

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	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
30/03/2016	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
31/03/2016	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
17/07/2020	Infections and Infestations	

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

Protocol serial number

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

Study type(s)

Other

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 pre-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 kits and went to the male friendly clinic.

Intervention Type

Behavioural

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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Study participating centre

Bangwe Health Primary Centre

Limbe

Malawi
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Sponsor information

Organisation

London School of Hygiene & Tropical Medicine

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

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

<u>Results article</u>	results	02/01/2019	Yes	No
<u>Results article</u>	qualitative results	01/03/2019	17/07/2020	Yes
<u>Protocol article</u>	protocol	24/07/2017	Yes	No
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No