Study Protocol Feasibility and Pilot Trial of Brief Behaviour Change Counseling Using Five as and a Guiding Style From Motivational Interviewing on Lifestyle Behaviour in Patients With Hypertension or Diabetes in Mangochi, Malawi: BBCC+5 A's+GS Quasi-experimental Study Protocol

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Study Protocol

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Abstract

Background

Diabetes and hypertension and their lifestyle risk factors are on the increase in sub-Saharan Africa. Despite positive effects of behavioural intervention such as brief behaviour change in some African countries, there has not been significant implementation of the same in Malawi. We therefore decided to conduct this study aimed at implementing brief behaviour change counseling using 5 As and a guiding style from motivational interviewing (BBCC + 5 As + GS) in Mangochi with specific objectives of determining its feasibility and its efficacy.

Methods

This study is a mixed, quasi-experimental, feasibility study which comprises an exploratory 2 arms quantitative part with a qualitative component at the end of the trial. Fifty consecutive eligible participants will be recruited among patients attending two Non-Communicable Diseases (NCDs) clinics (Mangochi District Hospital and Monkey Bay Rural Hospital) and allocated equally to intervention group (receiving brief behaviour change counseling) and non-intervention (routine care only). In addition to a qualitative process evaluation at the end of the third time points, the groups will be assessed at baseline - 12 weeks and 24 weeks' post-implementation on the following factors: feasibility outcomes, sociodemographic factors, lifestyle factors, body mass index, waist circumference, hip to waist ratio, lipids (cholesterols, triglycerides), glycated hemoglobin, quality of life domains and theory of planned behaviour constructs’ changes and process evaluation.

Discussion

It is anticipated that the results of this pilot trial will help to determine and assess the feasibility and the provisional efficacy of this intervention, as well as key useful elements of this trial in order to develop it for further exploration in a larger trial.

Registration and status of the trial

Trial registration: ClinicalTrials.gov, NCT04625452, registered 12 November 2020, https://clinicaltrials.gov/ct2/show/NCT04625452, and recruitment: June 1, 2021.

Background

The numbers of adults affected with diabetes in 2010 globally was 285 million and is expected to reach 552 million by 2030 [1]. In sub-Saharan Africa, during the same period, the estimates will double from 12.1 million to 23.9 million, [2,3]. In Malawi, the National Steps Survey conducted in 2009 showed diabetes’ prevalence of 5.6% among adults aged between 24 to 64 years old [1]. A more recent national review of NCDs prevalence in the country showed high rates of both hypertension and diabetes. Diabetes ranged between 2.4-5.6% while hypertension ranged between 15.8-32.9% [4]. In Sub-Saharan Africa, the
rise in the prevalence of diabetes and hypertension is compounded by several contextual factors such as weak health systems which are under resourced and fragmented, with low human resource, low financial capacity and poor infrastructure [5,6]. Individual and family factors also level several barriers to care [5,7].

While drug treatment for hypertension and diabetes has been the focus for management of these conditions, lifestyle risk factors modification is one of the pillars in management (of diabetes and hypertension) because, if neglected, modifiable risk factors contribute to the onset, morbidity and mortality from NCDs [8,9]. These modifications can use individual or group interventions. The existing health promotion approach to lifestyle risk behaviours among diabetics and hypertensive patients in Malawi is so far using group counselling model for delivery in form of health talks conducted at clinic's waiting space. It is also conducted in form of an individual simple advice for change in the consultation room. However, group-counselling fails to give room to patient's inner ability, strengths, potentials for change and individual needs. Simple advice, on the other hand, has limited effectiveness in practice of changing behaviour [10].

Brief behaviour change counseling (BBCC) is defined as an intervention embedded in a normal consultation, lasting 3–5 minutes, reinforcing confidence of a patient to change the behaviour in question using his own ability [11]. It emerged as an alternative to group-counseling and advice for change. Moreover, success in BBCC administration requires appropriate skills and evidence-based techniques beyond the “mechanical skills” displayed during group counseling or one on one advice. To achieve the above goal, skills in brief intervention which target behaviour and attitudinal change are the most appropriate as the approach presents several advantages. In this approach, patients adapt to individual readiness to change which potentially lead to successful behaviour change [12]. There is also facilitation of change from acute to chronic model of care [11] which is more appropriate in NCD’s and other chronic care.

