DOI:
10.1016/S2214-109X(23)00411-4

Document Version
Publisher's PDF, also known as Version of record

Safety and upscaling of remote consulting for long-term conditions in primary health care in Nigeria and Tanzania (REaCH trials): stepped-wedge trials of training, mobile data allowance, and implementation

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Summary

Background In-person health care poses risks to health workers and patients during pandemics. Remote consultations can mitigate these risks. The REaCH intervention comprised training and mobile data allowance provision for mobile phones to support remotely delivered primary care in Africa compared with no training and mobile data allowance. The aim of this study was to estimate the effects of REaCH among adults with non-communicable diseases on remote and face-to-face consultation rates, patient safety, and trustworthiness of consultations.

Methods In these two independent stepped-wedge cluster randomised controlled trials, we enrolled 20 primary care clusters in each of two settings (Oyo State, Nigeria, and Morogoro Region, Tanzania). Eligible clusters had 100 or more patients with diabetes, hypertension, and cardiovascular or pulmonary disease employing five health workers. Clusters were computer-randomised to one of ten (Nigeria) or one of seven (Tanzania) sequences to receive the REaCH intervention. Only outcome assessors were masked. Primary outcomes were consultation, prescription, and investigation rates, and trustworthiness collected monthly for 12 months (Nigeria) and 9 months (Tanzania) from open cohorts. Ten randomly sampled consulting patients per cluster-month completed patient reported outcome measures. This trial was registered with ISRCTN, ISRCTN17941313.

Findings Overall, 40 clusters comprising 8776 (Nigeria) and 3246 (Tanzania) patients' open cohort data were analysed (6377 [72·7%] of 8776 females in Nigeria, and 2235 [68·9%] of 3246 females in Tanzania). The mean age of the participants was 55·3 years (SD 13·9) in Nigeria and 59·2 years (14·2) in Tanzania. In Nigeria, no evidence of change in face-to-face consulting rate was observed (rate ratio [RR] 1·06, 95% CI 0·98 to 1·09; p=0·16); however, remote consultations increased four-fold (4·44, 1·34 to >10; p=0·01). In Tanzania, face-to-face (0·94, 0·61 to 1·67; p=0·99) and remote consulting rates (1·17, 0·56 to 5·57; p=0·39) were unchanged. There was no evidence of difference in prescribing rates (Nigeria: 1·05, 0·60 to 1·14; p=0·23; Tanzania: 0·92, 0·60 to 1·67; p=0·97), investigation rates (Nigeria: 1·06, 0·23 to 2·12; p=0·49; Tanzania: 1·15, 0·35 to 1·64; 0·58) or trustworthiness scores (Nigeria: mean difference 0·05, 95% CI –0·45 to 0·42; p=0·89; Tanzania: 0·07, –0·15 to 0·76; p=0·70).

Interpretation REaCH can be implemented and could improve intervention versus control health-care access. Remote consultations appear safe and trustworthy, supporting universal health coverage.

Funding The UK Research and Innovation Collective Fund.

Introduction

Around the world, the COVID-19 pandemic necessitated changes in how health care is delivered and received. High-income countries responded by replacing face-to-face health care with remote, virtual, and digital health consultations with urgency in March, 2020.[1] This step was encouraged by WHO for the safety of health-care workforces globally.[2] Alongside, countries are developing strategies towards delivering on universal health coverage commitments.[3] The shortage of devices, digital infrastructures, electronic records, information governance protocols, and a shortage of trained health workforce in most low-income and middle-income countries (LMICs) has restricted their ability to implement mobile consultation. This situation placed fragile health systems, specifically health workers and patients, at risk from COVID-19 and other communicable diseases.[4] People with existing non-communicable diseases were also at risk due to reduced access to health care. The benefits of remote consultations to health workers and patients in the management of multiple long-term conditions has been shown in the UK.[5] Evidence reviews and stakeholder engagement, including three workshops involving 61 decision makers, health workers, and residents in Nigeria and Tanzania,[4,6] indicated a need to build capacity rapidly in LMICs to

Lancet Glob Health 2023; 11: e1753–64

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For the Swahili translation of the abstract see **Online** for appendix 1

For the Yoruba translation of the abstract see **Online** for appendix 2

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Research in context

Evidence before this study

Our pre-trial scoping study of remote consulting in two low-income and middle-income country (LMIC) rural settings (Pakistan and Tanzania) and five urban slums (in Kenya, Nigeria, and Bangladesh) used policy and document reviews alongside secondary analysis of survey data from 5322 urban slum households and thematic analysis of engagements with 424 stakeholders. We found that regulatory frameworks were available in each country and remote consulting services were operating mostly through fee-paying provider platforms. At the primary care level and community level, there were examples of health-care workers using their own phones, often informally, for consultations, mostly for emergencies, advice, and care follow-up. Patients, health workers, and decision makers were highly supportive of remote consulting but identified challenges in technology, infrastructure, data protection, health system integration, and service acceptability. Health workers across all sites requested training in remote consulting. During the trial, we initiated an umbrella review to inform our analysis and interpretation of the evidence. We searched MEDLINE, Embase, Web of Science, and Google Scholar for reviews on remote consulting in LMICs, and WHO evidence reviews, without language restrictions, using terms equivalent to electronic mail, text messaging, social media, internet, video-conferencing, health service, telemedicine, LMIC, and review for articles published from Jan 1, 2020, to May 29, 2022. We found 39 reviews involving remote consulting in at least one LMIC. Despite variability across study outcomes and quality, remote consulting was generally shown to be acceptable to patients and health-care providers to positively support treatment adherence and patient retention, and to enhance patient quality of life. Several reviews showed efficacy of digital health in diabetes and cardiovascular services. No reviews reported directly on patient safety.

Added value of this study

These trials are the first, to our knowledge, to be completed internationally using robust clinical trial methods, investigating the safety of primary health-care delivery incorporating remote consultations. Qualitative studies and systematic reviews published since the COVID-19 pandemic have examined patient and clinician experiences of remote consultations, the different communication dynamics that require management, and areas in which safety can be compromised. The twin foci of these trials on safety relating to possible under prescribing or over prescribing and under investigation or over investigation and trustworthiness are mirrored in the published observational evidence from high-income and middle-income countries. Our trial findings show that remote consultations for non-communicable diseases can, in some contexts, increase a population's access to health care without compromising the pre-existing safety levels associated with face-to-face care only.

