

**A POSITIVE DEVIANCE NUTRITION EDUCATION
INTERVENTION TO IMPROVE NUTRITIONAL INTAKE,
SPUTUM CONVERSION AND CLINICAL SIGNS AMONG
TUBERCULOSIS PATIENTS IN KERICHO COUNTY,
KENYA**

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**A Positive Deviance Nutrition Education Intervention to Improve
Nutritional Intake, Sputum Conversion and Clinical Signs among
Tuberculosis Patients in Kericho County, Kenya**

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**A Thesis Submitted in Partial Fulfillment of the Requirements for the
Degree of Doctor of Philosophy in Public Health of the Jomo Kenyatta
University of Agriculture and Technology**

2026

DECLARATION

This thesis is my original work and has not been presented for a degree in any other University.

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DEDICATION

I give special dedication of this thesis to my wife Judith, Bravin junior, Ryan and Hyden and the entire family who dedicated their time through prayers, psychosocial and financial support during the entire time of my study period.

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ACRONYMNS AND ABBREVIATIONS

AFB	Acid-Fast Bacilli
AOR	Adjusted Odd Ratio
BMI	Body Mass Index
CHO	Carbohydrate
CI	Confidence Interval
COVID-19	Coronavirus Disease
CSS	Clinical Sign Score
DALYS	Disability-Adjusted Life Years
DID	Difference in Difference
DOTS	Directly Observed Therapy
HIV	Human Immunodeficiency Virus
MOH	Ministry of Health
MDR-TB	Multi Drug Resistance Tuberculosis
NACOSTI	National Commission of Science and Technology
PEM	Protein Energy Malnutrition
PD	Positive Deviance
PDI	Positive Deviance Inquiry

RCTs	Randomized Controlled Trials
RDA	Recommended Dietary Allowance
RDI	Recommended Dietary Intake
RH	Rifampicin and Isoniazid
RHZE	Rifampicin Isoniazid Ethambutol and Pyrazinamide
RR-TB	Rifampicin Resistance Tuberculosis
SC	Sputum Conversion
SC2	Sputum conversion at 2 nd month
SC5	Sputum conversion at 5 th month
SC	Sputum conversion at 6 th month
SEM	Structural Equation Model
SPSS	Statistical Package for Social Sciences
SDG	Sustainable Development Goal
XDR-TB	Extensively Drug-Resistant Tuberculosis
TB	Tuberculosis
WHO	World Health Organization

DEFINITION OF OPERATIONAL TERMS

Active tuberculosis	Refers to disease that occurs in someone infected with Mycobacterium tuberculosis. It is characterized by signs or symptoms of active disease, or both.
Clinical sign score	Refers to numeric representation of symptom and signs designed to accurately measure the severity or prognosis of a patient's condition, aiding health assessment and treatment.
Positive deviance	Process of identifying affordable, acceptable, effective, and sustainable practices that are already used by at-risk people and that do not conflict with local culture.
Nutritional status	Refers to the state of a person that results from the relationship between the intake and utilization of nutrients and the body's requirements for growth, health and well-being
Sputum smear conversion	Is defined as the change in a pulmonary tuberculosis (TB) patient's sputum test results from positive for acid-fast bacilli (AFB) to negative after a period of anti-TB treatment.
TB treatment outcome	Result or effect of a TB medication or intervention on a patient's health from tuberculosis treatment.
Treatment response	Refers to the outcomes or effects observed following a medical intervention or therapeutic procedure aimed at curing a TB condition. It encompasses the changes in nutritional status, sputum conversion and clinical sign score of a patient's condition after treatment or failure to respond.

ABSTRACT

Tuberculosis (TB) is one of the leading causes of death worldwide. In the recent years, Kenya has recorded a high prevalence of TB and a greater proportion of patients with negative treatment outcomes. This study addressed the challenge of negative treatment outcomes through a positive deviance-based nutrition education intervention for patients with active TB. The objectives of the study were: to determine the practices associated with TB treatment outcomes; the influence of nutrition education on nutritional status; the influence of the intervention on sputum smear conversion; and the effects of the nutrition intervention on clinical signs among TB patients. A quasi-experimental with pre-post-test design was adopted. Positive deviance inquiry was used to identify best practices among 216 persons who had completed treatment within the year preceding the study. The best practices were adopted for the intervention. For the intervention and control arms, 192 newly diagnosed TB patients were recruited through multistage cluster sampling. The sample was distributed such that 96 were enrolled in the intervention arm and 96 in the control arm. The intervention included fortnightly nutrition education on nutrient-dense meal, dietary diversity, and the provision of nutrient-rich meals for six months. Nutritional status and nutrient intake were determined through anthropometric measurements and food frequency questionnaires. Sputum smear microscopy and clinical signs were also assessed at critical points. Data analysis was conducted using R to obtain independent t-tests, chi-square, logistic regression, and difference-in-difference (DID). Anthropometric data were converted into BMI and categorized into nutritional status indicators using WHO cut-offs, while food frequency data were converted into daily nutrient yields and compared against Recommended Dietary Allowances (RDA). The significance level was set at $p < 0.05$. The results revealed that socio-demographic factors, health-seeking, lifestyle (alcohol, tobacco), low baseline BMI, comorbidities, and lack of adherence support were significantly linked to negative treatment outcome ($p < 0.01$). The intervention group showed significant increases in BMI at 2nd, 5th, and 6th months ($p = 0.01, 0.01, 0.001$). Adherence to recommended dietary intake for energy, protein, carbohydrates, vitamins A and C, zinc, and selenium improved remarkably (AOR = 1.84 – 2.14, $p < 0.01$). Sputum conversion rates in the intervention group exceeded 90% at all critical points of study, compared to 85.2% in the control group ($p < 0.01$). In the control group, only fat intake improved sputum conversion at month two ($\beta = 0.15, p = 0.026$). In the intervention group, higher energy ($\beta = 0.76\text{--}0.91, p < 0.007$), protein ($\beta = 0.67\text{--}0.95, p < 0.004$), carbohydrates ($\beta = 0.17\text{--}0.47, p < 0.004$), vitamin A ($\beta = 0.75\text{--}0.88, p < 0.003$), vitamin C ($\beta = 0.80\text{--}0.89, p < 0.001$), zinc ($\beta = 0.67\text{--}0.82, p < 0.005$), and selenium ($\beta = 0.53\text{--}0.79, p < 0.007$) were significantly associated with sputum conversion. Clinical signs such as cough and weight loss improved significantly in the intervention group. Higher odds of improvement were observed at 2nd, 5th, and 6th months of the study with AOR = 1.98 (95% CI: 1.02 - 3.82; $p = 0.041$), 1.79 (95% CI: 1.03 - 3.10; $p = 0.039$), and 2.46 (95% CI: 1.29 - 4.71; $p = 0.034$), respectively ($p < 0.05$). A possible limitation for this study was recalling bias and social desirability in diet reporting. In conclusion, multiple ‘best’ practices influenced treatment outcomes. The intervention improved nutritional status, sputum conversion and clinical signs and therefore enhanced treatment response.

The study recommends that: context specific factors should be used to design targeted interventions; nutrition education should be individually tailored to the patient needs with specific focus on locally available, and nutrient-dense foods rich in vitamins A and C, zinc, and selenium; nutritional support should be strengthened to accelerate sputum smear conversion during the treatment period. Further longitudinal research is recommended to assess the sustained effects of nutrition education interventions on the improvement and stability of clinical signs.

CHAPTER ONE

INTRODUCTION

1.1 Background

Tuberculosis (TB) is one of the top ten leading cause of death worldwide and remains a major concern for public health (Goletti et al., 2025). An estimated 10.8 million new cases of TB were recorded in 2024 worldwide, and 1.4 million people died from the disease (Chen et al., 2025). TB disease transcends across all spheres with the highest new infection rates observed in Southeast Asia and African countries which accounted for 43% and 25% of the global TB cases respectively (Xie et al., 2025). The burden of TB is disproportionately concentrated in low- and middle-income countries, particularly in regions such as South-East Asia, Africa, and the Western Pacific (Roxas et al., 2025). In the recent past, the countries that accounted for the largest proportion of this burden in Asia were India (26%); China and Indonesia (8.5% and 8.4%) respectively; Philippines and Pakistan (6.0% and 5.8%) respectively (Hossain et al., 2025). Nigeria (4.6%) and South Africa (3.3%) accounted for the largest proportion among African countries (Njelita et al., 2025). TB continues to be a major public health concern in Kenya, which is among the top ten high-burden TB countries globally (Kathure et al., 2026). For instance, Kenya reported a prevalence rate of 194 cases per 100,000 population in 2023 and a nearly similar prevalence, 197 cases per 100,000 population in 2024 (Wambura, 2024). TB-related deaths in the country were estimated at around 15,000 in 2024 (Hassan et al., 2026). The high prevalence of TB is worrying given the emergence of drug-resistant *Mycobacterium tuberculosis* strains, despite the global efforts to contain it using integrated interventions such as Directly Observed Therapy (DOT), patient education initiatives, and community health strategies (Farhat, et al., 2024). This is further complicated by difficulties in early diagnosis and effective treatment monitoring (Sulis, et al., 2016).

Though recent research has endeavored to improve early diagnosis and enhance understanding of the impact of drug-resistant strains, limited progress has been made to

improve treatment monitoring (Muteeb et al., 2023). The major challenge in TB monitoring for patients on treatment is the occurrence of delayed sputum conversion where patients continue to shed infectious bacteria for an extended period. Studies show that the prevalence of delayed sputum conversion at the end of the intensive phase can vary widely, from approximately 8% to over 30% in various settings, with some reports indicating rates prevalence as high as 35% (Bhatti & Khan, 2021). This delay significantly increases the risk of community transmission, treatment failure, and the development of drug-resistant strains (Khor et al., 2023). Similarly, delayed improvement in clinical sign scores, is associated with persistent symptoms and poor overall health (Bea et al., 2023). Additionally, this is indicative of negative treatment response which significantly contributes to prolonged suffering and poorer long-term outcomes for patients.