Brief behaviour change counseling has several shortfalls such as providers feeling ill-prepared for its use [13], lack of appropriate language and time, poor knowledge of lifestyle modification approaches and lack of continuity of care [14].

Complementing the BBCC approach is a well-structured, stepwise framework in form of 5 A’s (ask, advise, assess, assist, and arrange) reinforced by a Guiding Style (GS) from motivational interviewing (in form of specific question approaches summarizing different stages of the 5 A’s). These supplements streamline the administration of the approach and make it easy for learners to master the approach for its quick and straightforward implementation.

The provision of a well-structured, clear and simple protocol such as 5 A’s and a guiding style from motivational interviewing with high quality educative materials and system support to the intervention may increase the delivery of the intervention [15]. This protocol (of 5 A’s and GS) helps to clarify patient’s strengths and aspirations, evokes their own motivations for change, and promotes autonomy of decision making [10]. Previous evidence supports that additional motivation interviewing to BBCC can further
promote behaviour change, patient-doctor relationship, and efficiency of the consultation [10]. There have not been any studies conducted on BBCC + 5 A’s + GS (guiding style from motivational interviewing) in Malawi with respect to smoking cessation, alcohol reduction, unhealthy diet changes and increase in physical inactivity.

Although few brief behaviour change studies using 5 A’s have been conducted in South Africa, their focus was on training primary health care providers in provision of the approach [13,16,17]. A study in Nigeria focused on the use of BBCC+5A’s in hypertension management. In this study, the guiding style tailored to motivational interviewing was almost absent [18]. There is a difference in the operational definitions of 5A’s elements in Nigeria’s study with ours in that we have included the motivational interviewing component. We decided, therefore, to conduct this study aimed at assessing the feasibility and the efficacy of brief behaviour change using 5 A’s + GS (from motivational interviewing) on patients with hypertension or diabetes in Malawi. The specific objectives include:

1. To provide estimates of key trial design needed to design a full scale randomized controlled trial (RCT). The trial is warranted on the following: a) number of eligible participants, b) recruitment rate, c) retention rate, d) response rate to follow-up questionnaire.

2. To explore the experience of participants and health providers to: a) the brief behaviour change counseling, b) the study materials (informed consent and participant’s information sheet, pamphlets on BBCC, questionnaire), c) the time allocated for BBCC + 5 As + GS; d) being selected to intervention or usual care, e) integration of BBCC in routine care; f) complexity of the intervention and/or training, perceived efficacy of BBCC + 5 As + GS and the satisfaction of services offered.

3. To generate estimates for the variability of secondary outcomes: quality of life domains; theory of planned behaviour constructs; anthropometrics (BMI, waist circumference, waist-to-hip ratio), clinical factors (SBP, DBP) and biologic biomarkers (Lipids, HbA1C, Triglycerides, FBS) through different time points.

4. To estimate the sample size required to detect a statistically significant difference with statistical power of 80% between experimental and control groups.

**Methods**

**Design:**

The study will be a pilot, mixed, quasi-experimental study, two-arms feasibility design. We opted for quasi-experimental design because our study will select participants without randomization (randomization will follow in the full trial) in order to demonstrate causality between the intervention and the outcomes [19]. As a pilot trial, in case of efficacy, we expect to work with a small sample size, and therefore, the rationale of randomization becomes questionable [19]. Exploring the experience of participants by assessing the preliminary efficacy and the feasibility outcomes explains the mixed nature of the study. Participants will be assigned to one of the two groups: control group (which will receive the usual care as per Malawian
NCDs guidelines) and intervention group (which will receive, in addition to usual care, BBCC+ 5 A's + GS with printed education materials).

