Assessing the impact of a digital job aid on clients' experience of family planning counselling and choice of long acting contraception methods

Submission date	Recruitment status No longer recruiting	Prospectively registered		
08/02/2017		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
02/03/2017		Results		
Last Edited		Individual participant data		
06/08/2018	Pregnancy and Childbirth	Record updated in last year		

Plain English summary of protocol

Background and study aims

Marie Stopes International (MSI) seeks to help women choose a contraceptive method that suits their individual lifestyles and medical needs. In the past MSI provided family planning counselling provider training that focused on delivering information from provider to the client. In recent years MSIs' training has changed. Its training now places greater focus on meeting the clients' contraceptive needs and preferences. MSI wish to understand whether a job aid would reduce providers' offering of unnecessary or overwhelming range of options to clients, and help focus providers' intentions on clients' needs and tailor information accordingly. MSI have created a digital job aid known as the Digital Counselling Application (DCA), intended for use by the provider during client family planning counselling. It is an application that runs on a tablet and guides the client through a series of questions. The DCA offers different paths for clients who have a method in mind, as well as clients who are open to exploring other methods. At the end of the application, the DCA aims to provide a list of methods that best fits the client's responses. The provider using the DCA is then encouraged to discuss the top three ranked methods with the client, to explore their preferences and help them make a decision about which contraceptive method best fits their lifestyle and needs. By prompting a structured discussion between providers and clients about the client's preferences, the DCA could lead to more supportive, interactive and unbiased counselling sessions. The aim of this study is to assess providers' and clients' experience of the DCA, its impact on method choice, its impact on clients continuation of that method, and identify how the DCA can be improved. The study focuses on two countries, Ethiopia and Vietnam, to asses its suitability across countries and identify any aspects that require country-specific consideration.

Who can participate?

Women aged 18-49, who receive family planning counselling and then adopt an family planning method or switch methods

What does the study involve?

Participating clinics are randomly allocated to one of two groups. In one group providers are trained to use the DCA with their clients every day during the 4-month study. Providers in the other group (control group) are not required to do anything different to their everyday practice (usual care). Uptake of contraception methods and client satisfaction are measured by a telephone questionnaire with the client within 1 day of counselling.

What are the possible benefits and risks of participating?

Providers may benefit from receiving refresher training in modern family planning methods and practical training in the DCA job aide. Clients may also benefit by receiving what is anticipated to be a more focused and client needs based family planning counselling. Providers and clients in the control group receive no direct benefit and continue to offer/receive usual care. Neither client nor providers are anticipated to be at risk as a result of using the new DCA.

Where is the study run from?
Marie Stopes International, Monitoring & Evaluation Team (UK)

When is the study starting and how long is it expected to run for? October 2015 to December 2017

Who is funding the study?
Marie Stopes International (UK)

Who is the main contact?
Emily Robinson
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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MSIApp_V_E_Trial

Study information

Scientific Title

Evaluating the impact of Marie Stopes International's digital family planning counselling application (DCA) on the uptake of long-acting methods in Vietnam and Ethiopia: a multi-country randomised control trial

Study objectives

MSI's Digital Counselling Application offers a more client focused counselling that subsequently increases uptake of long acting and permanent methods, and improves client experience of counselling, amongst existing and new contraceptive-using female clients aged 18-49 presenting to MSI family planning static service delivery centres (clinics) in Ethiopia and Vietnam.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Marie Stopes International Ethics Review Board, 20/09/2016, ref: 007_16_May
- 2. Regional Health Bureaus of Ethiopia, 24/10/2016, ref: 30-214/22768; 18/11/2016, ref: 564 /1418/8; and 26/12/2016, ref: 1097/227
- 3. Ministry of Health Hanoi School of Public Health in Vietnam, 26/04/2016, ref: 226/2016/YTCC-HD3

Study design

Parallel-group two-arm cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Long-acting and permanent contraceptive method (LAPM) uptake, and client experience of counselling amongst family planning switchers and adopters

Interventions

The intervention being tested is the Digital Counselling Application (DCA). It is a job aid for use by the provider during client FP counselling. It is designed as an application on a tablet, to assist providers during counselling sessions to guide their clients through the process of making a decision about which contraceptive method best fits their lifestyle and needs.

Country clinics in Ethiopia (24) and then Vietnam (11) were listed alphabetically and numbered 1-35. Using Excel, a simple numeric randomisation was used to allocate the first 18 clusters (clinics) into the intervention arm (13 Ethiopia and 5 Vietnam). The remaining 17 were allocated to the control arm (11 Ethiopia and 6 Vietnam). The allocations within each country were visually checked that roughly half of clinics were in each arm.

