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Evaluation of serial self-testing supported contact tracing for COVID-19 in Brazil

Submission date
06/10/2022

Recruitment status
No longer recruiting

Registration date
11/10/2022

Overall study status
Completed

Last Edited
07/05/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and Study Aims
Equitable access to quality, affordable diagnostics for COVID-19 is critical to health systems' abilities to identify infections early, isolate cases of active infection, and provide effective case management. Self-testing for COVID-19 may reduce the demand on health facilities while addressing many of the usual barriers to uptake of services, leading to timely testing of infectious individuals. It can also enable earlier diagnosis, which may affect peoples' behavior to minimize onward transmission and seek earlier clinical intervention, improving outcomes. Self-testing has been shown to be accurate with minimal user errors with the potential to increase equity by providing more testing options. However, many questions must be answered before a recommendation can be made for widespread implementation of this testing modality. This study aims to generate evidence about integrating self-testing into public health system programs and strategies, including evaluating the operational feasibility of using self-tests within the public health contact tracing system, evaluating the concordance of supervised self-tests with professionally-administered tests, and exploring barriers and facilitators patients and healthcare providers face when using self-tests for COVID-19.

Who can participate?
People aged 7 or older living in Porto Velho or Curitiba and testing positive for COVID-19 may enroll in the study. People aged 7 or older living in Porto Velho or Curitiba who have had close contact with someone testing positive for COVID-19 may enroll in the study.

What does the study involve?
Patients testing positive for COVID-19 will complete a contact elicitation interview. Contacts will be invited to participate in the study and randomized to intervention or control. Participants in the control group will complete a daily questionnaire for 10 days. Participants in the intervention group will perform a self-test daily and complete a daily questionnaire for 10 days.

What are the possible benefits and risks of participating?
The study does not pose any significant risk to participants beyond potential pain, discomfort, or nosebleed associated with a nasal swab. There is a risk participant information may become

known to someone outside the study team, though all efforts are made to maintain confidentiality and data security. Participants in this study may benefit from convenient access to COVID-19 testing following an exposure.

Where is the study run from?
The primary enrollment center is CEPEM in Porto Velho, Rondonia, Brazil. PATH is headquartered in Seattle, Washington, USA.

When is the study starting and how long is it expected to run for?
December 2021 to July 2023

Who is funding the study?
PATH (USA) is sponsoring the study under an award from Unitaid (Switzerland)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
1889025-1

Study information

Scientific Title
Integration of serial self-testing into public health contact tracing programs: a pragmatic trial to assess the operational feasibility and impact of COVID-19 self-testing among exposed individuals in Brazil

Study objectives
Contact-tracing facilitated by serial self-testing identifies more positive COVID-19 cases among exposed close contacts than standard contact tracing over an approximately six-month period in Porto Velho, Brazil and Curitiba, Brazil.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/07/2022, The National Commission for Research Ethics (SRTV 701, Via W 5 Norte, lote D -Edifício PO 700, 3º andar –Asa Norte Brasília, Brazil; +55 (61) 3315-2951; conep@saude.gov.br), ref: 59179922.9.1001.0011
2. Approved 06/09/2022, World Health Organization Ethics Committee (Avenue Appia 201211 Geneva, Switzerland; +41 22 791 21 11; no email provided), ref: CERC.0167

Study design
Multicenter two-arm 1:1 randomized pragmatic trial of a COVID-19 contact tracing program with and without serial self-testing

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The intervention will use SARS-CoV-2 antigen rapid diagnostic tests (Ag-RDT) approved for self-testing by ANVISA in Brazil at the time of study start. Close contacts of confirmed positive cases of COVID-19 will be freely offered up to 10 self-tests and their use will be monitored through remote data collection.