**Setting and participants**

The study will be undertaken at two different settings. These are only NCDs clinics offering diabetes and hypertension services in Mangochi district, Malawi (Mangochi District Hospital and Monkey Bay Community Hospital). At both hospitals, diabetes represents on average 25 percent of patients ever registered. The two sites are 70 kilometers apart. They are both publicly owned and they operate twice and once weekly respectively.

The study population will comprise patients with diabetes and hypertension attending the Non-Communicable Diseases Clinics at these two hospitals. The following are the eligibility criteria: the patient must

- be at least 18 years’ old
- be registered at the clinic for a period of at least for 6 months
- have been screened for at least one lifestyle risk factor
- be willing to participate in the study
- be permanent resident of Mangochi district for at least 12 months from point of recruitment
- be fluent in Chichewa and/or Yao (two widely spoken languages in the area).

The following are the exclusion criteria:

- pregnancy
- severe concomitant physical conditions
- psychiatric condition

Participants will be screened for eligibility by a trained data clerk under a nurse's supervision. This will be done when patients visit NCDs clinics for their monthly medicine refill appointment. The clerk will inform patients about the study and those meeting the inclusion criteria will be briefed about the content of the participants’ information sheet. Those interested will proceed to sign the informed consent form.

Upon signing the consent, the patients, now as study participants, will be sent to a second team comprising a clinician (clinical officer) and a nurse who will confirm the consent and explain the whole procedures of the study.

A questionnaire comprising several components (related to sociodemographic data, quality of life, theory of planned behaviour constructs’ questions and feasibility) will either be read and answered by the participant or it will be done with assistance of a research assistant in case of illiterate participants. For ineligible patients, the clerk/nurse will record their number and reasons for not consenting or being ineligible. At this stage, we may have three categories of participants: eligible and willing to participate,
eligible and not willing to participate and ineligible. Reasons for declining participation or ineligibility will be sought and documented.

The intervention

The intervention will consist of counseling based on lifestyle risk factors of diabetic patients which will be themed around 5 points. The points are: (1) ask (for the behaviour, then assess and document in patient’s file); (2) alert/advise (provide information on the behaviour, tailor the advice to the patients at hand with already possible complications and express social support for change); (3) assess (allow the patient to assess his readiness to change or assess importance and confidence of change using a scale. Assess patient’s personal relevance using a scale); (4) assist (assist the patient to plan for change and acquire behavioural skills and confidence to succeed, Ask patient about social support system. Also supply educational and motivational materials and medical treatment; if necessary); and (5) arrange (set the date of next appointment as well as points for follow-ups. Emphasize counselor’s availability for any clarifications or further questions) [11].

We are going to administer the intervention at three time points: 0 week, 12 weeks and 24 weeks. During the intervention, brief behaviour change using 5 As will come with guiding principles from motivational interviewing which will allow flexibility well desired to support self-management and evoke behaviour change [11]. Rather than an expert, the health professional will be playing the role of a facilitator. Questions will respect the spirit of motivation interviewing which will be summarized in trying to convince the patient on why, what and how he may change [13].

Motivational interviewing is a patient-centered counseling style that augments an individual’s motivation to change behaviour and move to another goal [10]. Motivational interviewing achieves this through use of open-ended questions, affirmation, summarizing, reflective listening and change talk [11]. Information about BBCC + 5 As + GS will be provided as printed material following every counseling session. The intervention will be delivered by nurses trained in motivational interviewing for lifestyle. Due to lack of established expert in motivational interviewing, the principal researcher (a family physician with advanced training in motivational interviewing) will ensure the adherence to operational procedures and motivational interviewing. After obtaining consent, sessions will be audio recorded and analyzed during debriefing sessions between two time points to ensure fidelity to the intervention manual.

Comparator group

Participants in the comparator group will carry on their activities as usual during the study and receive the standard care of hypertension/diabetes as per Malawi’s protocol. Participants allocated to usual care will receive standard care for diabetes and/or hypertension as per Ministry of Health (MoH) and Government of Malawi NCDs interim guidelines. Participants in this group will receive baseline results to ensure consistency but they will not be provided with any additional counselling.

