
1. Prof. Hefeng Huang, huanghefg@hotmail.com
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Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Prediction of the fertile window and menstrual cycles with a wearable device via machine-learning algorithms

Acronym
PreFWMC

Study objectives
This study aims to develop fertile window and menstruation prediction algorithms through machine learning based on women's physiological parameters data collected by Huawei Band 6 pro for both regular and irregular menstruators.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/11/2021, Obstetrics and Gynecology Hospital of Fudan University Ethics Committee (No.419, Fangxie Road, Huangpu District, Shanghai, 200011, China; +86 21 53513815; fckyyllwyh@163.com), ref: 2021-195

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Prediction of fertile window and menstruation day through machine learning based on women's physiological parameters.

Interventions
This is a prospective observational cohort study conducted at the Obstetrics and Gynecology Hospital of Fudan University in Shanghai, China. Participants were recruited from November 2021 to September 2022 and followed up between December 2021 and April 2023. Women with a cycle length of 21-35 days and a period duration of no more than 7 days are regarded as being regular menstruators; otherwise, the participants are considered to have irregular menstrual cycles. Participants will be followed up with at least two complete menstrual cycles. Women are required to wear the Huawei Band 6 Pro at least for five hours during their every night sleep for recording parameters including wrist skin temperature (WST), heart rate (HR), heart rate variability (HRV) and respiratory rate. The day of ovulation will be determined by a senior gynecologist through follicular monitoring and serum sex hormone levels. The dataset of enrolled patients will be partitioned randomly into training and testing groups. Fertile

algorithms and menstrual algorithms will be built based on WST and HR data for both regular and irregular menstruators.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Huawei Band 6 pro

Primary outcome(s)
The sensitivity, specificity and accuracy of fertile-window prediction and menstruation prediction were measured using data collected from machine-learning algorithms based on the wrist skin temperature and heart rate after every participant completed the follow-up

Key secondary outcome(s))
The alteration pattern of wrist skin temperature, heart rate, heart rate variability, and respiratory rate during a menstrual cycle among regular and irregular menstruators will be measured with the Huawei Band 6 Pro at night sleep at least for five hours

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Age 18~45 years old
2. Non-pregnant women
3. Have a menstrual cycle
4. Subjects with regular menstrual cycle; the duration of cycle days must be between 21 and 35 days (including 21 and 35 days); the duration of the menstrual period must not exceed 7 days; the cycle must remain regular, and the difference in days between adjacent cycles must be less than 7 days
5. Subjects with irregular menstrual cycles: do not meet the conditions of regular subjects
6. Sign the informed consent form

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
229

Key exclusion criteria
1. Suffering from major systemic diseases
2. Pregnancy history within six months
3. Breastfeeding
4. Currently taking or planning to take hormones and other medications that affect the menstrual cycle
5. Passing across time zones
6. Sleep disorders
7. Other reasons that make researchers believe the patient is not suitable to participate in this study

Date of first enrolment
20/11/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
China

Study participating centre
Obstetrics and Gynecology Hospital, Fudan University
419 Fangxie Road, Huangpu District
Shanghai
China
200011

Sponsor information

Organisation
Obstetrics and Gynecology Hospital of Fudan University

ROR
https://ror.org/04rhdtb47

Funder(s)

Funder type
Industry

Funder Name
Huawei Device Co Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from huanghefg@hotmail.com. Data will be available immediately following publication and ending 5 years following article publication. Consent from participants was required and obtained. All data from participants will be anonymized, with all names, addresses and other personally identifiable information removed, and will be kept strictly confidential. There are no further ethical or legal restrictions.

IPD sharing plan summary
Available on request