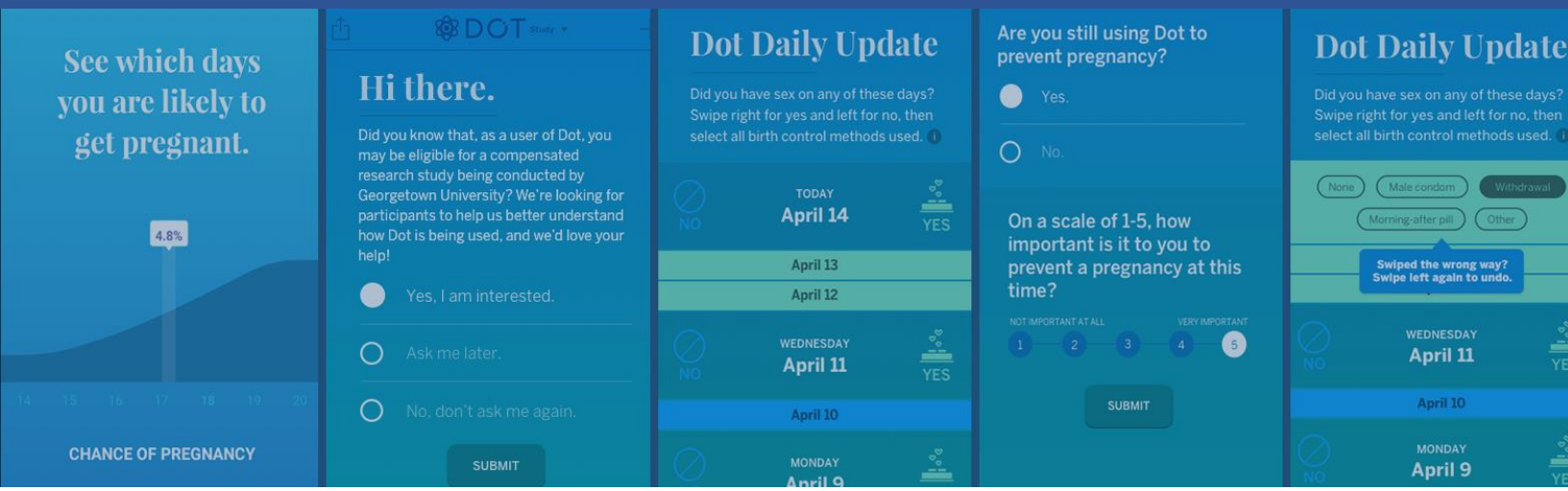
FACT

Fertility Awareness for Community Transformation



Dot is a patent-pending family planning method designed to enable users to prevent or plan pregnancy by tracking their period start dates.

The app uses an algorithm to predict probability of pregnancy on each day of a woman's menstrual cycle based on historical cycle data and her own cycle history. The app flags days of high and low fertility using only a woman's period start dates.

Dynamic Optimal Timing™ (Dot) Efficacy Study

STUDY OBJECTIVES

- Assess efficacy 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 (2013-2018)

RESEARCH ORGANIZATION
Institute for Reproductive Health, Georgetown University

DOT INVENTOR AND DEVELOPER
Cycle Technologies, Inc.

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 efficacy of the Dynamic Optimal Timing™ (Dot) App is the first of its kind to be conducted on an app-based family planning method. Theoretical efficacy of the Dot app has been statistically tested and validated. An efficacy trial will identify 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 data demonstrating efficacy of the Dot app, this study is also expected to generate information on partner communication and supportiveness, perception of risk, and coital frequency.

Dot Study Design

This prospective nonrandomized trial is collecting data from women for up to 13 menstrual cycles to assess the app's efficacy with typical and perfect use, following standard guidelines for contraceptive efficacy studies.

Over 700 women enrolled in the study during the recruitment period. When they enrolled, a research mode was activated on their app, allowing them to enter the necessary daily data for the study.

Date: February 2018

The majority of the data collection is being conducted in the app itself using pop-ups and brief questionnaires. Study participants are asked to enter daily sexual history data, noting the days in their cycle when they had intercourse and whether they used another method at that time.

If participants report that they used another method on fertile days, they are also asked which method they used (condom, withdrawal, morning-after pill or other).