Assessment of the intervention
Participants will complete a survey during the follow-up visits to the clinic at 12 weeks point (T₁) and 24 weeks point (T₂) after the baseline data collection at T₀ following their recruitment.

Table 2 provides parameters for assessment at different time points. A day before clinic visit for T₁ or T₂, a phone call will be made to remind the participant about the appointment. For those not answering, a second one will follow within 24 hours from the first. A patient not reached by these two call attempts will be categorized as lost to follow-up, until otherwise proven. Those in intervention will be asked to keep a journal on activities done: day, duration, frequency, changes observed after PA; cigarettes smoked (how long after waking-up, number of cigarettes); consumption of fruits and vegetables (number of times per day, per week) and alcohol consumption (type, number of standard drinks, number of days of more SD per a session).

At the end, qualitative design will be carried out to explore the acceptability/feasibility of BBCC on lifestyles of patients with diabetes or hypertension from guardians’ or providers’ perspectives. For the entire study, table 2 shows the exact dates, parameters and time points, number of times (if applicable) for enrollment, intervention and assessments.

During the whole study time, a statistician who will analyse data will be blinded after assignment of participants to the intervention by removing all identifiers.
Table: 2. BBCC + 5 As +GS intervention on lifestyles of people with diabetes and hypertension in Mangochi, Malawi: a questionnaire measured by assessment point.

| Measures included in the study questionnaire                                                                 | Assessment points |
|-------------------------------------------------------------------------------------------------------------|-------------------|
|                                                                                                              | $T_0^b$ | $T_1^b$ | $T_2^b$ |
|                                                                                                              | Baseline | 12 weeks | 24 weeks |
| 1. Number of participants as defined by each feasibility outcomes (recruitment rate, Number participants who consented to take part, proportion of participants who completed the study, Proportion of participants retained in the study, Proportions of participant's loss-to-follow-up). |          |          |          |
| Few are assessed at each time point, others at the baseline or at the end) [20]                           |          |          |          |
| 1. Change in Trans theoretical model phase [21]                                                           |          |          |          |
| 1. Change in alcohol consumption using Alcohol Use Disorder Identification Test- C (AUDIT-C) from baseline [22] |          |          |          |
| 1. Mean change in smoking using Short Fagerström Test for Nicotine dependence[23]                          |          |          |          |
| 1. Change in Global physical activity questionnaire from baseline (GPAQ) [24]                             |          |          |          |
| 1. Change in consumed diets using the lifestyle assessment form from baseline [11]                         |          |          |          |
| 1. Mean changes in Quality of life domains scores from baseline by the Malawian Chichewa WHOQOL-Brief tool [25] |          |          |          |
| 1. Change in theory of planned behaviour constructs scores Means (intention, attitude, subjective norms, and perceived behaviour control) from baseline [26] |          |          |          |
| 1. Means change in Body Mass Index from baseline                                                          |          |          |          |
| 1. Means Change in waist to hip circumference                                                             |          |          |          |
| 1. Means Change in the waist circumference from baseline                                                  |          |          |          |
1. Means Change in the seated through cuff mean systolic blood pressure (SBP) from baseline

| 1. Means Change in the seated through cuff mean diastolic blood pressure (DBP) from baseline |
| 1. Means change in the level of fasting blood glucose from baseline |
| 1. Means change of total cholesterol (TC) (mg/dl) from baseline |
| 1. Means change of triglycerides (TG)(mg/dl) from baseline |
| 1. Means change of HDLc (high density lipoproteins cholesterol) from baseline |
| 1. Means change of LDLc (low density lipoproteins cholesterol) from baseline |
| 1. Means change of glycated hemoglobin (HbA_{1C}) (%) from baseline |
| 1. Adverse outcomes and events (intervention arm only participants) |
| 1. Perception of participants and staff on BBCC + 5 As + GS (utility, inconvenience, perceived effectiveness, side-effects, how it is done, logistic constraints, time, space, staff, procedures, integration in the system and the community) |

