BAHIR DAR UNIVERSITY

COLLEGE OF MEDICINE AND HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

Effect of Nutrition Counselling on Dietary Adherence, Clinical Outcomes, and Nutrition-Related Quality of Life among Patients with Cardiometabolic Multimorbidity in South Wollo, Northeast Ethiopia

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11-March-2026

BAHIR DAR, ETHIOPIA

Introduction

Cardiometabolic multimorbidity (CMM), commonly involving T2DM and hypertension, represents the most prevalent and burdensome cluster of chronic diseases (1-3). These conditions are interrelated through shared lifestyle risk factors, and their co-occurrence significantly increases the risk of cardiovascular complications, disability, and premature mortality (4, 5). Nutrition plays a central role in the prevention and management of these conditions, yet dietary adherence among patients remains poor, contributing to uncontrolled blood glucose and blood pressure(6, 7). Nutrition counselling may improve patients' dietary behaviors by enhancing knowledge, self-management skills, and adherence to recommended diets(7); however, evidence on its effect among patients with multiple chronic conditions is limited.

In Ethiopia, national NCD guidelines do not provide specific dietary recommendations for patients with coexisting diabetes and hypertension, and nutrition counselling is poorly integrated into routine chronic care services (8-10). Patients are often managed mainly with medications, with limited structured dietary support, resulting in poor disease control and increased risk of complications, polypharmacy, and hospital utilization(9, 10). Generating context-specific evidence on the effect of nutrition counselling on clinical outcomes is therefore essential to strengthen nutrition care integration and inform guideline development.

Beyond clinical outcomes, patients with CMM frequently experience emotional distress, dietary limitations, and social challenges that negatively affect their well-being and functional capacity (11, 12). Nutrition-related quality of life (NQoL) is particularly compromised in this group due to the complexity of managing multiple dietary restrictions alongside heavy medication loads and symptom burden (13, 14). Structured nutrition counselling might have the potential to improve self-efficacy, psychosocial well-being, and patient satisfaction by addressing the multidimensional impact of diet on daily life. No study has evaluated the effect of nutrition counselling on NQoL among patients with CMM. Generating such evidence is vital to demonstrate the broader value of nutrition counselling, support its integration into Ethiopia's routine NCD services, and inform policies aimed at improving patient-centered outcomes.

Methods

This study will be conducted in South Wollo Zone, Amhara Regional State, Northeast Ethiopia, involving all 14 public hospitals as study clusters. A two-arm parallel cluster randomized controlled trial will be conducted to evaluate the effect of nutrition counselling on dietary adherence, clinical outcomes (blood pressure, fasting blood glucose (FBG), and low-density lipoprotein (LDL), and NQoL among patients with CMM. Fourteen public hospitals will be included, with seven randomly assigned to the intervention group and seven to the control group. A total of 308 adults with coexisting type 2 diabetes and hypertension will be recruited using systematic random sampling.

Participants in the intervention group will receive six individualized nutrition counselling sessions over three months, guided by the COM-B Model, while the control group will receive routine care. Intervention fidelity will be assessed using the five domains of the NIH Behavior Change Consortium framework. Data will be collected at baseline and post-intervention. Perceived dietary adherence will be assessed using a questionnaire adapted from the Perceived Dietary Adherence Questionnaire (PDAQ) and aligned with DASH diet principles. Clinical outcomes, including blood

pressure, FBG, and LDL levels, will be measured using standardized national and laboratory procedures. Fasting venous blood samples will be collected and analyzed following established specimen handling and quality assurance protocols.

Inclusion criteria

Adults (≥18 years) diagnosed with both T2DM and hypertension, who are receiving chronic care in each public hospital will be included in the study.

Exclusion criteria

Pregnant women will be excluded because of pregnancy-induced chronic conditions and distinct nutritional requirements. Similarly, lactating women will be excluded due to their unique nutritional needs.

Study Variables

Dependent Variables

Objective II: Dietary adherence (adherent /non adherent).

Objective III: Change in clinical outcomes (BP and FBG).

Objective IV: Change in NQoL scores.

Randomization and Blinding Procedures

Hospitals will be randomized in a 1:1 ratio (7 intervention group, 7 control) using stratified randomization. A fixed random seed will be used, and the randomization code will be archived to ensure reproducibility. Randomization will be conducted by an independent statistician who is not involved in recruitment, intervention delivery, or outcome assessment. Allocation will remain concealed until the start of the intervention.

Because of the nature of the intervention, complete blinding of health professionals delivering nutrition counseling will not be feasible. However, several steps will be taken to minimize bias. First, participants will not be explicitly informed about group assignment; both groups will continue to receive routine chronic disease care, with the intervention group additionally receiving nutrition counseling. Second, outcome assessors responsible for data collection and laboratory testing will be blinded to facility allocation to reduce detection bias.

To minimize the risk of information exchange between participants, randomization will be done at the facility level rather than the individual level.

Data processing and management

The data will be exported to a free statistical software R version 4.0.3 for further processing and analysis. The data will be cleaned before analysis through the running of frequencies and cross-tabulations to check for accuracy, consistencies, and missing values. Both descriptive and inferential statistics will be used to analyze the data.

