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Evaluating SMS to promote retention in and adherence to ART programs

Submission date
07/03/2016

Recruitment status
No longer recruiting

Registration date
09/03/2016

Overall study status
Completed

Last Edited
24/08/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The rapid uptake of mobile phones across the developing world in recent years has inspired a host of innovative concepts for how they may be used to promote public health, including encouraging people to adopt healthy behaviours and help with delivering health services. Yet, to date, few rigorous evaluations have been done to see how good these “mobile health” (mHealth) programmes (or interventions) really are. This study will look at whether a short message service (SMS) reminder system can be used to support HIV/AIDS patients in Burkina Faso. In the midst of the country’s push to escalate access to antiretroviral therapy (ART), the fact that many people do not continue with their treatment program long term has been identified as a concern. This is a two year study using SMS texts to follow-up on patients and encourage them to stick with their treatment programme. Testing how well the SMS intervention works will be tested as part of the study.

Who can participate?
Patients with HIV and currently being treated with antiretroviral. They should be at least 15 years old and have reliable access to a mobile phone.

What does the study involve?
Participants are randomly allocated to one of five different groups. Those in group 1 are placed in the control group and do not receive any SMS texts. Those in group 2 are placed in the “treatment 1” group, and receive one SMS text a week. Those in group 3 are placed in the “treatment 2” group, and receive two SMS text a week. Those in group 4 are placed in the “treatment 3” group, and receive one SMS text and one ASCII image a week. Those in group 5 are placed in the “treatment 4” group, and receive one ASCII image a week. The messages received by all participants remind them to take their antiretroviral medications and refill their prescriptions and their content varies every week. All participants receive their usual standard of care throughout the study period. Support to help them stick with the treatment and additional counselling sessions may also be offered in the community. They are assessed using surveys and via their medical records at the start of the study, after 2 months, after 6 months and finally, after 1 year.

What are the possible benefits and risks of participating?
Benefits of participating include the patients being reminded of taking treatment and being provided with a form of long-distance psycho-social support. Possible risks include the patient stopping their treatment as soon as they stop receiving the reminder messages. There is also the risk of other people being able to take a participants mobile phone and scroll through it, revealing their HIV+ status.

Where is the study run from?
A number of hospitals in Burkina Faso.

When is the study starting and how long is it expected to run for?
November 2014 to November 2017

Who is funding the study?
The 3ie-International Impact Evaluation Initiative and Institute of Social Studies, Erasmus University Rotterdam.

Who is the main contact?
1. Professor Arjun Bedi (public)
2. Dr Natascha Wagner (scientific)

Study website
www.iss.nl/sms-hivremindersystem

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
QW4/1218

Study information

Scientific Title
Evaluating SMS to promote retention in and adherence to ART programs: a multi-center randomized controlled trial

Acronym
sms-hiv-bf

Study objectives
1. Do SMS reminders promote retention in HIV treatment programs and encourage adherence to antiretroviral regimens?
2. Are health outcomes improved as patients receive SMS reminders?
3. Are subjective health outcomes improved as patients receive SMS reminders?
4. Can message fatigue be observed in the medium to long-term?
5. Do the type (text versus picture) and the frequency (once a week versus twice a week) of the SMS have a differential impact?
6. Are patients receiving the SMS messages more likely to work?
7. Have patients receiving the messages a better nutritional status?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ministry of Health, Ministry of Scientific Research and Innovation, Ethics Committee for Health-Related Research, 03/12/2014, ref: 2014-12-141

Study design
Multi-center randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
http://www.iss.nl/fileadmin/ASSETS/iss/Documents/Research_and_projects/EDEM/Burkina_Faso/SMS_to_support_HIVAIDS_patients.pdf

Health condition(s) or problem(s) studied
HIV (human immunodeficiency virus)

Interventions
Participants are randomly allocated to one of five treatments:

Treatment 0: Control group
Treatment 1: SMS text with varying content, low frequency, one message per week
Treatment 2: SMS text with varying content, high frequency, two messages per week
Treatment 3: SMS text with varying content and ASCII image, two messages per week
Treatment 4: ASCII image, low frequency, one message per week

All groups will receive the standard of care. Along with periodic clinical check-ups and treatment counseling, this includes routine monitoring of patient CD4 cells and viral load as measures of disease progression. Adherence support and/or additional treatment counseling may also be provided at the community level. This will be assessed during follow-up surveys.

