Effectiveness of a Digital Fertility Awareness-Based App for Contraception in the United States

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INTRODUCTION

 Natural Cycles is a digital fertility awareness-based method (FABM), cleared by the FDA and certified in the EU as a contraceptive device.

OBJECTIVE

 To investigate the real-world effectiveness of Natural Cycles in a cohort of users from the United States (US).

METHODS

How the app works

- The Natural Cycles app requires input of basal body temperature (BBT) recordings and dates of menstruation. Users may also enter LH urinary test results.
- The app returns a daily fertility status: green (not fertile) day or red (fertile day) based on the risk of pregnancy on any given day.

Figure 1: How Natural Cycles is used.



Study Design

- Participants were included if they signed up for the app between 01/09/2017 and 31/12/2017. The study end date was 31/12/2018. Three months of follow-up was given.
- Inclusion criteria: purchased an annual subscription, used app in "prevent a pregnancy" mode, entered 20 daily data entries, and were between 18 - 45 years old at the time of registration.
- A total of 3,417 women contributing 2,696 woman-years of data were included in the analysis.

RESULTS

Demographics

- Cohort demographics are shown in Table 1.
- Users of the app were on average 30 years old, in a relationship (86.3%), and did not have children (84%).
- 93% of the cohort had a regular menstrual cycle between 21 and 35 days long¹.

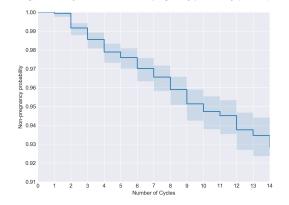
Contraceptive effectiveness

- In total, 160 pregnancies occurred during the study.
- Life table analysis showed that the typical-use 13-cycle pregnancy probability was 6.5% (Figure 2).
- One-year Pearl Index was 6.2 with typical-use and 2.5 with perfect-use.

Table 1: Cohort demographics (n=3417)

Characteristic		% of cohort
Age (mean)		30.0 ± 4.8
Body Mass Index (mean)		23.4 ± 4.3
Do you have children?		
	No	84.0
	Yes	16.0
Education level		
	PhD	17.1
	Bachelor degree	67.9
	Vocational/trade	7.3
	High School	7.4
	Elementary school	0.3
Relationship status		
	In a relationship	86.3
	Single	10.0
	Other	3.8

Figure 2: 13-cycle cumulative non-pregnancy probability (n=3417)



CONCLUSIONS

- The effectiveness of the Natural Cycles app for contraception was investigated in a cohort from the US.
- The 13-cycle cumulative non-pregnancy probability was 93.5%. One-year
 Pearl Index figures were 6.2 with typical-use and 2.5 with perfect-use.
- This is in line with previously published effectiveness estimates².

References: International evidence based guideline for the assessment and management of polycystic ovary syndrome, 2018 Berglund Scherwitzl et al. Contraception:96, 420-425, 2017