Natural Cycles App: Contraceptive Outcomes and Demographic Analysis of UK Users

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Abstract

Objective: Digital fertility awareness-based contraception offers an alternative choice for women who do not wish to use hormonal methods or are unable to use hormones due to medical reasons. It is also popular among women who may be planning a pregnancy over the coming years and wish to educate themselves about their individual menstrual cycle and fertility. The aim of this study was to investigate the key demographics of current users of the Natural Cycles app and assess the effectiveness of the app at preventing pregnancy for a cohort of women from the United Kingdom.

Setting: Users of the Natural Cycles mobile application.

Participants: 12,247 women in the UK who used Natural Cycles as their primary method of contraception.

Outcome Measures: Cohort demographics and risk of unintended pregnancy.

Study Design: Observational prospective real-world cohort study.

Results: Users contributed an average of 9.9 months of data for a total of 10,066 woman years of exposure. The mean age of the cohort was 30, mean BMI 23.4, the majority were in a stable relationship (83.2%) and had a university degree or higher (83%). The most common form of contraception used prior to natural cycles was combined oral contraceptive (COC)(39.3%). The one year typical use, PI was 6.1 (95% CI: 5.6, 6.6) and with perfect-use was 2.0 (95% CI: 1.3, 2.8). 13 cycle pregnancy probability was 7.1%. Age was found to be associated with contraceptive outcomes, those between 29-34 had a significantly higher pregnancy probability than those aged 34-45 (8.9% vs 5.0%; $p=0.0005$). In total 41.9% of users were still using the app at the end of the study.

Conclusion: This is the first study which describes the use of a digital contraceptive by women in the UK. It describes the demographics of users and how they correlate with the apps effectiveness at preventing pregnancy. Its findings support previously published effectiveness rates for Natural Cycles in a number of countries.

Key words: Fertility monitoring, Contraception, Mobile application, Fertility awareness

Word count:

Strengths and limitations of this study

- This study investigates the real-world effectiveness of the Natural Cycles app as a method of contraception in a large cohort of women from the UK.
- The results may be used by practicing clinicians to better understand the real-world performance of the method and to counsel patients appropriately.
- Behavioural traits were self-reported and assessed through in-app messaging and were not mandatory for study participation.

1. Introduction

A recent survey of unintended pregnancy in England showed that one third of women not using contraception stated they had not found a suitable method, and a further one third who were using a contraceptive were not satisfied with the method (1). There remains an unmet need for contraceptive choices, especially for non-hormonal methods (2–4).

Choosing a method of contraception that suits the individual requires consideration of many factors including a woman's personal needs, preferences, prior contraceptive experiences, and concerns, as these factors are known to impact method compliance and adherence (2,5). Many women are discontinuing or switching methods throughout their reproductive lifespan for multiple reasons such as changing reproductive needs or a desire to plan a pregnancy in the near future. This may be happening without clinical consultation (6).

Menstrual cycle tracking apps are currently used by many women and are becoming increasingly popular (7–11) however, they are not certified for use as contraceptives except for Natural Cycles which is CE marked and FDA approved. It is therefore important that the effectiveness Natural Cycles is investigated so that women can make an informed choice based on evidence rather than popularity. Investigation of effectiveness on a country specific level is important as contraceptive use is known to vary between cultures which may in turn affect effectiveness rates. Natural Cycles is a digital fertility awareness-based method (FABM) of contraception using menstruation data and basal body temperature (BBT) measurements to define the most fertile days of the cycle. The fertile window, defined as the number of fertile days per menstrual cycle, lasts for approximately six days with the probability of conception increasing as ovulation day approaches (12,13). The user measures their BBT first thing every morning, enters it into the app, and is provided with a daily fertility status, indicated by a green 'non-fertile' day or red 'fertile' day. Users also have the option to input results of urinary luteinizing hormone (LH) tests as a biomarker of ovulation. On fertile days, users are notified to use barrier methods or abstain from sexual intercourse since there is a chance of conception. Previous effectiveness studies have shown that the 13-cycle typical-use failure rate of Natural Cycles is 8.3% and women use the app to successfully prevent pregnancy (7,14). The aim of the current study was to investigate the contraceptive effectiveness of Natural Cycles in a cohort of users exclusively from the United Kingdom (UK) and to understand the key demographics of this group.