For groups 1-4, messages will be sent on a weekly basis. A total of 4-8 monthly text messages will thus be sent to each participant assigned to groups 1-4.

Intervention Type
Other

Primary outcome measure
1. CD4 count, BMI: Retrieved from patient medical records and measured by the health personnel, measured at baseline (February-April 2015) and in all three follow-up surveys (April-May 2016, October-December 2016, October-December 2017)
2. Subjective wellbeing: Survey responses from patients (1-5 Likert scale), recorded by enumerators, who are part of HIV support associations; measured at baseline (February-April 2015) and in all three follow-up surveys (April-May 2016, October-December 2016, October-December 2017)
3. Pill taking: Survey responses from patients, recorded by enumerators, who are part of HIV support associations; measured at baseline (February-April 2015) and in all three follow-up surveys (April-May 2016, October-December 2016, October-December 2017)
4. For patients that are lost to follow up we identify the reason based on administrative data. This happens at any point in time and will be used to assess retention

Secondary outcome measures

1. Weekly monitoring data from the SMS platform is collected electronically staring from October 2015. This information allows us to assess whether all patients received the SMS messages
2. Whether a patient worked during the last month, how many days and the amount of pay : Survey responses from patients, recorded by enumerators, who are part of HIV support associations; measured at baseline (February-April 2015) and in all three follow-up surveys (April-May 2016, October-December 2016, October-December 2017)
3. Consumption module with detailed list of foods consumed in Burkina: Survey responses from patients, recorded by enumerators, who are part of HIV support associations; measured at baseline (February-April 2015) and in the second follow-up survey (October-December 2016)

Overall study start date
25/11/2014

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. The patient must provide his/her informed consent to participate in the study
2. The patient must be at least 15 years
3. The patient must have reliable access to a mobile phone

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3800

Key exclusion criteria
1. No informed consent provided
2. Patient only makes use of the services of the health center once

Date of first enrolment
01/02/2015

Date of final enrolment
26/05/2015

Locations

Countries of recruitment

Burkina Faso

Study participating centre
Dédougou Regional Hospital (Centre Hospitalier Régional Dédougou)
Dédougou
Burkina Faso
-

Study participating centre
Boromo Medical Center (Centre Médical Boromo)
Boromo
Burkina Faso
-

Study participating centre
Nouna Medical Center (Centre Médical Nouna)
Nouna
Burkina Faso
-

Study participating centre
Solenzo Medical Center (Centre Médical Solenzo)
Solenzo
Burkina Faso
-

Study participating centre
Toma Medical Center (Centre Médical Toma)
Toma
Burkina Faso
-

Study participating centre
Tougan Medical Center (Centre Médical Tougan)
Tougan
Burkina Faso
-

Study participating centre
University Medical Center Banfora (Centre Médical Universitair Banfora)
Banfora
Burkina Faso
-

Study participating centre
Banfora Regional Hospital (Centre Hospitalier Régional Banfora)
Banfora
Burkina Faso
-

Study participating centre
Niangoloko Medical Center (Centre Médical Niangoloko)
Niangoloko
Burkina Faso
-

Study participating centre
Samandin Medical Center (Centre Médical Samandin)
Samandin
Burkina Faso
-

Study participating centre
Oasis Medical Center (Centre Médical Oasis)
Laye
Burkina Faso
-

Study participating centre
Clinique OST
Kadiogo
Burkina Faso
-

Study participating centre

Hope Medical Center and Life / Ouaga(Centre Médical Espoir et Vie/Ouaga)
Ouagadougou
Burkina Faso
-

Study participating centre
30 Medical Center (Centre Médical 30)
Ouagadougou
Burkina Faso
-

Study participating centre
Biomolecular Research Center Pietro Annigoni (Centre de Recherche Biomoléculaire Pietro Annigoni (CERBA))
Ouagadougou
Burkina Faso
-

Study participating centre
Saint Camille Medical Center (Centre Médical Saint Camille)
Saint Camille
Burkina Faso
-

Study participating centre
Pissy Medical Center (Centre Médical Pissy)
Pissy
Burkina Faso
-

Study participating centre
Youth Association for the Promotion of Orphans (Associations des Jeunes pour la Promotion des Orphelins (AJPO))
Ouagadougou
Burkina Faso
-

