

# Impact of Natural Cycles on unintended pregnancies in Sweden.

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## INTRODUCTION

There remains an unmet need for women seeking a contraceptive method which is natural, effective, and non-invasive. Natural Cycles is a fertility awareness-based mobile application certified in the EU and cleared by the FDA for contraception. The aim of this study was to investigate associations between the contraceptive effectiveness of Natural Cycles and users' previous choice of contraceptive and to evaluate the impact on the risk of unintended pregnancy.

## METHODS

### How the app works

- Natural Cycles is a digital fertility awareness-based method (FABM) of contraception. The app requires input of basal body temperature (BBT) recordings and dates of menstruation. Users may also enter LH urinary test results.
- The underlying technology is a statistical algorithm<sup>1</sup> that returns a fertility status for each day. Fertility is indicated during the 'fertile window', defined as the days immediately preceding ovulation day, as well as the ovulation day itself<sup>2,3,4</sup>.
- In addition, the algorithm computes the following parameters and their uncertainties: luteal phase length, follicular phase length and cycle length, and average body temperatures of the different phases.
- Over time the algorithm learns and improves its predictions using previously recorded cycles from the same woman and can provide predictions of the fertility status, upcoming ovulation and menstruation days for up to five cycles in advance.

### Study population

- Inclusion criteria were; women who were using the Natural Cycles app as their primary means of contraception and had signed up for an annual subscription between 01-09-2016 and 31-10-2017, resident in Sweden, and aged 18-45. Users had to have entered at least 20 daily entries of any type.
- The final date for user data entry was 31-03-2018 and for data collection was 30-04-2018 to allow time for follow-up.

### Data collection and analysis

- Real-world evidence was collected via the Natural Cycles mobile app and through survey questions asked both at the time of sign-up and during use.
- Data was collected for 16,331 Natural Cycles users regarding pregnancy status and previous contraceptive use.
- The one-year typical-use Pearl Index (PI) and the 13 cycle typical use failure rate of Natural Cycles was calculated for each sub-cohort, grouped by their stated previous contraceptive method, and compared to the entire cohort PI.

## RESULTS

### User characteristics

- The mean age of the Natural Cycles cohort is 29 years, with a mean BMI of 23.
- 42.6% of the cohort reported having used hormonal contraception prior to using Natural Cycles.
- The majority had never been pregnant before (70.7%) and were in a relationship, engaged or married (85%).

