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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

Registration date
12/04/2019

Overall study status
Completed

Last Edited
12/11/2019

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Stratified-pair, cluster-randomized field trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 does 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 measure
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.

Secondary outcome measures
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.

Overall study start date
10/08/2014

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

Age group
Adult

Sex
Female

Target number of participants
660 (330 from the intervention and 330 from the control areas)

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
0000

Study participating centre
Denibinagirarigie, Diremu, and Wokello health posts under Lemi health center
Ensaro district, Amhara
Ethiopia
0000

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
0000

Study participating centre
Budo Kera, Gersha Luchine, Sentema Goru, and Sikba Kake health posts under Sentema health center
Seka-Chekorssa district, Oromia
Ethiopia
0000

Study participating centre
Dube Godebamo, Golecheba, Hebot, Hebot Tirora, and Wanja Shola health posts of Ebot Tirora health center
Dalocha district, SNNP
Ethiopia
0000

Study participating centre

Azege Zemeda, Edeya, Hanger, Kerewa, Meleka, OyaKepho, and Shemona health posts of Fofa health center
Yem district, SNNP
Ethiopia
0000

Study participating centre
Adikahisu, Adiklite, Ftihi, Godifay, and Midrefelasi health posts of Adinebried health center
Laelay Adiabo district, Tigray
Ethiopia
0000

Study participating centre
Dekera, Finarwa, and Weyen health posts of Finarwa health center
Samre Sehart district, Tigray
Ethiopia
0000

Sponsor information

Organisation
JSI Research & Taining Institute, Inc.

Sponsor details
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Sponsor type
Other

Website
http://www.jsi.com

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, 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

Publication and dissemination plan
Disseminated at International SBCC Summit, Nusa Dua, Indonesia, April 2018, and International Family Planning Conference, Kigali, Rwanda, November 2018. Submitted for publication at Gates Open Research

Intention to publish date
01/05/2019

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

Stored in repository

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