



## P O L I C Y   B R I E F

# ComBaCaL: a new model for improving non-communicable disease care in Lesotho

Swiss TPH



**SOLIDAR  
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## Executive Summary

***ComBaCaL provides an innovative care model that uses eHealth tools to empower a new cadre of village health workers to screen, diagnose, and manage non-communicable diseases (NCDs) in resource limited settings. The 5-year project is currently being conducted in the districts Butha-Buthe and Mokhotlong, Lesotho, Southern Africa. ComBaCaL supports NCD care through up-to-date training and equipment at the facility and community level while new data and research inform national policy development.***

ComBaCaL is a Village Health Worker (VHW)-led, eHealth-assisted model of care for the screening, management, and care of hypertension (aHT) and diabetes (DM) in the community. At a second stage, the project will extend to other NCDs, including common mental health disorders. The project includes a baseline survey of NCDs and a large, randomized cohort trial in one hundred villages.

Other components of the program include:

- Capacitating health facilities to diagnose and treat aHT and DM through training, mentoring, and equipment
- Assessing the prevalence and burden aHT, DM, and mental health disorders in two rural districts
- Piloting the model in ten villages and assessing the model's effectiveness in one hundred villages
- Developing the academic careers of Basotho researchers working within the ComBaCaL project
- Supporting VHWs through income-generating activities

ComBaCaL is the collaborative effort of a consortium of institutions and led by the Swiss NGO SolidarMed together with the Swiss Tropical and Public Health Institute (University of Basel), the Lesotho Ministry of Health, and the National University of Lesotho. ComBaCaL is funded by the Swiss Agency for Development and Cooperation (SDC) and the World Diabetes Foundation (WDF).

## Background: Non-communicable diseases overtaking HIV/AIDS

***Cardiovascular diseases are overtaking HIV/AIDS as major causes of death and disability in sub-Saharan Africa. Efforts to decrease the morbidity and mortality due to aHT and DM are lacking. ComBaCaL capitalizes on the lessons learned from decentralization and task-shifting during the HIV/AIDS epidemic.***

Across sub-Saharan Africa, the prevalence of aHT and DM is increasing, resulting in increasing morbidity and mortality from cardiovascular complications such as stroke, heart attack, and heart failure. In the past these conditions were overshadowed by HIV/AIDS, and more recently by COVID-19, but they have now overtaken HIV/AIDS as the leading cause of premature death and disability in Lesotho. However, they receive little attention with few resources allocated at national, district, and facility levels. Like HIV, aHT and DM have long asymptomatic phases and affected individuals are often unaware of their condition. Left untreated, they may develop challenging and irreversible complications that can burden health care systems. But when diagnosed and treated early, individuals with HIV, aHT, and DM can achieve near normal life expectancy and quality of life.

Lesotho has used innovative and evidence-based approaches to successfully control the HIV/AIDS epidemic, leading to fewer new infections and reductions in morbidity and mortality. The Lesotho National Strategy for NCDs states that care for conditions such as aHT and DM should align with the national HIV program and apply principles proven successful in HIV care such as decentralization of services and task-shifting to lay cadres.

## The ComBaCaL model of care

***Prevention, screening, diagnosis, and first-line treatment for uncomplicated aHT and DM at the community level***

Because aHT and DM are chronic diseases needing lifelong regular follow-up and because the frail and elderly are sometimes concerned, the ComBaCaL model brings prevention, diagnosis, and care closer to the community. In each ComBaCaL village, one VHW, a trained and supervised lay-person, visits households on a regular basis to provide screening, diagnosis, lifestyle counselling, and first-line pharmacotherapy to prevent and treat aHT and DM.

## A new role: the Village Health Worker – Chronic Care (VHW-CC)

***The VHW-CC provides NCD screening and diagnosis at the household level. The ComBaCaL application with a clinical decision support system enables better care at the community level.***

ComBaCaL introduces a new cadre of VHW to the health system. Specializing in the care of chronic diseases, the VHW-CC receives a standardized training on all aspects of prevention, diagnosis, and care of aHT and DM. The training aligns with the clinical algorithms programmed in the ComBaCaL app and includes content on data collection and the clinical decision support system. VHW-CCs receive all required equipment, including glucose meter, blood pressure machine, weight scale, Android tablet, and a medication storage locker. They live in the village they serve, have at least a secondary level school certificate, and are elected by the village members.