Nutrition is a major monitoring indicator of TB prognosis and malnutrition is reported to delay sputum conversion and contribute to poor clinical signs progress among TB patients (Feyisa et al., 2024). Additionally, malnourished TB patients are 30% less likely to achieve sputum conversion compared to well-nourished counterparts (Morales et al., 2023; Wagnew et al., 2024). Similarly, poor nutritional practices such as inadequate meal diversity and poor food preparation are significantly associated with delayed sputum conversion during TB treatment (Bade et al., 2021; Izudi et al., 2024). Additionally, studies have shown that micronutrients such as zinc, vitamin A, vitamin C and selenium do not just play essential roles in sputum conversion, but also improves immune function and pharmacological response (Campa et al., 2017; Chandra, 2004; Koethe & Reyn, 2016). Both immune function and pharmacological response are critical factors in disease prognosis, and therefore essential for improving clinical sign scores (Diatlova et al., 2023).

Other factors that contribute to delayed sputum conversion and poor progress of clinical sign scores have been identified. They include non-adherence to medication, drug resistance tuberculosis, comorbidities and extreme biological variation, low levels of health and nutrition awareness, and lack of knowledge related to the disease (Diallo et al., 2018; Sawadogo et al., 2015). Studies have also shown that alcohol and tobacco use are

associated with delayed sputum conversion and clinical sign scores among patients on TB medication (Ren et al., 2019; Wagnew et al., 2024).

Therefore, monitoring nutrient intake while controlling for these factors during the treatment period is essential in preventing nutritional deficiencies and their impact on sputum conversion and clinical signs progress (Asres et al., 2018). Previous studies have reported that positive deviance (PD) interventions significantly improve nutritional and TB treatment outcomes (Anino et al., 2018; Baik et al., 2022). This information can be used to develop targeted nutritional interventions to improve treatment outcomes and reduce the burden of TB. Therefore, the current study sought to establish the role of nutrition intervention utilizing the positive deviance approach on the nutritional status of patients on TB medication, sputum conversion and clinical signs progress.

1.2 Statement of the Problem

Tuberculosis (TB) remains a major global public health problem, with an estimated 10.8 million new cases and 1.4 million deaths reported worldwide in 2024 (Chen et al., 2025). The African region bears approximately 25% of the global TB burden (Xie et al., 2025), with countries such as Nigeria (4.6) and South Africa (3.3) contributing substantially to the continental caseload (Njelita et al., 2025). In Kenya, the TB prevalence of 197 cases per 100,000 population remains higher than the global average of 132 per 100,000, with a marginal upward trend in recent years. Kericho County reports an even higher prevalence (219 per 100,000), with Bureti (224 cases per 100,000) and Ainamoi (220 cases per 100,000) sub-counties exceeding national levels (Ministry of Health, 2024). These reports show a persistent regional burden despite intensified national strategies such as expansion of Directly Observed Treatment (DOTS) and community health unit approaches (Mwanzui et al., 2025). Compared with neighboring counties Kericho recorded higher TB rates which exceeded those reported in counties such as Bomet (179 cases per 100,000) and Nandi (110 per 100,000) (Albert et al., 2025; Yismaw et al., 2025).

Although Kenya has recorded modest improvements in treatment indicators such as increased treatment success (from 86% to 88%) (Limo et al., 2025), improved cure rates (72% to 77%) (Ngari et al., 2025), reduced delayed sputum conversion (28% to 23%) (Wangari Maina et al., 2025) and declining mortality (6.7% to 6.0%) (Ngari et al., 2025), these outcomes remain below the WHO recommended thresholds. Kericho County continues to experience suboptimal outcomes, with delayed sputum conversion rates ranging from 24–28% and a substantial proportion of patients demonstrating poor clinical improvement (Wangari Maina et al., 2025). Severe malnutrition, lack nutrition education and delayed diagnosis have been identified as key contributors to these negative outcomes. Undernutrition compromises immune recovery, prolongs sputum positivity, increases the risk of treatment failure and multidrug-resistant TB, and sustains community transmission (Fâcă et al., 2025). Programmatic constraints in Kericho including high poverty levels, food insecurity, limited routine nutritional assessment and supplementation within TB programs, and delayed health-seeking practices further compound these challenges (Pilla & Dantas, 2016).

Given the strong association between nutritional status and sputum conversion, a positive deviance–based nutrition intervention is warranted to address context-specific dietary gaps using locally available resources. Positive deviance approaches identify beneficial nutrition practices already present among successful individuals within the same community and promote their adoption among at-risk groups. If successful, such an intervention could accelerate sputum conversion, reduce delayed conversion rates, improve clinical signs, and lower ongoing TB transmission within households and communities. This would ultimately strengthen TB control efforts by shortening the infectious period, reducing community transmission, and improving treatment outcomes among TB patients in Kericho County.

1.3 Justification

The WHO recommends approach to TB control that integrates medical treatment with supportive interventions such as nutrition, adherence support, and community engagement

(Frick, 2016). In Kenya, TB treatment follows the standard regimen of a two-month intensive phase consisting of Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol (RHZE), followed by a four-month continuation phase of Rifampicin and Isoniazid (RH) (Mburu, 2020). However, despite these standardized protocols, Kenya has not achieved the national targets of reducing active TB cases, treatment failure, and multidrug-resistant TB, indicating that additional supportive interventions are required to improve treatment outcomes (MoH, 2019).

Globally, the TB response is aligned with the health targets of the United Nations Sustainable Development Goals (SDGs). These targets aim to lower TB incidence and mortality by 2030. However, Kenya remains off-track in achieving the global targets of an 80% reduction in TB incidence and a 95% reduction in TB deaths (Goletti et al., 2025; WHO, 2018). This calls for innovative and context-specific strategies to strengthen existing TB control interventions. A major contributing factor to the slow progress is poor nutritional status which has been consistently associated with delayed sputum conversion, poor treatment adherence, and poor clinical signs scores among TB patients on medication (Anino et al., 2018). On this basis, it seems that nutrition-focused interventions could play an important role in improving treatment outcome.

The findings of this study have potential implications for both policy and program implementation. Evidence from the intervention supported the integration of nutrition education into existing TB management strategies such as the DOTS strategy, community health unit activities, and county-level nutrition programs. Because the intervention relied primarily on locally available foods and community-based health education structures it may be feasible for adoption within routine TB services. However, further research is recommended to evaluate the cost-effectiveness and scalability of integrating positive deviance-based nutrition interventions into TB prevention and control programs in Kenya.

1.4 Objectives of the Study

1.4.1 Broad Objective

To assess the outcome of a positive deviance nutrition education intervention on nutritional intake, sputum conversion, and clinical signs among TB patients in Kericho County, Kenya

1.4.1 Specific Objectives

1. To assess the healthcare seeking practices associated with treatment outcome among patients on TB medication in Kericho County.
2. To establish the influence of a positive deviance nutrition education intervention on nutritional intake at 2nd, 5th and 6th month among patients on TB medication in Kericho County.
3. To determine the effect of a nutrition education intervention on sputum smear conversion for acid fast Bacilli at 2nd, 5th and 6th month among patients on TB medication in Kericho County.
4. To determine the influence of a positive deviance nutrition education intervention on clinical signs at 2nd, 5th and 6th month among patients on TB medication in Kericho County.

1.5 Research Questions

1. Which healthcare seeking practices are associated with treatment outcome among patients on TB medication in Kericho County?
2. To what extent does a positive deviance nutrition education intervention improve nutritional intake at 2nd, 5th and 6th month among patients on TB medication in Kericho County?
3. To what extent does a positive deviance nutrition education intervention improve sputum conversion at 2nd, 5th and 6th month among patients on TB medication in Kericho County?

4. To what extent does a positive deviance nutrition education intervention improve clinical signs at 2nd, 5th and 6th month among patients on TB medication in Kericho County?

1.6 Scope of the Study

The research assessed the role of positive deviance intervention in improving nutritional status, sputum conversion, and clinical signs score among patients on TB medication enrolled in a positive deviance nutrition intervention and control study arms. The study further established the effects of the nutrition intervention on treatment outcome of patients on TB medication and its function in preventing transmission of TB among contacts of TB patients in Kericho County.

CHAPTER TWO

2.0. LITERATURE REVIEW

2.1 Tuberculosis Burden

2.1.1 Global Burden of Tuberculosis

Tuberculosis remains one of the most devastating infectious diseases worldwide. According to the WHO TB continues to pose a significant threat to global public health despite decades of control efforts (WHO, 2024). The disease is caused by *Mycobacterium tuberculosis* and primarily affects the lungs, although it can also affect other organs such as the kidneys, spine, and brain (Albert et al., 2025). Globally, TB remains among the leading causes of death from a single infectious agent, surpassing HIV/AIDS in some recent global health reports (Bi et al., 2025; Saeed et al., 2018). Recent WHO reports have indicated that approximately 10.8 million people developed TB in 2024, with about 1.4 million deaths among HIV-negative individuals and an additional 167,000 deaths among people living with HIV (Goletti et al., 2025). This shows the persistent global burden of TB despite widespread implementation of TB control strategies.

Further reports have shown that low- and middle-income countries have the greatest burden of TB. These countries accounts for about 95% of cases and deaths (Portnoy et al., 2023). High TB prevalence is strongly associated with poverty, malnutrition, overcrowding, weak health systems, and limited access to healthcare services (Ockenga et al., 2023). Sub-Saharan Africa and Southeast Asia have consistently reported the highest incidence rates due to the dual burden of TB and HIV infection (Bizuneh et al., 2025). Furthermore, the emergence of drug-resistant TB, especially, MDR-TB has complicated TB control efforts globally (Bade et al., 2021). MDR-TB occurs when the TB bacteria become resistant to first-line drugs such as isoniazid and rifampicin, making treatment longer, more expensive, and less effective (Vilchèze et al., 2018). According to WHO estimates, over 450,000 new cases of drug-resistant TB are reported annually worldwide

(Cui et al., 2025). Efforts to control TB globally involve integrated strategies including early diagnosis, prompt treatment, vaccination with Bacillus Calmette-Guérin (BCG), improved nutrition, and strengthened health systems (Elbehiry et al., 2025). International programs such as the End TB Strategy aim to reduce TB incidence by 90% and deaths by 95% by the year 2035 (Awaidy et al., 2025).

