Project Leadership:
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Collaborators:
Dr. Jens Kraus, CSEM
Dr. Simon Annaheim, EMPA (Swiss Federal Laboratories for Materials Science and Technology)
Pascal Koenig, AVA AG

Objectives:
Building a database for developing and validating an algorithm to detect the fertile days of the menstrual cycle (the "fertile window") based on physiological data measured continuously during the night. The algorithm was developed and trained on independent datasets.

Financing:
Co-financed through the Commission of Technology & Innovation.

Approvals:
The ethical committee of Canton of Zurich approved this clinical trial (KEK-ZH-Nr: 2015-0018).

Design:
Observational study. One year.

Participants:
41 healthy women ages 20 – 40, average age 31.8 years. No infertility indications or hormonal treatment. Recruited through University Hospital, Zurich. Data fully anonymized.

Main Outcome Measures:
The correlation of nine physiological parameters with the timing of the fertile window in 180 menstrual cycles, estimated using urinary LH and estrogen-3-glucuronide (metabolite of estrogen). Physiological parameters tracked during the study include bioimpedance, pulse rate, breathing rate, sleep, movement, heart rate variability, skin temperature, heat loss, and perfusion.

Conclusions:
The algorithm was able to detect an average of 5.3 fertile days per cycle with a precision of 89 percent. This reflects a sensitivity of 76.7 percent and a specificity of 91.5 percent for identifying fertile days in real time. The algorithm works from the first day of using the device and adapts to the individual user through a learning process over the first several cycles.

Future Studies:
The current product is designed for women without infertility indications and with cycles between 24 and 35 days. A service for women with highly irregular cycles (e.g. due to PCOS) is planned.

Presentations & Publications:
Dr. Brigitte Leeners, the lead scientist for this trial, presented the findings in a symposium at the Swiss Society of Gynecology and Obstetrics (http://f.sggg-kongress.ch/timetable#event-90). The results will also be presented at the yearly congresses of American Society of Reproductive Medicine (www.asrm.org) and the German Society of Gynecology and Obstetrics (www.dggg.de) in 2016.

Ava

Founded in Switzerland in 2014 by data scientists, experts in wearable technology, and women's health researchers, Ava is a medical technology company dedicated to bringing innovation to women's reproductive health. The Ava bracelet is the company's first consumer product. It uses new technology to precisely detect a woman's entire fertile window in real time. The company is currently recruiting for further clinical studies to refine its algorithms for use in both pregnancy recognition, pregnancy monitoring, and possible use as a non-hormonal contraceptive device. Ava's headquarters are in San

Francisco, USA, and Zurich, Switzerland. The medical advisory board consists of Prof. Elena Gates from UCSF, USA (www.ucsfhealth.org), and Dr. Brigitte Leeners from USZ, Switzerland (http://www.usz.ch).