IMPACT OF DIGITAL HOME OVULATION TEST USAGE ON STRESS, PSYCHOLOGICAL WELLBEING AND QUALITY OF LIFE DURING EVALUATION OF SUBFERTILITY: A RANDOMISED CONTROLLED TRIAL

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Introduction

- Ovulation tests (OTs) are a popular and helpful way for women trying to become pregnant to maximise their chances of a natural conception[1].
- They can also be very useful in a clinical setting as a convenient way to accurately time procedures[2].
- Timing of intercourse by using OT has been suggested to lead to emotional distress.
- However, the only controlled study found no impact of OT usage on women's psychological wellbeing when trying to conceive in a non-medical setting[3], and 77% more pregnancies were seen in the test versus control group.
- There have been no controlled studies examining the effect on women in a medical setting.

OBJECTIVE

This randomised, controlled trial examined use of OTs on self-reported levels of stress, psychological wellbeing and quality of life, and biochemical measures of stress, in new attendees at a fertility clinic.

Methods

This study was a randomised controlled trial of women referred for infertility treatment across 3 menstrual cycles; randomised to test group (Clearblue digital home OTs and written advice on timing of intercourse n=25), or control group (written advice only, n=25).

Both groups completed validated questionnaires that interrogate psychological wellbeing and quality of life; the Perceived Stress Scale (PSS), Short Form-12 (SF-12), and Positive and Negative Affect Schedule (PANAS), at baseline, day 6 (all 3 cycles) and day of ovulation (cycles 1 and 2 only). For the control group, day of ovulation was estimated by using volunteer's self reported average cycle length. In addition, urine samples were collected at the same time-points (except for baseline) for measurement of cortisol/creatinine and estrone-3-glucuronide/creatinine concentration as biomarkers of stress and mood.

Results

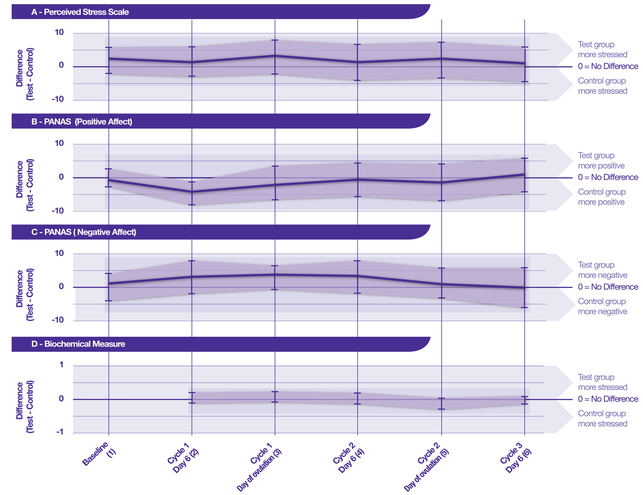
The demographics of the two groups are shown in table 1. All women had undergone investigations prior to study entry to exclude tubal damage/other physical factor/male factor or endocrine issue as a cause of infertility.

Table 1: Study Population Demographics

	Test			Control		
	Mean	Median (SD)	Range	Mean	Median (SD)	Range
Age (years)	33.57	35	27-43	31.88	33	23-39
Total previous pregnancies	0.4	0	0-3	0.26	0	0-2
Total live births	0.28	0	0-1	0.13	0	0-.1
Total miscarriages	0.06	0	0-1	0.27	0	0-2
Months trying to conceive	24.36	24	4-48	21.2	18	6-60
Cycle length (days)	28.52	28	25-35	28.96	28	25-35
Height (m)	1.65	(0.06)	1.-1.73	1.64	(0.06)	1.25-1.76
Weight (kg)	67.57	(12.20)	51.7-95.3	66.02	(11.51)	50.8-96.5
BMI (kg/m2)	25.04	23.39	18.32-36.44	24.65	24.27	19.19-38.17
Alcohol (units/week)	3.12	2	0-12	4.12	2	0-14
Exercise (h/week)	2.18	1	0-8	5.6	2	0-48
Smoking History						
Yes	0 (0%)			1 (4%)		
Ex	24 (96%)			22 (88%)		
No	1 (4%)			2 (8%)		
Previous ovulation test use						
Yes	17 (68%)			17 (68%)		
No	8 (32%)			8 (32%)		

No significant differences between groups was seen using the SF-12 at baseline (mean difference; physical scale = -1.5, CI: -3.8- 0.8, mental scale = -0.24, CI: -3.9 – 3.4) or at the end of the study (mean difference; physical scale =1.4, CI: -3.4-6.2, mental scale= -2 CI: -8.5-4.5). The only significant difference in PANAS and PSS between groups was on day 6 of cycle 1 (mean difference 4.5, CI:-8.6- -0.4), where the control group had a higher positive affect score. These results are shown in figures 1a-d.

Figure 1: Difference between test and control group in different measures of stress throughout the duration of the study.



Difference in level of stress between digital ovulation test users and the control group for each outcome measure at each study time point with 95% confidence interval. The biochemical measure of stress was log urinary cortisol/creatinine ratio (D).

CONCLUSIONS:

- Use of digital OTs by subfertile women under medical care had negligible negative effect and no detectable positive benefit on psychological wellbeing.
- The significant finding on day 6 of cycle 1 suggests that there may be increased anxiety when using the first OT, but these differences were resolved at all subsequent time points.
- Therefore, arguments that using digital OTs can cause stress in women are not supported by this study.
- Home ovulation tests have been found to have utility in both the clinical and home environment for women hoping to conceive. Reticence about their use due to unproven theories that they cause stress should now be dismissed.

References:
1 Brezina et al (2011) Fertil Steril 95:1867
2 Khattab et al (2005) Human Reproduction 20:2542-2545
3 Tiplady et al (2013) Human Reproduction 28:138-151.

Support:
These studies were funded by SPD Development Company Ltd., a fully owned subsidiary of SPD Swiss Precision Diagnostics GmbH, the manufacturers of ClearblueTM products. S Johnson and S Tiplady are employees of SPD Development Company Ltd. W. Ledger has received honoraria from SPD Development Company Ltd. for his involvement with this study.

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