2.1.2 Tuberculosis Burden in Africa

Africa has the largest burden of the global TB (Padayatchi et al., 2019). The continent has some of the highest TB incidence rates due to the interaction between TB and HIV infection, poverty, malnutrition, and weak healthcare systems (Ustero et al., 2017). Sub-Saharan Africa accounts for nearly one-quarter of the global TB burden (Karami et al., 2025). Several African countries are listed among the high-burden countries for TB, TB and HIV co-infection, and multidrug-resistant TB (Feng et al., 2025). The region's TB epidemic is strongly driven by HIV infection, which significantly weakens the immune system and increases susceptibility to TB infection and progression from latent TB to active disease (Khojasteh-Kaffash et al., 2025; Kumar et al., 2011). The recent WHO reports have shown that nearly 25% of TB cases in Africa occur among people living with HIV (Al Awaidy et al., 2025)(Sossen et al., 2025). For this reason, TB is the leading cause of death among HIV-positive individuals (Kiriazova et al., 2017). Additionally, the socio-economic environment in many African countries has also contributed to a larger extent to TB transmission (Limo et al., 2025a). Some of these include rapid urbanization, overcrowded housing conditions, limited access to quality healthcare services, and widespread poverty which create environments that favour the spread of TB infection (Rahman & Willott, 2025). In addition, delays in diagnosis and inadequate treatment adherence have contributed to the persistence of TB transmission in many communities (Skinner & Claassens, 2016). Health system challenges such as shortages of trained healthcare personnel, limited laboratory capacity for TB diagnosis, and inconsistent supply of TB medications have further complicated TB control in many African countries.

2.1.3 Tuberculosis Situation in Kenya

Kenya is among the high TB burden countries globally (MOH, 2021). The Kenya Ministry of Health reports have indicated high prevalence of tuberculosis despite the ongoing control interventions (MoH, 2024). It's on this backdrop that TB is considered a public health problem in the country. According to the National Tuberculosis, Leprosy and Lung Disease Program, Kenya records about 140,000 new TB cases annually (Ministry of Health, 2024). The majority of these cases occur among economically productive age groups (Thakur et al., 2026; Wingfield et al., 2016). Recent and past reports have ranked Kenya among the 30 high-burden countries for TB, TB/HIV, and MDR-TB globally (Kathure et al., 2026; Ustero et al., 2017). The estimated TB incidence rate in Kenya was reported to be about 197 per 100,000 population (Wambura, 2024). These further reveals the magnitude of the disease burden in the country. Some of the contributing factors to the high burden are the high urban informal settlements. For instance, Kibera in Nairobi has been reported as a high TB prevalence due to overcrowding, poor sanitation, and limited access to healthcare services (Mburu, 2020; Odera et al., 2020). Further studies conducted in the informal settlements have shown that delayed diagnosis, poor treatment adherence, and inadequate nutrition have largely contributed to TB transmission and poor treatment outcomes.(Bacelo et al., 2017; Mendes et al., 2025). Additionally, the interaction between TB and HIV remains a major challenge in Kenya. For instance, about 30% of TB patients in Kenya are co-infected with HIV, which significantly complicates treatment and increases mortality risk (Ngari et al., 2025). The government of Kenya, through the MoH has implemented several TB control strategies including DOTS, active TB case finding, integration of TB and HIV services and community-based TB control programs. Despite these interventions, Kenya continues to experience significant TB transmission due to persistent socio-economic challenges, stigma associated with TB disease, and gaps in health service delivery, and poor nutrition (Limo et al., 2025; Zamudio et al., 2015). Additionally, poor treatment outcome, which recent reports have indicated as the main challenge among patients on TB medication among Kenyans is largely attributed to poor nutritional intake (Chek et al., 2022).

2.2 Role of Nutrition in TB Treatment Outcomes

2.2.1 Nutrition and TB Prognosis

Nutrition is one of the important determinants of treatment outcomes in TB since it influences disease prognosis and treatment efficacy through a bidirectional relationship (Achkar & Jenny-Avital, 2011; Mendes et al., 2025). TB infection frequently precipitates malnutrition via a hypermetabolic catabolic state which is largely characterized by elevated energy expenditure, which could move up to 80% above baseline (Karunarathna et al., 2025). TB is also associated with muscle wasting, and weight loss, which is often referred to as the consumption state (Gea et al., 2018; Landi et al., 2019; Mashabela et al., 2019). Conversely, pre-existing malnutrition compromises immune defences and thereby elevates the susceptibility to active disease (Fâcă et al., 2025). This mechanism is set up by accelerating disease progression and impairing recovery (Xueyi Li1, 2025), and therefore doubling the likelihood of mortality among the malnourished patients (Ockenga et al., 2023). This vicious cycle is exacerbated in settings like Kericho County where food insecurity and HIV co-morbidity compound risks (Ejemot-Nwadiaro et al., 2020; Mendes et al., 2025; Osman & Prins, 2016). Further literature review showed moderate evidence quality, majorly from observational cohorts and cross-sectional studies which are susceptible to reverse causation and confounding biases. For instance, WHO policy syntheses reported consistent associations among malnourished patients on TB medication and poor treatment outcomes (Ockenga et al., 2023). However, these reports cautioned on their interpretation of results due to limited causal inference without prospective designs (Gegia et al., 2015). A key gap persists in high-altitude areas. It's reported that hypoxic stress may intensify catabolism in high altitude areas (Zhao et al., 2025), though multivariate models integrating local socioeconomic factors are absent.

2.2.2 Nutritional Status and TB Disease Progression

Malnutrition is known to impair TB progression with protein-energy malnutrition (PEM) and micronutrient deficiencies disrupting cell-mediated immunity essential for containing

Mycobacterium tuberculosis (Li et al., 2023; Sinha et al., 2019) Mechanistically, PEM induces lymphoid organ atrophy and depletes CD4⁺ T-cell subsets, while micronutrient shortfalls, particularly zinc, vitamins A/C/D, and selenium dysregulate cytokine profiles by reducing IFN- γ (Meng et al., 2025; Muzembo et al., 2018). They also compromise granuloma integrity, and hinder phagolysosome maturation for bacterial killing (Ashenafi & Brighenti, 2022; Campa et al., 2017; Menon et al., 2016; Rijnink et al., 2021). The specific immune response pathway varies for each nutrient. For instance, zinc deficiency impairs macrophage activation and IFN- γ production which are necessary for mycobacterial containment (Xiong et al., 2020). Vitamin A modulates T-cell differentiation, while vitamin D induces cathelicidin /LL-37 antimicrobial peptides via VDR signalling, while selenium bolsters glutathione peroxidase to mitigate oxidative stress (Muzembo et al., 2018; Wagnew et al., 2022). Tissue and pharmacokinetic effects have reported to vary among patients on medication based on the nutritional challenge they are experiencing. For instance, PEM is reported to delay bacterial clearance from pulmonary lesions and alters anti-TB drug absorption/metabolism (Făcă et al., 2025). Specifically, isoniazid bioavailability is reported to reduce by 20-30% in low-BMI states, which consequently yields subtherapeutic concentrations (Gizaw et al., 2023; Muteeb et al., 2023; Pang et al., 2024). A further evidence appraisal gives moderate rating from heterogeneous cohorts and case-controls (n<500), with animal models supporting mechanisms but inconsistent human assays. Gaps observed included paucity of East African longitudinal data; and even the high malnutrition rate reported among TB patients in Kericho demands mechanistic studies linking intake to immunity. Table 2.1. shows a summary of the mechanism of disease progression.

Table 2.1: Mechanism of TB Progression in Nutrition Context

Mechanism	Key pathways	Supporting evidence & limitations
PEM	Lymphoid atrophy; T-cell depletion	Cohorts; confounding high (Camarasa et al., 2025; Menon et al., 2016).
Micronutrients (Zn/A/D/Se)	IFN- γ ↓; cathelicidin↑; ROS↓	Mixed RCTs; dosing heterogeneity (Campa et al., 2017; Murugaiha, 2021).
Catabolism/PK	Lesion persistence; drug↓	PK models limited (Murao et al., 2025)

2.3 Nutrition Education Interventions in TB Management

Nutrition education interventions in TB management encompass a spectrum of strategies which ranges from conventional counselling and food provisioning to innovative behavioural models designed to elevate dietary intake, defined as daily energy (>2100 kcal), macronutrients (protein >1.2 g/kg body weight), and micronutrients at recommended dietary allowances (RDAs) (Mustafa & Aurangzeb, 2024). Adherence to these recommendations is well reported to address TB-induced catabolism, which elevates energy demands by 20-80% and precipitates malnutrition in over 60% of cases (Piccoli et al., 2023). PD, increasingly rolled out in Kenya's malnutrition alleviation programs since 2015 under MOH guidance, leverages local positive deviants – caregivers with well-nourished children thriving on accessible foods to foster sustainable behaviours, thus distinguishing it from external-input models (Anino et al., 2015). Evidence from systematic reviews of 17 randomized controlled trials (RCTs) indicated moderate GRADE-quality improvements in intake and clinical proxies (BMI gains of 0.5-2 kg/m²), though downgraded for intervention heterogeneity, short-term follow-up (<6 months), and confounding co-treatments like antiretrovirals (Margineanu et al., 2022).

PD approach enables tailoring diet to the needs of the patient and therefore can potentially address the shortcomings of the traditional approaches which yield incremental but often transient intake enhancements (Vidosi., 2025). For instance, didactic sessions on high-energy diets based on the WHO guidelines which emphasizes on protein-rich staples

produce 10-20% increases in energy and protein intake by month 2, alongside hemoglobin and erythrocyte sedimentation rate improvements ($p < 0.001$) (Xu et al., 2025). However, the effects wane without reinforcement due to appetite suppression and socioeconomic barriers (Ejemot-Nwadiaro et al., 2020). Additionally, food baskets, particularly provision of ready-to-use therapeutic foods (RUTF) boosts energy by 500-1200 kcal/day and cure rates (odds ratio [OR] 1.3) (Pajak et al., 2025). However, they have their shortcomings as well since they foster dependency and overlooks micronutrient bioavailability from local sources (Xiong et al., 2020). Nutrition education on fortified foods is associated with elevated serum levels (Martirosyan et al., 2022). For instance, advice on fortified Vitamin A rich foods is known to elevate vitamin A by 15-20% and thereby facilitate reduction in oxidative stress, but adherence falters amid treatment side effects like nausea (P. Muhammad et al., 2022).