Table 1. Demographics

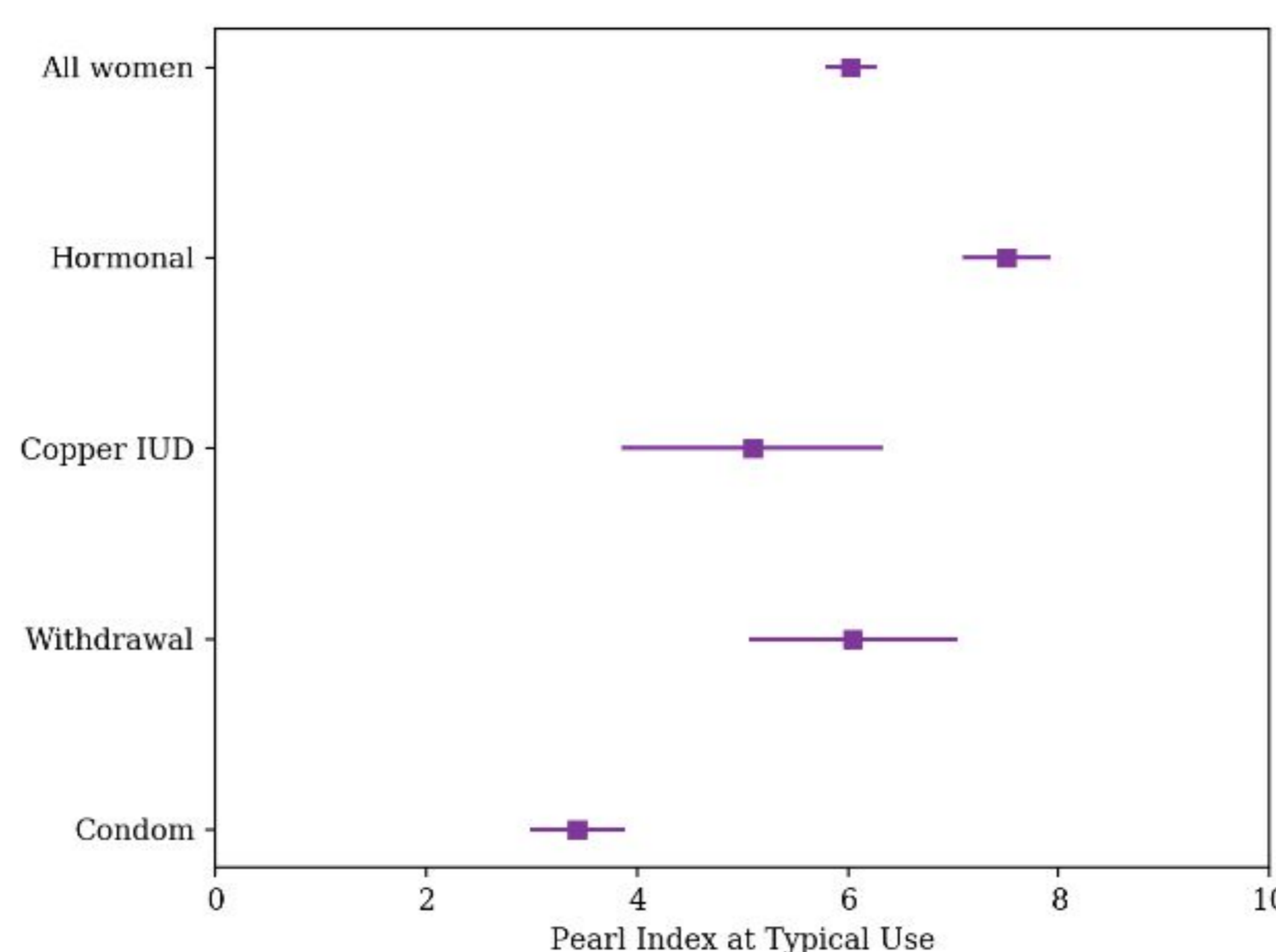
Characteristic	Swedish cohort* (%)
Age (mean)	29 ± 5
BMI (mean)	23 ± 4
Previous hormonal contraception	-
Yes	42.6
No	57.4
Previous pregnancies	-
0	70.7
1	14.8
2	8.5
3	6.0
Relationship status	-
In a relationship	51.8
Engaged or married	33.2
Single	10.9
Other	4.1

\*Data shown is for all Natural Cycles users resident in Sweden. BMI body mass index.