2. Materials and Methods

2.1. Study design

In this real-world prospective observational cohort study, user demographics were gathered via the app through 'on-boarding' at the time of sign-up and additional in-app survey questions during use. When registering with Natural Cycles, users were asked a series of mandatory questions about their

cycle parameters and previous contraceptive use (Table 1). Users were subsequently sent two in app messages (results combined) further investigating previous contraceptive use however, these were not mandatory and had a response rate of 50% of those users included in this study's analysis (Table 2). The inclusion criteria were women using the Natural Cycles app as their primary means of contraception who had registered as a paying user on an annual subscription between September 1st 2017 and 1st April 2018. Users had to have entered at least 20 daily data entries, have registered with the app in the UK, and were aged 18-45. The final date for data collection was March 31st 2019 to allow time for follow-up. These dates were chosen as they aligned with the most up to date version of the algorithm and allowed participants to contribute an average of 13-cycles of data. All users consented at registration to the use of their anonymised data for the purposes of research and could remove their consent at any time. The study protocol was reviewed and approved by the regional ethics committee (EPN, Stockholm, diary number 2017/563-31).

2.2. How the app works

The underlying algorithm uses BBT measurements, menstruation dates, and optional LH test results to identify the fertility status of an individual woman on any given day during the menstrual cycle. A more detailed description of how the algorithm works is described elsewhere (7,14,15).

2.3. Data analysis

The typical-use effectiveness of the method was calculated using both 13-cycle cumulative probability of pregnancy (life table analysis) and Pearl Index for the entire study cohort. Perfect-use PI was calculated using data from cycles where sexual intercourse during the fertile window was marked as protected and no unprotected sex was recorded on fertile days. Cycles were also designated as perfect-use if the user logged sexual activity during non-fertile days but answered that they use abstinence as their method of protection during the fertile window, and therefore did not log intercourse during the fertile window as previously used by Trussell and Portman (16) .

Differences in effectiveness between cohorts were assessed using the log-rank test. When multiple comparisons were needed, the Bonferroni correction was performed to ensure a consistent type I error across the study.

2.4. Determining pregnancy and discontinuation

Pregnancies were directly determined by the user entering a positive pregnancy test into the app, or switching to follow a pregnancy mode within the app. Pregnancy was also indirectly determined by users data indicating pregnancy (continued high temperature data following ovulation or by answering that they were pregnant in a follow-up questionnaire if they discontinued using the app). In cases where no confirmation or refutation of pregnancy was available, users who discontinued in the follicular phase, or later in cycle but with no ovulation detected were flagged as unlikely to be pregnant. Those who discontinued during the fertile window or the luteal phase were considered possibly pregnant. Those

who were lost to follow-up and grouped as ‘very unlikely pregnant’ were not included in the effectiveness analysis, those who were classed as ‘possibly pregnant’ were included in a worst case scenario effectiveness calculation as their pregnancy status was unknown. Users empty cycles were excluded from the study if they failed to add data for an entire cycle.

2.5. Patient involvement

No patients were directly involved in this study as only anonymised or aggregated data were used. However, the effectiveness of this app as a method of contraception is an area of significant interest to current and prospective users and medical professionals in the UK.

3. Results

3.1. Study population

The study included 12,247 women who contributed an average of 9.9 months of data for a total of 10,066 woman-years of exposure, 35.7% (4375) had contributed 13-cycles of data. The mean age of the cohort was 30.3, with the majority of users between 25 and 34 years old (66%). Body mass index (BMI) ranged from 12 to 55 with a mean of 23.4. The majority of the cohort reported being in a relationship (83.2%) and having a University degree level of education or higher (83%) (Table 1). The vast majority were nulliparous (84.5%).

Table 1. Characteristics of the cohort included in this analysis.