Data analysis

Descriptive statistics including mean/median, standard deviation (SD), and percentages will be applied to summarize the study participant's characteristics according to the distribution of variables. Both within-group and between-group comparisons will be performed to evaluate changes from baseline to endline

Objective II: Effect of Nutrition Counseling on Dietary Adherence

The effect of nutrition counseling on dietary adherence will be examined using a generalized structural equation modeling (GSEM) approach to appropriately account for the binary nature of the outcome. GSEM was selected because it allows simultaneous estimation of direct and indirect pathways. GSEM enables modeling of change over time by adjusting for baseline dietary adherence while estimating the effect of nutrition counseling on endline adherence. Importantly, it accommodates multiple mediators' COM-B constructs within a single coherent framework. It also used to consider latent variables such as COM-B constructs represented by five domains: perceived threat, perceived benefits, perceived barriers, cues to action, and self-efficacy. By incorporating covariates as exogenous variables and estimating indirect effects, GSEM provides effect estimates, making it well suited for evaluating complex intervention pathways.

Dietary adherence will be classified as good or poor and endline dietary adherence will be specified as the primary outcome variable. Baseline dietary adherence will be included as a predictor of endline adherence to control for pre-intervention differences and to model change over time.

COM-B constructs will be specified as mediators of the relationship between nutrition counseling and dietary adherence. Direct paths will be specified from nutrition counseling to COM-B constructs, and from these mediators to endline dietary adherence. Covariates will be included as exogenous variables with direct paths to the mediators and endline dietary adherence.

Indirect effects of nutrition counseling on dietary adherence through COM-B constructs will be estimated using the product-of-coefficients approach, with statistical significance assessed using bias-corrected bootstrap CIs. Results will be presented as adjusted odds ratios with 95% CIs to provide interpretation of the effect size.

Objective III: Effect of Nutrition Counseling on Clinical Parameters

The effect of nutrition counseling on clinical outcomes, including systolic blood pressure (SBP), diastolic blood pressure (DBP), and fasting blood glucose (FBG), will be examined using structural equation modeling (SEM). Endline SBP and FBG will be specified as outcome variables, and their respective baseline values will be included as predictors to account for baseline clinical status and to model changes over time.

Dietary adherence will be modeled as mediators of the intervention effect on clinical outcomes. Nutrition counseling will be specified as a variable predicting dietary adherence at endline, which will in turn be specified to influence endline DBP, SBP and FBG. Covariates will be included as variables with direct paths to the mediators and endline clinical outcomes.

Model fit will be assessed using a combination of fit indices. The Comparative Fit Index (CFI) and the Tucker–Lewis Index (TLI) will be reported, with values of ≥ 0.90 considered acceptable (15-17). The Root Mean Square Error of Approximation (RMSEA) will also be included, with values ≤ 0.08 interpreted as acceptable (17, 18). In addition, the Standardized Root Mean Square Residual (SRMR) will be presented, with values ≤ 0.08 considered to indicate good model fit (15, 17). These indices were chosen because they complement one another. The CFI and TLI assess incremental model improvement relative to a baseline model, the RMSEA evaluates model adequacy by measuring the discrepancy between the hypothesized model and the observed data per degree of freedom while accounting for both model complexity and data fit, and the SRMR assesses the standardized difference between observed and predicted correlations (17). Direct, indirect, and total effects will be estimated and reported as standardized path coefficients with 95% CIs, with mediation effects assessed using bias-corrected bootstrap procedures. Statistical significance will be set at $p < 0.05$.

Objective IV: Effect of Nutrition Counseling on Nutrition Quality of Life

The effect of nutrition counseling on NQoL will be examined using structural equation modeling (SEM). This approach allows for testing the hypothesized mediating role of dietary adherence and two clinical outcomes SBP and FBG in the relationship between intervention effect and NQoL. The structural model will specify direct paths from intervention to NQoL, as well as indirect paths operating through each mediator. Relevant covariates will be added to control for potential confounding.

Model fit will be assessed using the CFI, TLI, RMSEA, and SRMR. Model parameters will be estimated using maximum likelihood estimation. Direct and indirect effects will be reported as unstandardized and standardized regression coefficients with 95% CIs. Mediation effects will be evaluated using bootstrapped indirect effects, and statistical significance will be assessed at $p < 0.05$.

Ethical considerations

Ethical approval was obtained from the Institutional Review Board of the College of Medicine and Health Science, Bahir Dar University, before commencing the study. A letter of approval was further obtained from the Amhara Public Health Institute, and a cooperation letter was obtained from each hospital to get permission. All study participants were informed about the purpose of the study, the benefits the study that bring to the health system, the time taken to complete the interview, and the participant selection process. They were informed that participation is voluntary and that it is their right to withdraw at any time if they are not comfortable with the interview. Confidentiality will be assured through collecting anonymous information and by informing the participants that personal identifiers will not be revealed to a third party.

The nutrition counseling intervention is non-invasive, evidence-based, and designed to promote health without posing harm. However, any potential discomfort or concerns expressed during counseling will be addressed with empathy and referred to clinical professionals if necessary. Participants in the control group will continue receiving standard care, and following the study period, they will be provided with educational materials and counseling summaries, ensuring that they are not disadvantaged by their group assignment.

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