Implications of all the available evidence

Remote consultations delivered by trained health workers of all cadres incorporate two important features of quality health care—those relating to safety and to trustworthiness. Remote consultations, underpinned by nationally available training, which standardises these consultations, should be considered as part of a strategy to increase access to health care in LMICs. The funding of mobile data allowance provision on mobile phones and data packages—a known impediment to remote care—needs to be addressed as part of the strategy.

deliver remote health care from local facilities using the existing workforce efficiently and safely. We define use of remote consulting as a person with a perceived health need consulting a health-care provider by mobile phone using either the internet or telecommunications infrastructure and, where needed, use of the phone of a relative or neighbour.[4]

A recent systematic review from 2021 documents a large number of studies appraising the safety of different telemedicine interventions, including remote consulting, but primarily relating to specialist care provision.[7] The assessment of patient safety in primary care delivered through remote consulting in high-income countries has mostly focused on same day consultation requests for more acute health needs.[8] In that context, safety concerns for telephone triage were associated with complex conditions, which led to recommendations for remote consultations to be used for long-term conditions to mitigate safety risks. Paediatric safety risks in remote care have been reported relating to antibiotic over-prescribing.[9] However, prescribing behaviour associated with telemedicine trials and its effect on patient safety in LMIC primary care has not been studied. An increased focus and uptake of mobile communication technology in LMICs has occurred over the past decade. However, women, rural residents, and poorer communities generally have poorer access to resources, mobile phones, the internet, and mobile data allowance, which can exacerbate existing inequalities.[3,10,11]

In response to the global COVID-19 pandemic, which began in April 2020, we adapted our existing evidence-based remote consulting training course towards remotely delivered, self-directed learning, within a remote and rural setting in Tanzania.[4,5] The training course was a pilot evaluated pilot evaluated between May and August, 2020, with 63 health workers in Ifacara, Tanzania, and adaptions were made.[12] However, an evidence gap remained relating to whether training would increase remote consultations and whether resulting remote consultations would be safe, trustworthy, and implementable at scale in LMICs. In this study, we report the results from two stepped wedge randomised controlled trials in which we extended the use of remote consultations within Tanzania and

widened it to Nigeria. We aimed to assess whether: (1) training in remote consulting in primary healthcare (REaCH) and mobile data allowance will increase the rate of remote consulting; (2) it will not reduce the overall consultation rate among patients, and (3) the overall safety and trustworthiness of consultations will not be adversely affected, and whether implementation at scale is feasible.

Methods

Study design and participants

Two independent stepped-wedge cluster randomised controlled trials (appendix 3 p 13) and nested process evaluations were conducted in Nigeria and Tanzania. 35 urban and peri-urban primary health-care facilities in Ibadan, Oyo State, southwest Nigeria, and 21 rural and remote primary health-care facilities in five districts within Morogoro Region, eastern Tanzania were purposively recruited during the pandemic, based on their associations with the Oyo State Health Board (Nigeria) and remote location in Morogoro (Tanzania). The primary health-care facilities in Nigeria were publicly funded, consultations were free, and prescribed drugs were purchased at commercial pharmacy shops. In Tanzania, primary health-care facilities were a combination of public, faith-based, and private, in which, unless they were exempted or insured, were paid for consultations. Patients had to attend the primary health-care facility to collect and pay for prescriptions.

A stepped-wedge cluster randomised controlled trial design was used because staggering of the intervention roll-out was required due to capacity constraints; a likely benefit of the intervention was perceived during the COVID-19 pandemic, and in the stepped wedge design, all clusters receive the intervention; and clusters would likely and more readily participate due to the receipt of the intervention.

Cluster eligibility was one or more health facilities comprising: (1) 100 or more patients who had consulted within the previous 5 months for an eligible condition; (2) paper-based patient records of name, phone number, age, sex (obtained from facility records by a health facility staff who recorded only male or female sex based on the person's appearance), appointments attended and with whom, and pharmacy and investigation records were available; (3) a total of five or more health workers employed with at least one health worker being registered with a professional body (eg, physician or nurse); and (4) at least one facility manager in agreement to all parts of the study including process evaluation. Many clusters were made up of a single primary care facility (seven in Nigeria, 19 in Tanzania) with the remaining clusters comprising of two or three smaller, geographically proximate facilities. Senior investigators enrolled the clusters.

Health worker participation, ensuring male and female participation consistent with the facility profile was determined by the facility lead. Registered health workers (named tier 1 trainees) consented to undertake REaCH training, cascading training to colleagues, provide training data, reporting cascading activities, participating in interviews, and completing surveys. Tier 1 trainees required ownership of a smart mobile phone. Other cadres of health workers to whom training was cascaded (tier 2 trainees) were required to own a feature phone as a minimum. A feature phone is an earlier generation of mobile phone that uses press buttons and a small non-touch display screen. Feature phones use telecommunications infrastructure and 2G and 3G internet infrastructure and have more limited functionality than smartphones.

Within each facility, we included all patients meeting the following inclusion criteria: (1) aged 18 years or older; (2) had a diagnosis of one or more of the following conditions—diabetes, coronary heart disease, chronic obstructive airways disease, or hypertension; and (3) had consulted at the facility at least three times in the previous year. Regular health consulting indicated health seeking behaviours, which was an important requirement for an evaluation of consulting rate outcomes. These patients formed an open cohort for the course of the trial, such that if a patient did not attend the facility for 6 months or more, they left the cohort, and newly diagnosed patients or presenting patients meeting the criteria would join the cohort. We excluded patients who did not have access to a mobile phone, who were nearing end of life status or currently severely ill, and carers consulting on another person's behalf. The open cohort were not asked for consent as approved by all ethics committees.

Ethics approval were obtained from the Research Ethics Board, King's College London, UK (HR-20/21–21006), Research Ethics Review Committee, Oyo State Ministry of Health, and the University of Ibadan University College Hospital Ethics Committee, University of Ibadan Nigeria (UI/EC/20/0427), and the Medical Research Coordinating Committee, National Institute for Medical Research, Dar-es-Salaam, Tanzania (NIMR/HQ/R.8a/Vol. IX/3638). Both trials operated independently but were managed in parallel through the University of Ibadan Clinical Trials Unit with REaCH training, and process evaluation also delivered in unison including a shared trial steering group and a shared data monitoring committee.

