

Improving access to safe abortion in Indonesia

Submission date 13/03/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/05/2018	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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

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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