Study participating centre

URLBS
Ouagadougou
Burkina Faso
-

Study participating centre
Association of African Women Facing AIDS (Association des Femmes Africaines Face au Sida – (AFASI))
Ouagadougou
Burkina Faso
-

Study participating centre
Lamizana Medical Center (Centre Médical Lamizana)
Lamizana
Burkina Faso
-

Study participating centre
Positive Living Medical Center (Centre Médical Vie positive)
Ouagadougou
Burkina Faso
-

Study participating centre
Schiphra Medical Center (Centre Médical Schiphra)
Schiphra
Burkina Faso
-

Study participating centre
Kossodo Medical Center (Centre Médical Kossodo)
Kossodo
Burkina Faso
-

Study participating centre
Paul VI Medical Center (Centre Médical Paul VI)
Ouagadougou

Burkina Faso
-

Study participating centre
Ouargaye Medical Center (Centre Médical Ouargaye)
Ouargaye
Burkina Faso
-

Study participating centre
Tenkodogo Regional Hospital (Centre Hospitalier Régional Tenkodogo)
Tenkodogo
Burkina Faso
-

Study participating centre
Garango Medical Center (Centre Médical Garango)
Garango
Burkina Faso
-

Study participating centre
Koupela Medical Center (Centre Médical Koupela)
Koupela
Burkina Faso
-

Study participating centre
Zabré Medical Center (Centre Médical Zabré)
Zabré
Burkina Faso
-

Study participating centre
Tenkodogo Medical Center (Centre Médical Tenkodogo)
Tenkodogo
Burkina Faso
-

Study participating centre
Bittou Medical Center (Centre Médical Bittou)
Bittou
Burkina Faso
-

Study participating centre
Pouytenga Medical Center (Centre Médical Pouytenga)
Pouytenga
Burkina Faso
-

Study participating centre
Kaya Regional Hospital (Centre Hospitalier Régional Kaya)
Kaya
Burkina Faso
-

Study participating centre
Kongoussi Medical Center (Centre Médical Kongoussi)
Kongoussi
Burkina Faso
-

Study participating centre
Kaya Medical Center (Centre Médical Kaya)
Kaya
Burkina Faso
-

Study participating centre
Bam District Medical Centre (Centre Médical District Bam)
Bam
Burkina Faso
-

Study participating centre

Boulsa Medical Center (Centre Médical Boulsa)
Boulsa
Burkina Faso
-

Study participating centre
Barsalogho Medical Center (Centre Médical Barsalogho)
Barsalogho
Burkina Faso
-

Study participating centre
Sapouy Medical Center (Centre Médical Sapouy)
Sapouy
Burkina Faso
-

Study participating centre
Réo Medical Center (Centre Médical Réo)
Réo
Burkina Faso
-

Study participating centre
Koudougou Regional Hospital (Centre Hospitalier Régional Koudougou)
Koudougou
Burkina Faso
-

Study participating centre
Kolbe Sabou Medical Center (Centre Médical Kolbe Sabou)
Sabou
Burkina Faso
-

Study participating centre

Leo Medical Center (Centre Médical Léo)
Léo
Burkina Faso
-

Study participating centre
Pô Medical Center (Centre Médical Pô)
Pô
Burkina Faso
-

Study participating centre
Kombissiri Medical Center (Centre Médical Kombissiri)
Kombissiri
Burkina Faso
-

Study participating centre
Centre Médical Manga
Manga
Burkina Faso
-

Study participating centre
Saponé Medical Center (Centre Médical Saponé)
Saponé
Burkina Faso
-

Study participating centre
Fada Regional Hospital (Centre Hospitalier Régional Fada)
Fada
Burkina Faso
-

Study participating centre

Bogandé Medical Center (Centre Médical Bogandé)
Bogandé
Burkina Faso
-

Study participating centre
Diapaga Medical Center (Centre Médical Diapaga)
Diapaga
Burkina Faso
-

Study participating centre
Manni Medical Center (Centre Médical Manni)
Manni
Burkina Faso
-

Study participating centre
Pama Medical Center (Centre Médical Pama)
Pama
Burkina Faso
-

Study participating centre
Day hospital (Hôpital de Jour)
Bobo-Dioulasso
Burkina Faso
-

Study participating centre
Dafra Medical Center (Centre Médical Dafra)
Dafra
Burkina Faso
-