In Kenyan contexts, such as Nairobi and Murang'a RCTs using the PRECEDE-PROCEED model ($n=373$), counselling enhanced nutritional knowledge and health-related quality of life by 39%, while curbing household treatment costs. Critical appraisal: These RCTs offer moderate evidence strength but suffer from performance bias (non-blinded) and limited longitudinal tracking beyond 3 months, failing to capture plateaus or declines at 5-6 months (Mbuti Kimani et al., 2022). A summary of these studies are presented Table 2.2.

PD has been adapted for TB since 2019 as shown in Vietnam pilots, and has represented a paradigm shift by appraising communities to identify atypical successes such as TB patients maintaining intake via inexpensive greens (spinach for vitamin A/zinc), legumes, millet (selenium), and fruits (vitamin C)—then disseminating these through 12-15 participatory 'hearth' sessions. Unlike top-down counselling, PD builds self-efficacy and social norms, achieving cost-effectiveness (Anino et al., 2015). Additionally, PD has been shown to sustain 30% gains vs. 10% for counselling in most of the programs (Anino et al., 2018). However, quasi-experimental designs from which these findings are reported provide robust associations but risk selection/attrition bias with 15-20% dropout, thus

emerging RCTs are needed for causality or quasi experimental with more representative sample is desired (Izudi et al., 2024).

Table 2.2: Selected Nutrition Interventions in Management of TB in Context of Positive Deviance

Intervention type	Mean Intake Effect (Energy/Protein)	Sustainability	Key limitations
Counselling	+10-20% by month 2	Low (fades post-3 months)	Non-blinded; short follow-up (Misra et al., 2025)
Food baskets	+500-1200 kcal/day	Moderate (dependency risk)	Costly; ignores local adaptation (Persson et al., 2025)
RUTF supplements	+20-40% short-term	Low (palatability issues)	Adherence <60% long-term (Muhammad et al., 2025)

2.4 Influence of Nutritional Deficiencies and Interventions on Clinical Signs in TB Patients

2.4.1 Exacerbation of Clinical Signs by Nutritional Deficiencies

Clinical signs of TB particularly, persistent cough, prolonged fever (>38°C for >2 weeks), night sweats, significant unintentional weight loss (>5% body weight in <6 months), fatigue, and anorexia represent core diagnostic and monitoring markers under WHO guidelines, with resolution by month 2 signalling favourable treatment response (Luies & Preez, 2020). Malnutrition, documented in 50-70% of TB patients globally and exceeding 60% in low resourced areas intensifies these manifestations by compromising host defences and impeding *Mycobacterium tuberculosis* clearance (Ockenga et al., 2023). TB patients with poor nutritional status exhibit amplified symptom severity, such as accelerated cachexia (1-2 kg/month muscle loss) and prolonged inflammatory states, elevating risks of negative treatment outcome (15-25% vs. 5% in nourished peers) and relapse (Lu et al., 2024).

2.4.2 Mechanistic Pathways Linking Deficiencies to Sign Persistence

Nutritional deficiencies perpetuate clinical signs through interconnected immune, metabolic, and pharmacokinetic mechanisms (Majumdar et al., 2025). It has been observed that through immune dysregulation, PEM induces thymic atrophy and CD4+ T-cell depletion (CD4/CD8 ratio decline by 20-40%), destabilizing granulomas and sustaining fever/cough via unchecked bacterial replication (Majumdar et al., 2025). Zinc deficiency (<70 µg/dL) inhibits NF-κB signaling, reducing interferon-gamma (IFN-γ) production by 40-60% and macrophage phagocytosis (Wagnew et al., 2022), while vitamin D shortfalls (<20 ng/mL) impair cathelicidin (LL-37) expression (Kumar Barik et al., 2024), exacerbating night sweats through persistent Th1/Th17 imbalance (Luies & Preez, 2020). Another mechanistic pathway is through metabolic hypermetabolism where TB elevates resting energy expenditure (REE) by 73-80% (Malla et al., 2025), compounded by PEM-driven hypoalbuminemia (<30 g/L), which correlates with threefold higher fatigue and weight loss via cytokine storms (TNF-α/IL-6 upregulation) and proteolysis (Allison & Lobo, 2024). Finally, pharmacokinetic and pharmacodynamic alterations it is observed that malnutrition reduces gut surface area and CYP450 enzyme activity, slashing isoniazid bioavailability by 20-50% in low-BMI (<16 kg/m²) states (Ngcobo, 2025). This process fosters subtherapeutic levels, resistance emergence, and delayed lesion healing, particularly, via impaired collagen synthesis from vitamin C deficits. This prolongs cough and systemic inflammation (Luies & Preez, 2020). Preclinical models, pharmacokinetic studies, and large cohorts with n > 1000 robustly delineate mechanisms, yet observational designs introduce reverse-causation bias, with limited adjustment for HIV co-infection which is prevalent in Kenya (Bizuneh et al., 2025). A summary of the mechanistic pathway is presented in Table 2.3.

Table 2.3: Role of Mechanistic Pathway of Micronutrient in TB Progression

Deficiency pathway	Key mechanism	Affected Clinical signs	Quantitative impact
PEM/Zinc	IFN- γ ↓; phagocytosis impaired	Cough, fever persistence	OR 2.5-3.0 for delay
Vitamin D/A	Cathelicidin↓; Th2 shift	Night sweats, weight loss	Resolution 30% slower
Vitamin C/Selenium	ROS↑; PK disruption	Fatigue, cachexia	Relapse RR 1.8

2.4.3 Consequences for Treatment Efficacy and Relapse Risk

Undernourished patients demonstrated inferior outcomes in previous studies including delayed sign resolution - cough clearance at month 2: 45% vs. 75%, treatment failure (RR 2.0), relapse (HR 1.8), and mortality (OR 2.5), partly attributable to drug-induced micronutrient depletion as is the case with rifampicin which reduces B6 by 50% (Muhammad et al., 2025). WHO guidelines (2023) mandate nutritional screening as integral to DOTS, recognizing malnutrition's role in amplifying MDR-TB risks (Mendes et al., 2025). Meta-analyses of 16 RCTs affirm associations (high consistency), moderated by heterogeneity in malnutrition metrics (BMI vs. mid-upper arm circumference) (Misra et al., 2025).

2.5 Gaps in Literature

Nutritional deficiencies mechanistically exacerbate clinical signs and erode treatment efficacy via immune suppression, catabolism, and PK disruptions, with PD interventions offering promising, sustained reversal due to (1) predominance of short-term observational data; (2) inconsistent multi-timepoint assessments (e.g., absent 5/6-month sign trajectories); (3) Region-specific confounders like highland hypoxia and HIV-food insecurity interactions; and (4) limited head-to-head PD vs. standard care evaluations amid MOH rollout.

2.6 Conceptual Framework

The conceptual framework guiding this study explain the association between nutrition education and treatment outcomes among patients with active TB. Key to this framework is the intervention of nutrition education. The aim of this intervention was to enhance patients' knowledge and skills to improve their nutritional practices. The intervention was posited to directly influence patients' adherence to health-seeking behaviors such as adherence to medical advice and prescribed clinic visits, as well as their compliance with RDI. Furthermore, it encouraged the preparation and consumption of nutrient-dense meals which was a demonstration of the practical application of nutrition knowledge. However, the effectiveness of this intervention was moderated by socio-economic factors which included age, education level, sex, marital status, and income. These socio-economic factors are known to either facilitate or hinder patients' ability to implement nutritional recommendations and adhere to treatment protocols. Additionally, in this conceptual framework the investigator incorporated a temporal dimension by assessing these relationships at critical treatment milestones of the 2nd, 5th, and 6th months. This was necessary to take into consideration how adherence behaviors and outcomes changed throughout the TB treatment process. The dependent variable which was influenced by the intervention and the moderating variables was treatment outcomes. This was measured through three critical indicators of nutritional status, sputum conversion, and clinical signs score. The dependent variable was conceptualized to reflect successful therapy completion with improvements in nutritional status revealing the physical health benefits of adequate nutrient intake. In the same note, sputum conversion was conceptualized to serve as a biological marker of disease resolution whereas clinical signs scores indicated overall symptom improvement. Thus, the framework was conceptualized to show the importance of nutrition education as a necessary factor in enhancing adherence and clinical recovery in TB patients.

