

Pilot study to explore behavioral solutions to reduce the discontinuation of injectable contraceptive use in Ethiopia

Submission date 10/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/11/2019	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Over the past two decades, there have been significant advancements in improving access and quality of care for family planning and reproductive health services in Ethiopia. However, contraceptive discontinuation rates remain high, posing a significant opportunity for ensuring that women can follow through on their fertility intentions with methods of their choosing. The Last Ten Kilometers (L10K) project of the JSI Research & Training Institute, Inc. (JSI) proposes to implement and test a behavioral economics approach to address the issue of discontinuation of injectable contraceptives among women of reproductive age in Ethiopia. Behavioral economics studies how people form intentions, and make and act on (or fail to act on) decisions to identify predictable and systematic patterns in human behavior. A behavioral economics perspective allows us to approach and, if necessary, reframe behavioral problems in a way that helps us to understand the key psychological phenomena underlying undesirable behaviors, and thus open up avenues to design innovative solutions that can lead to desired behavioral outcomes.

With technical assistance from ideas42, a non-profit behavioral research and design firm, L10K/JSI has conducted a situational analysis of behavioral factors contributing to the discontinuation of injectable contraceptives. This analysis revealed five primary behavioral bottlenecks disrupting continuation of injectables. L10K/JSI has developed a preliminary package of proposed behavioral interventions intended to support new users of injectable contraceptives and enable them to follow through with their family planning intentions. In collaboration with Federal Ministry of Health (FMOH) and Regional Health Bureaus (RHBs), L10K/JSI finalized the package of behavioral interventions and implement a paired treatment-comparison pilot study in eight woredas (districts) in the L10K project area to test the impact of the package. Outcome data will be collected from eligible injectable contraceptive client interviews 12 months post exposure to the intervention.

The primary research questions at hand are, 1) Can behaviorally informed HEW job aids and tools increase contraceptive continuation at six months post initial take-up? and 2) Can this intervention package be feasibly implemented across the entire L10K project area?

Who can participate?

Women of reproductive age visiting the study area health-posts who are interested in using injectable contraceptives.

What does the study involve?

All participants from the study area will benefit from national family planning program including the family planning interventions supported by L10K/JSI. In addition, the intervention area participants are expected to benefit from the behavioural economics tools introduced to the HEWs

What are the possible benefits and risks of participating?

Although both the study arm participants are expected to be provided with proper counselling (informed choice and proper management of side-effects) and reminders for subsequent injectable contraceptive doses; the behavioural economics intervention would insure compliance with service delivery procedures better; thus more likely to meet their fertility goals.

Where is the study run from?

The Last Ten Kilometres Project, JSI Research & Training Institute, Inc., Kebele 03/05, Bole Sub City, Addis Ababa

When is the study starting and how long is it expected to run for?

February 2016 to December 2017

Who is funding the study?

Bill and Melinda Gates Foundation
William and Flora Hewlett Foundation

Who is the main contact?

Dr Ali Karim, ali.karim@gatesfoundation.org

Contact information

Type(s)

Scientific

Contact name

Dr Ali Karim

ORCID ID

<https://orcid.org/0000-0002-9396-6861>

Contact details

Bill & Melinda Gates Foundation
c/o ILRI, Kebele 12/13, Bole Sub City
Addis Ababa
Ethiopia
1000
+251944306780
ali.karim@gatesfoundation.org

Additional identifiers

Protocol serial number

BE1

Study information

Scientific Title

Application of behavioral economics principles to reduce injectable contraceptive discontinuation rate in rural Ethiopia: A stratified-pair, cluster-randomized field study

Study objectives

Behaviorally informed job aids for the health extension workers and client appointment cards can increase contraceptive continuation at 12 months post initial take-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/10/2015, John Snow, Inc. IRB #1 (44 Farnsworth Street, Boston, MA 02210, USA; IRB@jsi.com; +1 617 482 9485), ref: 15-022

And IRBs of the regional health bureaus of Amhara, Oromia, Tigray and Southern Nations, nationalities and Peoples' (SNNP) regions.

Study design

Stratified-pair cluster-randomized field trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Contraceptive use

Interventions

The study domain included two primary health care units (PHCU) from two districts from each of the four regions where JSI was implementing a family planning program. From each region one PHCU was randomly selected for intervention while the other was the control. The PHCUs are comprised of one health center and three to six satellite health posts serving a population of about 25,000 people. Two health extension workers (HEWs) at the health posts provide mainly preventive and basic curative services including injectable contraceptive services. The intervention area included 19 health posts while the control area included 21 health posts. The intervention area HEWs were trained to implement the intervention. The intervention package included 1) a planning calendar for the HEWs for prospective time management aid for future appointments and outreach services and sending reminders to injectable contraceptive clients; 2) client care checklist to ensure proper counselling of clients; and 3) an appointment card to be given to the family planning client as a reminder of the next doses of injectable relating the date

with religious events. Based on the study participation eligibility criteria, it was decided at least 10 months would be required to recruit the desired sample size (330 from each of the two study arms). The training of the HEWs was initiated in February 2016.