Study participating centre

OST Bobo
Bobo-Dioulasso
Burkina Faso
-

Study participating centre
Hope Medical Center and Life / Bobo (Centre Médical Espoir et Vie/Bobo)
Bobo-Dioulasso
Burkina Faso
-

Study participating centre
Dô Medical Center (Centre Médical Dô)
Dô
Burkina Faso
-

Study participating centre
Medical Center REVS+ (Centre Médical REVS+)
Bobo-Dioulasso
Burkina Faso
-

Study participating centre
Yèrêlon Medical Center (Centre Médical Yerelon)
Yer
Burkina Faso
-

Study participating centre
Houndé Medical Center (Centre Médical Houndé)
Houndé
Burkina Faso
-

Study participating centre

Orodara Medical Center (Centre Médical Orodara)
Orodara
Burkina Faso
-

Study participating centre
Ouahigouya Regional Hospital (Centre Hospitalier Régional Ouahigouya)
Ouahigouya
Burkina Faso
-

Study participating centre
AMIE Medical Center (Centre Médical AMMIE)
Burkina Faso
-

Study participating centre
Gourcy Medical Center (Centre Médical Gourcy)
Gourcy
Burkina Faso
-

Study participating centre
Séguénéga Medical Center (Centre Médical Seguénega)
Seguénega
Burkina Faso
-

Study participating centre
Titao Medical Center (Centre Médical Titao)
Titao
Burkina Faso
-

Study participating centre
Yako Medical Center (Centre Médical Yako)
Yako
Burkina Faso
-

Study participating centre
Boussu Medical Center (Centre Médical Boussé)
Boussé
Burkina Faso
-

Study participating centre
Ziniaré Medical Center (Centre Médical Ziniaré)
Ziniaré
Burkina Faso
-

Study participating centre
Zorgho Medical Center (Centre Médical Zorgho)
Zorgho
Burkina Faso
-

Study participating centre
Dori Regional Hospital (Centre Hospitalier Régional Dori)
Dori
Burkina Faso
-

Study participating centre
Djibo Medical Centre (Centre Médical Djibo)
Djibo
Burkina Faso
-

Study participating centre
Medical Center Gorom-Gorom (Centre Médical Gorom-Gorom)
Gorom-Gorom
Burkina Faso
-

Study participating centre
Sebba Medical Center (Centre Médical Sebba)
Sebba
Burkina Faso
-

Study participating centre
Dano Medical Center (Centre Médical Dano)
Dano
Burkina Faso
-

Study participating centre
Diébougou Medical Center (Centre Médical Diébougou)
Diébougou
Burkina Faso
-

Study participating centre
University Medical Center Gaoua (Centre Médical Universitair Gaoua)
Gaoua
Burkina Faso
-

Study participating centre
Gaoua Regional Hospital (Centre Hospitalier Régional Gaoua)
Gaoua
Burkina Faso
-

Study participating centre
Tiebele Medical Center (Centre Médical Tiebele)
Tiebele
Burkina Faso
-

Sponsor information

Organisation
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Sponsor type
University/education

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ROR
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Organisation
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Sponsor details
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Bobo-Dioulasso
Burkina Faso
-

Sponsor type
University/education

Funder(s)

Funder type
Research organisation

Funder Name
3ie-International Impact Evaluation Initiative

Funder Name
Erasmus Universiteit Rotterdam

Alternative Name(s)
Erasmus University Rotterdam, Erasmus Universiteit, EUR

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
We plan to publish a paper about the determinants of "good" health and wellbeing making use of the baseline information. We hope to have a working paper by August 2016. We further plan to prepare a paper on the impact of the study in the short-run (after 6 months of the intervention) on retention, adherence, health, work capacity. We plan to have this done by November 2016. We plan to have another impact paper on the same outcomes after the second follow up and one after the third follow up. These papers should be available in March 2017 and February 2018. All these paper are intended to be published as scientific publications. In addition, we plan a policy brief accompanying each paper. This one will be shared locally with the partnering hospitals and associations and internationally with practitioners.

Intention to publish date
31/08/2016

Individual participant data (IPD) sharing plan
-

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/08/2016	24/08/2022	Yes	No
Results article		23/05/2022	24/08/2022	Yes	No
Results article		09/01/2020	24/08/2022	Yes	No