- a: done at this given time point; b: baseline, 12 and 24 weeks;

Outcomes

Primary outcomes

The primary outcomes are; (1) participants find the study and the intervention to be feasible and/or (2) the full randomized controlled trial is warranted and feasible. Specifically, following parameters:
• Recruitment rate (the number of individuals recruited out of those interested), consent rate (percentage of individuals who consented to be involved in the study out of those deemed to be eligible), retention rate (proportion of participants who remained in the study during its entirety), lost to follow-up (participants who withdrew, lost to follow-up or who did not attend a follow-up visit) and adherence (total number of visits attended out of the total number of visits)” [20].

Secondary outcomes

The secondary outcomes are:

• Estimates of the variability/changes of:

  1. theory of planned behaviour constructs. The theory of planned behaviour posits that for someone to perform a given behaviour (for example, adopt a healthy diet) s/he is guided by three kinds of considerations: beliefs about the likely consequences and experiences associated with the behaviour (behavioural beliefs), beliefs about the normative expectations and behaviours of significant others (normative beliefs), and beliefs about the presence of factors that may facilitate or impede performance of the behaviour (control beliefs). In their respective aggregates; behavioural beliefs produce a favourable or unfavourable attitude toward the behaviour, normative beliefs result in perceived social pressure or subjective norm, and control beliefs give rise to perceived behavioural control or self-efficacy. Attitude and intention are added to the preceding constructs to make 5 main constructs. To measure those three components, a 7 points-scale is applied to each behaviour where high numbers (positive numbers) represent best outcomes while negative numbers represent worse outcomes. For attitude, the scale has bad-good; pleasant-unpleasant. For perceived norm it has agree-disagree and unlikely-likely. For perceived behavioural control it has true-false and disagree-agree. Lastly, for intention it has likely-unlikely and false-true. The higher the score, better the outcome [26].

  2. Trans-theoretical model: The study participants will be asked to state their intentions by choosing one of the following five statements to the question “when are you intending to change the behaviour?”

      • No, I do not intend in the next 6 months [Pre-contemplation]
      • I intend to in the next 6 months [Contemplation]
      • I intend to in the next 30 days [Preparation]
      • I have been doing so for less than 6 months [Action]
      • I have been doing so for more than 6 months [Maintenance] [21].

The change across time points will be done by comparing numbers of the stages at different time points. The higher the stage, the advanced the degree of changes. Same figure at two different time points means no progress on degree of behavior change. The less the figure, the negative the progress of change in time.
1. AUDIT score (Audit-C is a validated, self-reported measure of perceived severity (quantity and frequency) of consumption of alcohol comprising 3 questions whose score gives a global score from the 3 [22]. The scoring system of AUDIT-C is as follow; frequency of drink containing alcohol (scores: 0-4), number of standard drinks on a day (scores: 0-4), and frequency of 5 or more standard drinks on any one occasion (scores: 0-4). This global score is either below 5 (non-harmful alcohol use), or 5 and higher (harmful alcohol). The higher the score, the severe the drinking.

2. Short Fagerström Test: This is a test for Nicotine dependence among participants who are screened for smoking of any form (cigarettes, chewing, tobacco and pipe). Fagerström test uses two questions for scoring related to time between waking-up and taking the first cigarettes ($\leq 5$ min= 3, 6-30 minutes=1, 31-60 minutes=3) and number of cigarettes taken per day ($\leq 10$=0, 11-20=1, 21-30=2, and $\geq 31$=3). Score varies from 0 to 6 as follow: 0=very low risk and 6= very high risk.

3. The Global physical activity questionnaire score: Global physical activity questionnaire is a validated, self-report tool endorsed by the World Health Organization for its STEPS Approach to chronic diseases risk factor surveillance. It investigates the physical activity engagement, number of days of physical activity per week, duration spent per day of physical activity, physical changes observed while doing physical activity (breathing, sweating, heartbeats), type of physical activity and barriers to physical activity [24].

