

# ARMADILLO Trial: a research trial evaluating the effect of delivering sexual and reproductive health (SRH) information via SMS to young people on SRH learning and beliefs

<b>Submission date</b> 15/03/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/06/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

There is a high unmet need for sexual and reproductive health (SRH) information and services for youth (defined as between the ages of 15 and 24) worldwide. However, financial, cultural, social, and legal considerations often impede youth accessing SRH resources. There are efforts in place to make facility-based services and health providers 'youth-friendly'; however, a welcoming facility environment alone may not be enough to entice young people to enter and access the information and services available to them.

Creating demand among youth in need of SRH resources for those youth-friendly services requires an enabling environment. Innovative solutions have been used to create this enabling environment, including the use of mobile phone technology to engage and inform youth around SRH issues. These approaches offer significant advantages, including the wide availability of mobile phones within this age group and the discretion these devices offer.

Despite the apparent good fit between SRH and mobile phones, the evidence base supporting mobile health approaches is still underdeveloped due to limited rigorous research to assess impact. As the number of mobile health interventions increase, so does the need to demonstrate the coverage, impact, and cost effectiveness of mobile phone strategies to deliver high quality SRH information and drive appropriate use of SRH services.

Following a formative stage centred on the iterative refinement and finalization of a repository of SRH messages targeted towards youth (conducted in 2015-2016), this trial will seek to assess the effect of on-demand SRH information, delivered via SMS, on dispelling myths and misconceptions around contraception for young people in Peru (youth aged 13-17) and Kenya (youth aged 18-24).

### Who can participate?

Youth aged 13 to 17 years of age (Peru), youth aged 18 to 24 years of age (Kenya)

What does the study involve?

Participants will either receive access to on-demand information via SMS, followed by weekly quizzes (any quiz answer receives free airtime) or pushed SMS (varies by site) and invitation to participate in a quiz at the end of the week (again, any answer receives free airtime); or no intervention.

What are the possible benefits and risks of participating?

Benefits include participants being able to access validated sexual and reproductive health information (via messages developed by fellow young people) on a broad array of SRH topics, in communities where access to such information for these age groups is often extremely difficult. Intervention participants will have full access to ARMADILLO message content and at the end of the intervention and follow-up period, the full ARMADILLO system will be made available to all study participants (including Arm 3 and control participants). Risks to participation are minimal, but might consist of participants being uncomfortable with message content or a friend, partner, or family member seeing the messages without a participant's permission.

Where is the study run from?

1. International Centre for Reproductive Health (Kenya)
2. Universidad Peruana Cayetano Heredia (Peru)

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

April 2016 to July 2018

Who is funding the study?

UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (Switzerland)

Who is the main contact?

Ms Lianne Gonsalves (scientific)

## Contact information

### Type(s)

Scientific

### Contact name

Ms Lianne Gonsalves

### ORCID ID

<http://orcid.org/0000-0003-2409-5043>

### Contact details

World Health Organization  
Avenue Appia 20  
Geneva  
Switzerland  
1201

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

A65892b

## **Study information**

### **Scientific Title**

Adolescent/Youth Reproductive Mobile Access and Delivery Initiative for Love and Life Outcomes (ARMADILLO) protocol for research trial evaluating youth learning and information retention following delivery of SRH information via mobile phones.

### **Acronym**

ARMADILLO

### **Study objectives**

Youth given access to ARMADILLO's targeted SRH information on-demand through their mobile phones will be more knowledgeable about contraception and better able to dispel contraception myths and misconceptions than those without access to ARMADILLO.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

WHO Research Ethics Review Committee

### **Study design**

Randomised controlled trial. This is an three-armed, 'open-label' trial. Following a baseline survey, the intervention period lasts seven weeks after which participants complete an endline survey. An additional follow-up assessment is done eight weeks after endline.

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Community

### **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**

Sexual and reproductive health

## **Interventions**

The three arms consist of: 1) intervention: participants receive access to on-demand information via SMS, followed by weekly quizzes (any quiz answer receives free airtime); 2) intervention-lite: pushed SMS (varies by site) and invitation to participate in a quiz at the end of the week (again, any answer receives free airtime); and 3) control: no intervention.

ARMADILLO as an intervention (arm 1) consists of an automated, interactive, and on-demand SMS platform that will provide essential facts and address common misconceptions about a full range of SRH issues pertinent to youth, including puberty, relationships, sex, pregnancy, HIV and STIs, and contraception. The ARMADILLO system will be available to users at no charge.