For the **study protocol** see http://www.kcl.ac.uk/research/reach-trial

See **Online** for appendix 3

Randomisation and masking

Following enrolment, clusters were assigned to one of ten (Nigeria) or one of seven (Tanzania) sequences of intervention rollout (figure 1) by the trial team member (EA) responsible for randomisation. The clusters were placed in a random order by generating a uniform random variable In Microsoft Excel for each cluster and placing in ascending order. The allocated sequence was sent to trial staff by the trial team member (EA) for implementation. Health facilities and REaCH training facilitators were not masked to allocation sequence given

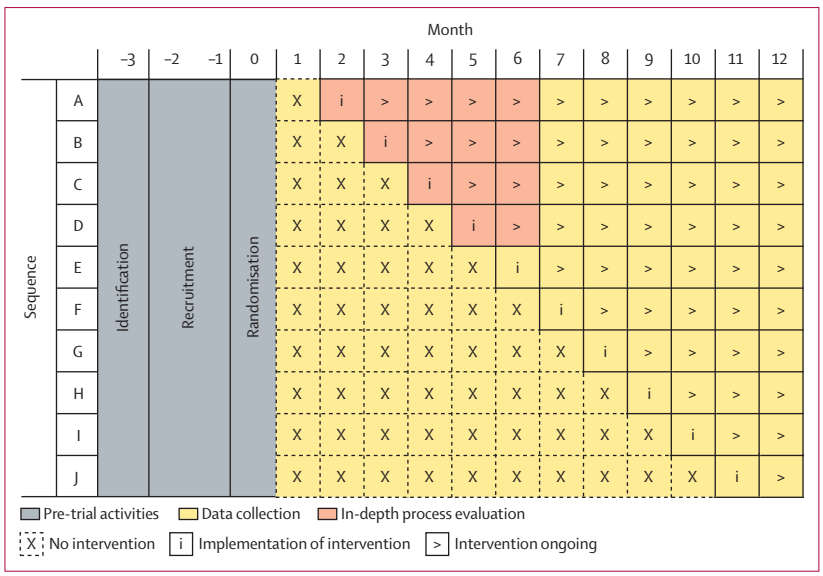

Figure 1: **Stepped-wedge trial design in Nigeria**
Tanzania followed a similar pattern with nine time periods.

the need to plan service delivery and prepare for training. At least one investigator and all research assistants who collected data remained masked to the intervention sequence. Each facility was given a unique identification number consisting of four digits and numbers to make it challenging for the research team to recall cluster identifications when discussing sequence plans with the unmasked REaCH training facilitators. At the beginning of every data collection activity, the researcher reminded the health worker and patient participant not to reveal whether the facility has undertaken REaCH training yet. Data entry was undertaken by research assistants who were masked to sequence allocation. All members of the team apart from the Nigerian statistician (JOA) were masked to patient safety data. Deviations from masking rules were considered at the bi-weekly clinical trial team meetings. The UK statistician (SIW) and UK investigators (JS, FG, BH, RR, JC, RH, KN, HM, RL) remained masked throughout.

Procedures

Interventions comprised a usual care or control period and an experimental period. Usual care was delivered in the routine way for each facility with no training and no mobile data allowance. Usual care for long-term conditions was provided face-to-face, sometimes in dedicated facility clinics by a doctor or a nurse. Community health workers provided support for patients in the community.

The experimental period comprised a complex intervention with three main components delivered at the cluster level, which were: (1) a tier 1 training curriculum delivered via an online learning smartphone app called Moodle over eight self-directed modules with online group facilitation with a REaCH trainer from the participating universities;[12] (2) a tier 2 cascade training process carried out by tier 1 trainees for health workers in their teams owning a feature phone as a minimum; and (3) mobile data allowance provided at the time of REaCH training commencement to support both engagement with training and the delivery of remote health consultations to any health facility patient by participating tier 1 and tier 2 trainees. Tier 1 training comprised 22 h during 14 days. Learning was self-directed using the Moodle app,[13] trainee and facilitator IT support was provided through using the Moodle app, and facilitated peer learning was though using WhatsApp. Tier 2 cascaded training comprised 4 h per day sessions for 4–5 days with facilitated and peer learning face-to-face and through using WhatsApp. The curriculum addressed practical, ethical, and philosophical differences when remotely consulting alongside health-care leadership modules. The REaCH training protocol and access to REaCH training was available free for not-for-profit use on request. Fidelity assessment data of Moodle training engagement determined whether the participants engaged in the learning as planned and achieved the desired learning outcomes. Engagement with five specific modules was determined to be core to having received a sufficient dose of learning. Figure 1 illustrates the progression of REaCH training delivery across the sequences and trial duration.

Data were collected on the same week of every month of every sequence (figure 1), and each cluster provided for the preceding month had a pseudonymised list of patients who had consulted, whether the consultation was remote or face-to-face, and whether any prescriptions and investigations were ordered. At each sequence the trial team member (EA) randomly sampled pseudonymous identifiers of patients who had consulted in the preceding month meeting the inclusion criteria and sent these pseudonyms to the facilities. Facility staff contacted the first 10–15 randomly ordered people on this list (depending on the number of eligible patients) to request their survey research participation. If they consented, the names and contact details were passed to fieldworkers who would phone them up to three times during the following 2 days. Participants on the list could be newly participating or they could have participated in a previous month. Following verbal informed consent procedures, approved by all ethical committees and undertaken by local fieldworkers, patient reported outcome surveys[14,15] were completed over the telephone. Fieldworkers were trained in taking informed consent and survey interviewing by each trial team. Fieldworkers were masked to whether the participant's consultation was face-to-face or remote. The data were recorded by the fieldworker directly onto ARCGIS Survey123, which is an online software.[16]

Guided by the Medical Research Council framework for complex intervention process evaluation,[17] we compiled process evaluation data on geography and

population from WHO and the World Bank websites. Using data obtained from tier 1 trainees, we documented the cadres of health workers trained, extent of engagement with the training modules, and trainee drop-out. To assess implementation of the intervention, 1 month after training completion in each cluster, we surveyed facility managers and tier 1 trainees.[18] In a random sample of five clusters trained during the first 6 months in each country, we collected copies of consecutive prescriptions issued to all open cohort patients for 1 week both before the training and 7 months after the training. Collated prescription data was categorised by drug type.

