

BMJ Open Community- and mHealth-based integrated management of diabetes in primary healthcare in Rwanda (D²Rwanda): the protocol of a mixed-methods study including a cluster randomised controlled trial

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ABSTRACT

Introduction In Rwanda, diabetes mellitus prevalence is estimated between 3.1% and 4.3%. To address non-communicable diseases and the shortage of health workforce, the Rwandan Ministry of Health has introduced the home-based care practitioners (HBCPs) programme: laypeople provide longitudinal care to chronic patients after receiving a six-month training. Leveraging technological mobile solutions may also help improve health and healthcare. The D²Rwanda study aims at: (a) determining the efficacy of an integrated programme for the management of diabetes in Rwanda, which will provide monthly patient assessments by HBCPs, and an educational and self-management mHealth patient tool, and; (b) exploring qualitatively the ways the interventions will have been enacted, their challenges and effects, and changes in the patients' health behaviours and HBCPs' work satisfaction.

Methods and analysis This is a mixed-methods sequential explanatory study. First, there will be a one-year cluster randomised controlled trial including two interventions ((1) HBCPs' programme; (2) HBCPs' programme + mobile health application) and usual care (control). Currently, nine hospitals run the HBCPs' programme. Under each hospital, administrative areas implementing the HBCPs' programme will be randomised to receive intervention 1 or 2. Eligible patients from each area will receive the same intervention. Areas without the HBCPs' programme will be assigned to the control group. The primary outcome will be changes in glycated haemoglobin. Secondary outcomes include medication adherence, mortality, complications, health-related quality of life, diabetes-related distress and health literacy. Second, at the end of the trial, focus group discussions will be conducted with patients and HBCPs. Financial support was received from the Karen Elise Jensens Fond, and the Universities of Aarhus and Luxembourg.

Ethics and dissemination Ethics approval was obtained from the Rwanda National Ethics Committee and the Ethics Review Panel of the University of Luxembourg. Findings will be disseminated via peer-reviewed publications and conference presentations.

Strengths and limitations of this study

- The study considers the context of Rwanda, its healthcare services and policies, and proposes a combination of a patient mobile app within the home-based care practitioners (HBCPs) programme, integrating the intervention into clinical care and healthcare system, instead of providing the technological solution standalone.
- To facilitate the implementation of intervention 2, patients will receive a smartphone with a mobile app, prepaid access to mobile internet and a solar battery pack.
- To our knowledge, there are no translated and validated tools for the assessment of medication adherence, quality of life of patients with diabetes, diabetes-related distress and health literacy, and therefore four questionnaires will be translated into Kinyarwanda and culturally adapted.
- The hospitals and the cells running the HBCPs' programme have been preselected by the Ministry of Health, thus leading to a selection bias and potential differences in the quality of the services delivered to the populations of their catchment areas.

Trial registration number NCT03376607; Pre-results.

INTRODUCTION

Non-communicable diseases (NCDs) were responsible for 41 million of the 57 million deaths globally in 2016, with cardiovascular diseases, cancers, respiratory diseases and diabetes being among the most common causes.¹ Approximately 78% of all NCD deaths were reported in low-income and middle-income countries (LMICs), with premature mortality (occurring before 70 years old) being notably higher.¹

The global prevalence of diabetes mellitus in adults 20–79 years is estimated at 8.8%.² In LMICs, the prevalence has been increasing at a faster pace, with demographic and lifestyle changes playing a role in this development.³ In sub-Saharan Africa (SSA) countries, where epidemiological studies are scarce and conducted with difficulty,⁴ the prevalence may vary by ethnicity and type of area (rural/urban).^{4–6} In Rwanda, age-adjusted diabetes prevalence has been estimated between 3.1% (population aged 15–64 years) according to the 2013 WHO STEPwise approach to Surveillance study⁷ and 4.3% (population aged 20–79 years) according to the 2017 edition of the International Diabetes Federation Atlas.²

Yet, undiagnosed diabetes is estimated at up to 90% in some SSA countries, and this can lead to complications as people are not screened for comorbidities.³ Although the majority of the patients present with type 2 diabetes,⁴ proper classification is challenged by various factors, including the lack of C-peptide testing,⁸ and the presence, although highly debated, of atypical forms of diabetes.^{4,9}

The burden of NCDs greatly affects patients with lower socioeconomic status, increasing inequalities and posing a daunting challenge to fragile health systems.¹⁰ In many parts of the world, there is an inadequate number of appropriately trained and motivated health workers, hindering access to healthcare services.^{11,12} The lack of regular follow-ups with the health provider can lead to complications in diabetic patients.¹³ Furthermore, there is evidence of insufficient adherence to treatment, posing risks for patient safety and treatment effectiveness.^{14,15} According to Gazmararian *et al*, there are individual, educational and system barriers to self-care management, such as the emotional impact of the diagnosis and required lifestyle changes, social isolation, knowledge gaps and the perceived need for follow-ups.¹⁶ Safety concerns about the treatment regimen and lack of understanding of the chronicity of the disease can also decrease adherence.¹⁷ Patients with low health literacy levels are often unable to recognise the signs and symptoms of diabetes and may access their healthcare provider late, hence presenting with more severe complications.¹⁸