Surveys are triggered after the first, fourth, seventh, and tenth cycles to collect data on risk perception, relationship status, behavior change on fertile days, and knowledge of the fertile window.

Study Eligibility

To participate in the study, a woman must:

- ✓ Be preventing pregnancy for at least 1 year
- ✓ Be 18-39 years old
- ✓ Have not used a hormonal contraceptive method in the last 3 months
- ✓ Live in the continental United States
- ✓ Have consistent cycles between 20-40 days
- ✓ Be currently sexually active with a male partner
- ✓ If breastfeeding, have had at least 3 periods since giving birth

Where Are We Now?

Study recruitment ended in July 2017 and over 700 participants were enrolled. As of January 2018, we are excited to announce that we have reached over 4,500 cycles. Participants have contributed a wealth of data to the study. 94% of participants have completed the cycle 1 survey and 83% completed the cycle 4 survey. So far, over 95% of participants say it is "very important" or "important" to prevent pregnancy at this time.

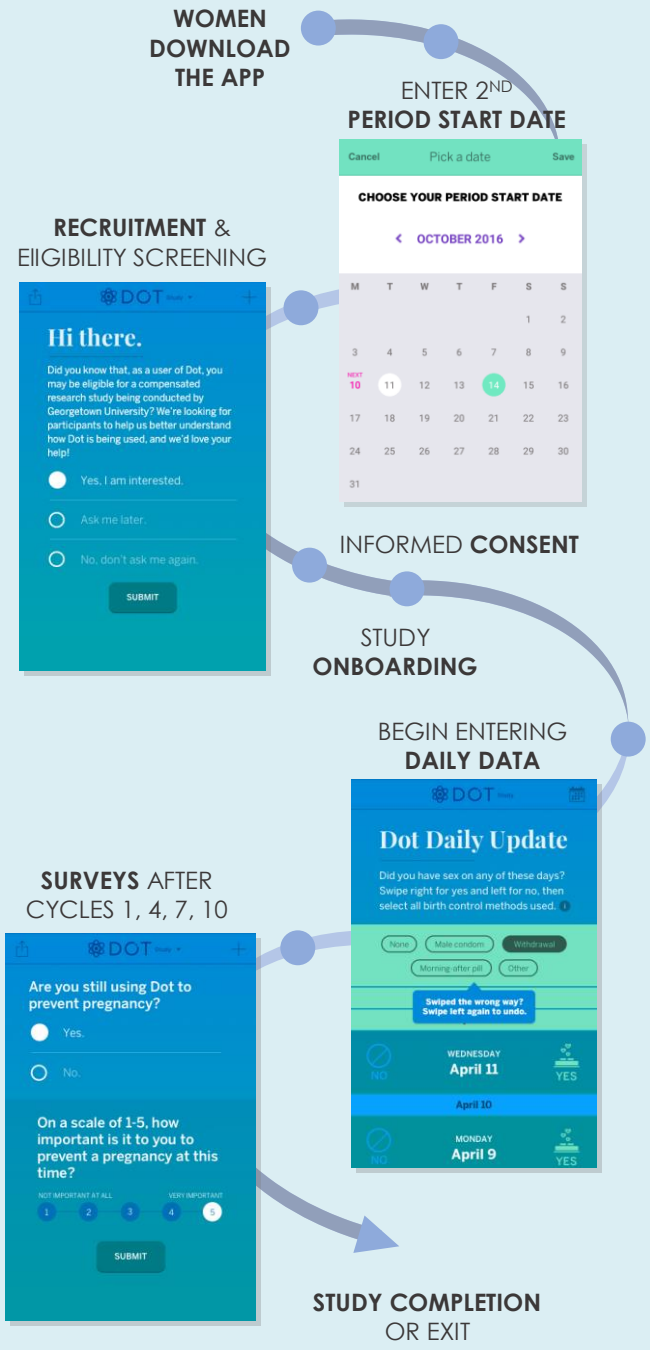
More to Come!

We have learned a great deal from the recruitment period of the study. We have submitted a manuscript for publication on the key results and lessons learned. Efficacy results after six cycles of use are expected in March 2018.

Final efficacy results are expected in Fall 2018.

STUDY PARTICIPATION

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



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