4. Lifestyle questionnaire score for nutrition: It is a questionnaire with eighteen closed questions assessing the type of diet with regards to type of flour consumed (colour of flour or bread); number of portions of vegetables/fruits consumed a day; low or free fat milk consumed; number of beans, split peas, lentils or soya consumed per week; amount of fats consumed; salts consumed; healthier food consumed between meals and sweetened drinks consumed [11].

5. Health-related quality of life using the World Health Organization quality of life tool (WHOQOL-Bref): WHOQoL is a validated, self-reported instrument that is a general measure of perceived health status comprising 26 questions and yielding 5 scores from 5 dimensions (with subscales). The 5 dimensions are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [25]. Each dimension has 3 levels: no problems, some problems, and extreme problems, with scores of 1, 2, and 3 representing each level, respectively. The Global score is given by the sum of scores in each dimension/domain. The change will be the differences in scores between the figures at x weeks’ menus figures at x-4 ($x= T_1$ or $T_2$). The low the score, the worse the quality of life.

• Mean Body mass index will be assessed after measurements of weight (kilograms) and height (meters) by dividing the weight (in kilograms) by the square of height (in meters). Values below 18.5 = underweight, 18.5-25 = healthy weight, 25-29.9 = overweight and $>30$: obesity; 30-35 = Grade I, 35-40 = Grade II, $\geq 40$ = Grade III.) [28]. It will also be assessed using waist circumference (a tape-measure placed horizontally at the point between the iliac crest process and the lower margin of the last palpable last rib in a patient standing on deep respiratory). Body mass index will also be assessed using hip circumference (measurements taken using a tape-measure placed horizontally at the point
of maximum circumference over the buttocks on a standing-up participants in deep expiration). The normal range value from 0.80 to 0.70. Measurements will be taken to the nearest 0.1 cm) [28].

- Blood pressure: This measure will be assessed in the morning with the patient relaxing in a sitting position before clinic starts. The third recorded pulse rate's reading from the battery powered digital blood pressure machine will be recorded. The normal values vary between 60 -100. Above these values we have tachycardia in adults and below we note a bradycardia [28].

- Means of Fast Blood Sugar (Clinical chemistry laboratory test of blood sugar using blood samples. The normal values are between 70 and 115 mg/dl. FBS≥ 115 = abnormal). Total Cholesterol (Means change from baseline to 12 weeks in the level of total cholesterol (TC) (mg/dl). HDL_C (Clinical chemistry laboratory test of lipids products assessment using blood sample. The normal value is values ≤ >1.15 millimole per deciliter). LDLc (Clinical chemistry laboratory test of lipids products assessment using blood sample. The normal value is values ≤ 150 mg/dl. Above these readings, a patient has elevated low density lipoproteins). Triglycerides (Clinical chemistry laboratory test of lipids products assessment using blood sample. The normal value is values ≤ 203.5 mg/dl. Any reading above this means one has high TGD.)

- Clinical chemistry laboratory test of lipids products assessment using blood sample. The normal value is ≤ 200 mg/dl. Triglycerides, High Density Lipoproteins, Low Density Lipoproteins, glycated hemoglobin (HbA_{1c}) (Means change from baseline in the level of glycosylated hemoglobin (HbA_{1c}) (Clinical chemistry laboratory test of glycosylate blood products assessment using blood sample. The normal value is 7.5%) [28].

**Sample size**

There is no need for power for feasibility studies in line with the UK National Institute for Health Research guidelines and others [29,30]. Our sample size is based on one of the feasibility guidelines which suggests a minimum of 24 and a maximum of 50 participants are needed [31]. For our case, we chose a convenient sample of 40 patients, and accounting for a drop-out of 25%; the sample size will be 50 which will be divided equally between 2 arms. This sample size will allow to estimate the standard deviations of our outcomes needed to come-up with power calculation for the main randomized control trial. The sample size of the main study will be calculated from this one as well.