In Rwanda, there were 0.064 physicians and 0.832 nurses and midwives per 1000 population in 2015.¹⁹ Taking into account only physicians, nurses and midwives, the total skilled health personnel ratio is calculated at 0.896 per 1000 population,¹⁹ which is significantly below the estimated 'sustainable development goals index threshold' of 4.45 healthcare professionals per 1000 population.²⁰ Aggravating the problem, the level of knowledge of diabetes among Rwandan patients is inadequate and its perceptions poor and biased.^{21,22}

Leveraging solutions using mobile devices (mHealth) to support healthcare services is promising, especially in resource-constrained settings.^{23–27} As in many countries of the world where smartphone penetration has overtaken cellular phones, mobile apps provide new cost-effective opportunities to increase user engagement and convenience.²⁸ They can also be employed in behavioural

change interventions addressing NCD risk factors.²⁹ Yet, although a wide range of text-based mHealth solutions exists in LMICs, there is limited evidence of app-based interventions for diabetes and inadequate knowledge regarding which of their components can lead to behaviour change.^{29,30}

It has been noted that the scarcity of theory-driven mHealth interventions may be a consequence of relying on evidence-based clinical guidelines, as well as due to the lack of models able to guide dynamic personalised and contextual adaptation.^{31–33} Still, the identification of the most effective components of mHealth interventions can enhance behaviour change through iterative development.^{29,34} Nundy *et al* suggested that, achieving better diabetes self-management through mHealth interventions may not only be the result of cueing to action; improvements may also be attained indirectly through enhanced self-efficacy, and better social support, health beliefs, knowledge and attitudes through feedback, frequent contact and daily messages.^{30,34,35} Behaviour change techniques, such as self-monitoring of outcomes of behaviour, goal setting and information about health consequences, have already been used in digital interventions in diabetic patients.^{36,37}

For the successful implementation of digital interventions, particular attention must be paid to patient and provider context-related factors, which, according to Opoku *et al* can be categorised into predisposing characteristics, needs and enablers.²⁷ Such factors include the reliability of power supply and access to technology, the burden of carrying multiple devices, their portability, the social acceptance of technology and fluency in language.^{27,38,39} The perceived usefulness and ease of use of a technology can also determine the extent to which this is used and accepted.^{27,40}

In recent years, two opportunities for improving the management of NCDs have emerged in Rwanda.

First, in response to the need for better management of NCDs at the community level, the Ministry of Health of Rwanda has introduced a new type of community health workers, the *home-based care practitioners (HBCPs)*.⁴¹ Approximately 100 cells, belonging to the catchment area of nine preselected hospitals, participate in the first phase of the HBCP programme (a 'cell' is a small administrative area under the larger areas called 'districts'). Every cell has two HBCPs, who must have completed high school and received six months of technical vocational education and training organised by the Ministry of Health and its partners. The training consists of basic and clinical management on NCDs and palliative care, including clinical courses on wounds dressing, pain management, physiotherapy and psychological behaviours to assist patients. In addition to the HBCPs, *NCD clinics* have been established in these hospitals, which are run by nurses and support the HBCPs in their work.

Second, there is a growing body of evidence for the efficacy of mHealth interventions in LMICs, particularly in improving treatment adherence, appointment

compliance, data gathering and providing support networks for health workers.²⁶ In the SSA region, the mobile penetration rate is higher than the accessibility rate to basic utilities, such as electricity and sanitation.⁴² According to the Rwanda Demographic and Health Survey 2014–2015, the most commonly owned household good is the mobile phone: 60% of the Rwandan households own one, representing a steep increase from 2010.⁴³ By June 2018, 46.4% of the nation's population was connected to the internet; the vast majority of people used mobile networks to do so.^{44 45} Evidence also suggests that only limited training is required to enable patients or providers to use an mHealth application in SSA.²⁷ In Rwanda, there is an urgent call to using mHealth interventions for the prevention and management of NCDs.⁴⁶

Combining the HBCP programme with facilitated access to a patient mobile app for diabetes, and integrating them into the nation's primary healthcare system constitute a novel approach for the management of diabetes in resource-restricted settings.

Aim

The first aim of the D²Rwanda (Digital Diabetes Rwanda) study is to determine the efficacy of an integrated programme for the management of diabetes in primary healthcare in Rwanda, which will provide: (1) regular patient assessments and disease management by the HBCPs participating in the programme of the Ministry of Health; (2) facilitated access to an mHealth tool for patient education and self-management of the disease.

