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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

Submission date
15/03/2018

Recruitment status
No longer recruiting

Registration date
29/05/2018

Overall study status
Completed

Last Edited
15/06/2023

Condition category
Other

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

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?
Protocol article	protocol	11/07/2018		Yes	No
Other publications	Implementation lessons	27/09/2019	03/10/2019	Yes	No
Results article	results in Kenya	06/01/2022	10/01/2022	Yes	No
Results article	results in Peru	10/02/2022	11/02/2022	Yes	No
Results article	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