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The effect of weekly text messaging to improve retention across the prevention of mother to child transmission of HIV program

Submission date
27/11/2014

Recruitment status
No longer recruiting

Registration date
09/12/2014

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

The human immunodeficiency virus (HIV) gradually weakens an infected persons immune system so that they are less able to fight infections and disease. It can be caught in a number of ways, including unprotected sex, sharing infected needles, transfusions of blood or blood products and from a mother passing it onto her baby. A mother with HIV (HIV-positive) can pass the virus to her child at any time during pregnancy, during birth and also while breastfeeding. A program, or intervention, called “prevention of mother-to-child transmission of HIV” (PMTCT) provides antiviral drugs, counselling and support that help mothers prevent passing on HIV to their infants. We are carrying out a study of pregnant and HIV infected women enrolled in a PMTCT program to compare how many women who receive weekly text messages (short message system) from health care providers complete the PMTCT programme compared to others that don’t. Our goal is to find out how best to use the short message system (SMS) to encourage as many woman to complete the program as possible. We will want to look at whether the SMS should be tailored according to age, time of HIV diagnosis, HIV infection disclosure and other factors. The study’s findings should help to improve the use of SMS in PMTCT and help to prevent more infants becoming infected with HIV.

Who can participate?

The WelTel PMTCT trial aims to recruit women coming for antenatal services for the first time in their current pregnancy, at three different health facilities. They must be aged >18 years, HIV-positive, resident of the study area and willing to be followed up until the infant is 20 months of age. They must own or have access to a mobile phone, able or have someone in close contact that they trust to read and send/respond to a text message in Kiswahili, willing to receive text messages from the PMTCT clinic and able and willing to provide informed consent.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 receive a weekly SMS from PMTCT health providers in Kiswahili asking about their health and provided with an opportunity to ask for help if needed. The message Mambo? (Kiswahili for “How are you?”) is sent on the same day every week and allows the patient to respond within 24 hours. A nurse

experienced in PMTCT is in charge of monitoring the WelTel SMS platform that automatically registers responses from the participants. This nurse calls participants who respond that they have a problem to follow up and offer assistance. Problems that cannot be immediately solved by the nurse are referred to the PMTCT clinical officer / doctor at the respective facilities who then decide if the patient needs to come to the facility or an answer given through the phone. Patients who do not respond within 48 hours are traced. Those in group 2 do not receive a weekly SMS. All participants are followed-up from day of recruitment until 20 months after the birth of their child.

What are the possible benefits and risks of participating?
There is no immediate direct benefit to those taking part, but there should be benefits to mothers attending the PMTCT program in the future in that it will encourage them to complete the program and lessen the risk of infecting their infant with HIV. The main risk of participating in this study is accidental disclosure of HIV status. However, this risk will be discussed with potential participants during the informed consent process and potential participants will be notified as to whom these events should be reported.

Where is the study run from?
1. Karolinska Institute (Sweden)
2. University of British Colombia, AMREF Health Africa (Kenya)
3. Moi University (Kenya)

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

Who is funding the study?
The Swedish Research Council (Sweden)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of weekly text messaging to improve retention across the PMTCT cascade for pregnant HIV- infected women: a randomized controlled trial

Acronym
WelTel PMTCT

Study objectives
The weekly mobile phone short messaging service (WelTel SMS) is an effective as well as cost-effective method to improve patient retention in PMTCT program

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Amref Ethics and Scientific Review Committee, 21/01/2014, ref. P95/2013
2. Moi University Institutional Research and Ethics Committee, 06/10/2014, ref. IREC 1292

Study design
Multi-center two-arm open randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Retention in PMTCT program

Interventions
1. Participants in the intervention group will receive an automated weekly short text message in Kiswahili asking about their health-related wellbeing and provided with an opportunity to request assistance. The message Mambo? (Kiswahili for “How are you?”) is sent on a fixed day of the week and allows the patient to respond within 48 hours as either that they are well for example ok or sawa or that they have a problem for example problem or shida. A male or female nurse experienced in PMTCT will be in charge of monitoring the WelTel SMS platform that automatically registers responses from the participants. The nurse will call participants who respond “problem” to follow up and triage their problems. Problems that cannot be immediately solved by the nurse will be referred to the PMTCT clinical officer / doctor at the respective facilities who will then decide if the patient needs to come to the facility or an answer given through the phone. Patients who do not respond within 24 hours are traced within the defaulter tracing outreach program that includes mentor mothers where available, community health extension workers (CHEWs) as linkage between facility and community and community health workers (CHWs) at the household level. Participants will be informed that the weekly SMS support service does not replace appointments for routine services such as counseling or clinical services and that all emergencies should be handled by usual means. All cell phone communication resulting from the SMS queries will be recorded by the technological platform, and the research assistant will be able to enter any actions taken directly into this system.
2. Participants in the control group attend a PMTCT clinic but do not receive the weekly short text messages.

Intervention Type
Behavioural

Primary outcome measure
Retention in PMTCT care defined as the proportion of HIV-exposed infants whose HIV status are confirmed at 18 months of age, measured as whether the infant was tested for HIV at 20- 24 months after birth (at or outside the selected clinics).

Secondary outcome measures
1. Feasibility and Acceptability of WelTel SMS intervention on PMTCT participants
2. Effects of WelTel SMS on single PMTCT components
3. Cost against (i) effectiveness from a providers perspective and (ii) cost against the utility

(differences in QUALYs between the 2 arms with the intervention arm having an improvement of 30%) from a patients perspective
4. A model framework for estimating cost-effectiveness of an m-health intervention to improve PMTCT outcomes, generalizable to other settings

Overall study start date
02/04/2013

Completion date
30/12/2017

Eligibility

Key inclusion criteria
1. Woman aged 18 and above
2. Evidence of pregnancy as confirmed by urine test
3. Evidence of HIV infection (confirmed by a rapid test if newly detected and those known to be infected and referred from comprehensive care clinic) whether on ARVs or not
4. Resident of the PMTCT clinic catchment area (in urban and rural Kenya) and plans to remain residents from recruitment until 20 months after delivery
5. Willing to be followed-up from recruitment until 20 months after delivery
6. Own a mobile phone and/or have a phone in possession at the time of enrollment /or have access to a phone
7. Able or have someone in close contact that they trust to read and send/respond to a text message in Kiswahili
8. Willing to receive text messages from the PMTCT clinic
9. Able and willing to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
600

Total final enrolment
600

Key exclusion criteria
Those not fulfilling the inclusion criteria

Date of first enrolment

12/01/2015

Date of final enrolment
12/08/2015

Locations

Countries of recruitment
Kenya

Study participating centre
Chulaimbo Hospital
Kisumu County
Kenya
-

Study participating centre
Matayos
Busia County
Kenya
-

Study participating centre
Port Victoria
Busia County
Kenya
-

Sponsor information

Organisation
Karolinska Institute (Sweden)

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Sponsor type
University/education

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Research council

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/07/2016		Yes	No
Statistical Analysis Plan	version v1	21/03/2020	23/03/2020	No	No

Results article	22/11/2021	24/11/2021	Yes	No
Results article	09/06/2023	12/06/2023	Yes	No