Characteristic	Percentage of cohort (N)
Age (years) (mean $\pm$ SD)	30.3 $\pm$ 5.3
19-24	13.5 (1648)
25-29	35.6 (4360)
30-34	30.4 (3727)
35-45	20.5 (2512)
BMI (mean $\pm$ SD)	23.4 $\pm$ 4.4
<18	5 (582)
18-24	68.7 (7995)
25-29	18.5 (2156)

>30	7.7 (900)
Previous Contraceptive*	
Hormonal	56 (6861)
Non hormonal	44 (5386)
Relationship status	
In a relationship	83.2 (6956)
Single	12.3 (1031)
Other	4.5 (375)
Education level	
PhD/MBA	8.8 (736)
University degree	74.2 (6210)
Trade/technical/vocational	8.9 (744)
High school degree	7 (587)
Elementary school	1.1 (94)
Parity	
No, I don't have children	84.5 (5688)
Yes, I have children	15.5 (1040)

*Hormonal contraceptive use within 12 months of starting to use Natural Cycles, BMI: body mass index, MBA: Master of Business Administration, PhD: Doctor of Philosophy, SD: standard deviation

The most common contraceptive methods used prior to Natural Cycles were combined oral contraceptives (39.3%) and condoms (25.7%) (Table 2). Lesser used methods were fertility awareness-based methods, hormonal ring, diaphragm, and spermicides (2.6%). In comparison the most recent data from community contraception clinics in England, for women aged 16-49, of whom 42% reported oral contraceptive use (COCP and POP) (NHS Digital. 2019 Statistics on Sexual and Reproductive Health Services (Contraception) England: 2017/18).

Table 2. Study participants by previous contraceptive method.

Previous contraceptive	Percentage of respondents*
Combined oral contraceptive	39.3
Condom	25.7
Mini-pill (progestin only)	9.1
Withdrawal	9.8
The implant	5.6
Copper IUD	4.6
Hormonal IUD	3.3
Fertility awareness-based method	1.2
Hormonal ring	0.8
Diaphragm	0.3
Spermicide	0.3

*Response of approximately 50% of users that answered yes to previous contraceptive use in the 12 months leading up to NC use and were not lost to follow up for onboarding questions related to previous contraceptive use.

On fertile days of the cycle, users are advised to use barrier methods or abstain from sexual intercourse. To assess additional contraceptive use, participants were asked what method they use on a fertile day. Of the respondents, 58.3% stated that they use a condom, 23.3% use withdrawal, and 9.3% abstain (Table 3).

Table 3. Study participants by choice of contraceptive on ‘red’ fertile days.

Contraceptive method	Percentage of respondents (n)
Condom	58.3 (3528)

Withdrawal	23.3 (1413)
Abstinence	9.3 (561)
Combination	5.7 (343)
None, I risk it	1.9 (118)
Diaphragm	1 (59)
Spermicide	0.5 (32)

The majority of the UK cohort were registered as living in London followed by Bristol, Manchester, Edinburgh, and Brighton and the north east of England. Figure 2 shows the spread of users across the UK as a proportion of the total population in each region (17–19).

Figure 2. Distribution of user registration across the UK. The colour bar corresponds to the percentage of the population for the region.

3.2. Intercourse logging and percentage green days

The proportion of the cycle assigned as green ‘non-fertile’ is an important parameter to assess as this impacts on satisfaction and compliance. The number of green days is related to the amount of data that is available to the algorithm, and therefore to the number of recordings of basal body temperature that the user logs. Percentage of green days was correlated with 3 groups of user based on the frequency with which they measured basal temperature within a cycle (i) <50%, (ii) 50% to 70% and (iii) >70% (Figure 3). The mean percentage of green days given in the first cycle to 50-70% users was 34.1% rising to 46.5% by cycle 13. This increased further in the >70% group whom in the first cycle received 36.8% green days rising to 54.5% in the last cycle (Figure 3).

Of all acts of intercourse logged, 57% of intercourse logged was on a red day, 43% was logged on a green day. 23% of red day intercourse was marked as unprotected by the users.

Table 4. Measuring frequency and proportion of users

Measuring frequency	Fraction of total users
<50%	55.1
50-70%	25
>70%	19.9

Table 4 demonstrates that 19.9% of users were highly engaged with the app, logging most frequently both basal body temperature.

Figure 3. Mean percentage of green days assigned per cycle correlated with user BBT measurement frequency. 95% confidence intervals (shade around line).

3.3. Contraceptive effectiveness

To investigate the effectiveness of Natural Cycles at preventing pregnancy, effectiveness estimates were calculated using a 13-cycle pregnancy probability life table method. This method addresses a limitation of the Pearl Index which tends to decrease as time intervals extend, due to the early drop-out of women who are more likely to become pregnant using the method. (16). This resulted in a 13-cycle cumulative pregnancy probability of 7.1% (95% CI: 6.5, 7.7) (Figure 4). This is in line with the previously published effectiveness rate (7).

Figure 4. Cumulative 13-cycle non-pregnancy probability over time (dark line) with 95% confidence intervals (shaded area).

One year typical and perfect-use PI was also calculated for the entire cohort. With typical-use, the PI was 6.1 (95% CI: 5.6, 6.6) and with perfect-use was 2.0 (95% CI: 1.3, 2.8). A worst-case scenario effectiveness calculation was performed to account for the 130 users who discontinued in the luteal phase and were considered “possibly pregnant”, resulting in a PI of 7.6 (95% CI: 7.0, 8.1).

Table 5. Percentage users retained, pregnancies, exit for other reasons and pregnancy probability over 13 cycles.

Cycle	Women enrolled at cycle start	Percentage of women retained overall	Pregnant	Exit for other reasons	Cumulative Pregnancy probability
1	12247	100	25	461	0.2
2	11786	96.2	45	797	0.6
3	10989	89.7	59	853	1.1

4	10136	82.8	64	803	1.7
5	9333	76.2	59	716	2.4
6	8617	70.4	57	701	3
7	7916	64.6	41	595	3.5
8	7321	59.8	63	576	4.3
9	6745	55.1	53	565	5.1
10	6180	50.5	35	613	5.6
11	5567	45.5	27	594	6.1
12	4973	40.6	25	598	6.6
13	4375	35.7	23	-	7.1
Total	-	-	576		

3.4. Sub-cohort effectiveness analysis

To assess whether any demographic factor had a significant impact on 13-cycle effectiveness rates, sub-cohorts were analysed. Age was found to be associated with contraceptive outcomes, those between 29-34 had a significantly higher pregnancy probability than those aged 34-45 (8.9% vs 5.0%; $p=0.0005$). Contraceptive outcomes of those aged 18-29 did not significantly differ from the mean.

3.5. Study dropout

In total, 41.9% (5137) users were still actively using the app at the end of the study period and 35.7% (4375) had contributed 13-cycles of data. A review of other FABM methods calculated 12 month continuation rates for the Standard days method of 46% and Two Days method of 52.7% (3,16). There were a total of 576 (4.7%) pregnancies reported during the study (Table 5) period and a further 6534 discontinued using the app for other reasons, including 130 who were classed as “possibly pregnant” because they discontinued during the fertile window or luteal phase. The most frequent product discontinuation reasons included: unknown (but unlikely to be pregnant) (22.1%), ‘it doesn’t work for me (7.2%), and trying to save money (6.5%), with confirmed pregnancy being the fourth most common reason for discontinuation (Table 5).

Table 5. Participant status at end of study period.

Study exit reason	No. users	% of cohort
Still using at end of study period	5137	41.9
Unknown*	2703	22.1
It doesn't work for me	876	7.2
Trying to save money	790	6.5
Pregnant	576	4.7
Other reasons	658	5.4
Starting hormonal contraception	474	3.9
I no longer need it	436	3.6
It took too much effort	467	3.8
Possibly pregnant**	130	1.1
Total	12,247	100

*Follicular phase (predicted fertile window based on previous cycles data) drop outs, lost to follow up.

**Discontinued during fertile window or luteal phase of cycle and did not respond to follow-up.

4. Discussion

The use of apps for fertility tracking and pregnancy prevention is becoming increasingly popular. Natural Cycles is the only app certified for use as a contraceptive in Europe and the US and therefore research into its effectiveness on country specific cohorts is important for both users and healthcare providers when discussing contraceptive options (10).