Outcomes

We assessed three primary outcomes using data from facility records, which were face-to-face consultation rate per patient-month, remote consultation rate per patient-month, and prescription rate per patient-month as a pragmatic proxy for safety during the pandemic. We further assessed data from the patient survey, which was patient trust in the care provided measured using the Physician Humanistic Behaviour Questionnaire,[14] which is a 25-item scale that assesses the presence of behaviours that are important to patients in their health worker-patient interactions.

The outcomes were selected to capture the complex effects of the intervention. For example, remote consultation could act as a substitute or as a complement to face-to-face visits, and so the face-to-face consultation rate could decrease (if used as a substitute) or increase (if used as an addition) in response to the intervention. To evaluate the effects of the intervention on access to care, we included both rates and hypothesised an increase in remote consultation. Similarly, if the standard of care differed by consultation type, then the mean rate of prescribing and patient trust in the care they received could also change. We hypothesised trained health workers would deliver care of equivalent quality across both consultation types. These outcomes were considered of primary importance to the evaluation of the REaCH intervention and were therefore included.[14]

Secondary outcomes were investigation rate per patient-month as a second proxy for safety from facility records, and patient activation measure (PAM-13) from from the patient survey[15] based on UK remote consulting research linking it with increased patient engagement with their long-term condition.[5] The PAM-13 assesses knowledge, beliefs, and skills that enable people to manage their long-term conditions. Intervention implementation outcome of training dose was assessed by monitoring completion of training modules. Intervention acceptability and feasibility was assessed using three standardised measures: (1) the four-item Intervention Acceptability Measure (AIM); (2) the four-item Intervention Appropriateness Measure (IAM); and (3) the four-item Feasibility of Intervention Measure (FIM), whose score range is 4–20 higher scores representing better outcomes.[18] All outcome data were centrally processed and analysed at the University of Ibadan Clinical Trials Unit.

Statistical analyses

We first summarised the patient characteristics according to the treatment status of the cluster period (means and standard deviations for all pre-intervention and all post-intervention periods). The data from each trial were analysed using a generalised linear mixed model framework, which is standard for stepped-wedge cluster randomised controlled trial designs.[19] 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 Physician Humanistic Behaviour Questionnaire score). For the count data, we specified a Poisson model, and for the continuous score, a linear model. We included random effects for the individual, cluster, and cluster-period. Non-linear mixed effects models can be difficult to estimate, so we compared results from quick approximate algorithms with slow but exact approaches to double check there were no convergence issues. Confidence intervals and p values were calculated using a permutation test that replicated the randomisation procedure.[20] We also re-calculated the confidence intervals and standard errors using a correction for multiple testing and report both for comparison (appendix 3 pp 2–4).[21] We report point estimates, confidence intervals, and p values, but do not make any claims of statistical significance and we do not use any arbitrary cutoffs of the p value for our interpretation of the evidence given strong arguments against doing so.[22] We instead considered magnitudes and uncertainty of estimated effect sizes, contextualising the trial findings with those of the process evaluation, and ensuring any explanations of the evidence could account for the findings across all our outcomes. Stata Special Edition (version 17) and R software (version 4.1.3) were used for analysis. Missing data analyses were pre-specified, however rates of missingness were extremely low, and so no such analyses were performed. An interim analysis of data was presented to the Data Monitoring Committee at 6 months specifically to monitor participant safety (appendix 3 p 4).

We hypothesised that the intervention would increase the remote consultation rate but not affect the face-to-face consultation rate, prescribing rate, or Physician Humanistic Behaviour Questionnaire score. For all outcomes, we aimed for sufficient precision to identify any clinically relevant change in the outcome. We therefore opted to design the trial around minimum detectable effect sizes rather than power to indicate the precision of the trial and the likely sizes of effect for which we can provide strong evidence. To deliver our final sample size calculation, we produced analyses of the power and precision for range of sample sizes and designs

based on what would be practicable and feasible, including a maximum number of clusters we could recruit during the complexities of the pandemic. We found we needed fewer clusters than we anticipated being able to recruit. Our calculations were based on the statistical models described above, assuming in each trial 20 clusters in ten sequences, with two clusters per sequence, in a full stepped-wedge design with 100 eligible patients per cluster (N=2000) for the rate outcomes and 20 consenting participants per cluster (n=400) for the Physician Humanistic Behaviour Questionnaire score. We assumed a power of 80%, a type I error rate of 5%, and an intraclass correlation of 0·05 and a cluster autocorrelation coefficient of 0·8, which were expected to be conservative. Minimum detectable effect sizes were derived from sample size methods for stepped wedge trials.[23] We note that multiple testing corrections were not included in the effect size calculations (appendix 3 p 4). A change in either consultation rate of an equivalent of one visit per person-year was considered to be clinically significant, which was well outside our minimum detectable range. Similarly, we estimated we would be able to identify reasonably small changes (around 0·15 SDs) in patient trustworthiness score, although we did not hypothesise a change in this outcome. The Delta checklist informed our methods.[24]

The CONSERVE checklist, which reports on completed trial changes, mitigations and effects due to the ongoing pandemic, was completed.[25] The Nigeria trial proceeded as per protocol with no deviations. Tanzania deployed a modification to enable completion within the funding window. The numbers of clusters per sequence increased from two to three, reducing the number of sequences from ten to seven and shortening their length. This change was necessary because firstly in December, 2020, the Tanzania government at the time denied COVID-19 and any reference to it on government-related documents.[26] The trial had COVID-19 in the title, and ethical approval, and consequently facility recruitment was delayed until we retitled it. Furthermore, the UK Government funder reduced its overseas development budget and a time-only extension was not possible. Modifications were designed by the UK, Nigeria, and Tanzania principal investigators with statistical input and approved by the Trial Steering Group.

This trial was registered with ISRCTN, ISRCTN17941313.

Role of funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

35 health facilities were recruited between Dec 21, 2020 and Jan 21, 2021, in Nigeria forming 20 clusters. 21 health facilities were recruited between Nov 9, 2020 and Jan 21, 2021, in Tanzania forming 20 clusters. Patient cohorts were established in both trials between Feb 1, 2021 and March 31, 2021. Surveyed participants were recruited between March 18, 2021 and March 13, 2022, in Nigeria and between April 12, 2021 and Jan 11, 2022, in Tanzania. No facilities were excluded from participation following expression of interest and not one facility dropped out.

