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Determining trustworthiness and safety of remote consulting during the COVID-19 pandemic in primary healthcare for chronic disease populations in Nigeria and Tanzania

Submission date
09/12/2020

Recruitment status
No longer recruiting

Registration date
20/01/2021

Overall study status
Completed

Last Edited
20/10/2023

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
During the COVID-19 pandemic, face-to-face healthcare appointments put health workers and their patients at risk. Patients are reluctant to attend clinics for management of chronic diseases, for example, to collect medicines, which may harm their health. Remote healthcare, by phone or Internet, is advised by the World Health Organisation. This is difficult in Nigeria and Tanzania due to limited digital infrastructure, so the study team have developed a training programme for health workers called REaCH. REaCH enables health workers to deliver trusted and safe care using the phone and limited internet availability.

This study will look in particular at patients with type 2 diabetes, hypertension, Chronic Obstructive Pulmonary Disease (COPD), and/or coronary heart disease who typically require contact with health facilities several times per year. These conditions are common and patients are vulnerable to poor outcomes from communicable diseases.

REaCH training aims to increase the number of appointments held by phone for patients with long-term conditions. The study team want to test whether these remote appointments are as acceptable, safe, and trustworthy as face-to-face appointments. It is hoped that the programme will strengthen health care across Africa following REaCH training, that health workers and patients will be protected from COVID-19, and that stronger scientific research teams will be developed in Nigeria.

Who can participate?
Adult patients receiving healthcare for type 2 diabetes, hypertension, COPD, and/or coronary heart disease from participating care facilities.

What does the study involve?
This study will involve 20 health clinics in both Nigeria and Tanzania and train healthcare workers in remote consulting in two of the clinics a month for ten months. The study team will collect

monthly information on appointment types and the number of prescriptions and investigations given by each clinic. Ten to 15 patients in each clinic per month will be asked to complete questionnaires about their trust in their healthcare provider, and the knowledge, beliefs, and skills that enable them to manage their long-term condition.

What are the possible benefits and risks of participating?
There are no direct benefits for the patients taking part, except knowing they are potentially helping future patients.

There are no expected risks associated with participation in this study. If any of the participants become upset or distressed during the interview sessions they will be offered time out of the interview and then they may carry on or stop the interview completely. In addition, the services of a counsellor will be made available at no cost to the participants should their services be needed.

Where is the study run from?
Ibadan Clinical Trials Unit, University of Ibadan (Nigeria)

When is the study starting and how long is it expected to run for?
From August 2020 to March 2022

Who is funding the study?
The UK Research and Innovation (UKRI) Collective Fund comprising the UKRI (UK), the Global Challenges Research Fund (GCRF) (UK), and the Newton Fund. (UK)

Who is the main contact?
Ms Rebecca Rogers
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Contact information

Type(s)
Scientific

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Prof Jackie Sturt

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Grant Ref: EP/V028936/1

Study information

Scientific Title
COVID-19: Determining trustworthiness and safety of REmote Consulting in primary Healthcare for chronic disease populations in Nigeria and Tanzania using a stepped wedge design - The REaCH Trial

Acronym
REaCH

Study objectives
REaCH training will increase the rate of remote consulting. This remote consulting will not affect patient trust in, and the safety of, primary care consultations for long-term conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2020, King's College London Research Ethics Board (King's College London, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London SE1 9NH; +44 (0)20 7848 4020/4070/4077; rec@kcl.ac.uk) ref: HR-20/21-21006

Study design
Multi-centre international stepped-wedge cluster randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic disease, type 2 diabetes, hypertension, chronic obstructive pulmonary disease, coronary heart disease

Interventions
Current intervention as of 12/06/2023:
The intervention involves REaCH training for healthcare workers to deliver remote consulting via mobile phone to patients and will be compared to care as usual. The study will take place in Nigeria (urban/MIC/West Africa) and Tanzania (rural/LIC/East Africa). In each country, 20 primary care facility clusters (each cluster is made up of one or more clinic/facility, which between them has ≥10 healthcare workers) will be recruited. Tier 1 trainees are healthcare workers with a higher diploma or degree who speak, read and write in English; Tier 2 trainees are other cadres e. g. community health workers, pharmacy assistants, and medical assistants who may communicate in English or in local languages. The tier 1 and tier 2 trainees work as a team within the facility. Health workers will be in the trial for between one and six months depending upon when they receive REaCH training and whether they take part in the process evaluation.