Close contacts will be randomized 1:1 within each site to intervention or control by index case using a sealed envelope.
Arm 1 (Control) will proceed with contact tracing per standard practices, receiving a

professionally-administered COVID-19 Ag-RDT following their notification of exposure. They will be followed up for 10 days and asked to complete a short survey each day.
In addition to completing a supervised self-test and receiving a professionally-administered COVID-19 Ag-RDT following their notification of exposure, Arm 2 (Intervention) will receive 10 self-tests to self-administer for 10 days of follow up and asked to complete a short survey each day. Arm 2 participants will also be given up to 3 additional self-tests per household member to give to each household member (considered secondary exposures) to use as they see fit. Secondary exposures may opt to anonymously complete a short survey each time they use a self-test. Index cases may be considered an additional arm of this study; after completing the contact elicitation interview, index cases will be followed up for 10 days and asked to complete a short survey each day.

Intervention Type
Behavioural

Primary outcome(s)
Proportion of primary exposure close contacts who test positive per index case measured using COVID-19 Ag-RDT result reported on daily follow-up questionnaire Days 1-10. Self-reported COVID-19 self-test result reporting to a public health authority on daily follow-up questionnaire Days 1-10. Use of COVID-19 self-test by secondary exposures reported on optional anonymous survey upon use of self-test. Number of critical errors incurred during supervised self-test, measured per manufacturer instructions for use at baseline visit. Supervised self-test result and professionally-administered self-test result at baseline visit.

Key secondary outcome(s))
Measured as per the primary outcome measure:
1. Proportion of Ag-RDT positive contacts per index case who report adhering to recommended treatment, quarantine, or isolation guidelines at the time study is running
2. Proportion of exposed contacts in the self-testing group (Arm 2) who report test results as per local guidelines
3. Number of self-tests used by individuals with secondary exposures
4. Proportion of exposed contacts who perform a self-test per manufacturer instructions without critical errors, under supervision
5. Concordance of self-test result with professional use Ag-RDT test result

Completion date
14/07/2023

Eligibility

Key inclusion criteria
1. Participants will be confirmed COVID-19 cases (index cases) and their associated close contacts.
2. Index cases will be 7 years of age or older.
3. Primary exposure close contacts will be enrolled in the main study, including children aged 7 and older.
4. Secondary exposure close contacts (household members of primary exposure close contacts enrolled in Arm 2) will be given self-tests to use in the observational sub-study.
5. A subset of patients/primary exposure close contacts, caregivers of primary exposure close

contacts, health unit workers, and other key stakeholders will also have the option of participating in a usability workshop and/or focus group discussions. These participants will be aged 18 years and older

Participant type(s)
All

Healthy volunteers allowed
No

Age group
All

Lower age limit
7 years

Sex
All

Total final enrolment
793

Key exclusion criteria
1. Study site employee who is involved in the protocol and may have access to study-related data
2. Inappropriate to enroll
3. Previous study participant
4. Contraindication to nasal swab

Date of first enrolment
05/12/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Brazil

Study participating centre
Centro de Pesquisa em Medicina Tropical de Rondônia (CEPEM)
Avenida Guaporé
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Porto Velho
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76812-329

Study participating centre
Fiocruz Paraná
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Sponsor information

Organisation
PATH

Funder(s)

Funder type
Charity

Funder Name
PATH

Alternative Name(s)
Program for Appropriate Technology in Health, Program for the Introduction and Adaptation of Contraceptive Technology

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
United States of America

Funder Name
Unitaid

Results and Publications

Individual participant data (IPD) sharing plan

Current IPD sharing plan as of 17/04/2024:
The dataset analysed during the current study will be published and stored in a publicly available repository (Infectious Diseases Data Observatory). Data may be accessed by applying to the Data Access Committee (https://www.iddo.org/covid19/data-sharing/accessing-data). The type of data stored is tabular demographic and follow-up data related to the intervention, consisting of continuous and categorical variables, such as age, gender, education level, professional COVID test result, COVID self-test result, masking and isolation behavior. The timing for availability is when these data have been submitted and undergone curation by the IDDO team. Consent from participants was obtained as stated in the protocol and these data were deidentified before submission in the repository.

Previous IPD sharing plan:
De-identified data used in published analyses will be made available in accordance with open-access data and journal policies. Additional details regarding data sharing will be made available at a later date.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/10/2023	05/10/2023	Yes	No
Basic results			07/05/2024	No	No
Protocol file	version 1.0	31/08/2022	11/10/2022	No	No
Statistical Analysis Plan	version 1.1	01/10/2023	14/11/2023	No	No