Dot™ is a proprietary fertility app developed by Cycle Technologies. It enables users to prevent or plan pregnancy by tracking their period start dates. Dot uses an algorithm to predict probability of pregnancy on each day of a woman's menstrual cycle and to flag those days as high or low fertility.

Following a prospective, 13-cycle effectiveness trial, researchers calculated a 5% failure rate with typical use and a 1% failure rate with perfect use.

STUDY OBJECTIVES

- Assess effectiveness of the Dot app for preventing pregnancy during perfect and typical use
- Describe associations between user characteristics and Dot use
- Utilize study experience to guide mobile contraceptive research and optimize user experience

DONOR
U.S. Agency for International Development (USAID) under the Fertility Awareness for Community Transformation (FACT) Project

RESEARCH ORGANIZATION
Institute for Reproductive Health, Georgetown University

Dynamic Optimal Timing™ (Dot) Effectiveness Study

WHY STUDY FERTILITY APPS?

There are thousands of menstrual cycle tracking apps on the market. But most are not tested, and very few are designed to prevent pregnancy. When it comes to pregnancy prevention, women and couples should be given the opportunity to make decisions grounded in evidence.

The study to assess the effectiveness of the Dynamic Optimal Timing™ (Dot) App is the first of its kind to be conducted on an app-based family planning method. The effectiveness trial determined how women are actually using the method – how they interpret and act upon the the messages and information they receive about their fertility.

In addition to demonstrating effectiveness of the Dot app, this study also examined partner communication and supportiveness, perception of pregnancy risk, and sexual behavior.

WHY STUDY DOT?

The Dot app's algorithm had a clear evidence base prior to the effectiveness study, and the science underlying the development of the algorithm was robust. Dot is easy to use and only requires women to enter the first day of menses to receive information about fertile and non-fertile days during their cycles.

Date: March 2019

DOT STUDY DESIGN

The prospective, nonrandomized trial collected data from women for up to 13 menstrual cycles (or about one year) to assess the app's effectiveness with typical and perfect use, following standard guidelines for contraceptive effectiveness studies.

718 women enrolled in the study during the recruitment period. Participants were actively screened to ensure that they met study criteria.

To participate in the study, women were:

- ✓ Planning to prevent pregnancy for at least 1 year
- ✓ 18-39 years old
- ✓ Not using a hormonal contraceptive method in the last 3 months
- ✓ Having consistent cycles between 20-40 days long
- ✓ Sexually active with a male partner
- ✓ At least 3 periods post-partum

Collecting Data

The research platform was activated when participants enrolled in the study. The majority of the data collection was conducted within the app itself using pop-ups and brief questionnaires.

Study participants were asked to enter daily sexual behavior data – noting the days in their cycle when they had intercourse and whether they used another method at that time – so that correct-use effectiveness could be accurately calculated.
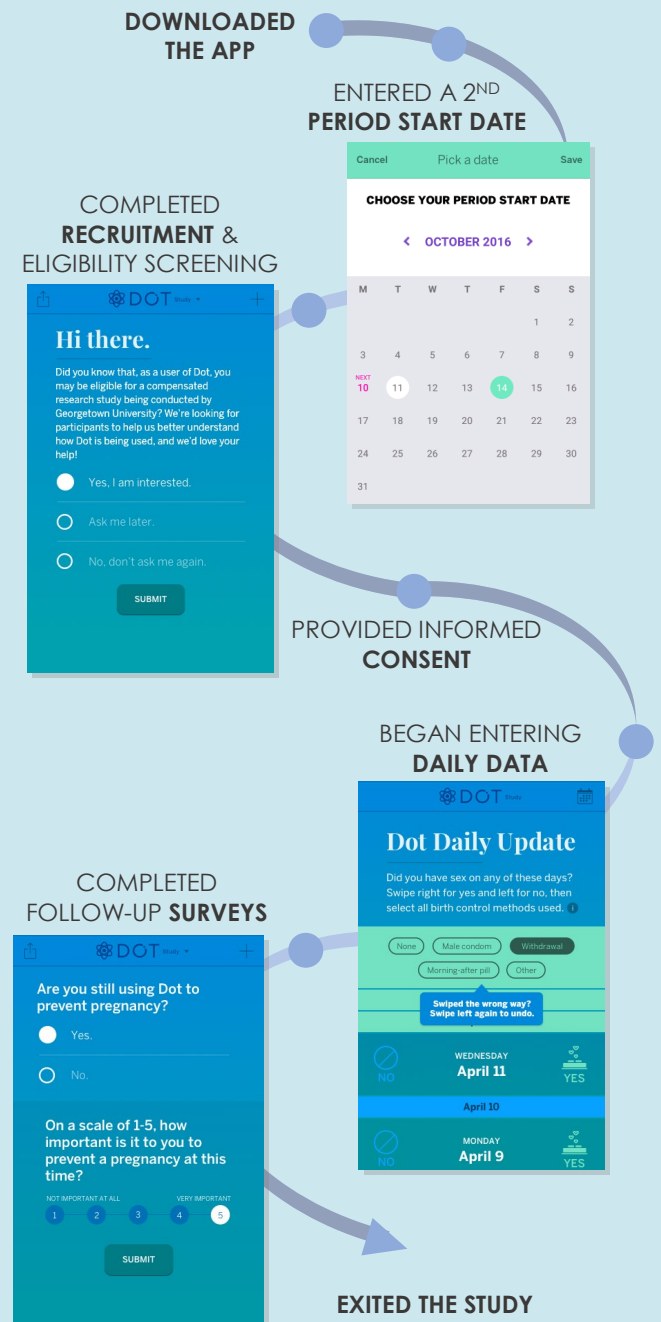
If participants reported that they used another method on fertile days, they were also asked which method they used (condom, withdrawal, morning-after pill or other).