At the beginning of the intervention, all clusters are randomised into groups of two (a sequence) and allocated a monthly timeslot to receive REaCH training over a ten-month period. This will be done by generating a random number for each cluster and then clusters assigned to each sequence in ascending order of the generated number. The randomisation will be conducted by the trial statistician who will be blinded to cluster name. The intervention implementers and clinics will not be blinded to allocation sequence as this is impractical given the need to plan and prepare training. In each local trial delivery team, one investigator and 1 research assistant will remain blinded to the month during which REaCH training was delivered to each cluster. Each facility is given a unique identification number consisting of 4 digits. 4 digit numbers are used to make it more difficult for the research team to recall cluster IDs when discussing with the unblinded education team. This will reduce bias when monthly data collection is undertaken. When education and research teams meet together, clusters will be referred to by identification number only. At the beginning of every data collection activity the researcher will remind the health worker or patient participant not to reveal whether the facility has undertaken REaCH training. Data entry will be undertaken by a database assistant who will be blinded to whether the data is from a cluster in the intervention or the control. At the bi-weekly trial team meetings, there will be an agenda item to check with every blinded member whether they think they have been unblinded in relation to the identity of a randomised cluster during the previous two weeks. All UK investigators will be blind to cluster randomisation except the Birmingham trial statistician.

Data from the Open Cohort dataset are taken at the first of the month from all Clusters both before and after they have received their individual randomised monthly training. The training goes on for 10 months, from month 1 to month 11, but data will be gathered from month 0 through month 12 following the stepped wedge design.

Thirty participants are randomly sampled from each Cluster every month with the expectation that twenty of these will give informed consent to take part in the structured interviews (approximately 60 min duration) and undertake the questionnaires (10-15 participants in each cluster, 20-30 participants in each sequence, and therefore 200-300 participants each month in each country). Patient participants will remain in the trial for the time it takes to complete two questionnaires (which are estimates to take less than 60 minutes). If they offer consent to be interviewed they will remain in the study for a further six weeks from the point of conducting the survey to give sufficient time for the sampling framework to be consulted and an interview to be set up and completed.

The Physician Humanistic Behaviour Questionnaire (PHBQ) will be used to determine patient trust in healthcare providers as it assesses the degree to which healthcare providers communicate humanistically with their patients. Humanistic communications engender trust between the patient and the healthcare worker. The PHBQ has face and content validity with patients and health workers for assessing these behaviours during remote consultations. The Patient Activation Measure (PAM-13) will be used to determine patient engagement with their health as this questionnaire aims to understand the knowledge, beliefs and skills required by people to enable them to manage their long-term conditions. It has been successfully used in African populations. Previous research found that patient activation increases with remote consulting and that the PAM-13 has face and content validity for assessing the impact of remote consulting.

The data from each trial will be analysed using a generalised linear mixed model framework standard for stepped-wedge cluster designs. Data from each time point will be considered a repeated cross-section given the difficulty linking observations between patients in different time periods. The primary outcomes are of two types: count data (the number of consultations by mode of delivery and the number of prescriptions) and a continuous score (the patient trust outcome).

Previous intervention:
The intervention involves REaCH training for healthcare workers to deliver remote consulting via mobile phone to patients and will be compared to care as usual. The study will take place in Nigeria (urban/MIC/West Africa) and Tanzania (rural/LIC/East Africa). In each country, 20 primary care facility clusters (each cluster is made up of one or more clinic/facility, which between them has ≥10 healthcare workers) will be recruited. Tier 1 trainees are healthcare workers with a higher diploma or degree who speak, read and write in English; Tier 2 trainees are other cadres e. g. community health workers, pharmacy assistants, and medical assistants who may communicate in English or in local languages. The tier 1 and tier 2 trainees work as a team within the facility. Health workers will be in the trial for between one and six months depending upon when they receive REaCH training and whether they take part in the process evaluation.

At the beginning of the intervention, all clusters are randomised into groups of two (a sequence) and allocated a monthly timeslot to receive REaCH training over a ten-month period. This will be done by generating a random number for each cluster and then clusters assigned to each sequence in ascending order of the generated number. The randomisation will be conducted by the trial statistician who will be blinded to cluster name. The intervention implementers and clinics will not be blinded to allocation sequence as this is impractical given the need to plan and prepare training. In each local trial delivery team, one investigator and 1 research assistant will remain blinded to the month during which REaCH training was delivered to each cluster. Each facility is given a unique identification number consisting of 4 digits. 4 digit numbers are used to make it more difficult for the research team to recall cluster IDs when discussing with the

unblinded education team. This will reduce bias when monthly data collection is undertaken. When education and research teams meet together, clusters will be referred to by identification number only. At the beginning of every data collection activity the researcher will remind the health worker or patient participant not to reveal whether the facility has undertaken REaCH training. Data entry will be undertaken by a database assistant who will be blinded to whether the data is from a cluster in the intervention or the control. At the bi-weekly trial team meetings, there will be an agenda item to check with every blinded member whether they think they have been unblinded in relation to the identity of a randomised cluster during the previous two weeks. All UK investigators will be blind to cluster randomisation except the Birmingham trial statistician.

Data from the Open Cohort dataset are taken at the first of the month from all Clusters both before and after they have received their individual randomised monthly training. The training goes on for 10 months, from month 1 to month 11, but data will be gathered from month 0 through month 12 following the stepped wedge design.