This study demonstrates that the Natural Cycles app has a 13-cycle cumulative pregnancy probability of 7.1% and a typical-use PI of 6.1 in a cohort of users from the UK. The effectiveness estimates shown in the analysis presented here are in line with these previously published data [8].

The study cohort were on average 30 years old, had a BMI within the healthy range, reported being in a relationship, and had a university degree level of education. Of those recording a contraceptive prior to starting Natural Cycles 25.7% were using condoms, and 9.8% withdrawal, both methods which have typical-use effectiveness rates lower than that of Natural Cycles (20). Of those recording prior

contraception 58.1% switched from short or long-acting hormonal contraception, indicating dissatisfaction with these methods, despite their high efficacy.

The Natural Cycles app is user dependent as it relies on frequent temperature data entry, engaging with the app for daily fertility status, and compliance with abstaining or using barrier protection on fertile days. The main reason for contraceptive failure of the Natural Cycles method is having unprotected sex on a fertile day (21). The majority of this UK cohort (58.3%) reported that they use condoms on fertile days and a further 9.3% abstain. However, 23.3% reported that they use withdrawal which is typically associated with low effectiveness. This high use of a potentially risky method during fertile days identifies an area of potential sexual education for users of the app in the UK. User behaviours such as method compliance, using a secondary method effectively, and understanding the level of risk involved in having sexual intercourse on fertile days, will impact the effectiveness of the Natural Cycles app, and further qualitative and quantitative studies are required to explore this.

The Natural Cycles app has the potential to be used as a platform for fertility education. This might include informing women who are interested in ceasing the use of hormonal contraceptives prior to planning a pregnancy, and understanding the cycle before trying to conceive. Natural Cycles has a strong potential to exist as an educational platform for both women's health and preconception, potentially improving both contraceptive effectiveness and time to pregnancy.

One limitation of the study is that all data was self-reported and was not verified as it would be in a traditional clinical study setting. We therefore cannot be sure of the motivation of the users which may partially explain the higher pregnancy probability in the 29-34 year age group in this analysis. Neither the responses to in-app questions nor sexual intercourse logging was mandatory for study inclusion, so only a subset of cycles (18%) contained information regarding user behaviour during the fertile window. Those who discontinued using the app during the study period were contacted for follow-up information to assess potential pregnancy status. However, due to the nature of the product, a proportion declined to reply and were lost to follow-up.

Cycle tracking apps have come under scrutiny regarding the data supporting their use in fertility monitoring (22). The assumption of pregnancy in users lost to follow up, during the fertile window or luteal phase, is recognised as generating a conservative pregnancy rate estimate, and was used in this study (23). Furthermore, our inclusion criteria require that the user is in "Prevent a Pregnancy" mode and that she has entered 20 daily data points. We chose not to limit the inclusion criteria by cycle length or regularity as this was a real world observational design and aims to assess the effectiveness of the app in a cohort similar to the user population as a whole.

In order to have a more complete data set, and to reduce loss to follow up, prospective clinical studies are planned which will assess multiple factors and user traits in a more structured clinical environment. It remains to be seen whether clinical ‘prescribing’ of the app would lead to higher user retention rates.

5.0 Conclusions

This study describes the contraceptive outcomes and key demographics of a cohort of users from the UK. Digital fertility awareness-based methods are a reality for many women of reproductive age and it is important that country specific scientific evidence describing the effectiveness of such methods is encouraged.

The Pearl Index for one –year typical use of the Natural Cycles app was 6.1, and 13-cycle pregnancy probability was 7.1%. The perfect use Pearl Index was 2.0. The percentage of women retained after 13 cycles was 35.7%.

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Supplementary Information

Response rates to onboarding and in-app questions

In-app question	Response rate (% of cohort)
Enter date of birth = age	100
Have you recently used hormonal contraception?	100
Enter height and weight = BMI	95
What is your relationship status?	80.2
Do you have any children?	80.7
Which form of contraception do you use on red days?	76.9
What is your level of education?	73.8