Each site will implement a three armed trial, with intervention and control arms. An additional third arm 'intervention-lite' will vary by country: Peru will test the delivery of this intervention via pushed-messages (rather than 'pull' on-demand messages), while in Kenya, youth will receive only the SRH domain as a prompt. Intervention and intervention-lite arms in both countries will have weekly quizzes where participants receive free airtime for any response. All arms will be free for participants to engage with.

This study utilizes an open, individually-randomized, three-arm comparative design with eligible participants (from a randomly selected list of eligible households) randomized in a 1:1:1 allocation ratio to intervention, control or Arm 3. The randomization of participants to each arm was completed by a tool developed using Node.js and docker.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Myths and misconceptions of contraception, as determined by a questionnaire about contraception administered by a researcher, with answers collected on a mobile phone, measured at baseline, at the end of the intervention (seven weeks), and eight weeks following the end of the intervention (15 weeks from baseline). The questionnaire uses a series of multiple choice and/or true/false questions which are combined into one large survey (with 40+ questions, most of which also have sub-questions).

## **Secondary outcome measures**

1. Knowledge of contraception
2. Knowledge of puberty, anatomy and sexuality
3. Knowledge of HIV/AIDs and its transmission
4. Knowledge of attitude around engaging in sex (with self and others)
5. Attitudes around intimate partner violence
6. Previous behaviour around sex and contraception use

The following outcome measures are measured using a questionnaire, with answers collected on a mobile phone. Measured at baseline, at the end of the intervention (seven weeks), and eight weeks following the end of the intervention (15 weeks from baseline). The questionnaire uses a series of multiple choice and/or true/false questions which are combined into one large survey (with 40+ questions, most of which also have sub-questions).

**Overall study start date**

01/04/2016

**Completion date**

01/07/2018

## Eligibility

**Key inclusion criteria**

Eligibility criteria for the general ARMADILLO study is as follows:

- 1.Youth between the ages of 13-24 (age range narrowed as needed for each site);
- 2.Literate
- 3.Have their own mobile phone (meaning it is primarily in their possession, and they control when and with whom they share access) and report regular use
- 4.Have a mobile phone with them at the time of recruitment
- 5.Report current use of text messaging

**Participant type(s)**

Other

**Age group**

Child

**Lower age limit**

13 Years

**Upper age limit**

24 Years

**Sex**

Both

**Target number of participants**

1476

**Total final enrolment**

1452

**Key exclusion criteria**

Those that do not meet the eligibility criteria

**Date of first enrolment**

15/01/2018

**Date of final enrolment**

18/03/2018

## Locations

**Countries of recruitment**

Kenya

Peru

**Study participating centre**

**International Centre for Reproductive Health - Kenya**

Mombasa

Kenya

80103

**Study participating centre**

**Universidad Peruana Cayetano Heredia**

Lima

Peru

15102

## **Sponsor information**

**Organisation**

UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

**Sponsor details**

Avenue Appia 20

Geneva

Switzerland

1211

+41 (0)22 791 2970

agh-info@who.intx

**Sponsor type**

Other

**Website**

[http://www.who.int/reproductivehealth/about\\_us/en/](http://www.who.int/reproductivehealth/about_us/en/)

**ROR**

<https://ror.org/01f80g185>

## **Funder(s)**

**Funder type**

Not defined

## Funder Name

UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

## Results and Publications

### Publication and dissemination plan

Plan to publish protocol: 15/07/2018

Regional and national level results dissemination to Ministry of Health partners in each site: 15/08/2018

Planned publication of results in high-impact peer reviewed journal

### Intention to publish date

01/06/2019

### Individual participant data (IPD) sharing plan

Not provided at registration

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	11/07/2018		Yes	No
<a href="#">Other publications</a>	Implementation lessons	27/09/2019	03/10/2019	Yes	No
<a href="#">Results article</a>	results in Kenya	06/01/2022	10/01/2022	Yes	No
<a href="#">Results article</a>	results in Peru	10/02/2022	11/02/2022	Yes	No
<a href="#">Results article</a>	Mixed-methods study on pharmacies as contraception providers to Kenyan young people: who uses them and why?	08/07/2020	15/06/2023	Yes	No