First Bluetooth[®] connected ovulation test with App to predict ovulation and track cycles

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Introduction

- Fertility Apps offer the convenience of menstrual cycle tracking and storage of data over multiple cycles
- However, accuracy of ovulation prediction by most free Apps was found to be very poor^{1,2}
- Therefore, an App that uploads accurate ovulation test data would be of benefit to women seeking to conceive
- This study examined women's usage and experience of the new Clearblue[™] Connected **Ovulation Test System**

Test description

The Clearblue[™] Connected Ovulation Test System is designed for home use by women who are either planning or trying for a pregnancy. This is achieved by identifying those days in a woman's cycle on which intercourse is most likely to lead to conception.

The product defines three phases of fertility through urine hormone measurement:

- Low (small chance of conceiving)
- High (increased chance of conceiving) which is achieved by the detection of a rise in the level of estrone-3-glucuronide (E3G)
- Peak (highest chance of conceiving) which predicts the day of ovulation by detecting the luteinizing hormone (LH) surge that precedes ovulation by 24-36 hours³⁻⁵



The product has a connectivity function, via Bluetooth[®] Low Energy. Test results are uploaded directly to a mobile App and are viewable via a cloud-based web-hosted user account. The App displays test result information and further information relating to the user's menstrual cycle, e.g. a cycle summary. The user has the ability to upload additional information to the App and user account, such as dates of menses and intercourse.

Figure 1: Clearblue[™] Connected Ovulation Test System provides test results directly to a mobile App. A calendar enables viewing of daily information, and a cycle comparison screen enables easy viewing of fertility information in previous cycles.



Methods

This home-based UK study required volunteers to pair the Bluetooth® (where 1 is extremely easy to use, and 7 is extremely difficult). Connected Ovulation Test System to their mobile phone using the Volunteer results and pattern of usage were all available in the Cloud, associated App, then use the App and ovulation test for one cycle. enabling detailed analysis of user experience when using the App. Volunteers completed a simple ease-of-use questionnaire when pairing Previous testing of this product had concentrated on iOS phones, the App with the device. After 4 weeks' usage, they completed a more therefore this study aimed to recruit Android phone users, with a smaller detailed usability questionnaire, ranking attributes on a 7-point Likert scale subset of iOS users.

Results

- A total of 191 Android users returned the ease-of-use questionnaire, and 164 returned the 4-week usage assessment forms
- A total of 27 iOS users returned the easeof-use questionnaire, and 23 returned the 4-week usage assessment forms

Demographics

• Mean age of the volunteers was 33 years (range 22-45), and 97.9% were white European. Mean self-reported menstrual cycle length was 28 days (range 22–40)

Initial connection of device

• 84.3% of Android users and 100% of iOS users were satisfied with the experience of connecting the device to the App

Usage experience

 Cloud data showed women conducted tests on the right days and chose to add additional data, e.g. dates of intercourse and menses. Volunteers also successfully uploaded their test results to the App, providing a central, concise record of data. An example of the pattern of usage is shown in Figure 2

Usability questionnaire after 4 weeks' usage

Questions

How EASY was the test to use?

How EASY was the smartphone App to use How EASY TO UNDERSTAND was the leafly How CLEAR was the advice in the smartph How EASY TO READ were the test results o How EASY was it to determine between a t wake-up stick?

Figure 2: Graphic of volunteer usage experience with the Clearblue™ Connected Ovulation Test System

Retrospectively added data Prospectively added data



^a One dot equals spotting; two dots equals light flow;

Conclusions

The Clearblue™ Connected Ovulation Test System combines the convenience of an App with the accuracy and benefits of a home ovulation test.

References

- 1. Moglia ML, et al. Obstet Gynecol. (2016) 127: 1153-1160.
- 2. Setton R, et al. Obstet Gynecol. (2016) 128: 58-63.
- 4. Johnson S, et al. Clin Chem Lab Med. (2015) 53: 1099-1108.
- 5. Godbert S, et al. Arch Gynecol Obstet. (2015) 292: 1153-1161.



	Android		iOS	
	n	Percentage scoring 3 or less	n	Percentage scoring 3 or less
	162	98.1	23	100
se?	164	93.3	23	95.7
flet?	164	93.3	23	95.7
hone App?	164	95.7	23	95.7
on the App?	162	96.3	23	95.7
test stick and the	164	97.6	23	95.7

3. Roos J, et al. Eur J Contracept Reprod Health Care. (2015) 20: 438-450.

Declaration of interest

This study was funded by SPD Development Company Limited, a wholly owned subsidiary of SPD Swiss Precision Diagnostics GmbH. the manufacturers of Clearblue[™] pregnancy and ovulation tests. Sarah Johnson, Bola Grace, and Lorrae Marriott are employees of SPD Development Company Limited. Bluetooth[®] is the trade mark of Bluetooth SIG. Inc.