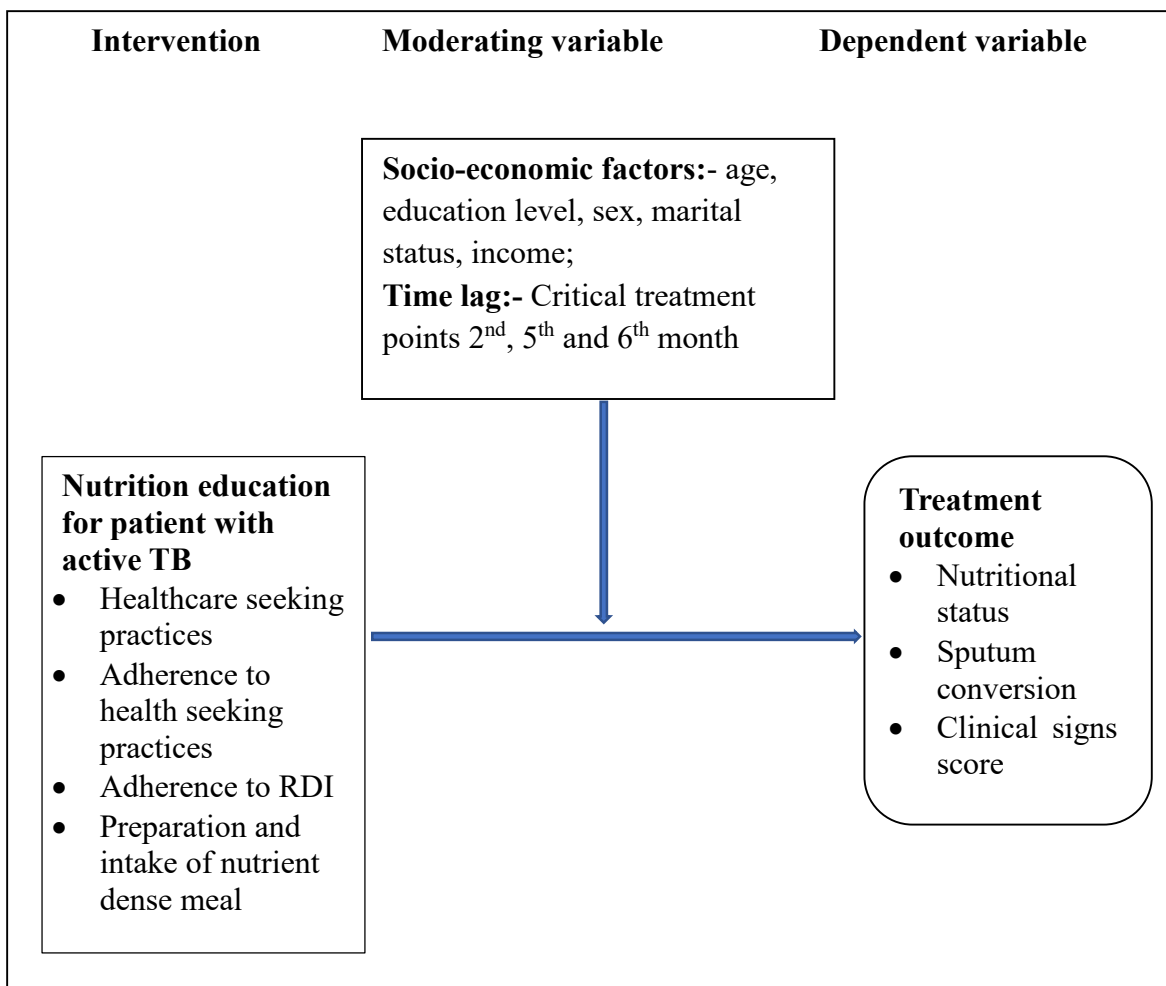


Figure 2.1: Conceptual Framework

CHAPTER THREE

MATERIALS AND METHOD

3.1 Study Design

The study employed a sequential two-phase exploratory design. The first phase involved a qualitative Positive Deviance Inquiry (PDI) which was carried out as a cross-sectional study aimed at identifying context-specific optimal practices and informing the development of the intervention, while the second phase comprised a pretest–posttest quasi-experimental, non-randomized, cluster-based design to evaluate the effectiveness of the developed intervention, consistent with approaches applied in similar studies (Anino et al., 2015b; Huerga et al., 2017; Ombogo et al., 2026; Serpoosh et al., 2020) Given the use of pretest – posttest quasi – experimental cluster-based design without randomization, the study findings will enable deduction of inference of a plausible intervention effect and association but causal attribution will be limited due to potential confounding and inherent cluster-level differences between the study sites (Pereira Macedo et al., 2025). While randomization was not feasible given the nature of the study design and cluster-based allocation of study sites, potential bias was minimized through a number of ways including 1) baseline comparability assessments (Fatouros et al., 2025); 2) inclusion of a control group (Ferrand et al., 2025); 3) application of a pretest – posttest design to account for temporal changes (Huang et al., 2026); and 4) use of standardized intervention protocols and analytical approaches that adjusted for clustering and key confounders (Izudi et al., 2025). A diagrammatic representation of the study design is presented in Figure 3.1.

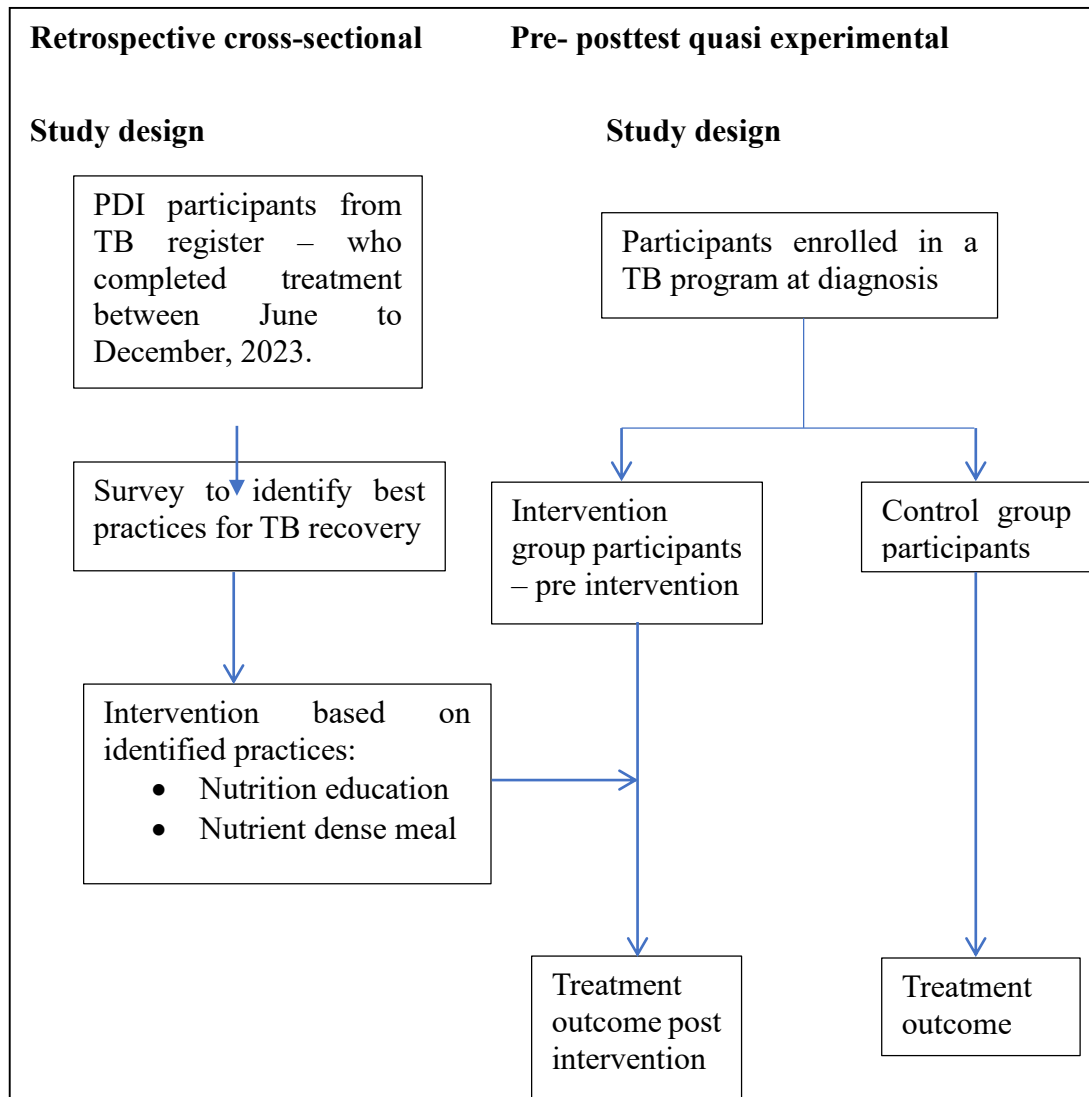


Figure 3.1: Flow chart Illustrating Study Design and Execution Processes

Key: PDI denotes positive deviance inquiry.

3.2 Study Area

The study was carried out in Kericho County, Bureti and Anaimoi Sub Counties, which is located in Southern Rift valley of Kenya. The county is positioned geographically between latitude 0° 10' and 0° 40' south and longitude 35° 02' and 35° 40' east (Kipngeno A., 1999).

Additionally, the County bordered with Nandi and Kisumu County on the North, Bomet County to the South, and Nyamira and Homabay counties to the West. The climatic condition is favourable for agricultural activities especially cash crops such as tea and maize, additionally other source of income is dairy farming. The region's agricultural productivity plays a crucial role in the community livelihood and the national economy.

Kericho County administratively is made up of six sub-counties which are; Bureti, Belgut, Ainamoi, Soin/Sigowet, Kipkelion West and Kipkelion East. Additionally, the county is further sub divided to 85 locations and 209 sub-locations which contribute to the local governance and assist in service delivery (Cheruiyot et al., 2025). In spite of being a major agricultural hub, the County faces challenges linked to youth unemployment and nutritional deficiencies among the population especially in rural areas (Mendes et al., 2025). Furthermore, the county has a well-structured health linkage comprising of one county referral hospital, seven sub county hospital and 180 health centers and robust 159 network dispensaries across the county (Tareh et al., 2023).

3.3 Study Population

The study were patients with active TB in Bureti and Ainamoi Sub-Counties. For the initial cross-sectional study, the study participants were individuals who previously had TB and completed treatment regimen.

3.3.1 Inclusion Criteria

The inclusion criteria for the current study were.

Active TB Patients

1. Positive sputum TB results
2. Diagnosis within a month prior to onset of the study
3. Registration as an active TB case in the facilities within Bureti Sub-County.

Treatment Failure Patients

1. Positive sputum follow-up after the second and fifth month of active TB treatment.

3.3.2 Exclusion Criteria

Exclusion criteria for both categories of patients with active TB and treatment failure were:

1. Life threatening complications
2. Hospitalization
3. Pregnancy

3.4 Sample Size Determination

3.4.1 Positive Deviance Inquiry Sample Units

The study adopted fisher formula as described by (Mugenda & Mugenda, 1999) to determine the sample units for positive deviance inquiry. This is because positive deviance inquiry was to be carried out to measure the exposure and outcome at the same time (Mugenda & Mugenda, 1999). The fisher formula is described below:

$$n = \frac{Z^2 pq}{d^2}$$

In this formula, n is the desired sample size, Z is the standard normal deviate which is 1.96 and corresponds to 95% confidence interval (CI), P is the proportion of the target population estimated to have the desired characteristic (q=1-p) and d is the degree of accuracy usually set as 0.05.

The prevalence of active TB in Bureti Sub-County is 16.9% (MoH, 2019). Therefore, the desired sample size (n) when p is 16.9 % is;

$$n = \frac{1.96^2 \times 0.169 \times 0.831}{0.05^2} = 216$$

Therefore, 216 individuals who previously had TB and successfully completed the treatment regimen was sampled for positive deviance inquiry.

3.4.2 Intervention and Control Sample Units

The study adopted sample size determination formula described by (Lwanga & Lemeshow, 1991) and (Cornish, 2006) as shown below.

$$n = \frac{P_1(1 - p_1) + P_2(1 - P_2)}{(P_1 - P_2)^2} \times f(\alpha, \beta)$$

Where n is the required sample size per group, P_1 is the baseline proportion, P_2 is the expected proportion after intervention, and $f(\alpha, \beta)$ is a constant determined by the selected level of significance and statistical power.