The second aim is to use qualitative methods to explore: (1) the ways the interventions are enacted in practice; (2) expected and unexpected effects of the interventions; (3) perceptions and challenges that may have impacted the intervention, and; (4) changes in patients' health behaviour and HBCPs' work satisfaction that the intervention brought about.

Research questions

For the first aim, the study will address the following research questions regarding the HBCP programme:

1. Does the HBCP programme improve glycated haemoglobin (HbA1c) levels in patients compared with those without the programme?
2. Do patients show improvements in medication adherence, health-related quality of life (HRQoL), diabetes-related distress and health literacy levels through participation in the HBCP programme?

Furthermore, the study will estimate the effect of the integration of the mobile tool into the HBCP programme:

1. Does the integration of an mHealth tool for patients in the HBCP programme reduce HbA1c levels further compared with patients who will only receive care by the HBCPs and will not have access to the mHealth tool?
2. Do patients show better medication adherence and report increased HRQoL, improvements in self-reported

diabetes-related distress and health literacy levels through the integration of the mHealth tool with the HBCP programme?

For the second aim, the study will employ qualitative methods to explore the following research questions: (1) Patients: What challenges do patients face in receiving care? What are the barriers to good quality of life? What influences their disease-related decision-making? What are the needs and concerns they have in receiving care? What are the reasons for non-adherence to medication? What are the challenges in using the mobile app? How the intervention contributed to health behaviour change? (2) HBCPs: What are the challenges in their work? What is the level of satisfaction from their work? What are the challenges they face? What were the challenges in integrating the app to the routine visits? What are the differences they note from patient to patient?

METHODS AND ANALYSIS

The study involves a sequential explanatory design, consisting of two consecutive phases: (1) a one-year cluster randomised controlled trial addressing the first study aim; (2) a qualitative study at the end of the trial to address the second study aim.^{47 48} Emphasis will be given to the quantitative phase of the study. Quantitative and qualitative results will be integrated on completion of data analysis.

PHASE I: CLUSTER RANDOMISED CONTROLLED TRIAL

Study design

The one-year open-label parallel-group, cluster randomised controlled trial is designed as an evaluation of the efficacy of two interventions (interventions 1 and 2) aiming at improving the management of diabetic patients at the primary healthcare level, compared with routine practice (control group). Intervention group 1 will receive access to the newly established HBCP programme, with regular monthly health assessments, disease management and lifestyle advice by the HBCPs, and referral to the hospitals when needed.

In addition, in the intervention group 2, HBCPs will actively encourage the use of a mobile app by assisting patients to access it (this process is known as '*facilitated access*').^{49 50} The mobile app, which is currently under development in Rwanda, will use a variety of behaviour change techniques, including feedback on outcomes of behaviour, self-monitoring of outcomes of behaviour, social support, prompts/cues, pharmacological support, instruction on how to perform a behaviour, use of credible sources and social rewards.³⁷ The app will provide a personalised experience enabling patients to: (1) take note of their progress by keeping track of such measurements as blood glucose data and blood pressure; (2) record and share their concerns and questions in a diary; (3) receive notifications for the next scheduled appointments of the HBCPs and/or to the hospital; (4) keep

