

# Independent Expert Fact Sheet on Natural Cycles – a Certified Contraceptive App

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## What is Natural Cycles?

Natural Cycles is a mobile application classified in the EU and by the FDA as a medical device for contraception. The app is used by women in combination with a basal thermometer and protection (or abstinence) on fertile days, as indicated by the app.

## How Does it Work?

A woman measures her temperature under the tongue every morning, enters the temperature, as well as menstruation data into the app and an algorithm informs the woman if she has a “red day” or a “green day”, depending on whether or not there is a risk of pregnancy. In order to prevent a pregnancy, women are required to use protection (or abstain from sex) on red days.

Users with fairly regular cycles, who enter temperature data 5 times or more per week, can expect to reach around 60% green days/ cycle after 3 months of usage (i.e. no need for protection on these days).(1) Note that the fraction of red & green days can affect user satisfaction and ultimately discontinuation rates.

The following factors may increase the number of red days:

- Having recently discontinued hormonal contraception
- Highly irregular cycles
- Atypical fluctuating temperatures<sup>a</sup>

## What Studies Have Been Conducted and How Effective is Natural Cycles?

Several clinical studies have been conducted to evaluate the effectiveness of the app for contraception.(2,3) They have shown that Natural Cycles, when used for contraception, improves the efficacy of traditional fertility awareness based methods. No randomized studies have compared the effectiveness of the oral contraceptive pill to that of Natural Cycles.

### *Typical-use Effectiveness of 93%*

The app has a typical-use failure rate of 6.8, which means that in total 6.8 women out of 100 will become pregnant during one year of use due to all possible reasons (e.g. wrongly attributed green days, having unprotected intercourse on red days and failure of the contraceptive method used on red days).(3) This can be compared to a typical-use failure rate of 9 women out of 100 reported for the oral contraceptive pill.(4)

### *Perfect-use Effectiveness of 99%*

The app has a perfect-use failure rate of 1.0,(3) which means that 1 out of 100 women who use the app for one year and who become pregnant will do so either due to:

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<sup>a</sup>E.g. due to medical conditions (thyroid) or lifestyle (irregular sleep (+/- 2 hours than normal), use of certain medication, hangover from extensive alcohol consumption, insomnia, smoking or drugs, an infection or feeling ill, or working a night shift.

- A. Unprotected intercourse on a green day that was falsely attributed as non-fertile (i.e., method failure); or
- B. Protected intercourse on a red day, but the chosen method of contraception failed.

The perfect and typical-use data is based on the result of a series of retrospective and prospective clinical studies on contraceptive effectiveness with 22,785 women using the app for 9.8 months on average.(3) The results of these studies were published in peer-reviewed journals.

#### Pearl Index of the Natural Cycles App and Other Commonly used Short-acting Contraceptives (3,4)

Contraceptive Method	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at one year
	Typical use	Perfect use	
Natural Cycles	7	1	46
Traditional <sup>b</sup> fertility awareness-based methods	24	0.4-5	47
Male condom	18	2	43
Combined Pill and progestin-only pill	9	0.3	67

The Natural Cycles typical-use Pearl Index demonstrates an improvement to traditional fertility awareness-based methods. This is possibly due to the automated temperature chart analysis in the app and the removal of the manual charting and analysis process.

### How Safe is Natural Cycles?

There are no known side-effects or associated health risks from using this contraceptive method.

### Who is it for?

A large group of women are looking for a more 'natural' approach to birth control and a way to better understand their body and menstrual and reproductive cycle. Natural Cycles increases contraceptive choice and may provide an effective option for these women. Women using Natural Cycles should be at least 18 years old.

Today, the typical woman using Natural Cycles is on average 29 years old, has a daily routine, and is in a stable relationship.

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<sup>b</sup>Non-digital, without the help of a personalized algorithm

## What are the Benefits and Drawbacks of Using Natural Cycles?

<b>Benefits</b>	<ul style="list-style-type: none"> <li>● Effective, hormone free contraception with no known side effects</li> <li>● Meets a woman's desire for a more 'natural' approach to contraception and a better way to understand her body and cycle</li> <li>● Non-invasive</li> <li>● Provides personalized information on fertility</li> <li>● Data can be used to facilitate conception when the wish arises</li> <li>● Tracks physiological markers that may have clinical diagnostic value</li> </ul>
<b>Drawbacks</b>	<ul style="list-style-type: none"> <li>● Less effective than long-acting reversible contraception (LARC)</li> <li>● No protection against sexually transmitted infections (STIs)</li> <li>● Daily routine of temperature measuring required</li> <li>● A couple must be willing to use protection (or abstain from sex) on red days</li> <li>● No hormone-related benefits for diagnosed medical conditions, such as endometriosis and heavy menstrual bleeding or for bleeding management and cycle control</li> </ul>

## What Certifications are Required for Medical App Manufacturers?

The approval of contraceptive products is regulated in the vast majority of countries. If an app is intended to be used for contraception, it generally requires that the app manufacturers comply with regulations for medical devices. For example, it means that the product must have a valid CE mark in Europe and FDA clearance in the US.

### *CE Marked in Europe and Cleared by FDA*

An EU Notified Body and the United States Food and Drug Administration (FDA) have classified Natural Cycles as a medical device intended for use as contraception. In Europe Natural Cycles is classified as a class IIb medical device and in the US as class II. All manufacturers of medical devices in class IIb in Europe or class II in the US are subject to assessments and audits performed in regular intervals.

### *References:*

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