Randomised controlled trial of connected ovulation test system demonstrates double the chances of pregnancy in first cycle and reveals other factors affecting pregnancy likelihood.

Johnson S, Warren G, Bond S, Bench-Capon S
SPD Development Company Ltd., Bedford, UK

Background

• There are only a limited number of days in a woman’s cycle where unprotected intercourse can lead to pregnancy, known as the fertile window.
• Timing of intercourse to the fertile window maximises chances of natural conception, and has been shown to reduce the time to pregnancy.
• Home ovulation tests, especially those that measure estrogen (the estrogen metabolite estrone-3-glucuronide; E3G) as well as luteinising hormone (LH) to identify the full fertile window, provide an accurate tool for timing intercourse.
• Free apps are now very popular but can lack accuracy.
• A new connected ovulation test aims to combine the accuracy of hormone measurements with the convenience of an app (Figure 1).

Objective

To determine whether the Clearblue® Connected Ovulation Test System increases chances of pregnancy, and investigate what other factors are related to likelihood of natural conception.

Methods

• Home based, randomised, controlled study of 844 women aged 18-40 who were seeking to conceive.
• Volunteers were randomized 1:1 into the test or control arm.
• Test group used the Clearblue® Connected Ovulation Test System. The control group were instructed not to use ovulation tests.
• Randomization was stratified by the age of the volunteers, with two cohorts (>35 and <35 years of age).
• Volunteers participated for two full cycles if pregnancy was not achieved.

Results

• More women became pregnant after one cycle using the test system (25.4%) compared to the control group (14.7%; P=0.001), with an odds ratio of 2.0. After two cycles pregnancy rate was still higher in the test group (36.2% vs 28.6%; P=0.026), with an odds ratio of 1.4. Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Pregnancy rate (95% confidence interval)</th>
<th>Odds ratio (95% confidence interval)</th>
<th>Fischer’s exact test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test group</td>
<td>25.4% (21-30.3%)</td>
<td>2.0 (1.4-2.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Control group</td>
<td>16.7% (14-19.6%)</td>
<td>1.4 (1.0-1.9)</td>
<td>0.026</td>
</tr>
</tbody>
</table>

• The test group reported less frequent intercourse per cycle compared to controls (9 vs 10; P=0.027), however, the test group did report greater timing of intercourse (88.5% vs 57.8%; P<0.001).
• The control group indicated they had used methods, most commonly apps (40.0%) and cervical mucus (35.2%).
• Neither use of a non-study app nor cervical mucus monitoring was associated with a higher pregnancy rate (figure 2).
• Other factors related to likelihood of pregnancy were folic acid use (p=0.004), average cycle length (p=0.021) and intercourse/month (p=0.0001). The odds ratio for pregnancy was 2.0 for folic acid users vs non-users (figure 2).
• Shorter (<25 days) cycles had lower conception probability (figure 2).
• Interestingly, the higher number of intercourse acts, the lower the likelihood of conception; odds ratio for pregnancy 6.0 for ≤5 acts, 4.0 for 6-10, 2.6 for 11-15 and 1.0 for 16-20 vs >20 acts (figure 2).

Discussion

• With women delaying pregnancy and desiring control over their future, tools demonstrated help to conception, such as the Clearblue® Connected Ovulation Test System, are of great relevance today.
• This system identifies a woman’s personal fertile window based on direct measurement of E3G and LH, so provides accurate information to the user. Studies have found calendar-based apps to be inaccurate for fertile phase prediction and measurement of E3G and LH, so provides accurate information to the user. Studies demonstrated to help conception, such as the Clearblue® Connected Ovulation Test System.
• Folic acid use is probably a surrogate marker for women adopting a healthier lifestyle and having greater awareness of factors relating to healthy conception.

Conclusion

The test arm (connected ovulation test system) had double the odds of conception compared to the control arm (no ovulation test) in first cycle.

Declaration of interest

Authors are employees of SPD Development Company Ltd, a wholly owned subsidiary of SPD Swiss Precision Diagnostics GmbH, the manufacturer of Clearblue® pregnancy and fertility tests. The study was funded by SPD Development Company Ltd. Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Clearblue® is under license. Other trademarks and trade names are those of their respective owners.

References