Group 1 (Intervention): All providers within the intervention clinics will be recruited to receive refresher training on client-centred FP counselling approaches and on the use of the Digital Counselling App. It is anticipated that 13 and 5 clinics in Ethiopia and Vietnam will be recruited respectively.

Group 2 (Control): In all control arm clinics providers will receive no intervention, namely no additional refresher training on client-centred FP counselling unless they have received no training within the last 18 months, and no DCA training, and will continue to offer clients their usual family planning counselling; termed here as 'usual care'.

Clients are followed up at 4 months.

Intervention Type

Device

Primary outcome measure

- 1. Uptake of LAPM of contraception, measured via telephone questionnaire with client within 1 day of counselling
- 2. Client satisfaction (scaled), measured via telephone questionnaire with client within 1 day of counselling

Secondary outcome measures

- 1. Length of and quality of consultation using the DCA based on pre-defined quality checklist, measured via 14 structured observations of provider client counselling with 1 provider over three days, for each of the 8 intervention clinics in Ethiopia and 6 intervention clinics in Vietnam)
- 2. Association between provider cadre and experience on adherence to DCA, measured via 14 structured observations of provider client counselling for each of the 8 intervention clinics in Ethiopia and 6 intervention clinics in Vietnam
- 3. Themed responses from the providers on their experience of using the DCA, measured via indepth interviews with providers in Vietnam and Ethiopia who are observed using the DCA during the 3 days of structured observation
- 4. Themed responses from clients on their experience of the FP counselling and its influence on method choice and continuation, measured via in-depth interviews with clients who receive DCA counselling, and are observed by a researcher, within 3 days receiving counselling
- 5. Continuation rates of methods chosen by clients, measured via telephone interviews with clients who received telephone questionnaires and subsequently agreed to a follow up phone questionnaire 4 months after their FP counselling
- 6. Clients' post counselling response to their chosen FP method, measured via telephone interviews with clients who received telephone questionnaires and subsequently agreed to a follow up phone questionnaire 4 months after their FP counselling

Overall study start date

01/10/2015

Completion date

31/12/2017

Eligibility

Key inclusion criteria

Recruiting clients:

- 1. All female clients recruited must be between 18 and 49, and have received FP counselling
- 2. They must be adopting an FP method, or switching from one FP method to another
- 3. In the intervention arm, they must have received counselling using the app
- 4. Clients who consented to participate in the research

Recruiting providers:

1. Providers who work in clinics assigned to the intervention

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Ethiopia: 1725 clients over 24 centres – approx. 75 clients per centre. Vietnam: 750 clients over 10 centres – approx. 75 clients per centre.

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/06/2016

Date of final enrolment

31/03/2017

Locations

Countries of recruitment

Ethiopia

Viet Nam

Study participating centre Marie Stopes International Ethiopia

Addis Ababa Ethiopia 5775

Study participating centre

Marie Stopes Vietnam

Units 201-205, A1 Building Van Phuc Diplomatic Compound No. 298 Kim Ma Street Ba Dinh District Hanoi Viet Nam 0000

Sponsor information

Organisation

Marie Stopes UK

Sponsor details

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Sponsor type

Charity

Website

https://www.mariestopes.org.uk/

ROR

https://ror.org/05mnyyy56

Funder(s)

Funder type

Charity

Funder Name

Marie Stopes International

Results and Publications

Publication and dissemination plan

- 1. Two planned publications in high-impact peer reviewed journals
- 2. An internal report containing recommendations for action by MSI, and will be converted into guidelines for use of the DCA by MSI and country programmes
- 3. The results of the study will also be used to feedback into the second versions of DCA and associated training package, in order to improve the design and training delivery. This information will include feedback on the contexts in which the DCA will be most effectively deployed
- 4. The participating centres and providers will be given specifically tailored feedback on the results of the study. The findings will also be shared with the clients in the form of posters at the various centres where the study is to be conducted, and any participating client returning to MSI to receive services will be updated on the results of the study

Intention to publish date

01/03/2017

Individual participant data (IPD) sharing plan

Please contact Emily Robinson (Emily.Robinson@mariestopes.org) for access to anonymised and extracted interview quotes (provider and client) used in the data analysis and interpretation, and access to individual anonymised observation (provider) and telephone questionnaire data (client).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/08/2018		Yes	No