**Data management and analysis**

All quantitative data will be double-entered and stored together with qualitative data in a locked cabinet in the PI's office. Participants will be assigned first IDs upon enrolment and second after allocation to their different arms. Those IDs will reinforce anonymity and therefore be used throughout the study during different follow-up visits and communications between research team members and study team-participants. A soft copy of data will be uploaded by staff member on a computer's tablet which will be password protected. Data quality will be checked monthly and backups will be saved monthly. The final de-identification data set and analysis will be conducted by a blinded statistician. A strict intention to treat will direct quantitative data analysis.
We will use a statistical package for Social Science IBM SPSS Version 20 (Armonk, NY, USA). Means, proportions and with their 95% confidence intervals will be given to show precision of certain key variables. The main study will be analysed using chi-square to compare proportions, t-test (ANOVA) for comparison of means if data are normally distributed while non-parametric tests will process very skewed data. Paired equivalents to chi-square and t-test will be used to analyse changes overtime in outcome measures between the time points. Rates for process outcomes or feasibility metrics (recruitment rate, number of participants who consented to take part, proportion of participants who completed the study, proportion of participants retained in the study, proportions of participant's lost-to-follow-up) will be computed. Reasons for non-participation and attrition will also be collected to inform recruitment and retention during the full trial in future.

The qualitative data will be audio-recorded, and later transcribed verbatim to ensure fidelity. Their analysis will use the Framework approach - matrix-based method for collating, reviewing, and understanding qualitative data [32]. Atlas.ti cloud software will facilitate the organization and coding of qualitative data.

**Project management**

Being part of an academic assignment, the day to day management of the feasibility study will be conducted by the Principal Investigator (PI) along with research assistants. The operational management comprising adherence to planned timescale, adherence to the intervention and detailed plans for data management and analysis will be the responsibility of the principal investigator, the supervisor and the mentors under the project called NCDs Brite and the local Institutional Review Board /IRB (COMREC). NCD BRITE will also oversee the project through some quarterly dissemination meetings where progress reports in form of presentations with feedback from four to six faculties, researchers and policy-makers in the field of NCDs will be assisting us to improve and adjust contents and progress (to the set timeline). Finally, the US Government’s National Heart, Lung and Blood Institute (NIH branch), funder of the research project will provide the financial resources to carry out the project through the above local project.

**Ethics and Knowledge Translation**

This study has received an ethical clearance from The College of Medicine Research and Ethics Committee; COMREC (Ref. no. P. 03/20/2971, July 2020). Any modifications made to the content of this protocol will be further resubmitted to the COMREC for a new approval. Permission to conduct this study has been granted by the Research Committee of the Mangochi District Assembly. The study protocol was registered retrospectively on the November 12th, 2020 in ClinicalTrials.gov (number NCT04625452). Throughout this study, all methods will be carried out in accordance with relevant guidelines and regulations.

Results will be shared through presentations in conferences (local or international). The results will also be publishing in Peer-reviewed International Open-access journals. In terms of knowledge translation (KT), this study has three major shortfalls [33]. Firstly, being a pilot study (with small sample size), there
is uncertainty on the need to disseminate preliminary results to the end users (care providers). It is anticipated that these preliminary results have to be confirmed after generating sufficient level of evidence which gives confidence in the conclusion after conducting a full trial. Secondly, the small budget allocated to pilot study cannot fit general ways of dissemination aligning with KT apart from publishing in peer reviewed journals and presentations at conferences. Finally, KT that requires clinician participation (which is time-consuming) may impose additional time for him when he is among our consumers.