VHW-CCs visit all households in their village on a half yearly basis, entering and updating the status of all household members in the app and providing counselling, screening, and care where indicated. For household members diagnosed with aHT and/or DM they provide lifestyle counselling and at times, first-line medications. Complex and acutely ill cases are referred to the nearest clinic. VHW-CCs will support the community through chronic disease care without burdening the existing VHW cadre who have demanding work in the fields of mother and child health, HIV, TB, and COVID-19.

## The ComBaCaL eHealth application

***The ComBaCaL eHealth application supports the VHW-CC in providing quality care for people with aHT and/or DM. Safeguards in the ComBaCaL app algorithm ensure that appropriate procedures are followed and that patients with danger signs are immediately referred.***

The ComBaCaL mobile Android application uses *Community Health Toolkit* (CHT), an open-source program managed by *Medic Mobile*, with specialized programming provided by students from the National University of Lesotho and the University of Zürich. The app contains clinical algorithms for the screening, diagnosis, and care of aHT and DM and includes safety checks and drug side-effect monitoring. It also provides aggregated dashboards for the Ministry of Health to monitor and supervise the care provided in the community. Ongoing evaluation, including qualitative research and user satisfaction assessments, will ensure its continuous improvement.

## Supporting the VHW-CC through entrepreneurship

***VHW-CC are provided with business training and have access to financial support to start businesses and increase longevity and sustainability of ComBaCaL.***

ComBaCaL has opted for an alternative and novel way to sustainably finance the VHW-CCs. In addition to being entitled to the government stipend, the VHW-CCs recruited in the project are being empowered to become micro-entrepreneurs in their spare time. Initial market research has indicated that many VHW-CCs already have some ‘entrepreneurial ideas’ that can be harnessed and with appropriate support developed into income generating activities.

A pilot is now underway whereby VHW-CCs are introduced to the ‘Start and Improve Your Business’ training (SIYB), developed by the International Labour Organisation. The programme has a strong track record of promoting the development of micro-enterprises. In the past 40 years, 23.7 million people have received the training and by the end of 2020, it is estimated that the implementation of SIYB had led to the start-up of at least 5.4 million new businesses, creating more than 10.4 million jobs globally<sup>1</sup>. The VHW-CCs in the ComBaCaL project will have access to micro-financing to implement their business idea as well as ongoing supervision and mentoring with the goal to become self-reliant.

## Supporting the NCD Program of the Lesotho Ministry of Health

***ComBaCaL supports the Ministry of Health NCD Program through expertise and resources at national, district, and facility levels and strives to revive the NCD policy dialogue in Lesotho. New operational and clinical findings inform national policy.***

### Support for the NCD Department

The ComBaCaL project has created a position for a medical doctor to be seconded to the NCD department of the Ministry of Health. Based in Butha-Buthe, this position assures the alignment of ComBaCaL with the national strategy and supports a department with limited human resources while reactivating and maintaining a regular policy dialogue on NCDs. Further, ComBaCaL provides small budget support to the NCD Department, allowing the department to plan and conduct monitoring and training activities in the country, as well organizing regular Technical Working Group meetings.

### Training and Equipment

The ComBaCaL project provides trainings on NCD management for health care providers in Butha-Buthe and Mokhotlong. Health care facilities in these districts also receive targeted support through small equipment (glucose meter, BP machines, etc.).

### Policy

The ComBaCaL project generates results and evidence that will inform future national NCD policies and management guidelines. Project partners collaborate closely with Ministry of Health leaders to develop new policies that enhance NCD care in Lesotho. Tools and teaching material developed by ComBaCaL will be available for dissemination throughout Lesotho.

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<sup>1</sup> International Labour Organisation, Expanding Entrepreneurship: 23 million and counting Start and Improve Your Business Global Tracer Study 2016-20

## Academic career support

ComBaCaL offers opportunities for academic development to Basotho Masters and PhD students. Several Basotho Masters and PhD students will be identified to enroll in university programs in Southern Africa or Switzerland. Thanks to our international and multidisciplinary consortium, ComBaCaL offers an ideal platform for aspiring young Basotho researchers in a variety of academic fields.

## Baseline survey to improve understanding of NCDs in Lesotho

***In 2021-2022, we are conducting a large household survey in Butha-Buthe and Mokhotlong to assess the prevalence and burden of NCDs.***

The most recent population-based survey on the prevalence of aHT and DM in Lesotho was conducted in 2012. Updated data are urgently needed to inform policy decisions. This survey not only screens over 7,500 individuals for aHT and DM but also assesses the severity of the diseases and the burden created by complications. Individuals diagnosed with aHT are evaluated for disease complications in the heart, kidneys, and eyes. Individuals diagnosed with DM are evaluated for disease complications in the kidneys, feet, and eyes and receive specialized (Hemoglobin A1c) blood testing. Further, the survey assesses risk behaviour among adolescents as well as various aspects of mental health.

Data from this comprehensive survey will provide a clearer picture of the prevalence and burden of NCDs in Lesotho and enable better planning for NCD responses in the future.

## Pilot trial

***All ComBaCaL trials will start once approved by the Lesotho National Research and Ethics Committee. A pilot trial in ten villages has been under way since early 2022.***

Since early 2022, we are piloting the ComBaCaL model in ten villages in Mokhotlong and Butha-Buthe. Using mixed methods, this pilot trial assesses the feasibility, acceptance, safety, and clinical effectiveness of the community-based model. The ComBaCaL pilot study protocol (approved by the Lesotho National Research and Ethics Committee in March 2022) focuses on app functionality, VHW-CC adherence to algorithms, clinical outcomes, VHW-CC workload, and community acceptance. The ComBaCaL model of care will be further adapted and improved based on the results of the pilot trial.

## Main trial (Pragmatic, randomized)

***A cluster-randomized trial to evaluate the ComBaCaL model of care in one hundred villages aims to start mid-2022.***

Using knowledge and experience from the pilot trial, a pragmatic cluster-randomized trial in one hundred villages will provide information on the scalability, clinical outcomes, and cost-effectiveness of the ComBaCaL model. In fifty villages (control group) the VHW-CC provides only the screening and diagnosis of aHT and DM. In the other fifty villages (intervention group), the VHW-CC provides additional care for uncomplicated aHT and DM, including the provision of first line medications. Clinical outcomes for patients and populations will be assessed after two years. Facility level data will also be tracked in a third, control district to determine the impact of the model as compared to no intervention at all. The pragmatic trial method allows the model to be adapted over time.

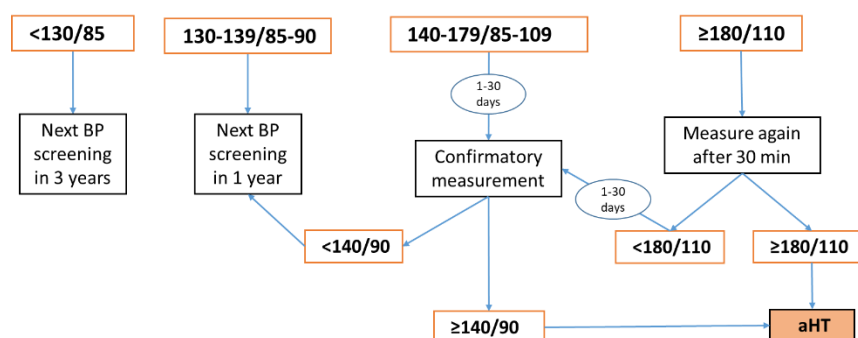
## Guidelines and algorithms for the primary care level management of cardiovascular NCDs

### Cardiovascular NCD care principles

- Evidence-based, simple, cost-effective treatment algorithms using the drugs with the highest effectiveness and lowest side effect risk should be applied.
- The same diagnostic and therapeutic algorithms should be applied among all health care providers at community, health center, and district hospital levels to enhance quality of care, reduce prescription errors, and increase consistency of communication towards the patients.
- Asymptomatic cardiovascular NCDs require active, provider-initiated screening at health facility and community levels.
- Regular monitoring and dose-adjustments are required to ensure best possible disease control.
- For a significant and sustainable reduction of cardiovascular NCD burden, awareness within the population and among health care providers needs to be fostered. Disease education is key for the prevention of cardiovascular NCDs, as well as for adherence to lifestyle and drug treatment for patients already diagnosed. This message needs to be emphasized at all levels.

### Screening and diagnosis of arterial hypertension

Provider-initiated hypertension (aHT) screening is recommended for all individuals eighteen years or older. The measurements should be obtained by taking three consecutive readings using a correctly sized cuff and with the patient rested and seated with the arm supported. The average of the last two measurements is calculated and recorded. For a diagnosis of aHT, two elevated measurements in the range of 140-179/85-109 mmHg on two different days are required. Two measurements, taken at least 30 minutes apart on the same day, which are greater than or equal to 180/110 mmHg can also be used to diagnose aHT.



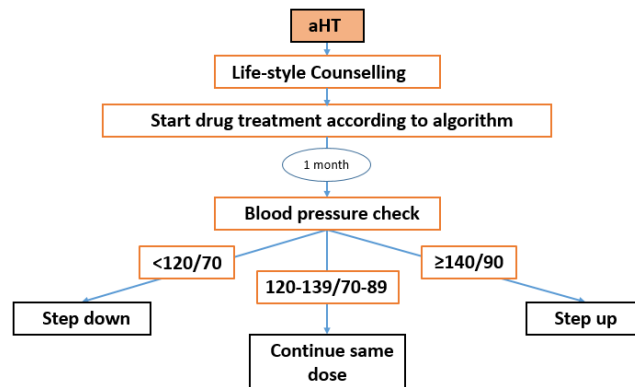
Screening and diagnostic algorithm for hypertension

### Treatment of arterial hypertension aHT

All patients diagnosed with aHT should be offered lifestyle counseling together with drug treatment. The treatment target for all patients is 120-139 mmHg of systolic blood pressure. Check-ups one month after drug initiation or dose adjustment are recommended. Dosage step-up or step-down according to the drug treatment algorithm is recommended for all patients with a measurement outside the target window. For patients within the target window and not requiring dose adjustments, check-ups every three months are recommended.

The recommended antihypertensive first-line treatment consists of a single-pill combination including amlodipine (Aml) and hydrochlorothiazide (HCTz). For patients not reaching the treatment targets

under a maximum dose of Aml/HCTz, a RAAS inhibitor (either an ACE inhibitor or an Angiotensin II receptor blocker) should be added. If a third compound is needed, a triple therapy combination pill is preferred. If a triple therapy combination pill is not available, the RAAS inhibiting compound may be added individually; (i.e., enalapril or losartan, which are readily available in Lesotho.)



*Treatment algorithm for hypertension with monthly check after initiation or dose adjustment*

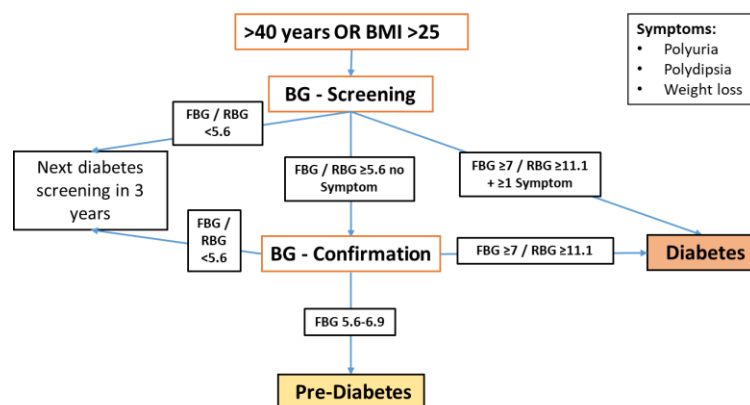
## Screening and diagnosis of diabetes

All participants over forty years of age or with a body mass index (BMI) over 25 kg/m<sup>2</sup> are screened for DM with a blood glucose (BG) test. In line with international standards, the ComBaCaL algorithm requires two elevated blood glucose measurements on two separate days to diagnose DM. Considering resources and practicability, the diagnostic algorithm allows for either fasting blood glucose (FBG) or random blood glucose (RBG) measurements at the first encounter, but usually requires an FBG at a second encounter. The ComBaCaL app is programmed to screen for life threatening problems, including ketoacidosis, and instructs the VHW-CC to refer these cases to a health facility.

Patients with a blood glucose level in the diabetic range (FBG ≥7 mmol/l or RBG ≥11.1 mmol/l) with at least one cardinal symptom of uncontrolled diabetes (polyuria, polydipsia or weight loss) fulfill the diagnostic criteria for DM. Patients with an FBG or an RBG value in the diabetic range presenting with all three cardinal symptoms of DM should be assessed for ketoacidosis using urine dip sticks. In case of relevant ketonuria, patients should be immediately referred to a higher-level health facility.

For patients with an elevated blood glucose level, not fulfilling the diagnostic criteria for diabetes, a confirmatory measurement is required for diagnosis of DM or pre-diabetes (pre-DM). The diagnosis of DM is made if the confirmatory measurement is in the diabetic range. Pre-DM is diagnosed if the FBG is between 5.6 and 6.9 mmol/l. In patients with an FBG or RBG below 5.6 mmol/l, diabetes can be excluded, and the next screening is recommended in three years.

As alternative to capillary blood glucose, hemoglobin A1c testing (HbA1C) is recommended for the diagnosis of DM and pre-DM where available with the threshold of ≥6.5% for the diagnosis of DM and the range of 5.7-6.4% for the diagnosis of pre-DM. For the diagnosis using HbA1C a single measurement is sufficient and fasting status of the patient does not need to be considered.



Algorithm for screening and diagnosis of diabetes. (FBG: Fasting Blood Glucose, RBG: Random Blood Glucose, BG: Blood Glucose, BMI: Body-Mass-Index)

## Treatment of uncomplicated type 2 DM within the main trial intervention group

In the intervention group of the main trial, the VHW-CC treats uncomplicated DM at the household level with lifestyle advice, metformin, and atorvastatin to reduce blood sugar and the overall risk of cardiovascular disease. Safety mechanisms within the ComBaCaL app ensure that patients requiring additional care are referred to a health facility.

All patients with confirmed DM and without referral criteria will be counselled on lifestyle modifications and will start the oral antidiabetic medication metformin. Metformin is generally well-tolerated and broadly available in Lesotho. In line with updated international recommendations, all patients with DM also receive the lipid lowering agent atorvastatin to reduce cardiovascular risk.

Metformin dosage is gradually increased while checking for possible side effects. Currently, the treatment algorithm does not foresee an additional oral antidiabetic agent and patients with insufficient glycemic control through lifestyle modification and metformin alone are referred to the health facility. As part of the overall project, ComBaCaL will strive to replace some of the older oral antidiabetic agents currently used in Lesotho with newer and safer drugs. Glibenclamid, which carries a risk of severe hypoglycemia, should be replaced with another sulfonylurea, gliclazide, and/or SGLT2 inhibitors from the WHO Essential Medicines List.

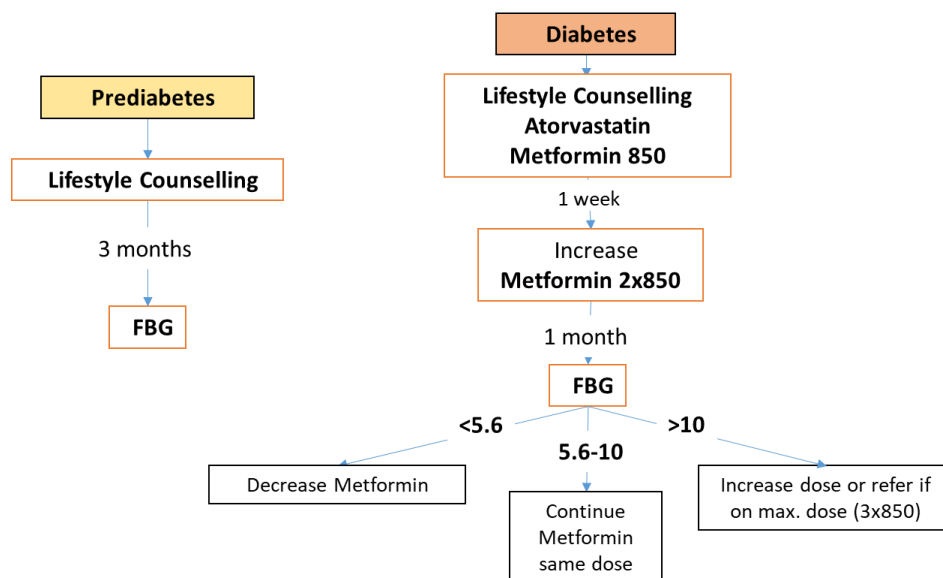
Individuals diagnosed with DM or pre-DM should receive lifestyle counselling according to the content outlined below. Pre-diabetic patients will be followed-up with blood glucose checks every three months. Diabetic patients should be initiated on a pharmacologic treatment with metformin 850 mg twice daily (starting with a one week titration phase with 850 mg once daily) and atorvastatin 10 mg once daily. A follow up visit and FBG is recommended one month after any treatment initiation or dose adjustment. For patients within the treatment target window of FBG 5.6 to 10 mmol/l, no dose adjustment is required and check-ups should be scheduled every three months thereafter. If blood glucose control is insufficient (above 10 mmol/l), a third dose of metformin 850 mg per day should be added and if control remains insufficient, the addition of a second oral antidiabetic drug from the SGLT2 inhibitor class is recommended. If no SGLT2 inhibitor is available, Gliclazide is recommended. Gliclazide should be added at 30 mg per day and may be increased up to a maximum of 120 mg per day if required.

If the target is not reached using metformin 850 mg x 3 plus a high dose SGLT2 inhibitor or Gliclazide 120 mg, the patient should be referred to a higher-level health facility for initiation of insulin treatment or triple oral antidiabetic treatment.

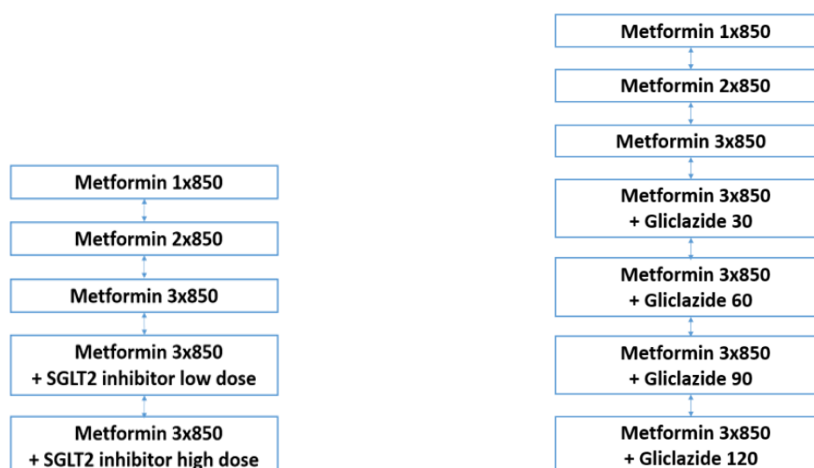


All diabetic patients should receive a cholesterol-lowering treatment to reduce their cardiovascular risk. The preferred medication is atorvastatin, as it offers the highest pharmacological effectiveness, a long half-life (to allow for once-a-day intake at any time of the day), and no interactions with antiretroviral therapy. If atorvastatin is not available, simvastatin or pravastatin should be used but potential drug-drug interactions need to be considered.

Where available, half-yearly HbA1C measurements should be used to complement treatment monitoring for diabetic patients receiving pharmacological treatment. The HbA1C target window for most patients is 7-7.5%, while higher values (up to 9.0%) should be tolerated in older patients or patients with severe co-morbidities.



*Treatment algorithm for DM and pre-DM*



*Drug treatment algorithm for DM using an SGLT2 inhibitor (left); algorithm if no SGLT2 inhibitor is available (right)*

## Lifestyle counselling for aHT and DM

***Lifestyle counselling is a key component of aHT and DM prevention and treatment and is integrated throughout the project.***

Lifestyle counselling is an essential cornerstone in the management of cardiovascular NCDs. Lifestyle advice should be communicated empathically and should contain simple and pragmatic messages tailored to the patient's health status, lifestyle, culture, habits, and socioeconomic conditions.

The key recommendations are:

- abstain from smoking
- avoid excess alcohol intake
- adhere to a healthy diet:
  - limit daily calorie intake to maintain a healthy bodyweight (BMI 20-25)
  - avoid sugar, sweets, and sweetened beverages
  - choose high-fiber and low-glycemic index foods
  - eat 3-5 daily portions of vegetables and/or fruits
  - avoid fried food and fatty meat
  - Reduce salt intake (especially for patients with aHT)
  - avoid snacking between meals (especially for patients with DM)
- increase physical activity
  - start with walking for half an hour at least every second day
  - if possible, increase to a more intensive physical activity program

In addition to these recommendations, patients should also be educated on the risk factors and possible complications of cardiovascular disease as well as on the chronic nature of NCDs. Patients are advised that treatment is often lifelong and that good adherence to both medications and lifestyle changes is the key to success.

## For further information

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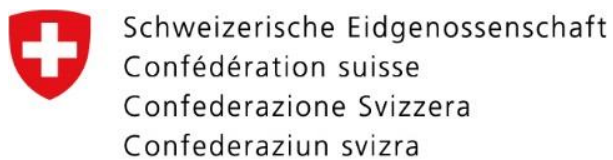
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### Website

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## The ComBaCaL Consortium



**Swiss Agency for Development  
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WORLD **DIABETES** FOUNDATION



Lesotho Ministry of Health



National University of Lesotho