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Improving access to safe abortion in Indonesia

Submission date
13/03/2018

Recruitment status
No longer recruiting

Registration date
22/05/2018

Overall study status
Completed

Last Edited
22/05/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In Indonesia, the provision of induced abortions is highly restricted, and abortion is technically only allowed in cases where a woman's life is at risk. In settings where abortion is legally restricted, as well as where it is permitted but not widely accessible, women are increasingly choosing medications such as mifepristone and/or misoprostol to terminate their pregnancies outside of the formal healthcare system. In contexts where mobile phones are common but healthcare access is limited, mobile health (mHealth) programs have been shown to increase knowledge and agency, and even demonstrate improvements in health outcomes.
Who can participate?
Women aged 15 and over who are pregnant at 13 weeks gestation or below

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care from the safe abortion hotline, and get access to a smartphone application which contains further information about medication abortion.
Those in the second group receive stand care telephonic support from the hotline.
Participants are followed up after three weeks with an online questionnaire.

What are the possible benefits and risks of participating?
There no direct benefit to participating in the study. Risks include feeling uncomfortable answering sensitive questions, though participants can skip any question. There is a small risk of loss of privacy for participants who give others access to their smartphone, as it is possible that others may see the smartphone application or may see the survey link. To minimize these risks, the smartphone application is password protected, and participants are asked to set a passcode on their phone if they don't already have one.

Where is the study run from?
Indonesia

When is the study starting and how long is it expected to run for?
May 2016 to December 2018

Who is funding the study?
David and Lucile Packard Foundation (USA)

Who is the main contact?
1. Dr Caitlin Gerdts (Scientific)
2. Ms Ruvani Jayaweera (Public

Contact information

Type(s)
Scientific

Contact name
Dr Caitlin Gerdts

ORCID ID
http://orcid.org/0000-0002-2488-5072

Contact details
1330 Broadway Suite 1100
Oakland
United States of America
94612

Type(s)
Public

Contact name
Ms Ruvani Jayaweera

ORCID ID
http://orcid.org/0000-0003-0609-9892

Contact details
1330 Broadway Suite 1100
Oakland
United States of America
94612

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
INDO 05216

Study information

Scientific Title
Effect of a smartphone application on abortion preparedness and feelings of support compared to standard counseling among callers to a safe abortion hotline in Indonesia seeking information on medication abortion

Study objectives
The aim of the study is to evaluate the feasibility and acceptability of a smartphone application to support women who are self-managing their abortions with counseling support from a safe abortion hotline. We hypothesize that women who use the smartphone application along with telephonic support from a safe abortion hotline (intervention arm) will feel more supported and be more prepared for their abortion experience than those who receive telephonic support alone (control arm).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Allendale Institutional Review Board, 28/04/2016, no public reference number available.

Study design
Single-center randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Abortion

Interventions
Eligible participants who contact a safe abortion hotline for information on first trimester medication abortion are randomized into two study arms:
Intervention Arm: participants in this group receive standard of care from the safe abortion hotline. This consists of comprehensive, reliable, and accurate information and support to women who are seeking information on how to self-manage their abortion. Participants in this group also have access to a third-party smartphone application which is downloaded via a link. This contains information on medication abortion protocols, what to expect, warning signs and complications, contraception, healthy relationships, and other sexual and reproductive health related topics.

Control Arm: Participants in this group receive standard care of telephonic support from hotline counselors, which includes compassionate, gestational specific counseling on evidence-based medication abortion protocols, what to expect, how to manage symptoms and side effects, and warning signs of complications.

Intervention Type
Other

Primary outcome measure
1.Preparedness for abortion symptoms/what to expect
2. Confidence in following the abortion regimen
3. Feeling supported during the process
All outcome measures are assessed using an online questionnaire three weeks after randomization.

Secondary outcome measures
1. Number of times contacted the hotline during their abortion process

Overall study start date
01/05/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. At least 15 years old
2. Able to give informed consent
3. Able to speak Bahasa Indonesia or English
4. Contact the hotline seeking information about medications for induced abortion and are 13 weeks gestation or below
5. Starting a new medication abortion process
6. Own an Android or iPhone smartphone
7. Willing to download a third-party application and receive SMS messages

Participant type(s)
Other

Age group
Mixed

Sex
Female

Target number of participants
500

Key exclusion criteria

1. Call the hotline but have already started their abortion process
2. Aged younger than 15
3. Do not own a smartphone

Date of first enrolment
01/02/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Indonesia

Study participating centre
Safe abortion hotline
Indonesia
withheld because of privacy concerns

Sponsor information

Organisation
Ibis Reproductive Health

Sponsor details
1330 Broadway Suite 1100
Oakland
United States of America
94612

Sponsor type
Research organisation

ROR
https://ror.org/01va7e105

Funder(s)

Funder type
Charity

Funder Name
David and Lucile Packard Foundation

Alternative Name(s)
David & Lucile Packard Foundation, The David and Lucile Packard Foundation, Packard Foundation, The Packard Foundation, The David & Lucile Packard Foundation, DLPF, PF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal, and submission to sexual and reproductive health focused academic conferences.

Intention to publish date
01/02/2019

Individual participant data (IPD) sharing plan
Data will be held in a password protected computer by the Principal Investigator; participant level data will not be made available as participants were assured during the informed consent process that individual level information would not be shared outside of the study team.

IPD sharing plan summary
Not expected to be made available