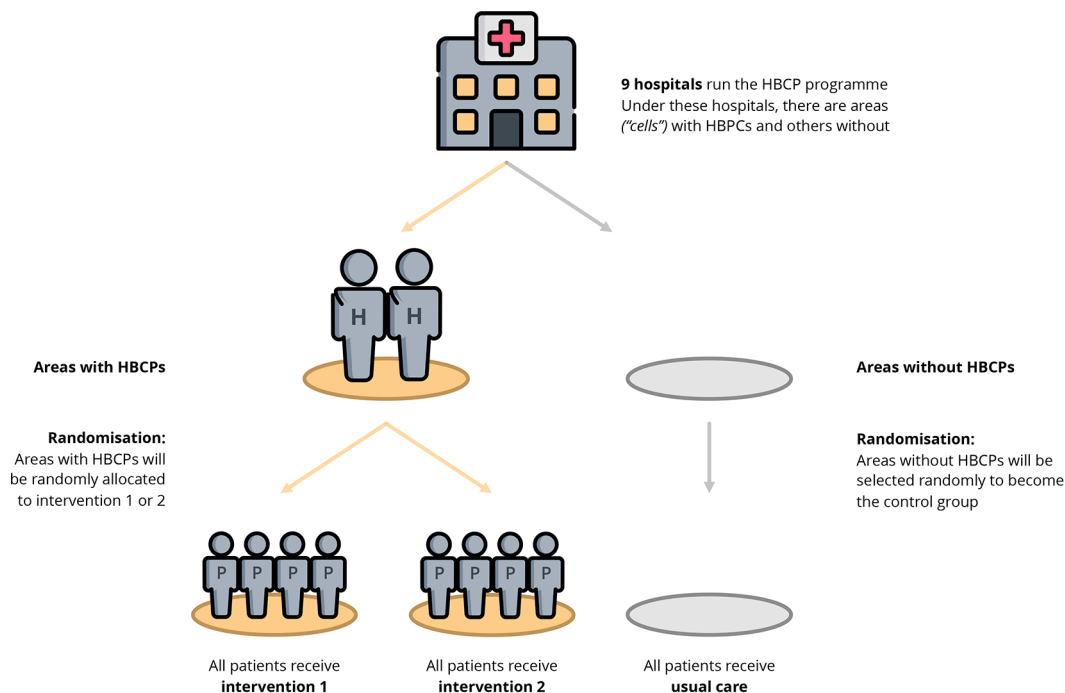


Figure 1 Cluster randomisation of the trial. HBCP, home-based care practitioner; P, patient.

track of their medications, and; (5) access contextualised educational material which include videos, rich-media articles and quizzes. The educational material will differ in patients receiving insulin, with additional relevant information provided to them.

For the implementation of intervention 2, patients will receive a mobile phone with the mobile app preloaded, prepaid access to mobile internet and a solar battery pack. Nurses of the NCD clinics and the HBCPs will be given access to a web-based panel connecting with the mobile app to facilitate care coordination and patient monitoring.

Sites and randomisation

Nine hospitals and ~100 cells from their catchment areas have been preselected by the Ministry of Health of Rwanda to participate in the HBCP programme: Bushenge, Kibuye, Kinihira, Ruhengeri, Ruhango, Rwamagana, Kibungo, Kabutare and Muhima. All nine hospitals will be included in the study.

The unit of randomisation will be the cluster, defined by the cell. The cell-level cluster randomised design was chosen as contamination between the intervention and control groups must be limited.⁵¹

In each cell, two HBCPs are working. For each hospital, cells participating in the HBCP programme will be randomly selected to receive intervention 1 or 2. The patients from each group will receive the same intervention. An equal number of cells from those not participating in the HBCP programme and which are located

at a two-hour distance on foot from the hospital, will be randomly selected and assigned to the control group (figure 1).

Randomisation will be performed prior to the enrolment of study participants. For each of the nine hospitals, computer-generated random numbers will be used to: (1) identify the cells participating in the HBCP programme and to assign them to either intervention 1 or 2, and; (2) select the same number of cells from those without the HBCP programme to be allocated to the control group of the trial (targeted ratio 1:1:1).

We will verify the balancing property of a set of observable characteristics between the cells without HBCPs (control group) versus those assigned to run the HBCP programme (and will therefore be allocated to either intervention 1 or 2). The observable characteristics include the distance of the cells from the hospital, their population density and the number of urban and rural communities of each cell. When the balancing property is not achieved, a rerandomisation procedure will be applied to improve covariate balance.⁵²

Inclusion and exclusion criteria

The study population will consist of diabetic patients and HBCPs. No distinction between type 1 and 2 diabetes will be made due to the lack of access to more advanced laboratory tests, as well as the atypical presentations of the disease.^{4 8 9}

Inclusion criteria for diabetic patients:

1. Adult patients (male and female) aged between 21 and 80 years (people aged over 80 years will not be included as they may present clinical, functional and psychosocial conditions, which require particular attention and careful personalisation of self-management educational material).⁵³
2. Diagnosed and confirmed as diabetic patient (as defined by the national guidelines in Rwanda)⁵⁴ at least six months prior to study start.
3. Living in cells of the hospitals participating in the HBCP programme.
4. Residing, and planning to reside within a two-hour travel distance on foot from the study site for the duration of follow-up.
5. Willing and able to adhere to the study protocol.
6. Willing and able to give informed consent to participate in the study.

Exclusion criteria for diabetic patients:

1. Severe mental health conditions, including cognitive impairments, as registered in their clinical records.
2. Severe hearing and visual impairments as registered in their clinical records.
3. Terminal illness.
4. Illiteracy.
5. Pregnancy or postpartum period.

Inclusion criteria for the HBCPs:

1. Permanent residence in one of the cells of the study.
2. Willing and able to give informed consent to participate in the study.

Exclusion criteria for the HBCPs:

1. Not capable of accomplishing questionnaires due to reading or communication problems.

Outcomes

Primary outcomes

1. Change in HbA1c from baseline to 12-month follow-up.

Secondary outcomes

The secondary outcomes consist in:

1. Medication adherence (change from baseline to 12-month follow-up).
2. Number of dropouts, lost appointments to the NCD clinic of the hospital.
3. Mortality, number of complications, number of referrals.
4. Health literacy (change from baseline to 12-month follow-up).
5. HRQoL (change from baseline to 12-month follow-up).
6. Diabetes-related distress (change from baseline to 12-month follow-up).
7. Percentage of patients with at least one measurement of: HbA1c, fasting blood glucose (FBG) levels, creatinine, urine proteins, blood pressure, body mass index (BMI) (change from baseline to 12-month follow-up).
8. FBG, creatinine, urine proteins, blood pressure, BMI (change from baseline to 12-month follow-up).

