

## SUMMARY

### Reliable family planning without hormones: 99.4 percent safety thanks to fertility tracker and smartphone app

Improving the application safety of the method through the use of an additional, mobile application (app): results of a retrospective study

#### Introduction

Can a smartphone app improve the safety of a fertility tracker in preventing a pregnancy? This was the research question that Valley Electronics AG, Zurich, Switzerland, commissioned a study to answer. To this end, a survey was conducted among 800 women who are using the fertility tracker Daysy with the accompanying app for smartphones DaysyView.

The fertility tracker Daysy helps women to narrow down the moment of their ovulation and differentiate between fertile and infertile days during their cycle. Daysy can be used on its own, but also – and this is what makes it special – in combination with the smartphone app DaysyView.

The efficiency of methods of contraception is based on the Pearl Index (PI). It is calculated, among others, using the number of women who became pregnant in the course of one year. The lower this number, the safer the method. The so-called ‚practical‘ Pearl Index is important here. It indicates how a method proves itself in everyday life. The ‚theoretical‘ Pearl Index, on the other hand, describes how well the contraceptive works when used accurately. The bigger the difference between these two values, the more important the correct handling by the user. Conversely, errors in use matter less the smaller the difference between these values.

#### The following aspects were taken into consideration in the study:

- Since the barriers for use are very low for apps, they integrate themselves seamlessly into our everyday lives. They are virtually always at our disposal because information is quickly and easily retrievable. Earlier studies have already shown that ‚health‘ apps augment the interest and motivation of patients for their health concerns significantly. Above all else this is attributable to the fact that via their graphic interface, apps enable the depiction of complex facts in a simple manner.
- More and more women are observing their cycle with the help of an app. Be that in order to know when to expect their period, prevent a pregnancy or become pregnant.

- There are more than 90.000 health apps available in the Apple iTunes Store. Out of these, 6300 (7%) are for women on the issues of health, period and pregnancy (Source: Institute for Healthcare Informatics).
- Apps are fundamentally a very good option for depicting individual physiological facts such as the female cycle in a simple and comprehensible manner. But since apps are always merely as good as the data that was inputted, errors and misinterpretations made by users are a frequent occurrence.
- A US study further confirms that more than half of all users quickly lose interest in the usage of a ‚health‘ app. The main reason behind this is that users perceived the daily input of data as too tedious.
- For clinically proven medical products such as Daysy, the opposite is true. These devices are very accurate and underlie strict guidelines and controls through internal and external inspectors. Furthermore, transmission failures caused by the user can be ruled out because the transmission of data functions automatically and mistakes are compensated for by the integrated software and the algorithm. The problem with these products is that they don't possess the graphic possibilities and flexibility of a mobile app.
- Daysy is the only fertility tracker worldwide that enables users to convey their recorded data to an app (DaysyView) as an additional option. Thus, clinical precision is combined with the features of an app.

### How does Daysy work?

The handling of Daysy is very simple for its users: every morning, while still in bed, Daysy measures the basal temperature in the mouth, records it and immediately displays whether it is a fertile or an infertile day. This is done via small LED lamps on the fertility tracker.

- Green means that the user is in her infertile phase
- Red means fertile. These days can be used to plan for a baby, or an additional method of contraception should be used in order to prevent a pregnancy.
- Yellow means that Daysy is still in its learning phase or that the user's cycle is shifting. In order to prevent an unwanted pregnancy, yellow days need to be treated like red days.

## The algorithm

- The database within each device contains menstrual cycle data of women from real life scenarios. Many kinds of specific and diverse menstrual cycle scenarios have been integrated into the database over these 30 years, including menstrual cycles affected by stress, lack of sleep, alcohol and other factors. This data comes from our practical experience working with millions of women over three decades.
- The algorithm is created by combining two elements - the acquisition and learning of new data (your daily basal body temperature, start and end of menstruation, accumulated past cycle data) and statistical methods (eg. the temperature rises after ovulation) that allow prediction of the coming cycle. In this way, it is possible to derive individual infertile (green) days after menstruation.
- After a learning period, during which Daysy gathers your personal data, the algorithm begins to pinpoint your ovulation and start your fertile window 5 days before the earliest possible date of your ovulation. In order to determine an increase in temperature by the algorithm, a sustained characteristic temperature increase at the expected time of ovulation is required. If the algorithm has confidently recognized your ovulation, Daysy will show you subsequent individual infertile (green) days until the next menstruation.
- In the background, the algorithm takes into account the previous average temperature for each measurement, so it is also possible to tolerate "outliers" or measurement failures. In order to not take any risks, Daysy will display yellow in the case of doubt and remember the event for the coming cycle -Daysy learns-.
- Additionally, Daysy uses a very precise sensor to measure the basal body temperature. Uniquely, this sensor waits for the final temperature value to stabilize. This is why Daysy may take 30 to 60 seconds to record the temperature. Your basal body temperature does not jump, the sensor has to warm up from room temperature until it reaches the final temperature value.