### Effectiveness analysis by previous contraceptive

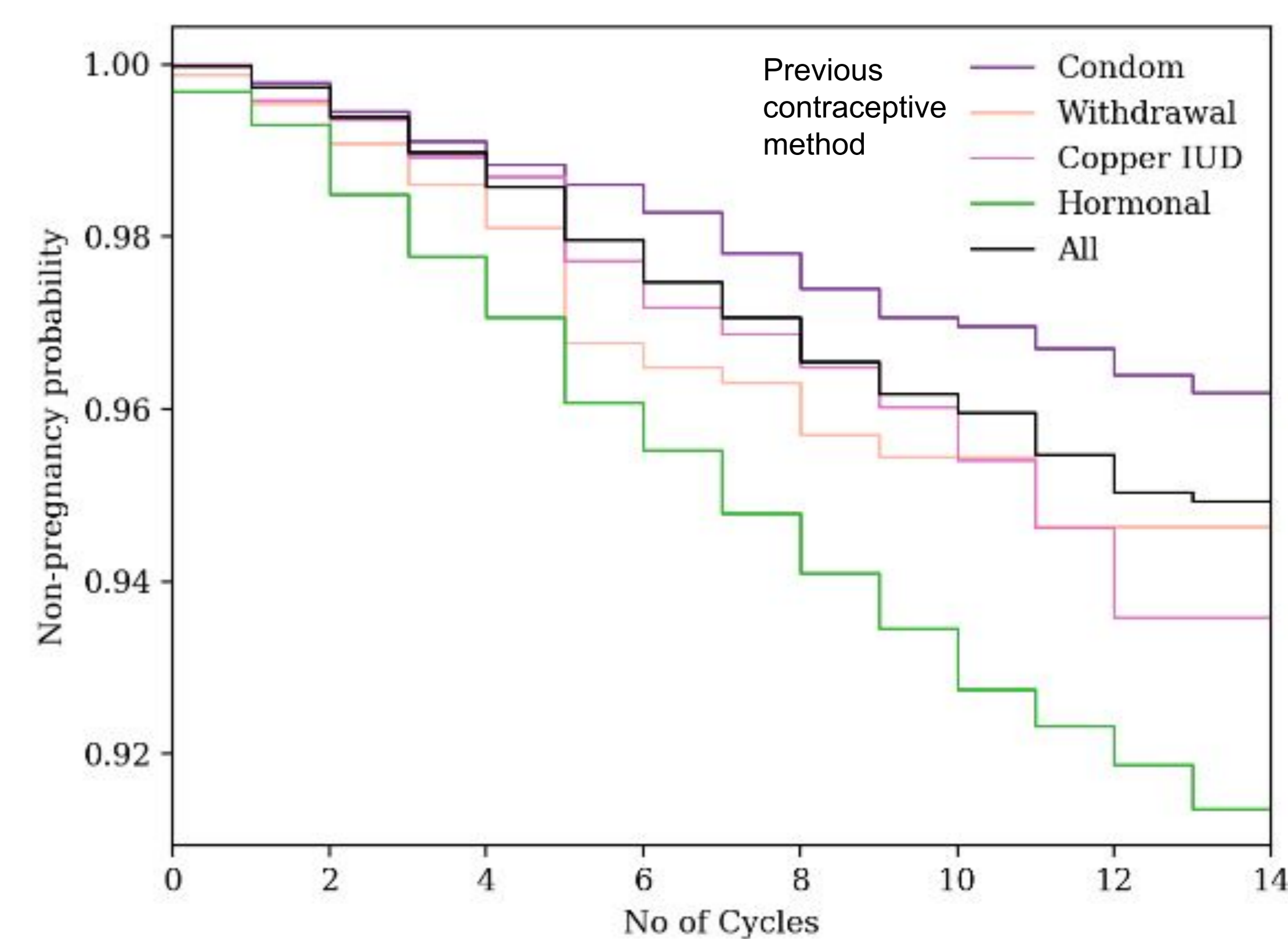
- The typical-use PI was  $6.0 \pm 0.2$  and 13 cycle failure rate was  $6.3\% \pm 0.6\%$  for the entire cohort.
- When split into sub-cohorts based on reported previous contraceptive use, the lowest typical-use PI was  $3.4 \pm 0.4$  and the 13 cycle failure rate was  $3.6\% \pm 1.0\%$  for women who had used condoms prior to Natural Cycles.
- For participants who had recently used any type of hormonal method, the PI was  $7.5 \pm 0.4$  and the 13 cycle failure rate was  $8.1\% \pm 1.0\%$ .

Figure 1. Pearl index by previous contraceptive



Each data point is the typical-use Pearl Index ± 1 standard error of the mean. PI was not calculated for other contraceptive methods due to sample size. All n=16331; Hormonal includes mini-pill, combined pill, mirena IUD and implant; IUD intrauterine device

Figure 2. 13-cycle life table analysis (n=16331)



Cumulative non-pregnancy probability per cycle. All n=16331; Hormonal includes mini-pill, combined pill, mirena IUD and implant; IUD intrauterine device

## CONCLUSIONS

- The effectiveness of Natural Cycles is associated with previous contraceptive choice, which should be considered when evaluating the suitability of the method for the individual.
- PI of Natural Cycles is lowest for women who had previously used condoms.
- It is possible that these users are satisfied with using condoms on fertile days and have a higher level of compliance.
- We estimate that Natural Cycles usage can reduce the overall likelihood of having an unintended pregnancy when switching from less effective methods.
- These preliminary findings motivate further research to explore the behavioural traits of different cohorts and to investigate the impact on abortion rates.

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## DISCLOSURES

E.B.S. and R.S. are the scientists behind the application Natural Cycles and the founders of the company with stock ownership. J.B., O.L. and S.R. are employed by Natural Cycles Nordic AB. K.G.D. serves on the medical advisory board of NC and has received honorarium for participating in advisory boards and/or giving presentations for matters related to contraception and fertility regulation for Ferring, Exelgyn and Mithra. J.T. declares explicitly that there are no conflicts of interest in connection with this article.