9. Registered number of: smokers, pack years, alcohol intake per week (change from baseline to 12-month follow-up).
10. Number of smokers, number of cigarettes per day, alcohol intake per week (change from baseline to 12-month follow-up).

Measurements

Baseline and follow-up assessments will be performed at the NCD clinic for intervention and control groups. Measurements will be undertaken at four time-points in each group, as illustrated in [table 1](#).

Glycated haemoglobin

HbA1c will be measured every six months at the hospitals. All selected hospitals are equipped with an identical analysis device.

Other clinical and laboratory examinations

1. FBG will be measured every three months by nurses by taking a blood test after eight hours of fasting.
2. Creatinine will be measured at baseline and after 12 months.
3. Urine proteins will be measured every six months.
4. Blood pressure, waist circumference, weight and height will be measured every three months and the BMI will be calculated accordingly.
5. Foot examination.

Lifestyle

Alcohol intake and smoking will be evaluated every three months.

Health-related quality of life

HRQoL will be assessed with the *Diabetes-39* questionnaire, which covers five dimensions: energy and mobility, diabetes control, anxiety and worry, social burden and sexual functioning.⁵⁵ This self-administered tool enables patients to provide answers based on their own concept of quality of life. The reported Cronbach's α of the questionnaire is 0.81–0.93, and has strong correlation with generic quality of life tools, such as the Short-Form 36 questionnaire.^{56 57} Measurements will take place every six months and the questionnaire will be administered by a nurse.

Diabetes-related distress

The 20-item *Problem Areas in Diabetes* questionnaire will be administered to evaluate the diabetes-related distress. It has high internal consistency (Cronbach's α : 0.93–0.95), strong correlation to generic and disease-specific quality of life instruments and has been reported as a significant predictor of glycaemic control.^{57 58} Measurements will take place every six months and the questionnaire will be administered by a nurse.

Health literacy

The *Information and Support for Health Actions Questionnaire* will be employed to assess the level of health literacy. It was developed for LMICs and in contexts where decisions on health-related issues often take place collectively, within

Table 1 Schedule of enrolment, interventions and assessments of the randomised controlled trial

	Enrolment	0	3	6	9	12
Enrolment						
Eligibility screen	X					
Informed consent and information sheet	X					
Assessments by nurses						
Anamnesis, demographics		X				
Height		X				
Weight, waist circumference, blood pressure, FBG, foot exam		X	X	X	X	X
Complications assessment		X	X	X	X	X
Smoking and alcohol intake		X	X	X	X	X
Pill count		X	X	X	X	X
HbA1c, urine proteins		X		X		X
Creatinine		X				X
ISHA-Q		X				X
BMQ		X		X		X
D-39		X		X		X
PAID		X		X		X
Interventions						
Monthly home visits by HBCPs: only for patients of the intervention groups 1 and 2		●—————●				

BMQ, Brief Medication Questionnaire; D-39, Diabetes-39; FBG, fasting blood glucose; HbA1c, glycated haemoglobin; HBCPs, home-based care practitioners; ISHA-Q, Information and Support for Health Actions Questionnaire; PAID, problem areas in diabetes.

the family or other peer groups.⁵⁹ It has good psychometric properties, strong construct validity and reliability. Measurements will take place every 12 months and the questionnaire will be administered by a nurse.

Medication adherence

The 2003 revised version of the *Brief Medication Questionnaire (BMQ)* will be used to assess medication adherence. It evaluates patients' medication-taking behaviour, reported side-effects, concerns and barriers to adherence.⁶⁰ It was developed to facilitate the evaluation of multidrug regimens and has already been used in diabetic patients.^{61 62} Measurements will take place every six months, and the questionnaire will be administered by a nurse.

Information will also be gathered from the pharmacies that dispense medications in order to calculate *pill count*. The formula that will be used is: (Number of dosage units dispensed – number of dosage units remained) / (prescribed number of dosage unit per day × number of days between two visits).⁶² Such a count will be carried out in an attempt to triangulate the information received from the BMQ with a more objective, although potentially challenging, method.

Questionnaires

In preparation for the use of the study's questionnaires both their translation into Kinyarwanda and their cultural

adaptation will be carried out, following the standard procedures described in the guidelines of Beaton *et al.*⁶³

Implementation fidelity

To enable delivery of the interventions according to the study protocol and the standard operating procedures, the following training sessions are scheduled:

1. A one-day training course for the nurses and study co-ordinators of each site.
2. A one-day course for the HBCPs of each site.
3. One-on-one training on the web-panel for the nurses.
4. A workshop for the HBCPs of intervention 2 of each site on the use of the web-panel and the patient's mobile app.
5. A refreshing training course on diabetes management for HBCPs.
6. Regular and ad-hoc refreshing training courses for HBCPs (depending on every site's needs).