Surveys triggered after the first, fourth, seventh, and tenth cycles collected data on perceptioin of pregnancy risk, relationship status, behavior change on fertile days, and knowledge of the fertile window.

Researchers collected data from February 2017 until October 2018. During that time, participants contributed data from 6,616 menstrual cycles.

Participating in the Study

Women participated in the Dot study for 13 cycles, or about 1 year. Along the way, participants entered daily sexual behavior data and complete surveys after their first, fourth, seventh, and tenth cycles.

DOWNLOADED THE APP

ENTERED A 2ND PERIOD START DATE

COMPLETED RECRUITMENT & ELIGIBILITY SCREENING

PROVIDED INFORMED CONSENT

BEGAN ENTERING DAILY DATA

COMPLETED FOLLOW-UP SURVEYS

EXITED THE STUDY

Exiting the Study

Participants exited the study for a variety of reasons. Dot is designed for women with cycles 20-40 days long with less 10 days variation among cycles. Approximately, 13% of study participants became inelgible to use Dot for pregnancy prevention and were exited from the study. Other participants exited the study due to technical issues with their phones or because they were no longer using Dot to prevent pregnancy.

Determining Pregnancy

Researchers actively followed up with women who reported a potential pregnancy or did not enter a period start date by the 41st day of the cycle. The research team express-mailed potentially pregnant participant's two urine pregnancy tests with instructions to confirm the pregnancy, either by digital image or free return shipment. Those who confirmed a pregnancy verybally, by email, google survey, or by returning a urine pregnancy test were categorized as pregnant.

STUDY RESULTS

Categorizing Cycles

To determine typical use effectiveness, a life-table analysis was conducted using all cycles in which intercourse was reported at any point in the cycle. This includes all cycles in which pregnancies occurred as well as perfect use and incorrect use cycles. Incorrect use was defined as cycles with one or more instances of unprotected intercourse during the days that Dot identified as potentially fertile. Unprotected intercourse included the use of withdrawal, emergency contraception, some 'other' unspecified method and/or no method. Correct use was defined as either use of a condom or not having intercourse during the days that Dot identified as potentially fertile.

Sensitivity Analysis

A sensitivity analysis was used to assess potentially unaccounted-for pregnancies. Women who discontinued use after the onset of the fertile window and reported unprotected intercourse one or more times during the fertile window were classified as 'possibly pregnant'. Although pregnancy status among these participants was undetermined, a sensitivity analysis resulted in a worst-case typical-use life-table failure rate of 10.3%.

1% PERFECT USE FAILURE RATE

5% TYPICAL USE FAILURE RATE
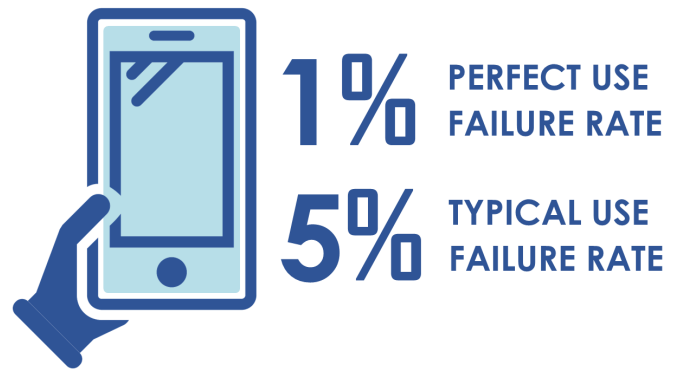
Typical Use Effectiveness

Twenty-five women became pregnant over the course of the study. All 25 pregnancies were reported as unintended. In 24 of these cases, the participants reported having sex without a condom during the fertile window. Researchers calculated a typical use failure rate of 5.0%.

Perfect Use Effectiveness

One participant became pregnant in cycle 11. She reported using the method correctly during this cycle. Researchers calculated a perfect use failure rate of 1.0%.

Participant Profile

The Dot study participants were diverse in age, ethnicity, relationship type, and whether they had previously been pregnant. Given the diversity of the study sample, researchers conducted additional analyses and found no statistical associations between these sociodemograhpic characteristics and pregnancy.

FURTHER READING

13-cycle perfect and typical-use effectiveness of the Dot fertility app; results from a prospective contraceptive trial European

Journal of Contraception and Reproductive Healthcare, 2019

Estimating six-cycle efficacy of the Dot app for pregnancy prevention: preliminary results

Contraception, October 2018

Lessons From the Dot Contraceptive Efficacy Study: Analysis of the Use of Agile Development to Improve Recruitment and Enrollment for mHealth Research

JMIR mHealth and uHealth

Assessing the efficacy of an app-based method of family planning: the Dot study protocol

JMIR Research Protocols, January 2017

Personalised estimation of a woman's most fertile days

European Journal of Contraception and Reproductive Health Care, June 2016

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CONCLUSIONS

✓ With a typical-use failure rate of 5.0% and a perfect-use failure rate of 1.0%, Dot is comparable to family planning methods such as the pill, vaginal ring, and other fertility awareness-based methods.

✓ Women of different ages, ethnicities, and relationship types can use Dot successfully to prevent pregnancy.

✓ Dot can be considered a valid addition to the family planning method mix.

IMPLICATIONS FOR THE FIELD

✓ The Dot study demonstrates that the best-practice guidelines for assessing family planning methods can be applied to apps.

✓ Dot has the potential to reach many women with an unmet need for family planning and those interested in healthy timing and spacing of pregnancies, especially given the growing reach of mobile technology and the relative ease of contextualizing apps to different age groups and cultures.

✓ As with other fertility awareness-based methods, potential Dot users should consider whether they can use the method correctly by reliably entering their period start dates and managing fertile days.