Intervention Type

Behavioural

Primary outcome(s)

Injectable contraceptive discontinuation rate within 12 months of uptake.

To measure the primary outcome of interest, i.e., the injectable contraceptive discontinuation rate within 12 months of uptake, first the duration of injectable contraceptive use was measured from the three survey items: (1) the month and year the eligible participant visited the health post between intervention onset and November 2016 (uptake month); (2) whether the participant was still using the injectable contraceptive without interruption at the time of the survey, or with a maximum of a month (30 days) of interruption (survey month); and (3) if the participant was not currently using the injectable contraception, then the month and year the participant had last obtained injectable contraceptive without interruption or with a maximum of one month of interruption (dropout month). The duration of injectable contraceptive use from uptake is the difference between uptake month and survey month, or uptake month and dropout month. The duration was measured in months. In a few of the dropout cases, where the participant could not accurately describe the last time she obtained an injectable contraceptive (without interruption), then the duration of use was obtained by asking how long (in months) she had used injectable contraception without interruption.

Key secondary outcome(s)

1. Mean number of correct side effects of injectable contraceptive spontaneously recalled by the participant
2. Mean number of different types of contraceptive methods spontaneously recalled by the provider
3. Mean number of correct actions to be taken spontaneously recalled by the participant if she experienced side effects from injectable contraceptives
4. Whether the participant was told about the side effects of injectable contraceptives by the provider
5. Whether the participant was told what to do if she experienced side effects
6. Whether the participant was informed about other methods of contraception
7. Whether the participant was told, during her last visit to the health post for injectables, about a local holiday or event as a reminder of the next appointment date
8. Whether the participant was given an appointment card during the last visit to obtain an injectable contraceptive
9. Whether the participant missed an appointment for injectable contraceptives.

Completion date

01/12/2016

Eligibility

Key inclusion criteria

1. Women of reproductive age who visited the study area health posts during the intervention period and fulfilled any of the following three criteria
 - 1.1 Initiating use of injectable contraceptives

1.2 Returning to the use of injectable contraceptives after at least a six-month lapse

1.3 Switching to injectable contraceptives from another family planning method

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

743

Key exclusion criteria

1. Not a family planning client
2. Using other methods of contraceptives
3. Other method users not planning to switch to injectable contraceptives
4. Already an injectable contraceptive client before the study period

Date of first enrolment

01/02/2016

Date of final enrolment

30/11/2016

Locations

Countries of recruitment

Ethiopia

Study participating centre

AdalAgata, Alefa, Gulim, Wadra, and Zalema health posts under Alefa health center

Burie Zuria district, Amhara

Ethiopia

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Study participating centre

Denibinagirarigie, Diremu, and Wokello health posts under Lemi health center

Ensaro district, Amhara

Ethiopia

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Study participating centre

Dabotobo, Delebe, Halilu Adhessa, Hawaenber, Hawa Geba, Shengela, Sololo, and Utanone health posts under Kumbabe health center

Illu Ababora district, Oromia

Ethiopia

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Study participating centre

Budo Kera, Gersha Luchine, Sentema Goru, and Sikba Kake health posts under Sentema health center

Seka-Chekorssa district, Oromia

Ethiopia

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Study participating centre

Dube Godebamo, Golecheba, Hebot, Hebot Tirora, and Wanja Shola health posts of Ebot Tirora health center

Dalocha district, SNNP

Ethiopia

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Study participating centre

Azege Zemeda, Edeya, Hanger, Kerewa, Meleka, OyaKepho, and Shemona health posts of Fofa health center

Yem district, SNNP

Ethiopia

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Study participating centre

Adikahisu, Adiklite, Ftihi, Godifay, and Midrefelasi health posts of Adinebried health center

Laelay Adiabo district, Tigray

Ethiopia

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Study participating centre

Dekera, Finarwa, and Weyen health posts of Finarwa health center

Samre Sehart district, Tigray

Ethiopia

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Sponsor information

Organisation

JSI Research & Training Institute, Inc.

ROR

<https://ror.org/05pgv5n44>

Funder(s)

Funder type

Charity

Funder Name

William and Flora Hewlett Foundation

Alternative Name(s)

William + Flora Hewlett Foundation, Hewlett Foundation, William & Flora Hewlett Foundation, The William and Flora Hewlett Foundation, HF, WFHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Bill and Melinda Gates Foundation

Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

The raw data (*.csv) and analysis procedures (in Stata 15.1) are stored in publically available repository (Karim AM. 2019. DOI: 10.5281/zenodo.2592313) and remain there.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	non-peer-reviewed results	13/06/2019	12/11/2019	Yes	No