In this study, a two-sided significance level (α) of 0.05 and statistical power of 80% ($\beta = 0.20$) were assumed, corresponding to $f(\alpha, \beta) = 3.8$ (Cornish, 2006b). The baseline treatment failure rate (P_1) in Bureti and Ainamoi Sub-Counties was estimated at 5% (0.05) based on (Ministry of Health, 2021), while the expected proportion after intervention (P_2) was set at 1.7% (0.017) which was consistent with the global treatment failure rate reported by the (World Health Organization, 2020) at the onset of the study. This reflected an anticipated absolute effect size (risk difference) of 3.3 percentage points.

Substituting these values into the formula:

$$n = \frac{0.05(1 - 0.05) + 0.017(1 - 0.017)}{(0.05 - 0.017)^2} \times 3.8 = 204$$

Thus, the minimum required sample size was 204 participants. However, due to the cluster-based implementation of the intervention, participants were organized into 18 positive deviance (PD) groups comprising 11 individuals each, yielding a total of 198 participants. Six participants were subsequently excluded based on predefined exclusion

criteria. This slight reduction from the calculated sample size was considered acceptable given operational constraints and the structured group-based intervention design.

3.5 Sampling Procedure

The study was carried out in two phases which aligned with the previous studies (Brière et al., 2021; Toorop et al., 2020). The first phase was a cross-sectional survey using PDI approach. This was conducted retrospectively to identify the ‘best practices’ which promoted recovery from TB, while the second phase was an intervention based on the identified ‘best practices. The participants for positive deviance inquiry were selected from the TB register using systematic random sampling. The inclusion criterion for these participants was completion of TB treatment. A total of 216 participants were included in the first phase of the study as determined using Fischer formula. In the second phase of the study, for both intervention and control study arms, a multistage cluster sampling was adopted. Participants were recruited and enrolled to the study based on the cluster sampling technique.

Clusters in this study were defined geographically at the sub-county level and operationally at the health facility level, with participants nested within selected TB treatment facilities. In the first stage of sampling, Bureti and Ainamoi Sub-Counties were purposively selected and assigned as intervention and control clusters, respectively, based on their comparable high TB burden and similarity in health service delivery structures (Mburu, 2020). This enhanced feasibility and contextual relevance of the intervention while minimizing contamination between study arms. Although random allocation of clusters was not feasible, probability sampling was employed in the selection of health facilities which enabled representativeness and minimized selection bias within clusters.

In the second stage, the investigators adopted simple random sampling technique to select eight of the 13 health facilities which at the time of study were used as treatment sites for patients with tuberculosis disease in both Ainamoi and Bureti sub-Counties. In the last stage, 18 groups of 11 patients were recruited at diagnosis totaling to 198 participants for

both intervention and control groups. All patients at first diagnosis who met the inclusion criteria were recruited. However, six of the sampled participants were excluded from the study based on the established exclusion criteria. The inclusion criteria adopted in the current study included being smear positive for sputum TB results, diagnosed within a month prior to the onset of the study and registered as an active TB case in the study sites. Those who had life threatening complications, hospitalized and pregnant at the time of the study were excluded. The sampled participants were equally distributed to the two study arms.

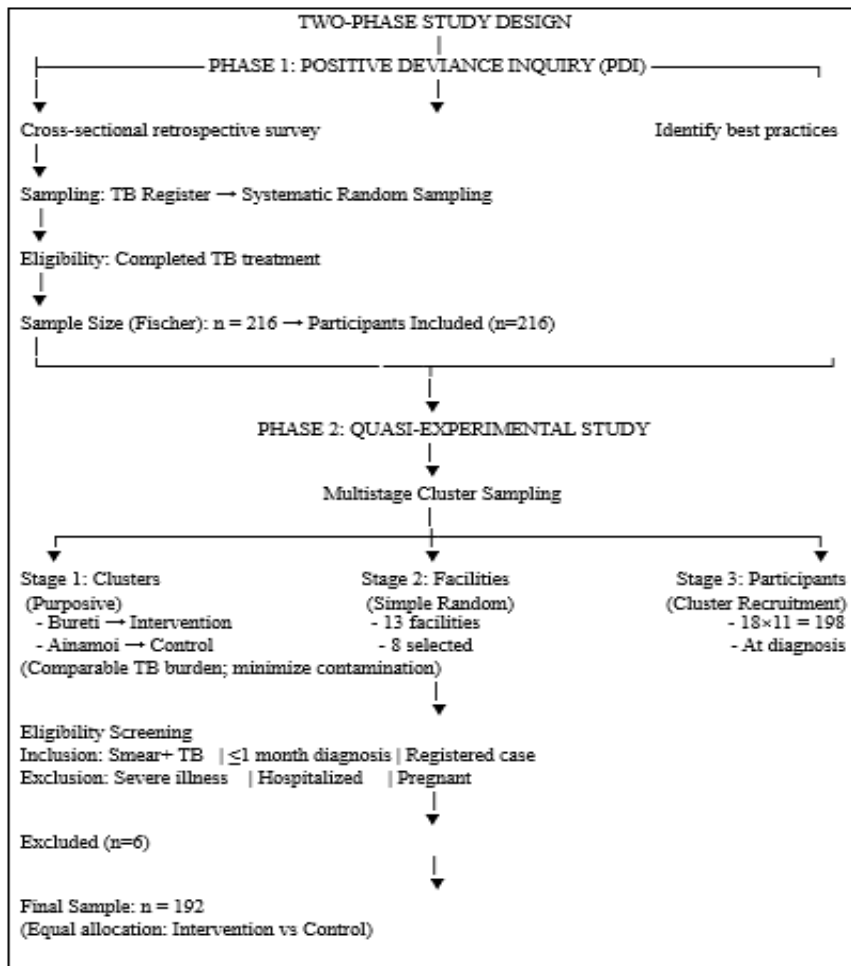


Figure 1.2: Sampling Selection

3.6 Data Collection

3.6.1 Data Collection Instruments

In this study, a variety of data collection tools were employed. SECA weighing scales and stadiometers, sputum mug, cool box, positive deviance inquiry questionnaires, food frequency questionnaire (FFQ), follow up questionnaires, post intervention questionnaires. Prior to the onset of data collection in the chosen health facility, the questionnaires were pretested at the health facility, this was conducted to familiarized with the process of data collection, assess the feasibility of the study, determine the accuracy of the tools and identify challenges so as to do the necessary adjustments based on the findings.

3.6.2 Positive Deviance Inquiry

Research administer questionnaire was used to collect information on the practices of the participants who took part in the positive deviance inquiry in the month of February 2023. The data gathered on practices were associated with socio-demographic characteristics, dietary intake at the time of their medication, and health seeking behaviors. Additionally, their retrospective data on nutritional status and sputum results were retrieved from the medical records at their respective treatment sites. Additionally, information on their treatment outcome upon completion of the treatment regimen was also obtained from the records. The positive deviance inquiry questionnaire was administered to the participants prior to the onset of the intervention at their place of residence. The questionnaire was designed to assess various sociodemographic, clinical, and behavioral factors related to TB treatment and patient outcomes. Key variables included demographic information (age, gender, education, occupation, income), health status (BMI, sputum results, comorbidities), healthcare access (clinic accessibility, waiting times, drug availability), adherence (drug intake, side effects, treatment completion), and knowledge and attitudes towards TB. The estimated time to administer the questionnaire was approximately 30 minutes

3.6.3 Intervention and Control

The intervention was developed based on findings from the PDI, which identified beneficial nutrition and health practices associated with successful TB treatment outcomes. These practices informed the development of a structured nutrition education curriculum adapted to the local context and guided by the Positive Deviance framework.

The intervention comprised two integrated components:

1. Structured nutrition education, and
2. Practical demonstration through preparation and consumption of nutrient-dense meals.

A total of 198 newly diagnosed TB patients in the intervention arm were organized into 18 PD groups, each consisting of approximately 11 participants. This grouping was informed by evidence suggesting that smaller groups (10–12 participants) enhanced participation and effectiveness of PD interventions (Anino et al., 2015; Ombogo et al., 2026).

Each group participated in fortnightly sessions over a six-month period, with each session lasting approximately two hours and conducted in an outdoor setting to promote interaction and infection control. Sessions were facilitated by trained health promoters using a standardized facilitation guide to ensure consistency and fidelity of implementation.

The nutrition education curriculum covered key domains including:

- TB treatment adherence
- Role of treatment supporters
- Risks of alcohol and tobacco use
- Household ventilation practices
- Meal diversity, food composition, and nutrient requirements

- Preparation of locally available nutrient-dense meals

In addition to theoretical learning, participants engaged in hands-on meal preparation and consumption during each session. The meals were designed using locally available and culturally acceptable foods commonly consumed in the study areas to ensure adequacy in macronutrients and key micronutrients essential for TB recovery, particularly proteins, energy, vitamin A, vitamin C, zinc, and selenium.

The typical nutrients dense meal components included:

- Carbohydrates: Ugali, rice, or sweet potatoes
- Proteins: beans, green grams (ndengu), eggs, and occasionally beef or chicken
- Vitamin A-rich foods: sukuma wiki (kale), spinach, and pumpkin leaves
- Vitamin C sources: tomatoes, cabbage, and fruits such as oranges and pawpaw
- Zinc and selenium sources: legumes, whole grains, and animal-source foods

These meals contributed significantly toward daily recommended nutrient intake and reinforced practical skills through experiential learning. Participants in the control group continued to receive standard TB care under the DOTS strategy without additional nutrition education or meal-based intervention

3.6.4 Sputum Collection Protocol

The monitoring of treatment response among patients with active tuberculosis in this study followed standard national and international guidelines as outlined by (Nahid et al., 2019). The specific steps followed are described below based on critical time points as described by (Arentz et al., 2011; Calderwood et al., 2021).

Step 1: Baseline Assessment (Month 0)

At baseline, the investigator conducted sputum examination using smear microscopy, confirmed presence of *Mycobacterium tuberculosis* and established bacteriological status (positive baseline).

Step 2: Definition of Primary Outcome

This was done by measuring sputum conversion at 2 months (end of intensive phase). The conversion was defined as positive (baseline) → negative (month 2).