### The DaysyView App

- DaysyView is a free mobile app to be used in combination with the fertility tracker Daysy.
- As an additional option, the fertility tracker Daysy can be connected to a smartphone or tablet (iOS / Android) using a small cord.
- With the app, users can transfer their recorded data from Daysy onto their smartphone. Via the app, individual cycle calendars, temperature curves, statistics and prognoses are displayed.
- The app provides the option of sharing this information with a partner, doctors or internal specialists in order to address questions that are relevant for the cycle.

### Research question and study design

The method-related as well as the user-related safety of the fertility tracker LadyComp/Pearly have been tested in a clinical study with a Pearl Index of 3,8 and 0,7 respectively (Freundl et al., 1998). Since Daysy is based on the same algorithm as these fertility trackers, the same methodical Pearl Index (0,7) could be assumed. However, the fertility tracker Daysy does distinguish itself through a simplified design as well as the option to transfer recorded temperature data onto the app DaysyView. It is here that users can view temperature curves, statistics as well as prognoses regarding their cycle or share them with, for instance, their doctor or partner.

The main research question of the current study was whether through the optional use of a mobile app to display the individual cycle, the interest, involvement, and with it, the application safety could be improved.

For the retrospective study, 6278 users of Daysy were contacted via email worldwide in-between November and the end of December of 2016. Of the 1969 women (31%) who followed the invitation, 798 (13%) filled out the complete survey. The survey contained no personal data except for date of birth, height and weight. Among others, it addressed questions regarding the individual cycle, experience with other methods of contraception, pregnancy and the use as well as approval of the app. The study protocol was reviewed and approved by the Regional Ethics Committee (FAU / Erlangen / 276\_16B).

### Findings of the study (summarized)

- The study confirms that the additional use of the app improves the usability, understanding and correct handling of the fertility tracker.
- The simple display of the individual cycle data leads women to engage more frequently and intensively with their cycle.
- Fertility trackers that use the same algorithm (LadyComp; Pearly) but are conceptualized differently and do not offer an additional app as a display served as comparison in the study. The application safety of these devices has already been confirmed in a clinical study with a practical Pearl Index of 3.8. Placing the focus upon methodical safety yielded a Pearl Index of 0.7.
- The findings of the current study show that the methodical Pearl Index has improved only slightly from 0.7 to 0.6, thereby confirming the safety of the fertility tracker and its integrated algorithm.
- When the application safety is investigated, the Pearl Index improves by more than half from 3.8 to 1.3.
- In summary, the study confirms the hypothesis that the combination of a fertility tracker and its associated methodical safety and an app and its associated involvement of the user with her cycle lead to an overall higher application safety.

### Facts and figures

- Overall 798 women completed the survey
- The total number of recorded cycles was 4738
- The average age of the participants was 29 years.
- The average body mass index (BMI) amounted to 23,02.
- 668 participants used the fertility tracker Daysy for less than 13 cycles, their data were not included in the calculation of the Pearl Index.
- 125 women used Daysy for a minimum of 13 cycles or 1 year.
- Two out of 125 women reported an unwanted pregnancy during that time.
  - This yields a practical Pearl Index of 1,3.
- One of these two women became pregnant because she had unprotected intercourse on a ,red' and thus fertile day. This amounts to a theoretical Pearl Index of 0,6.

- Of the overall 798 participating women:
  - 65% used the app daily.
  - 29% used the app weekly.
  - 6% used the app monthly.
- 9% of the participating women used Daysy to fulfill their desire to have children. Of these 69 women, 39% became pregnant in less than a year.
- Of those that did not become pregnant while they were using Daysy, six (21%) had already tried to become pregnant unsuccessfully before using Daysy.
- 84% of participants stated that they had a better understanding of themselves and their cycle with the DaysyView app.
- Further analysis yielded the result that 63% of participants used the DaysyView app to share their temperature curve and cycle statistics with their partner or doctors.
- 1 year after the study was started (November 1st, 2016) the status of 776 (98%) DaysyView accounts is "Ready", therefore DaysyView and the fertility tracker Daysy are still in use.
- 20 (2%) of the DaysyView accounts and the corresponding serial numbers of Daysy have been deleted from the server.
- Of the 778 remaining DaysyView accounts, 618 (79%) were synchronized with Daysy after June 1<sup>st</sup> 2017.
- Surprisingly, 99% of the women stated that they would recommend Daysy to a friend.

### Conclusion:

Through the additional use of an app and the associated visualization, involvement and education about the personal cycle, the method and application safety of the fertility tracker Daysy can be improved significantly.