**Discussion**

This paper describes a protocol for a pilot feasibility mixed study of brief behaviour change using 5 As and a guiding style for motivational interviewing (BBCC + 5 As +GS) for lifestyle among patients with diabetes or hypertension using two NCDs clinics in Mangochi district in Malawi. It looks at whether administration of BBCC + 5 As + GS can reduce lifestyle effects in patients with diabetes and hypertension in Mangochi. This is important in light of current evidence which shows economic implications of NCDs in sub-Saharan Africa where all-age total DALYs (Daily Adjusted Life Years) due to NCDs increased by 67·0% between 1990 to 2017 in Africa, that is from 90.6 million to 151.3 million [34]. This study is also important as it will pave way for brief behaviour change in lifestyle of patients in a resource constrained country by providing conditions for its feasibility, elements of its acceptability from a qualitative lens, provision of its efficacy, and most importantly determination if recruitment for a full trial is possible. If so, it will also provide parameters for calculation of its sample size. The study will accomplish this by providing evidence for the acceptability, the adverse effects profile of the study, the appropriateness of research measures, the recruitment and retention rates, and finally key information for calculation of the power which will be used in sample size calculation from dropouts and standard deviation of outcome measures.

This study has several strengths. It emphasizes on patient-centeredness through the use of motivational interviewing as a guiding style. It also emphasizes the need to move from general features of any counseling (or Rogerian skills such as acceptance, expressing empathy and being nonjudgmental) to those specific to motivational interviewing (or spirit of motivational interviewing which is summarized in collaboration, evocation and autonomy) [35]. Motivational interviewing also constitutes a good fit for behaviour change in our case of lifestyle. MI further works by rolling with resistance, developing discrepancy between client values and behaviour, supporting client self-efficacy about changing, helping in the process to achieve change and eliciting and reinforcing change talk [36]. Also, the use of five A’s framework which is widely supported by literature in counseling is also another strength.

**Study limitations**

Lifestyle risk behaviours in this study will use a self-reporting approach from participants. Taken as such, the risk for reporting bias remains very high [37]. However, using a combination of behavioural screening tools such as AUDIT, anthropometric, clinic and biologic seem very thoughtful in terms of reducing the impact of self-reporting on behaviour change.
**Conclusion**

It is anticipated that the findings of this pilot study will help to determine the feasibility and the efficacy of brief behaviour change using 5 As and a guiding style from motivational interviewing for lifestyle in patients with hypertension or diabetes in Mangochi, Malawi. We should also be able to identify the key aspects of this intervention which could assist in developing a full randomized trial.

**Abbreviations**

ACEPHEM: African Center of Public Health & Herbal Medicine

ANOVA: Analysis of Variance

AUDIT: Alcohol Use Disorder Identification Test

AUDIT-C: Alcohol Use Disorder Identification Test (shorter version)

BBCC + 5 A’s + GS: Brief Behaviour Change using 5 As and a Guiding Style (from motivational interviewing)

BBCC: Brief Behaviour Change Counseling

BMI: Body Mass Index

Cm: Centimeter

COMREC: College of Medicine Research and Ethical Committee

DALYs: Daily Adjusted Life Years

DBP: Diastolic Blood Pressure

FBS: Fast Blood Sugar

Five As: Ask, Alert/Advise, Assess, Assist, and Arrange (These are five steps in counselling)

GPAQ: General Physical Activity Questionnaire

HBA$_{1C}$: Glycosylated Hemoglobin

HDL: High Density Lipoproteins Cholesterol

IDs: Identifications

IRB: Institutional Review Board
Declarations

Ethics Approval and Consent to participate

Ethical approval was provided by the College of Medicine Research and Ethical Committee (COMREC Approval Number: P03/20/2971; July 2020). All participants provided to the research assistant nurse written informed consent to take part. Manuscript will be handled anonymously - only the research staff
will have access to data. Furthermore, data will be kept locked in a cabinet. The manuscript was also registered with the ClinicalTrials.gov (NCT04625452)

**Consent to publish**

Not applicable. The manuscript does not contain any identifiable data.

**Availability of data and materials**

Not applicable

**Competing Interests**

The authors declare that they have no competing interests.

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**Authors’ contributions**

PL and AM conceived the idea for this work. PL developed the protocol and drafted the manuscript under supervision of AM. Both authors approved the final version of the manuscript.

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Figure 1

Study flow chart. BBCC + 5 As + GS in South-Eastern Mangochi
### Figure 2

Schedule for enrollment, intervention and assessments

### Supplementary Files

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