Step 3: Follow-Up Monitoring

Sputum smear microscopy was conducted at the following critical time points:

- Month 2 → Early treatment response
- Month 5 → Assessment of treatment failure
- Month 6 → Confirmation of cure

Step 4: Interpretation of Results

The results were interpreted as follows:

- Negative smear → Treatment response/cure
- Persistent positivity (month 5 or 6) → Possible treatment failure or delayed response
- Initiate further evaluation (e.g., drug susceptibility testing)

Step 5: Diagnostic Approach

The primary diagnostic method was sputum smear microscopy. Additional method, culture was used only if treatment failure or drug resistance was suspected.

Step 6: Sputum Collection Procedure

The procedure followed was to instruct patient to produce deep cough sputum (not saliva). The investigator ensured collection in a well-ventilated environment. Two specimens were collected at each follow-up as described by (Bade et al., 2021; Padayatchi et al., 2019). These were done at:

- Early morning sample
- Spot sample at the facility

3.6.5 Data Collection Procedure

Data collection was conducted from March 2023 to September 2023 for both intervention and control groups. Study participants were enrolled from TB treatment sites, with the intervention implemented in Bureti Sub-County and Ainamoi Sub-County serving as the control site. All participants were patients with active tuberculosis receiving standard treatment under the DOTS strategy at the time of recruitment. At the onset of the study, a PDI was conducted retrospectively among individuals who had successfully completed TB treatment within six months prior to the study period. Participants for the PDI were identified from TB registers (February 2023 records), yielding a total of 216 eligible participants. The purpose of the PDI was to identify context-specific health, nutrition, and behavioral practices associated with successful recovery.

Data for the PDI were collected using a structured questionnaire comprising sections on socio-demographic characteristics, anthropometric measurements, dietary intake (7-day FFQ), clinical signs and symptoms, sputum conversion outcomes, and practices related to nutrition, treatment adherence, and prevention of comorbidities as shown in appendix 2. For the main study, a standardized questionnaire was administered to both intervention and control groups at baseline and during follow-up to assess key variables including socio-demographic characteristics, nutritional status, treatment adherence, health behaviors (alcohol and tobacco use), treatment support systems, and household

environmental factors such as ventilation. The questionnaire required approximately 30 minutes to administer. Additionally, dietary intake was assessed using a 7-day food frequency questionnaire. Follow-up data were collected monthly for six months post-intervention to monitor progress in both groups. Measures were taken to minimize recall and social desirability bias through the use of trained data collectors, standardized tools, and consistent interviewing procedures, although such biases could not be completely eliminated.

3.7 Pretest Study, Validity and Reliability

Prior to the commencement of data collection, the study tools; PDI questionnaire and the 7-day FFQ were pretested to assess their relevance and suitability within the study area. This was done among 20 participants (10% of the sample size) who met the inclusion criteria at Fort Tenan Health Centre and Londiani Sub-County Referral Hospital in Kipkelion Sub-County. These two health facilities had similar characteristics to the study sites (Kirui et al., 2018). These facilities were not included in the final study sample as they are in a different Sub County. The purpose of the pretesting was not only to familiarize the research team with the tools, but also to evaluate the clarity of questions, appropriateness of response options, flow of the questionnaire, and time required for administration. Feedback obtained from participants and research assistants during the pretesting phase led to several refinements which included rephrasing of ambiguous questions, adjustment of sequencing for better logical flow, and modification of selected items to improve cultural relevance and comprehension. Content validity of the PDI and FFQ questionnaires were ensured through expert review by a panel of five specialists in Public Health and Nutrition from the University of Kabianga. The experts evaluated these tools for relevance and clarity, and their recommendations were incorporated into the final versions of the questionnaires.

Reliability of the study instruments was assessed using Cronbach's alpha coefficient. The PDI questionnaire yielded a reliability coefficient of 0.89, while the overall tool, including the FFQ component, yielded a coefficient of 0.76, indicating acceptable internal

consistency (Fathima et al., 2024). The 7-day FFQ used in this study is a standardized dietary assessment tool that has been widely applied in diverse populations to assess habitual dietary intake. To enhance its contextual relevance, the FFQ was adapted to include locally available foods and common dietary practices (Kilburn et al., 2025). This adapted version was also pretested to assess its comprehensibility, acceptability, and consistency, and minor revisions were made accordingly. These steps ensured that the study tools were both valid and reliable for use within the local study context.

3.8 Data Analysis

Data were analyzed using IBM SPSS Statistics and R. Descriptive statistics, including means, standard deviations, frequencies, and percentages, were used to summarize socio-demographic characteristics and key study variables. Treatment outcomes and sputum conversion rates at critical time points (2nd, 5th, and 6th months) were expressed as proportions. The primary level of statistical significance was set at a two-sided p-value of < 0.05 . Where multiple comparisons were performed, results were interpreted cautiously with acknowledgment of the increased risk of Type I error.

To assess the effect of the intervention over time, a difference-in-differences (DID) analytical approach was employed to compare changes in outcomes between intervention and control groups at baseline and end-line. Associations between categorical variables were initially assessed using chi-square tests, while continuous variables were compared using independent t-tests. To examine predictors of treatment outcomes, multinomial and binary logistic regression models were fitted, adjusting for key baseline covariates including age, sex, baseline BMI, and socio-economic factors. Given the cluster-based study design, mixed-effects regression models with random effects at the cluster (health facility) level were used to account for intra-cluster correlation and improve estimation accuracy. Structural equation modeling (SEM) was further employed to explore complex relationships between nutritional intake, clinical outcomes, and sputum conversion across critical treatment time points. Adherence to RDI was operationalized by comparing individual daily nutrient intake estimates derived from the 7-day FFQ with age- and sex-

specific RDA as provided by the WHO and FAO reference tables (Appendix X). For each nutrient, intake was expressed as a percentage of the recommended value. Participants were classified as having adequate adherence if intake was $\geq 100\%$ of the recommended level and inadequate if $< 100\%$.

Missing data were assessed for pattern and extent prior to analysis. Where data were missing at random, multiple imputation techniques were applied to minimize bias. Sensitivity analyses using complete-case datasets were also conducted to assess the robustness of findings. Analyses were primarily conducted under an intention-to-treat (ITT) principle, whereby participants were analyzed in their originally assigned groups regardless of adherence to the intervention.

In addition to the general analytical procedures described, specific analytical approaches were applied based on the nature of the data collected for each study objective. For objective 1 (healthcare seeking practices and treatment outcomes), both independent and outcome variables were categorical in nature. These were summarized using frequencies and percentages, and associations were examined using chi-square tests. Logistic regression models were then applied to determine adjusted associations while controlling for potential confounders.

For objective 2 (nutritional intake), dietary data collected using the 7-day FFQ were processed by converting reported consumption frequencies into daily intake equivalents using standard portion sizes. Each food item was linked to established food composition tables to derive quantitative nutrient intakes, including energy, macronutrients, and micronutrients. Nutrient intake was analyzed as continuous variables and also standardized relative to RDA, as already described. The use of t-tests, chi-square tests, DID, and mixed-effects models was appropriate given the continuous and categorical nature of the variables and the longitudinal study design. In addition, SEM was applied under this objective to model nutritional intake as a latent construct derived from multiple observed nutrient variables, enabling simultaneous assessment of interrelationships

between nutrients and their overall effect on nutritional status across multiple time points. Where cells count were < 5 , Fisher exact test was used instead of chi-square.

For objective 3 (sputum conversion), the outcome variable was binary, and thus proportions, chi-square tests, and mixed-effects logistic regression models were appropriate. SEM was further applied to examine complex pathways linking nutrient intake and sputum conversion outcomes over time. This enabled simultaneous estimation of multiple predictors and time-dependent effects.

For objective 4 (clinical signs and anthropometric outcomes), anthropometric data including weight and height were used to compute BMI, which was analyzed both as a continuous variable and as categorical (underweight, normal, overweight, obese) based on WHO classification. Continuous anthropometric measures were summarized using means and standard deviations and analyzed using t-tests, while categorical classifications were analyzed using chi-square tests. Longitudinal changes were assessed using mixed-effects models and DID analysis. SEM was also applied under this objective to model clinical outcomes (including BMI and clinical signs) as latent variables. By doing this the investigator was able to assess the direct and indirect effects of nutritional intake on patient recovery across the 2nd, 5th, and 6th months. This approach was particularly appropriate given the multidimensional and interrelated nature of nutritional and clinical variables.

Multivariable analyses adjusted for potential confounders including socio-demographic characteristics (age, sex, education, marital status, occupation, and income), clinical factors (baseline BMI, nutritional status, comorbidities, and baseline clinical indicators), behavioral factors (alcohol use, tobacco use, and dietary practices), and health system factors (health-seeking behavior, treatment adherence, and access to care). Additionally, given the cluster-based design, intraclass correlation coefficients (ICCs) were estimated to assess the degree of clustering of outcomes within health facilities. Mixed-effects models with random intercepts for clusters were applied to account for within-cluster correlation

3.9 Ethical Consideration and Approval

The study approval was sought from the Ethics and Scientific Review Committee of University of Eastern Africa Baraton B0207122022 (Appendix 4) and Kericho County Referral Hospital P/23/23219 (Appendix 4). A research permit was obtained from National Commission of Science and Technology (NACOSTI) NACOSTI/P/23/23219 (Appendix 4). Additionally, permission was sought from Kericho County Commissioner and Education offices MISC.19 VOL.III/68 (Appendix 4) and KER/C/ED/GC/2/VOL.II 1/16 (Appendix 4) respectively (Appendix 4). The investigators enrolled participants who had consented both verbally and in writing (Appendix 5) to participate in the study. Additionally, the investigators assured the participants of their confidentiality and privacy. This was achieved by locking the signed in consent forms in a secure and lockable cabinet whose access was limited to the lead investigators. The identification of the patients was done through unique codes to mask their identity. The study was carried out in private rooms which ordinarily were used for patient counseling.

The purpose of this study was explained to the participants and thereafter obtains their informed verbal and written consent. There were no incentives in forms of gifts, refunds or any other offering since participation to this study was entirely voluntary. Declining to participate in the study did not hinder service delivery at the TB clinic by the service providers and advise was generally be given to all clinic attendees on the general risks and effects of treatment failure and MDR-TB. The study participants were assured of the confidentiality and this assurance was strictly adhered to. Since data collection explored in this study was through administration of questionnaires, anthropometry, sputum collection, nutrition education and a positive deviant meal, there were no known risks to participants. Additionally, participants who were interested in getting feedback on their progress during intervention were requested to provide their working mobile phone numbers.