In Nigeria, 8776 patients were included in the stepped-wedge cohort and 3246 patients in Tanzania (figure 2). The mean age of participants was 55·3 years (SD 13·9) in Nigeria and 59·2 years (14·2) in Tanzania. There were 6377 (72·7%) of 8776 females and 2399 (27·3%) males in Nigeria and 2235 (68·9%) of 3246 females and 1011 (31·1%) males in Tanzania (table 1). Hypertension was the predominant condition (8145 [90·9%] of 8776 in Nigeria; 2723 [77·8%] of 3246 in Tanzania). Characteristics of the monthly random sample in both countries were similar across intervention and control groups (table 1). In both trials, over 95% of people (2610 people in Nigeria and 1350 people in Tanzania) reported personal access to a mobile phone with 90% or more (1272 people in Nigeria and 622 people in Tanzania) reporting a stable telecoms network. Internet access showed the greatest differences between Nigeria and Tanzania participants. Data on consultation, prescription, and investigations were extracted from patient records, which were all fully completed. For the random sample survey of selected participants from whom data was collected for the patient activation measure[15] and Physician Humanistic Behaviour Questionnaire,[14] very few, 18 (0·6%) of 2717 participants did not complete the survey in Nigeria.

An increase in the rate of remote consultations from 3 per 1000 patient-months (SD 4·2) to 13 per 1000 patient-months (148·0) shows superiority of REaCH training in Nigeria (table 2). In Tanzania, there was no increase in remote consulting rates. The three primary outcomes of face-to-face consulting rate, prescription rate, and patient trust did not change between intervention and control periods in both trials.

The estimated treatment effects shows little evidence of change in the face-to-face consulting rate in Nigeria associated with the intervention (rate ratio [RR] 1·06, 95% CI 0·98 to 1·09; p=0·16; table 3). The overall increase in consulting rates resulted from a large increase in the remote consulting rate (4·44, 1·34 to >10; p=0·0102). No evidence of a reduction in safety was observed with the prescription rate remaining fairly constant (1·05, 0·60 to 1·14; p=0·23). Similarly, patient trust did not change (mean difference 0·05, SD –0·45 to 0·42; p=0·89). In Tanzania, there was little evidence of a difference in the face-to-face consulting rate (0·94, 0·61 to 1·67; p=0·99); however, in contrast to Nigeria, the remote consultation rate (1·17, 95% CI 0·56 to 5·57; p=0·39) did not increase. Patient safety (0·92, 0·60 to 1·67; p=0·97) and patient trust (mean difference 0·07, SD –0·51 to 0·76; p=0·70) showed little evidence of change associated with the intervention.

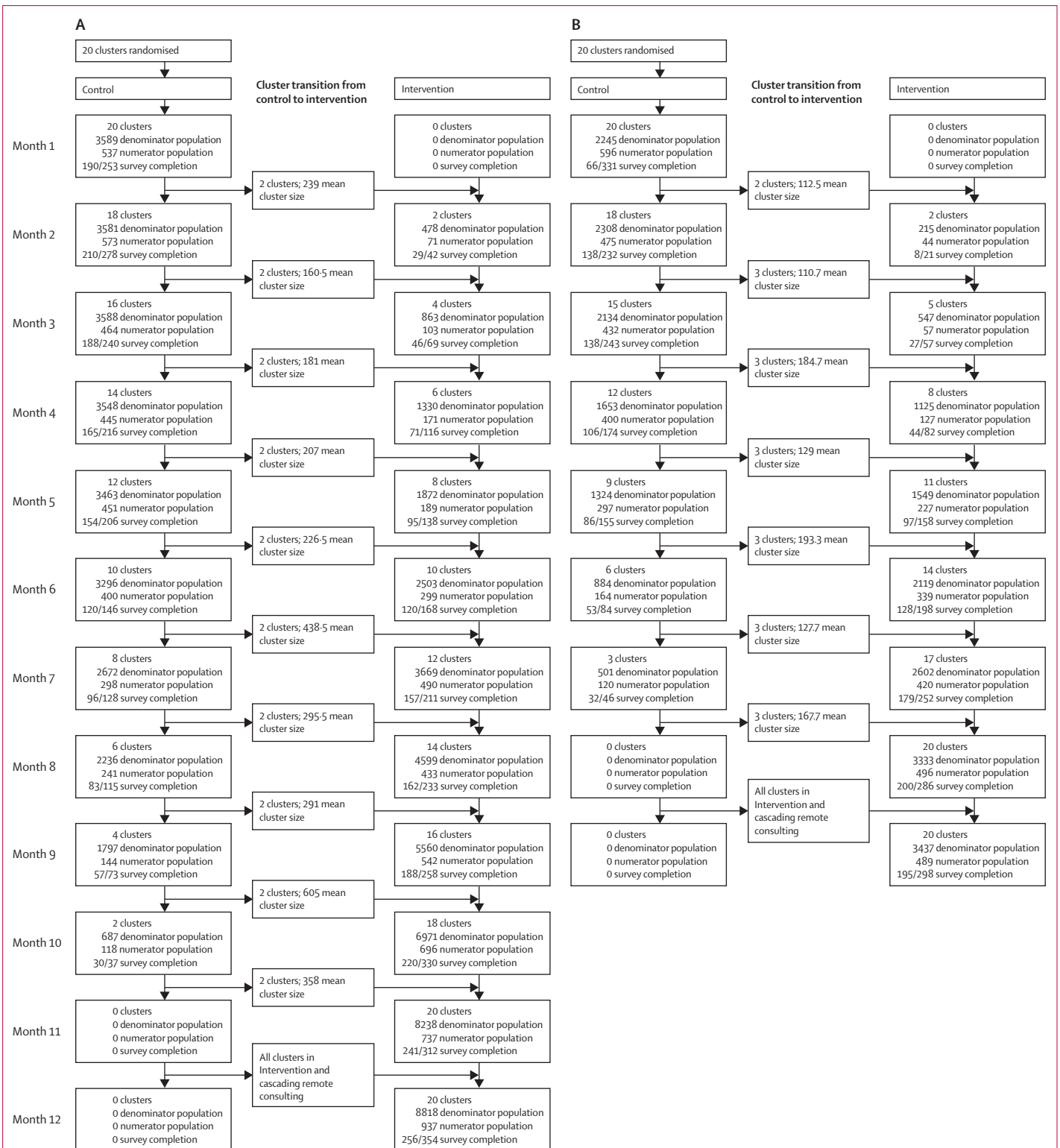

Figure 2: **Nigeria (A) and Tanzania (B) trial profiles**

	Nigeria			Tanzania		
	Pre-intervention	Post-intervention	Total	Pre-intervention	Post-intervention	Total
Open cohort						
N	..	..	8776	..	..	3246
Age, years	..	..	55·3 (13·9)	..	..	59·2 (14·2)
Sex						
Female	..	..	6377 (72·7%)	..	..	2235 (68·9%)
Male	..	..	2399 (27·3%)	..	..	1011 (31·1%)
Diabetes	..	..	618 (6·9%)	..	..	540 (15·4%)
Hypertension	..	..	8145 (90·9%)	..	..	2723 (77·8%)
COPD	..	..	190 (2·1%)	..	..	130 (3·7%)
Coronary heart disease	..	..	5 (0·1%)	..	..	105 (3·0%)
Random sample of consulting patients						
N	1351	1366	2717	719	698	1417
Age, years	57·3 (13·9)	55·6 (12·9)	56·5 (13·5)	58·7 (11·8)	59·6 (12·0)	59·2 (11·9)
Sex						
Female	957 (70·8%)	960 (70·3%)	1917 (70·6%)	502 (69·8%)	474 (67·1%)	976 (68·9%)
Male	394 (29·2%)	406 (29·7%)	800 (29·4%)	217 (30·2%)	224 (32·9%)	441 (31·1%)
Diabetes	114 (8·1%)	137 (9·5%)	251 (8·8%)	217 (24·2%)	176 (20·4%)	393 (22·4%)
Hypertension	1275 (90·4%)	1289 (88·9%)	2564 (89·7%)	614 (68·5%)	607 (70·4%)	1221 (69·5%)
COPD	21 (1·5%)	24 (1·7%)	45 (1·6%)	23 (2·6%)	22 (2·6%)	45 (2·6%)
Coronary heart disease	..	..	..	42 (4·7%)	57 (6·6%)	99 (5·6%)
Unemployed	197 (14·6%)	122 (8·9%)	319 (11·7%)	125 (17·4%)	206 (29·5%)	331 (23·4%)
Lives alone	97 (7·2%)	68 (5·0%)	165 (6·1%)	53 (7·4%)	58 (8·3%)	111 (7·8%)
Personal access to mobile phone	1312 (97·1%)	1333 (97·6%)	2645 (97·4%)	651 (90·5%)	637 (91·3%)	1288 (90·9%)
Access to stable mobile phone network	1272 (94·2%)	1338 (98·0%)	2610 (96·1%)	663 (92·2%)	687 (98·4%)	1350 (95·3%)
Access to the internet	783 (58·0%)	799 (58·5%)	1582 (58·2%)	626 (87·1%)	685 (98·1%)	1311 (95·2%)
Travel time to clinic, minutes	15 (10–30)	15 (10–30)	15 (10–30)	30 (15–45)	25 (15–30)	30 (15–30)

Data are n (%) or mean (SD).

Table 1: **Baseline characteristics of the open cohort and random sample of consulting patients population**

	Nigeria		Tanzania	
	Pre-intervention (n=3752)	Post-intervention (n=4088)	Pre-intervention (n=2428)	Post-intervention (n=1679)
Face-to-face consulting rate (visits per person-month)	0·145 (0·435)	0·154 (0·430)	0·312 (0·518)	0·291 (0·546)
Remote consulting rate (visits per person-month)	0·003 (0·042)	0·013 (0·148)	0·119 (0·243)	0·138 (0·318)
Prescription rate (visits per person-month)	0·139 (0·408)	0·147 (0·416)	0·312 (0·503)	0·287 (0·557)
Patients trust (PHBQ) score	96·9 (10·26)	96·0 (11·44)	95·1 (7·48)	96·6 (5·06)
Investigation rate (visits per person-month)	0·028 (0·212)	0·029 (0·223)	0·129 (0·426)	0·148 (0·343)
PAM score	52·2 (7·89)	53·6 (7·97)	53·1 (4·67)	54·3 (2·99)

Data are mean (SD). PAM=Patient Activation Measure. PHBQ=Physician Humanistic Behaviour Questionnaire.

Table 2: **Summary statistics for outcome measures per patient month in Nigeria and Tanzania**

The mean scores of the four primary outcomes for each Nigerian cluster and month relative to the timing of the intervention showed no obvious outliers. A notable increase in the remote consultation rate during the intervention period was observed in which remote consultations account for around one in six consultations, compared with almost zero before the intervention (appendix 3 p 6). Other outcomes do not exhibit any clear trend. A similar pattern was observed in the outcomes for Tanzania but with greater heterogeneity across clusters. In both countries, the facility health worker consulting staff levels remained stable and unchanged across the trial period, however, the median number of consulting minutes per month across all staff rose from 748 min to 1145 min in Nigeria and declined in Tanzania from 653 min to 514 min (appendix 3 pp 6–7).

Intervention delivery and fidelity was assessed via Moodle engagement of 60 tier 1 trainees, WhatsApp group meeting messages, and voice notes for 47 training events, tier 1 trainee reports on cascading activities within 34 health facilities, and implementation surveys of 78 trainees and facility managers. The in-depth process evaluations of five clusters used prescription data for 509 medications associated with 167 face-to-face or remote consultations.