Thirty participants are randomly sampled from each Cluster every month with the expectation that twenty of these will give informed consent to take part in the structured interviews (approximately 60 min duration) and undertake the questionnaires (20 participants in each cluster, 40 participants in each sequence, and therefore 400 participants each month in each country). Patient participants will remain in the trial for the time it takes to complete two questionnaires (which are estimates to take less than 60 minutes). If they offer consent to be interviewed they will remain in the study for a further six weeks from the point of conducting the survey to give sufficient time for the sampling framework to be consulted and an interview to be set up and completed.

The Physician Humanistic Behaviour Questionnaire (PHBQ) will be used to determine patient trust in healthcare providers as it assesses the degree to which healthcare providers communicate humanistically with their patients. Humanistic communications engender trust between the patient and the healthcare worker. The PHBQ has face and content validity with patients and health workers for assessing these behaviours during remote consultations. The Patient Activation Measure (PAM-13) will be used to determine patient engagement with their health as this questionnaire aims to understand the knowledge, beliefs and skills required by people to enable them to manage their long-term conditions. It has been successfully used in African populations. Previous research found that patient activation increases with remote consulting and that the PAM-13 has face and content validity for assessing the impact of remote consulting.

The data from each trial will be analysed using a generalised linear mixed model framework standard for stepped-wedge cluster designs. Data from each time point will be considered a repeated cross-section given the difficulty linking observations between patients in different time periods. The primary outcomes are of two types: count data (the number of consultations by mode of delivery and the number of prescriptions) and a continuous score (the patient trust outcome).

Intervention Type
Behavioural

Primary outcome(s)
1. Patient trust in healthcare provider measured using the Physician Humanistic Behaviour Questionnaire (PHBQ) at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months

2. Face to face consultation rate defined as the number of visits per month for the eligible patient population where the patient is seen in person by the consulting health worker measured from the open cohort data at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months
3. Remote consultation rate defined as the number of visits per month for the eligible patient population conducted using a telephone measured from the open cohort data at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months
4. Prescribing rate defined as the number of prescriptions issued and collected to the eligible patient population per month. This outcome is a proxy for patient safety as a change in this outcome is an indicator of changes in safety and confidence measured from the open cohort data at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months

Key secondary outcome(s))
1. Patient engagement with their health measured using the Patient Activation Measure (PAM-13) at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months
2. Patient safety assessed from the number of investigations processed by the facility monthly, matched to the patient's consultation type (where an increase may indicate a higher safety threshold when the person cannot be examined, and a decrease may indicate missed health needs) measured from the open cohort data at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Receiving healthcare from participating primary care facilities
2. Able to speak, read and write in English or local language
3. Give consent to participate in the study
4. Aged ≥18 years
5. Receiving treatment and/or monitoring for ≥1 of the following conditions:
5.1. Type 2 diabetes
5.2. Hypertension
5.3. Chronic obstructive pulmonary disease
5.4. Coronary heart disease
6. Contact with health facility ≥3 times per year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
12022

Key exclusion criteria
1. No access to a mobile phone or fixed phone in the community
2. Identified by health workers as nearing the end of life or currently severely ill
3. Carers consulting on another person's behalf
4. Unable to provide informed consent

Date of first enrolment
18/03/2021

Date of final enrolment
13/03/2022

Locations

Countries of recruitment
Nigeria

Tanzania

Study participating centre
College of Medicine, University of Ibadan
University College Hospital Campus
Queen Elizabeth II Road
Oritamefa
Ibadan
Nigeria
-

Study participating centre
St Francis University College of Health and Allied Sciences
Ifakara Health Institute (IHI)
Box 53
Ifakara
Tanzania
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Global Challenges Research Fund

Alternative Name(s)
The Global Challenges Research Fund (GCRF), The Global Challenges Research Fund, GCRF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Newton Fund

Alternative Name(s)
The Newton Fund, NF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 12/06/2023:
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Jackie Sturt, King's College London, Jackie.sturt@kcl.ac.uk, and Professor Akinyinka Omigbodun, University of Ibadan omigbodun@yahoo.com. Trial data are available with immediate effect. Informed consent was obtained from the denominator participants who undertook the surveys and interviews but not from the numerator population as none of their personal data was transferred out of the clinic and so that population represented a minimal risk to the research participants. If we had requested informed consent this would have required the disclosure of contact information to research staff and represented an unnecessary transfer of identifiable data. This is detailed in our protocol v.2 20.08/21 and was approved by our Ethics Committees.
For comments on data anonymization, please see protocol v.2. 20.08.21, Informed consent, pg 4-5; Data management/Data transfer pages 12-13.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Rebecca Rogers, rebecca.e.rogers@kcl.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2023	20/10/2023	Yes	No
Abstract results	Abstracts from the IDF World Diabetes Congress 2022 - 0837	15/03/2023	07/06/2023	No	No
Participant information sheet	version v1	30/10/2020	20/01/2021	No	Yes
Protocol file	version 2	20/08/2021	12/08/2022	No	No
Statistical Analysis Plan			12/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes