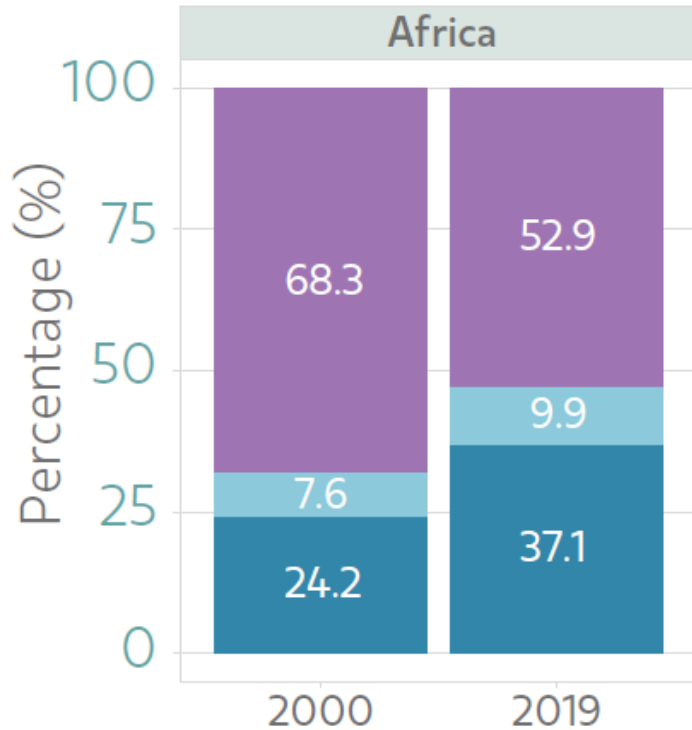




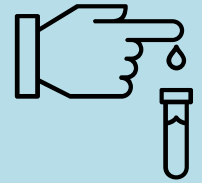
Community Health Worker-led versus facility-based type 2 diabetes care in rural Lesotho: a cluster-randomized trial within the ComBaCaL cohort study

Presented by Dr. Mamakhala Chitja on behalf of the
ComBaCaL Team

Type 2 diabetes burden



Type 2 Diabetes Mellitus (DM)



- **828 million** people affected
- 80% in low- and middle-income countries
- Fourfold increase since 1990

Causes of death WHO 2022:

- Communicable diseases
- Injuries
- Noncommunicable diseases

DM care access problem in rural Lesotho and ComBaCaL project

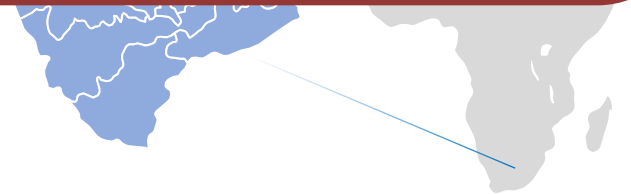
- DM care access problems of remote, rural villages in Lesotho
- Existing **Community Health Worker**



Evidence review gap: No study assessing independent CHW-led HTN or DM care (including drug prescription and titration)



-
-
- districts of Butha-Buthe and Mokhotlong
- Investigating the chronic disease burden & innovative service delivery models to improve chronic care



Is lay CHW-led DM care effective and safe?

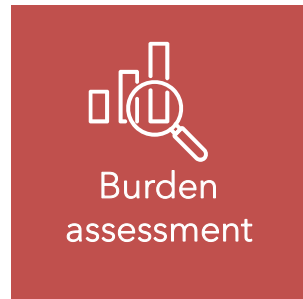
Cohort study



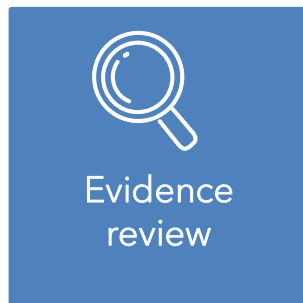
Nested Trial

2023-2025

ComBaCaL model of care

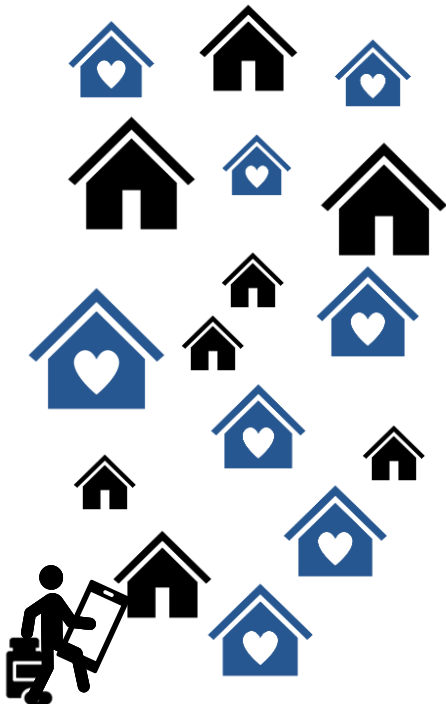


**Task-shifting to
CHWs**



Hypothesis and study design

Hypothesis: The ComBaCaL model of care improves blood sugar compared to CHW-led screening with referral among people with DM/HTN in rural Lesotho



Cluster-randomized Trials within Cohort



52 intervention villages, 51 control villages



Community-based hypertension care



Community-based diabetes care

Control & intervention arm

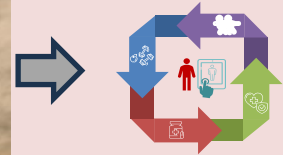
Control

eHealth-supported
community-led screening
and referral



Intervention

CaL model
is applied

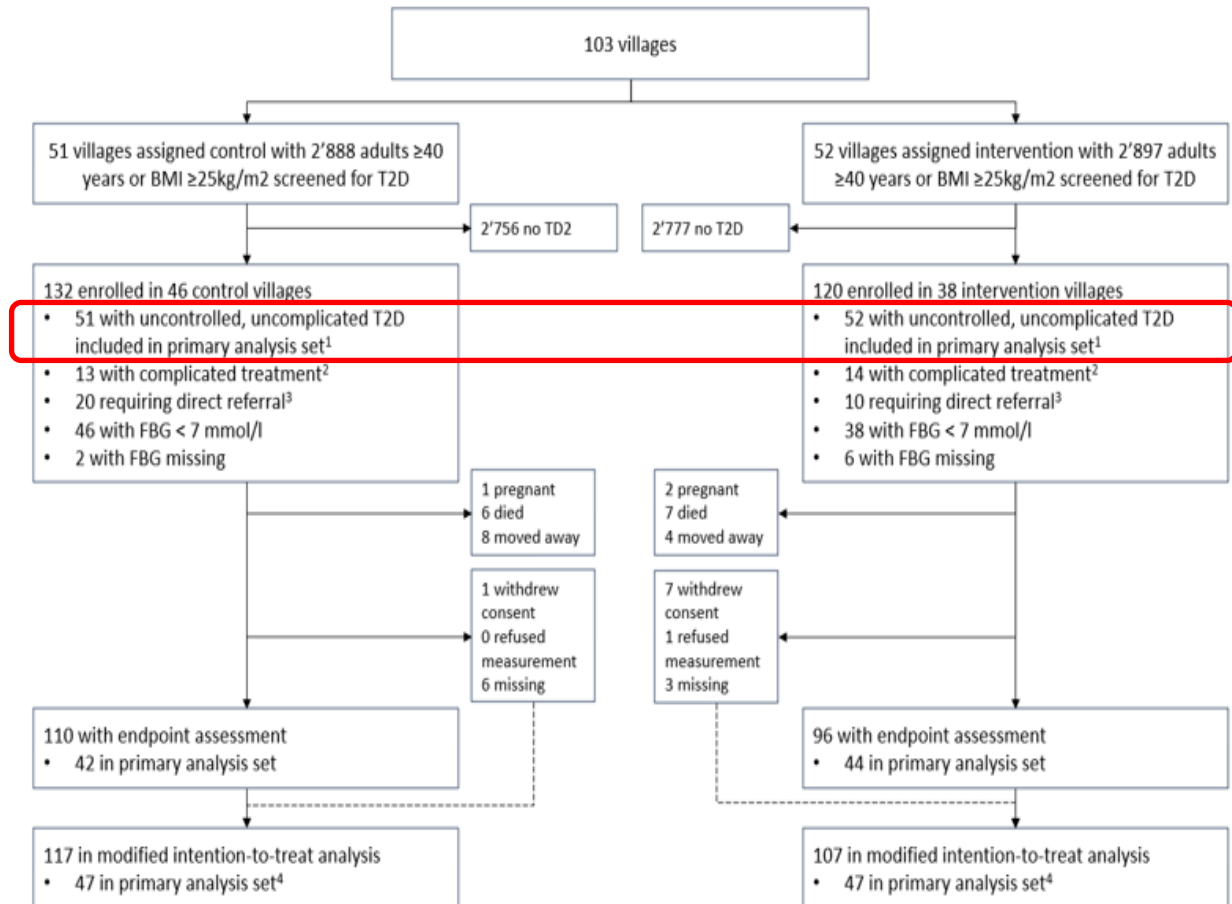


ComBaCaL CHWs in action



Results

- **5'785** ComBaCaL cohort participants aged ≥ 40 years or with a BMI ≥ 25 kg/m² screened for DM
- A total of **252 (4.4%)** were identified with DM and enrolled in the trial
- **103** had uncomplicated, uncontrolled DM (primary analysis set)



Primary analysis population:

- FBG ≥ 7 mmol/l and no treatment or only one oral antidiabetic drug at baseline

Baseline characteristics primary analysis set (n=103)

Individual-level participants	Control (n=51)	Intervention (n=52)	Total (n=103)
Female, n (%)	34 (67%)	42 (80.8%)	76 (73.8%)
Age, years, mean (SD)	61.4 (11.7)	63.2 (14.0)	62.3 (12.8)
BMI, kg/m ² , mean (SD)	29.3 (6.1)	30.6 (5.7)	30.0 (5.9)
HbA1C (%), mean (SD)	7.2 (1.5)	7.2 (1.4)	7.2 (1.5)
FBG, mean (SD)	8.7 (1.5)	8.9 (1.9)	8.7 (1.5)
Engagement in DM care, n (%)	31 (60.8)	38 (73.1)	31 (60.8)

Primary and secondary outcomes primary analysis population

Primary endpoint at 12 months	Control (n=47)	Intervention (n=47)	Adjusted mean difference (95% CIs)	P-value
HbA1c	7.1 (2.0)	6.5 (1.3)	-0.43 (-1.11;0.25)	0.22
Key Secondary end points at 12 months primary analysis population	Control (n=47)	Intervention (n=47)	Adjusted mean difference or adjusted odds ratio (95% CIs)	
FBG, mmol/l	8.3 (3.6)	6.9 (1.7)	-1.13 (-2.37;0.110)	
Engagement in care (%)	31 (66.0)	43(91.5)	5.38(1.32;21.91)	
Linkage to care	16(41.0)	25(80.6)	8.41(2.38;29.67)	

- No statistically significant change in HbA1C (potentially due to small sample size)
- However patterns of higher linkage, engagement in care and improved HbA1C control and across all sensitivity analyses

Safety endpoints at 12 months in primary analysis population

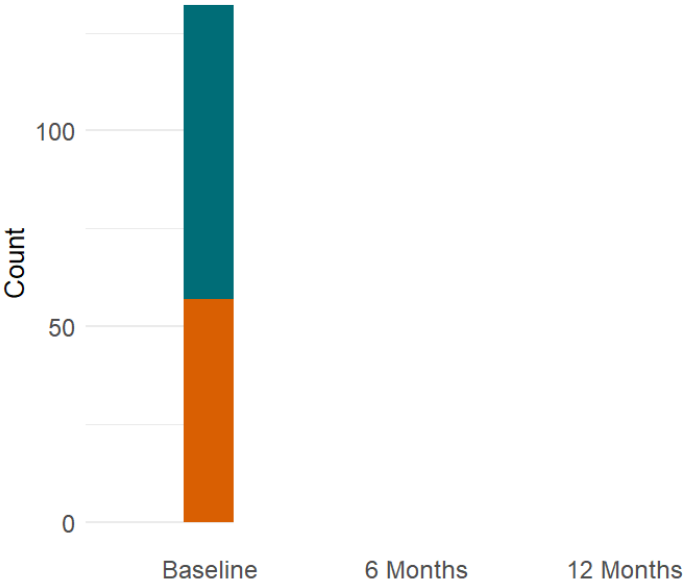
	Control (n=51)	Intervention (n=52)
Adverse events of special interest, n (%)	9 (17.6)	7(13.5)
Nonfatal serious adverse events, n (%)	2 (3.9)	2(3.8)
Deaths, n (%)	2(3.9)	2(3.8)

- **Most of the adverse events of special interest due to hyperglycemia**
- **No major difference in safety events between intervention and control arm**

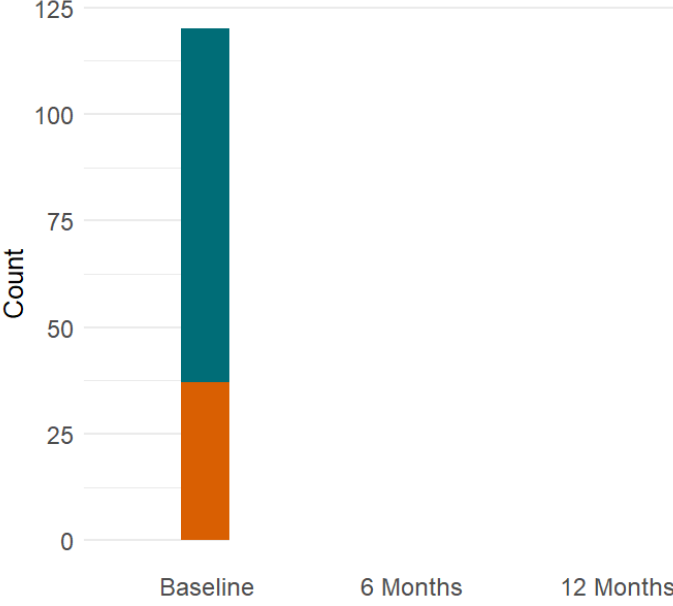
DM care engagement over time

study arms overall DM population

Control Group



Intervention Group



- In CHW care
- In facility care
- Not in care
- No outcome available

Discussion

- First trial to show the **feasibility** of a lay CHW-led, CDSS-assisted DM intervention with independent drug prescription by CHWs
- **Non-significant trend towards improved DM control** in the primary analysis set
- **Patterns of improvement** also for engagement in and linkage to care
- **No relevant difference in safety events** between study arms

Acknowledgements



Our thanks go to the amazing VHWs...



...and everyone else who
made ComBaCaL possible



Reference



www.combacal.org

niklaus.labhardt@usb.ch

r.gupta@solidarmed.ch

m.Chitja@solidarmed.ch

The trial is registered on clinicaltrials.gov (NCT05743387), where a full protocol and statistical analysis plan are available