Training was accessed and completed by six cadres of health workers of both sex in both urban and peri-urban settings (Nigeria) and rural and remote settings (Tanzania). Trainee engagement with REaCH and its

	Nigeria (n=7840)			Tanzania (n=4107)		
	Estimate	Without correction (95% CI; p value)	With correction (95% CI; p value)	Estimate	Without correction (95% CI; p value)	With correction (95% CI; p value)
Primary outcomes						
Face-to-face consulting	RR 1·06	0·98 to 1·09; 0·16	0·56 to 1·09; 0·37	RR 0·94	0·61 to 1·67; 0·99	0·55 to 1·74; 0·99
Remote consulting	RR 4·44	1·34 to >10*; 0·0102	1·75 to >10*; 0·01	RR 1·17	0·56 to 5·57; 0·39	0·44 to 15·78; 0·99
Prescription rate	RR 1·05	0·60 to 1·14; 0·23	0·59 to 1·16; 0·39	RR 0·92	0·60 to 1·67; 0·97	0·59 to 1·91; 0·96
Patient trust (PHBQ) score	Mean difference 0·05	−0·45 to 0·42; 0·89	−0·65 to 0·56; 0·88	Mean difference 0·07	−0·51 to 0·76; 0·70	−0·65 to 0·56; 0·70
Secondary outcome						
Investigation rate	RR 1·06	0·23 to 2·12; 0·49	..	RR 1·15	0·35 to 1·64; 0·58	..
PAM score	Mean difference 0·02	−0·26 to 0·52; 0·55	..	Mean difference 0·11	−0·63 to 0·75; 0·85	..

95% CIs and p values are presented with and without correction for multiple testing across the four primary outcomes. PAM=Patient Activation Measure. PHBQ=Physician Humanistic Behaviour Questionnaire. RR=rate ratio. *The upper limit of the confidence intervals could not be accurately or meaningfully estimated using a permutaton-test approach given the large number of zero counts of the outcome variables; therefore we present the minimum value of the upper limit instead.

Table 3: **Estimated treatment effects of REaCH training on health workers and remote consulting on their patients for primary and secondary outcomes**

cascading was shown to be high (tables 4, 5). Implementation scores in Nigeria on all components of acceptability (mean 17·81 [SD 2·72]), appropriateness (17·49 [2·82]), and feasibility (17·53 [2·48]) indicate that REaCH and remote consulting is implementable in these settings.[18] These findings were mirrored in Tanzania.

An increase in antibacterial medication prescribing was observed in Nigeria between the intervention and control periods whereas such prescribing was reduced in Tanzania (appendix 3 p 7). In Nigeria, the number of prescriptions also increased in the intervention period for non-narcotic analgesics, antipyretics, and non-steroidal anti-inflammatory drugs. These were unchanged in Tanzania (appendix 3 p 7).

	Nigeria*			Tanzania†		
	Tier 1	Tier 2	Total staff in study facilities	Tier 1	Tier 2	Total staff in study facilities
Medical doctor	10	..	14	24	5	66
Clinical officer	..	..	..	11	21	84
Assistant medical doctor	..	..	..	7	6	46
Nurse	10	20	51	..	38	431
Community health officer	..	33	50	..	..	..
Community health extension worker	..	42	79	..	..	52
Technical and administrative staff	..	..	..	..	27	372

*Oyo State to 28 454 km²; population: 7 840 864 to urban centres to peri-urban and remote rural communities. †Morogoro Region to 73 039 km²; population: 2 218 492 to mostly remote rural to some urban centres and peri-urban areas.

Table 4: **Roles of participating health workers in study facilities**

Discussion

Providing REaCH in Nigeria resulted in a four-fold increase in remote consultations, representing one in six of all consultations, for people with long-term conditions. Maintenance of face-to-face consultation rates indicate that REaCH improved the populations' net access to health care. The number of consulting minutes per month rose with no increase in staff numbers. We found no change in remote consulting rates in Tanzania where the control period rates were much higher than in Nigeria. In both countries, the limited change in the safety outcomes indicate remote consultation appropriateness in future infectious disease outbreaks. REaCH increased remote consulting rates, and consequently access to health care, in territories without remote consultation before the intervention but not in the context when remote consulting was already embedded.

No differences in consultation trustworthiness followed the introduction of remote consultations. Baseline health-care trustworthiness scores differed between the two countries with lower scores observed in Nigeria. REaCH training and remote consulting both received high scores for acceptability, appropriateness, and feasibility by health facility managers and health worker trainees. Over 90% (115 individuals in Nigeria and 139 individuals in Tanzania) of REaCH trainees, of all cadres, engaged with or completed REaCH training and passed the competency test. Engagement was high with both the Moodle-supported and the cascaded elements of the training. Involvement in the facilitated WhatsApp peer-learning meetings was more challenging in rural and remote settings in Tanzania due to limitations in digital infrastructure. Female sex participants were well represented as health worker trainees, research participants, and service users. Male sex participants were fewer, but numbers of consultations increased after the intervention in both countries.

The estimated treatment effect in the trial suggested no change in the prescribing and investigation rates supporting our hypothesis that consultation safety is maintained. The process evaluation found antibiotic prescribing and pain relief medication to rise in Nigeria and antibiotic prescribing to decline in Tanzania. Further

	Nigeria	Tanzania
REaCH training dose delivered		
Tier 1 dropouts	0/20 (0%)	3/42 (7%)
REaCH training dose received		
Tier 1 trainees who downloaded core modules 1, 2, 3, 5, and 7 from Moodle platform	Module 1: 19/20 (95%); Module 2: 17/20 (85%); Module 3: 17/20 (85%); Module 5: 16/20 (80%); Module 7: 14/20 (70%)	Module 1: 38/39 (97%); Module 2: 39/39 (100%); Module 3: 38/39 (97%); Module 5: 38/39 (97%); Module 7: 38/39 (97%)
Tier 1 Trainees who participated in WhatsApp or Moodle Student Forum	WhatsApp Chats: (n=9), Module 2: 9/9 (100%), Module 3: 9/9 (100%); Student Forum: 0/20 (0%) tier 1 trainees	WhatsApp Chats: (n=7), Module 2: 4/7 (57%), Module 3: 3/7 (43%); Student Forum: 25/39 (64%) tier 1 trainees
Tier 1: Moodle pass score	14/20 (>70%)	36/39 (>70%)
Tier 2: Completion rate	95/95 by tier 2 trainees	97/98 by tier 2 trainees*
Assessment of implementation of remote consulting†		
Acceptability (AIM; 4–20)‡	17·81 (2·72)	17·51 (3·38)
Appropriateness (IAM; 4–20)‡	17·49 (2·82)	17 (3·58)
Feasibility (FIM; 4–20‡	17·53 (2·48)	16·94 (2·83)

Data are n (%) or mean (SD), unless stated otherwise. AIM=Acceptability of Intervention Measure. IAM=Intervention Appropriateness Measure. FIM=Feasibility of Intervention Measure. *1 Tier 2 trainee did not complete due to other study commitments. †Scores are out of 20. ‡Are possible scores for each measure. Each measure has four items and measured on a Likert scale of 1–5.

