

To predict the fertile window and menstrual cycles with the bracelet

Submission date 17/08/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/09/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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

2. Dr. Yanting Wu, yanting_wu@163.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Efficacy

Participant information sheet

No participant information sheet available

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Huawei Band 6 pro

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

05/10/2021

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

200

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

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.fckyy.org.cn/>

ROR

<https://ror.org/04rhdtb47>

Funder(s)

Funder type

Industry

Funder Name

Huawei Device Co Ltd

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/10/2024

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