The courses consist of lectures, interactive exercises, demonstrations and group reflection. Printed educational material on diabetes will be handed to HBCPs. All nurses and HBCPs will receive manuals for the use of the web-panel and mobile app.

Coaching and close monitoring of the recruitment of the first patients will be offered to all nurses. Pharmacists and lab technicians will also receive a brief training, and their activities will be closely monitored.

Data entry will be performed using a paper-based forms. Study documents will be monitored to ensure they are appropriately filled in on a weekly basis by the site coordinator. Through electronic visit logs, HBCPs will report on the frequency, duration and contents of the home visits. The perceived acceptability and appropriateness of the interventions will be discussed and regularly assessed with nurses, HBCPs and other clinical and administrative staff at the sites.

Sample size

According to our estimates, in the hospitals running the HBCP programme, there should be approximately four to seven diabetic patients per cell. Lacking other data on diabetes in Rwanda, the SD from a study of Levitt *et al* in South Africa was used to calculate the within and between variance.⁶⁴ A one-point difference in HbA1c is considered as a clinically significant outcome based on previous studies.⁶⁵ For the power calculation, we assume a within variance of 4.76, a between variance of 0.53, an intraclass correlation of 0.1.

Assuming four patients per cell, the number of clusters per group needed is 27 for a total number of 108 patients per group to achieve 80% power with a 5% level of significance (total number of patients: 324, total number of cells: 81). One hundred and forty-four patients per group (total number of patients: 432; total number of cells: 108) will be needed to allow for a 30% attrition.

Statistical analysis

The pretreatment sociodemographic characteristics of the sample distributions will be checked to assess whether they match the key variables and characteristics of the reference population. Additional analysis will be conducted to verify the balance on the measured covariates between the treatment and the control groups, while ad-hoc statistical models will be used in cases where randomisation will fail the random allocation of the intervention, leading to potential bias estimates.

To avoid a potential post-treatment complication, such as noncompliance behaviour after treatment assignment, the standard intention-to-treat estimate will be of primary interest. To assess the mean difference in HbA1c among the three groups of the study, the primary analysis will be a repeated-measures analysis, with time as the within-subject factor and intervention as a between-subject factor. Other continuous outcomes, including the scales of the four questionnaires and the results of the laboratory and clinical measurements, will be analysed with repeated-measures designs as well. Post-hoc analysis will be conducted to further compare the outcomes between the three groups of the trial, and the Bonferroni correction will be applied to counteract the problem of multiple comparisons. In case of variables' lack of normality assumption, changes over time in groups will be assessed with related-samples Wilcoxon tests and effects of the intervention on changes will be evaluated using independent samples Kruskal-Wallis tests.

The presence or absence of self-reported nonadherence (adherence screen of the BMQ), and the percentage of the patients with registered examinations and clinical information, will be examined using χ^2 tests.

Multiple-imputation-based methods will be used in order to address missing data at follow-ups. Non-compliance and drop-out behaviour with post-treatment assignment will be handled in a principled manner, to identify the impact of the two interventions on the primary and secondary outcomes in the subpopulation of those who completed the follow-up assessments. A sensitivity analysis that takes into account biases caused by interference (such as the social networks) will also be performed.

PHASE II: QUALITATIVE STUDY

At the end of the trial, two types of focus group discussions (FGDs) will be conducted: (1) with patients of the two intervention groups, and (2) with HBCPs delivering the two interventions of the study.

Participants

Patients and HBCPs from the two intervention groups of the trial will be chosen to participate by purposive sampling. Although maximum variation will be sought (based on age, gender, economic and educational level, and adherence for patients; and age, gender and previous occupation for HBCPs) to ensure variability within the primary data, the main objective is not to achieve a representative sample, but to gain a deeper understanding of the participants' opinions. For each type of FGD, we will aim for saturation; therefore, it is suggested that at least two FGD per type will be conducted.

Data collection and analysis strategy

An interview protocol will be developed before the onset of the second phase addressing the second study aim. Each patient or HBCP will be invited to participate in an FGD of about two hours. Discussions will be audio recorded. The FGDs will be carried out in Kinyarwanda. Two or more native speakers will facilitate the FGDs and/or take notes. Audio recordings will be transcribed word-for-word into a digital document in Kinyarwanda. The translated transcripts will be imported in a heuristic tool for thematic coding and analysis, in which the underlying meaning or concepts behind each statement will be identified and grouped into codes and themes. A coding template will be developed from a few of the early transcripts and will be used to code later transcripts in an ongoing process as data is collected. After each FGD, the researchers will discuss the emerging coding structure and will reach a consensus as to whether new themes emerge or saturation has been reached.

