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A trial investigating multiple potential interventions for increasing uptake of HIV testing and linkage into care for male partners of pregnant women attending antenatal clinic through HIV self-testing

Submission date
30/03/2016

Recruitment status
No longer recruiting

Registration date
31/03/2016

Overall study status
Completed

Last Edited
17/07/2020

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The human immunodeficiency virus (HIV) is a type of virus known as a retrovirus. HIV attacks and weakens the immune system, making it more difficult for a sufferer to fight infections. It is a highly contagious disease, through bodily fluids such as blood, semen and vaginal fluids. It is particularly common in sub-Saharan Africa and it is especially important that people in these regions are tested for HIV in order to minimise the spread of the disease. Wide roll out of availability of HIV tests has led to increases in numbers of people getting tested and starting on antiretroviral treatment (ART) in sub-Saharan Africa. Despite such remarkable progress, men continue to lag behind in HIV testing, including men in well-established relationships where HIV transmission is still surprisingly high. It is therefore important to investigate techniques to increase the number of men who are tested and can be linked into care (if they have HIV) or HIV prevention for men. The aim of this study is to compare the effectiveness of a range of interventions (programs) to encourage men in relationships to get tested for HIV and to link to a care or prevention service.

Who can participate?
All women attending their first antenatal clinic of a participating health clinic and their male partners.

What does the study involve?
36 clinic days across the three participating clinics are randomly allocated to one of seven groups. After agreeing to take part in the study, women complete a 10 minute interview with a research assistant about the woman's and her partner's personal information and HIV testing. For those attending clinic days in the first group, they are given a personalised invitation letter to give to her partner so that he can use the letter to come to the trial "male friendly clinic" alone or together with her. Those attending clinic days in the second group receive the letter

and at least two self-test kits to give to their partners. Those in the third group receive the letter, self-test kits and a $3 incentive when they link into male friendly clinic. Those in the fourth group receive the letter, self-test kits and a $10 incentive when they link into male friendly clinic. Those in the fifth group receive the letter, self-test kits and are entered into a lottery with a 10% chance of winning $30 when they link into male friendly clinic. Those in the sixth group receive the letter, self-test kits and are followed up with a phone call to remind them to use the rests and link into male friendly clinic. Those in the final group receive two self-test kits to deliver to their male partner, a as a phone call reminder the next day and five days later. When the women in all groups return for their next appointment four weeks later, they are interviewed to find out whether they faced any problems and whether or not her partner tested and linked to the "male friendly clinic".

What are the possible benefits and risks of participating?
Male participants who attend the "male friendly clinic" will benefit from receiving care or prevention services. There are no direct risks to participating in the study except that some participants may be uncomfortable with some of the questions that will be asked.

Where is the study run from?
Three primary health clinics in urban Blantyre (Malawi)

When is the study starting and how long is it expected to run for?
March 2016 to June 2017

Who is funding the study?
Wellcome Trust (UK) (Grant number: 105828/Z/14/Z)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Investigating interventions to increase uptake of HIV testing and linkage into care or prevention for male partners of pregnant women in antenatal clinics in Blantyre, Malawi: an adaptive Phase II multi-arm multi-stage cluster randomised trial

Acronym
Partner-provided self-testing and linkage (PASTAL)

Study objectives
What are the most promising candidate interventions for increasing uptake of HIV testing and linkage into care or prevention for partners of pregnant women attending antenatal clinics?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London School of Hygiene & Tropical Medicine Ethics Committee, 10/06/2016

Study design
Phase II adaptive multi-arm multi-stage cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
HIV

Interventions
36 clinic days will be randomised in blocks of different sizes to any of the six trial arms in stage 1 of the trial. All three clinic days available in one day will be per-identified before the randomisation such that the arm recruiting at a particular clinic on particular day will be known within the randomisation sequence.

Control arm: Women receive a letter addressed to their male partners.

Intervention arm 1: Women receive a letter and self-test kits to deliver to their male partners.

Intervention arm 2: Women receive a letter and self-test kits to deliver to their male partners who will get an incentive of $3 when they link into male friendly clinic and receive HIV care or HIV prevention services.

Intervention arm 3: Women receive a letter and self-test kits to deliver to their male partners who will get an incentive of $10 when they link into male friendly clinic and receive HIV care or HIV prevention services.

Intervention arm 4: Women receive a letter and self-test kits to deliver to their male partners who will be entered into a lottery with a 10% chance of winning $30 when they link into male friendly clinic and receive HIV care or HIV prevention services.

Intervention arm 5: Women receive a letter and self-test kits to deliver to their male partners who will receive a phone call to remind them to test and link into male friendly clinic to receive HIV care or HIV prevention services.

Intervention arm 6: Women receive two self-test kits to deliver to their male partner. A phone call reminder to self-test and link into care or prevention will be made to the male partner next day and after 5 days.

Participants in all groups are interviewed at their next appointment to determine the amount of male partners who used the self-test its and went to the male friendly clinic.

Intervention Type
Behavioural

Primary outcome measure
Proportion of male partners who test for HIV and link into care or prevention within 28 days is determined by the male partner undergoing HIV testing and receiving HIV care or prevention.

Secondary outcome measures
1. Proportion of women who participate in their allocated study arm is determined by face-to-face questionnaire at baseline.
2. Proportion of male partners who test for HIV within 28 days is determined by the male partner undergoing HIV testing
3. Cumulative incidence of intimate partner violence associated with each study arm is determined by audio computer assisted self-interview with women at 28 days
4. Total cost of implementing the service per study arm is determined by a costing questionnaire

Overall study start date
01/03/2016

Completion date
01/06/2017

Eligibility

Key inclusion criteria
All women attending antenatal clinic for the first time at Ndirande PHC in urban Blantyre and their male partners

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
120 women and 120 men per arm in stage 1. Numbers for stage 2 will be determined at interim analysis.

Key exclusion criteria
1. Have had couple or partner testing in this pregnancy
2. Under 18 years of age
3. The man is already aware of their HIV positive status and receiving treatment
4. Subsequent ANC visit
5. Already recruited in this trial
6. Not urban Blantyre resident

Date of first enrolment
01/06/2016

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
Malawi

Study participating centre
Ndirande Primary Health Centre
Ndirande
Blantyre

Malawi
265

Study participating centre
Zingwangwa Primary Health Centre
Soche East
Blantyre
Malawi
265

Study participating centre
Bangwe Health Primary Centre
Limbe
Malawi
265

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

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Sponsor type
University/education

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be disseminated to HIV Unit in Malawi Ministry of Health, College of Medicine in Blantyre, and through conference presentations and publication in a peer-reviewed journal.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan

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?
Results article	results	26/06/2017		Yes	No
Protocol article	protocol	24/07/2017		Yes	No
Results article	results	02/01/2019		Yes	No
Results article	qualitative results	01/03/2019	17/07/2020	Yes	No