Table 5: **Intervention delivery and assessment of implementation**

investigation is warranted at the individual patient or facility level relating to remote prescribing and its role in patient safety.[8,9]

Observational studies in LMICs report high patient satisfaction with remotely delivered health care although they conclude that expansion remains to be modest, largely constrained by the few telemedicine policies, professional and patient biases, and insufficient digital infrastructure.[27] Training for health workers is among the recommendations to support the utility of telemedicine in general in this region.[27,28] E-learning platforms like Moodle are widely available across Africa for teaching clinical skills, but not widely evaluated.[13] REaCH training has shown that it is possible to cascade e-learning programmes across different health worker cadres and contexts. Many of these health workers are women who can be underserved by current continuing professional development.[12]

The development of the REaCH complex intervention and the delivery of both trials was undertaken at a scale and speed unprecedented in any normal, non-pandemic, context. This context limits our theoretical understanding of the relative importance of REaCH's twin components of training and mobile data allowance provision. The trial sites were deliberately contrasting in geographical context and found to have differing population characteristics and internet access. These differences could underpin the variation of remote consulting rates found by country. Earlier cluster sequences had experienced shorter pandemic lockdown periods compared with later sequences. Restricted health-care access due to lengthier lockdown periods might have meant patients and participants were more unwell at the point of receiving access to remote consultations. Individual or local cultures surrounding health-seeking behaviours could also have introduced population bias. We do not know how people who chose to undertake telephone survey interviews differed from those who did not choose to be surveyed. The potential temporal biases could also have strengthened health worker learning for the later sequences as the REaCH facilitators were more experienced in their role of supporting trainees. Although we worked with facilities to nominate trainees with a gender balance representative of their setting, we have incomplete data to evidence whether this occurred. Primary care facilities were keen to participate and welcomed the investment brought with REaCH. Being required to identify patients meeting the eligibility criteria often resulted in the development of local disease registers. Such registers are fundamental first steps to quality improvement initiatives and developing dedicated clinics and coalescing expertise.[29]

These trials were small but with good precision. Differences observed between trial sites relating to population and health delivery contexts enable the reader to anticipate whether the Nigeria or the Tanzania remote consulting rate outcomes could be most closely mirrored in their country or context. Across both sites, the similar outcomes observed makes the remote consulting safety and trustworthiness findings generalisable in similar settings.

In conclusion, remote consultations, underpinned by nationally available standardised training, should now be considered as part of national strategies for achieving universal health coverage and maintaining public health in LMICs and informing digital and tele-health ambitions. The funding of mobile data allowance packages—a known impediment to remote care[4,6]—needs to be addressed as part of the strategy. Understanding the nature of consultations for different

conditions and contexts and their effect on clinical outcomes will further inform targeting of this care delivery model, which remains somewhat novel in many African settings.

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Contributors
JS, FG, SP, AK, AD, and TM developed, pilot evaluated, and amended the REaCH intervention. JS, FG, AO, EO, BH, RL, and SIW designed the trial. JS, AO, SP, BC, EO, EA, RR, RH, MA, HM, JOA, RL, and SIW delivered the trial. FG, BH, KN, OF, TM delivered the process evaluation. EOC, DAA, AK, SN, EA, VK, and ML delivered the intervention and designed the evaluation of the intervention dose delivered and received by trainees. BC, TM, MA, and OF led the data collection. EA, JOA, SIW, BH, and OF directly accessed and verified the underlying data. SIW and BH developed the statistical and process evaluation analysis plans, and with JOA, FG, OF, and KN, led the analysis. JC, RH, RL, and VK chaired the project management committees. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. All authors read and approved the final version of the manuscript.

Declaration of interests
RH has leadership or fiduciary roles as follows: Trustee at Marie Curie; co-chair of the African Palliative Care Association Research Network; member of the British HIV Association Standards steering committee; and Vice-Chair of the Worldwide Hospice Palliative Care Alliance. SIW has received standard research grants from The National Institute for Health and Care Research, Medical Research Council, and The National Institute of Mental Health (USA) as either principal and co-investigator. All other authors have no competing interests.

Data sharing
The datasets generated and analysed during the study are available upon request from Jackie Sturt, King's College London, via Jackie.sturt@kcl.ac.uk, and Akinyinka Omigbodun, University of Ibadan, via omigbodun@yahoo.com. Trial data are available with immediate effect and with no end date. All study documents are included in the supplementary materials or available on request.

Acknowledgments
We wish to thank members of the Trial Steering Committee: Jeremy Dale (University of Warwick), Doyin Odubanjo (University of Ibadan), and Eric Van Praag (freelance Public Health Adviser, Dar-es-Salam), and thank members of the Data Monitoring Ethics Committee: Funmilola OlaOlorun (University of Ibadan), Segun Bello (University of Ibadan), and Gabriel Upunda (St Francis University College of Health and Allied Sciences, Dar-es-Salam) for their careful scrutiny and guidance of the twin trials. From Tanzania, we are grateful to the primary care leadership of Kusirye Ukio and medical officers in charge, and district medical officers from Ulanga, Malinyi, Mlimba, Kilosa, and Mvomero districts, and Town Medical Officer from Ifakara. From Nigeria, we thank the leadership of the Oyo State Primary Health Care Board and the University College Hospital Community Health Centres. Both trial sites worked closely with data collectors to obtain, manage, and process the large quantities of data, and we acknowledge Marcusy Balagaju, Frola Theophil Stephano in Tanzania, and Abiola Oladejo, Omolara Popoola, Daniel Ayinmoro, Habeeb Alabi, Oluwatoyin Oluyinka, Precious Ayodele, Rebecca Ojuade, and Abiodun Alliu in Nigeria for their important contributions. We thank Ahmed Olanrewaju for IT support making the REaCH training available in Nigeria. Supporting qualitative analysis with the University of Warwick team, we thank Chinwe M Onuegbu and Wendy Higman. We are grateful to Samantha Shaw, Publication Coach, King's College London for their review of earlier drafts. Our utmost gratitude lies with the health workers and the patients who generously participated in the research. We acknowledge funding from The UK Research and Innovation Collective Fund and support from the National Institute for Health and Care Research Applied Research Collaboration West Midlands, University of Birmingham, UK.

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