Ethics and dissemination

The study is registered on ClinicalTrials.gov (NCT03376607); all necessary information according to the WHO recommendations is provided (table 2).

Table 2 WHO trial registration dataset

Data category	Information
1. Primary registry and trial identifying number	ClinicalTrials.gov NCT03376607
2. Date of registration in primary registry	18 December 2017
3. Secondary identifying numbers	–
4. Source(s) of monetary or material support	Karen Elise Jensens Fond, Aarhus University, University of Luxembourg
5. Primary sponsor	Aarhus University
6. Secondary sponsor(s)	Karen Elise Jensens Fond, University of Luxembourg
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9. Public title	Community- and mHealth-Based Integrated Management of Diabetes in Primary Healthcare in Rwanda
10. Scientific title	Community- and mHealth-Based Integrated Management of Diabetes in Primary Healthcare in Rwanda: The D ² Rwanda Study
11. Countries of recruitment	Rwanda
12. Health condition(s) or problem(s) studied	Diabetes Mellitus, Telemedicine, Community Health Workers
13. Intervention(s)	<i>Intervention 1: HBCP programme</i> The newly established Home-Based Community Practitioners (HBCPs) programme will provide monthly health assessments, disease management and lifestyle advice by the HBCPs, and referral to the district hospitals when needed. <i>Intervention 2: behavioural: mobile health application</i> HBCPs will actively encourage the use of a mobile app by assisting patients to access it (this process is known as 'facilitated access'). The app will enable: (1) the registration of measurements, such as blood glucose and weight; (2) the registration of concerns and questions in a diary; (3) the reception of alerts and notifications for the appointments to the health facilities, and; (4) access to advice on lifestyle improvement and other patient educational material.

Continued

Table 2 Continued

Data category	Information
14. Key inclusion and exclusion criteria	<p><i>Inclusion criteria for patients:</i></p> <ol style="list-style-type: none"> 1. Adult patients (male and female) aged between 21 and 80 years. 2. Diagnosed and confirmed as diabetic patient at least six months prior to study start. 3. Living in the administrative areas (called 'cells') of the district hospitals participating in the first phase of the HBCP programme. 4. Residing, and planning to reside within a two-hour travel distance on foot from the study site for the duration of follow-up. 5. Willing and able to adhere to the study protocol. 6. Willing and able to give informed consent for enrolment in the study. <p><i>Exclusion criteria for patients:</i></p> <ol style="list-style-type: none"> 1. Severe mental health conditions, including cognitive impairments, as registered in their clinical records. 2. Severe hearing and visual impairments as registered in their clinical records. 3. Terminal illness. 4. Illiteracy. 5. Pregnancy or postpartum period. <p><i>Inclusion criteria for HBCPs:</i></p> <ol style="list-style-type: none"> 1. Permanent residence in one of the cells of the study. 2. Willing and able to give informed consent for enrolment in the study. <p><i>Exclusion criteria for HBCPs:</i></p> <ol style="list-style-type: none"> 1. Not capable of accomplishing questionnaires due to reading or communication problems.
15. Study type	<p>Type: interventional</p> <p>Study design:</p> <ul style="list-style-type: none"> ▶ Allocation: randomised. ▶ Intervention model: parallel assignment. ▶ Masking: none (open label). ▶ Primary purpose: treatment.
16. Date of first enrolment	11 January 2019
17. Sample size	432
18. Recruitment status	Enrolling by invitation
19. Primary outcome(s)	Change in glycated haemoglobin (HbA1c) (time frame: change from baseline to 12-month follow-up)

Continued

Table 2 Continued

Data category	Information
20. Key secondary outcomes	<ul style="list-style-type: none"> ▶ Medication adherence (time frame: change from baseline to six-month and 12-month follow-up). The Kinyarwanda version of the Brief Medication Questionnaire (BMQ) will be administered at: baseline, after six months, and on trial completion (after 12 months). Data will also be gathered from the pharmacies dispensing medications to calculate the pill count, in an attempt to triangulate the information received from the BMQ with a more objective method. ▶ Number of dropouts of the NCD clinics of the district hospitals (time frame: from baseline to 12-month follow-up). ▶ Number of lost appointments to the NCD clinics of the district hospitals (time frame: from baseline to 12-month follow-up). ▶ Mortality (time frame: from baseline to 12-month follow-up). ▶ Number of complications (time frame: from baseline to 12-month follow-up). ▶ Number of referrals (time frame: from baseline to 12-month follow-up). ▶ Health literacy (time frame: change from baseline to 12-month follow-up). The Kinyarwanda version of the Information and Support for Health Actions Questionnaire (ISHA-Q) will be employed to assess the health literacy level (at baseline and after 12 months). ▶ Health-related quality of life (time frame: change from baseline to six-month and 12-month follow-up). The Kinyarwanda version of the Diabetes-39 questionnaire will be used to measure health-related quality of life (at baseline, after six months and on trial completion (after 12 months)). ▶ Diabetes-related distress (time frame: change from baseline to six-month and 12-month follow-up). The Kinyarwanda version of the Problem Areas in Diabetes questionnaire will be administered to evaluate psychological well-being (at baseline, after six months and on trial completion (after 12 months)). ▶ Percentage of patients with at least one measurement of HbA1c (time frame: change from baseline to 12-month follow-up). ▶ Percentage of patients with at least one measurement of fasting blood glucose (FBG) levels (time frame: change from baseline to 12-month follow-up). ▶ Percentage of patients with at least one measurement of creatinine (time frame: change from baseline to 12-month follow-up). ▶ Percentage of patients with at least one measurement of urine proteins (dipstick) (time frame: change from baseline to 12-month follow-up). ▶ Percentage of patients with at least one measurement of blood pressure (time frame: change from baseline to 12-month follow-up). ▶ Percentage of patients with at least one recording of body mass index (BMI) (time frame: change from baseline to 12-month follow-up). ▶ Fasting blood glucose (FBG) levels (time frame: change from baseline to 12-month follow-up). ▶ Creatinine (time frame: change from baseline to 12-month follow-up). ▶ Urine proteins (dipstick) (time frame: change from baseline to 12-month follow-up). ▶ Blood pressure (time frame: change from baseline to 12-month follow-up). ▶ Body mass index (BMI) (time frame: change from baseline to 12-month follow-up). ▶ Recorded number of smokers (time frame: change from baseline to 12-month follow-up). Recording of whether a patient is smoker or not. ▶ Number of patients with recorded pack years (time frame: change from baseline to 12-month follow-up). ▶ Number of patients with recorded alcohol intake per week (time frame: change from baseline to 12-month follow-up). ▶ Number of smokers (time frame: change from baseline to 12-month follow-up). ▶ Number of cigarettes per day (time frame: change from baseline to 12-month follow-up). ▶ Alcohol intake per week (time frame: change from baseline to 12-month follow-up).
21. Ethics review	Ethical approval has been obtained from the Rwanda National Ethics Committee (100/RNEC/2017; amendment approved in 463/RNEC/2017; renewed in 113/RNEC/2018; renewed in 192/RNEC/2019) and the Ethics Review Panel of the University of Luxembourg (ERP 17-014 D ² Rwanda; amendment approved in ERP 17-048 D ² Rwanda).
22. Completion date	31 May 2020 (anticipated)
23. Summary results	n/a
24. IPD sharing statement	Undecided

Consent will be obtained before any of the study procedures take place. Study personnel will hand out information sheets to all potential participants and written informed consent will be sought. All necessary procedures and precautions will be taken to maintain the confidentiality of study participants. Information collected will be pseudonymised so that individual identities cannot be retrieved.⁶⁶ All study forms will be kept in designated locked cabinets and digital files will be stored on a password-protected computer.

The mobile app has a low person-specific and intervention-specific risk.^{67–69} Privacy and confidentiality, loss of phone, networks issues, inappropriate app usage and inadequate user training have been taken into consideration, and necessary measures will be employed (eg, storage on a local server in Rwanda, data encryption, secure connections, remote deactivation of accounts, facilitated access and continuous education and so on).

Study findings will be communicated to study participants, study sites, the Ministry of Health and the ethics committees. Results will be presented at the universities (Aarhus, Luxembourg and Rwanda), disseminated in scientific fora, including scientific conferences and seminars, and written up for publication in peer-reviewed journals.

Reimbursements

Participants will be required to travel to study sites to attend follow-up visits for the study. For visits for which participants are required to spend a significant amount of extra time at the study sites for study-related procedures, a small fixed reimbursement will be offered. All participating HBCPs will receive a monthly reimbursement for the additional reporting and travelling during the trial, and a solar battery pack to facilitate their fieldwork.

Role of the funding source

The D²Rwanda study has received financial support from the Karen Elise Jensens Fond (Denmark), and the Universities of Aarhus and Luxembourg. The sponsors of the study had no role in the study design and preparation, and will have no role in the data collection, analysis and interpretation or writing of the publications.

Patient and public involvement

Patients and public were not involved in the design of the protocol. After completion of the study, results will be disseminated to the study participants and general public.

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Contributors CL, JPU, CV and PK conceived of the study and developed the design and protocol. MB made substantial contributions to sample calculation and the statistical analysis plan. JC contributed to the development of the protocol. CL wrote the first draft of the manuscript and all authors contributed to revising it critically.

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Competing interests None declared.

Patient consent for publication Not required.

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Provenance and peer review Not commissioned; externally peer reviewed.

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