CHAPTER FOUR

RESULTS

4.1 Response Rate

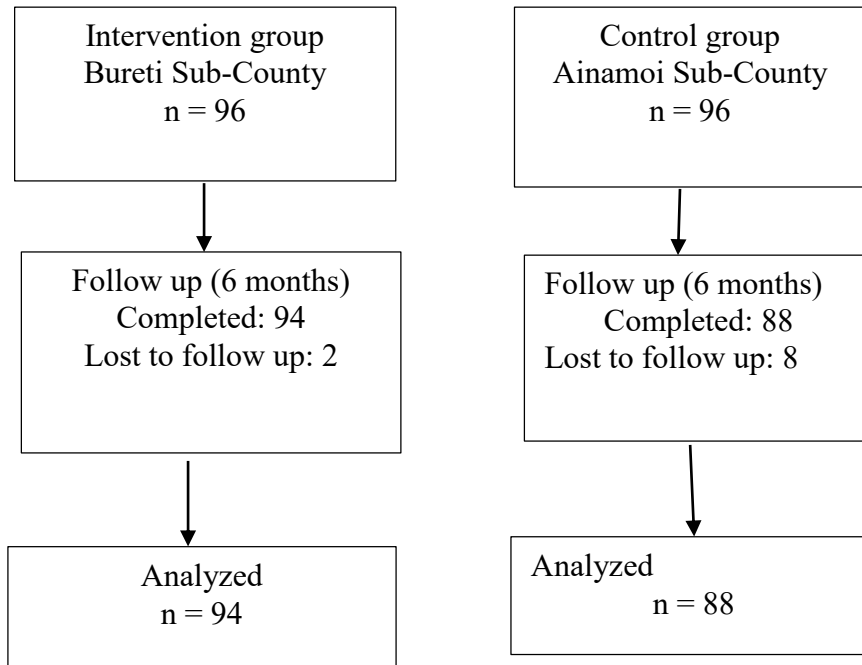


Figure 2.1: Enrollment, Recruitment and Loss to Follow Up of the Study Participants

The baseline response rate was 94% ($n = 192$) while endline response rate in the control arm was 91.7% ($n = 88$), and 97.9% ($n = 94$) for the intervention arm. The variation between baseline and endline data was as a result of the participants lost to follow up in the intervention but losses to follow up and attrition for the control group. All these losses were observed within the intensive phase of treatment.

4.2 Interclass Correlation Coefficient

Intraclass correlation coefficients (ICCs) were estimated to assess clustering at the health facility level. The ICC for BMI was approximately 0.10, while sputum conversion

demonstrated an ICC of approximately 0.08, indicating moderate within-cluster similarity. These findings justified the use of mixed-effects models to adjust for clustering in subsequent analyses.

4.3 Socio-Demographic Characteristics of the Participants during Positive Deviance Inquiry

The age distribution showed that the majority of participants (58.8%) were within 18-35 age range, followed by 34.3% in the 36-59 age group as shown in the Table 4.1. A significant majority of the participants were Christians (81.9%) compared to non-Christians (18.1%). In terms of gender, 67.6% of participants were male, while 32.4% were female. The married were 41.2%. Additionally, the participants who had primary level of education were 40.6% while 48.6% were engaged in self-employment.

Table 4.1: Demographic and Socio-Economic Characteristics of the Participants at Positive Deviance Inquiry

Variable	Frequency n = 216	Percent (%)
Age		
18-35	127	58.8
36-59	74	34.3
≥ 60	15	6.9
Religion		
Christian	177	81.9
Non-Christian	39	18.1
Gender		
Male	146	67.6
Female	70	32.4
Marital status		
Married	89	41.2
Single	93	43.1
Separated	14	6.5
Window/Widower	10	4.6
Divorced	10	4.6
Education		
Informal education	16	7.3
Primary	88	40.6
Secondary	83	38.5
Tertiary	29	13.6
Occupation		
Formal employment	19	8.8
Self-employment	105	48.6
Unemployed	92	42.6
Adequate ventilation		
Yes	189	87.5
No	27	12.5
Average monthly income		
<5000 Ksh.	159	74
5001-10000 Ksh.	34	15.6
10001-15000 Ksh.	13	5.8
>15001Ksh.	10	4.6

4.4 Characteristics of Participants in both the Intervention and Control Study Arms at Baseline and End-Line

A total of 192 participants were recruited into the study resulting in 96 participants being grouped to the control and intervention groups respectively as shown in Table 4.2. However, attrition occurred during the course of the study reducing the participants to 88 in the control group and 94 in the intervention group. There were no significant differences

observed for socio-demographic and economics characteristics of the participants between the intervention and control groups at baseline and endline.

Table 4.2: Demographics and Socio-Economic Characteristics of the Participants in both the Intervention and Control Arms at Baseline and Endline.

Variables	Baseline		χ^2	P value	Endline		χ^2	P value
	Control n (%)	Intervention n (%)			Control n (%)	Intervention n (%)		
Sex			0.000	1.0			1.869	0.172
Female	31 (32.3)	30 (31.3)			30 (34.1)	30 (31.9)		
Male	65 (67.7)	66 (68.7)			58 (65.9)	64 (68.1)		
Age			0.954	0.621			1.437	0.488
18-35	60 (62.5)	61 (63.5)			51 (58.0)	59 (62.8)		
36-59	29 (30.2)	28 (29.2)			28 (31.8)	27 (28.7)		
>60	7 (7.3)	7 (7.3)			9 (10.2)	8 (8.5)		
Marital status			5.631	0.228			2.756	0.43
Married	32 (33.3)	33 (34.4)			28 (31.8)	33 (35.1)		
Single	51 (53.1)	46 (47.9)			50 (56.8)	46 (48.9)		
Separated	5 (5.2)	7 (7.3)			5 (5.7)	6 (6.4)		
Widow/widower	6(6.3)	5(5.2)			4(4.6)	5(5.3)		
Divorced	2 (2.1)	5 (5.2)			1 (1.1)	4 (4.3)		
Education level			0.233	0.974			5.773	0.123
No education	6 (6.3)	7 (7.3)			5 (5.7)	6 (6.4)		
Primary	38 (39.6)	39 (40.6)			35 (39.8)	38 (40.4)		
Secondary	36 (37.5)	37 (38.5)			33 (37.5)	37 (39.4)		
Tertiary	16 (16.6)	13 (13.6)			15 (17.0)	13 (13.8)		
Employment status			3.652	0.302			3.875	0.144
Formal employment	16 (16.7)	15 (15.6)			15 (17.0)	15 (16.0)		
Self-employment	41 (42.7)	49 (51.1)			38 (43.2)	48 (51.1)		
Unemployed	39 (40.6)	32 (33.3)			35 (39.8)	31 (32.9)		
Average monthly income			4.140	0.247			3.247	0.355
0-5000 Ksh.	76 (79.1)	72 (75.0)			72 (81.8)	70 (74.5)		
5001-10000	7 (7.3)	14 (14.6)			6 (6.8)	14 (14.9)		
10001-15000	6 (6.3)	6 (6.3)			5 (5.7)	6 (6.3)		
>15001	7 (7.3)	4 (4.1)			5 (5.7)	4 (4.3)		
Employment status			3.652	0.302			3.875	0.144
Formal employment	16 (16.7)	15 (15.6)			15 (17.0)	15 (16.0)		
Self-employment	41 (42.7)	49 (51.1)			38 (43.2)	48 (51.1)		
Unemployed	39 (40.6)	32 (33.3)			35 (39.8)	31 (32.9)		

In this table, χ^2 refers to chi square, while p = p value.

4.5 Association between the Socio Demographic Factors and the TB Treatment Outcome

There were significant association between socio-demographic and economics characteristics with treatment outcome as shown in Table 4.3. Specifically, religion ($p < 0.001$), marital status ($p = 0.04$), education level ($p = 0.04$), house individual lived in ($p = 0.01$), and education level ($p < 0.001$) were the characteristics associated with the TB treatment outcome. However, age and occupation were not associated with treatment outcome among TB patients.

Table 4.3: Association between Socio-Demographic Characteristics and TB Treatment Outcome

Variables	N (%) 216 (100%)	Treatment outcome		p-value
		Negative 36 (16.7%)	Positive 180 (83.3%)	
Age				
18-35	130 (60.3%)	26 (77.2%)	104 (57.9%)	0.54
36-59	70 (32.4%)	8 (22.3%)	62 (34.4%)	
Above 60	16 (7.4%)	2 (5.6%)	14 (7.8%)	
Religion				
Christian	178 (82.4%)	18 (10.1%)	160 (89.9%)	0.00
Non-Christian	38 (17.6%)	18 (47.4%)	20 (52.6%)	
Gender				
Male	148 (68.5 %)	28 (77.8%)	120 (66.7%)	0.20
Female	68 (31.5%)	8 (22.2%)	60 (33.3 %)	
Marital status				
Single	114 (52.8%)	22 (61.1%)	92 (51.1%)	0.04
Married	88 (40.7%)	10 (27.8%)	78 (43.3%)	
Separated	8 (3.7%)	4 (11.1%)	4 (2.2%)	
Divorced	2 (0.9%)	0 (0.0%)	2 (1.1%)	
Widowed	4 (1.9%)	0 (0.0%)	4 (2.2%)	
Education level				
None	8 (3.7%)	2 (5.6%)	6 (3.3%)	0.04
Primary	78 (36.1%)	22 (61.1%)	56 (31.1%)	
Secondary	96 (44.4%)	8 (22.2%)	88 (48.9%)	
Tertiary	34 (15.7%)	4 (11.1%)	30 (16.7%)	
Occupation				
Government	4 (1.9%)	2 (5.6%)	2 (1.1%)	0.06
Private	14 (6.5%)	2 (5.6%)	12 (6.7%)	
Business	30 (13.9%)	6 (16.7%)	24 (13.3%)	
Bodaboda	22 (10.2 %)	6 (16.7%)	16 (8.9%)	
Farmer	50 (23.1%)	2 (5.6%)	48 (26.7%)	
Housewife	18 (3.3%)	2 (5.6%)	16 (8.9%)	
Unemployed	78 (36.1%)	16 (44.4%)	62 (34.4%)	
House family live on				
				0.01

Variables	N (%) 216 (100%)	Treatment outcome		p-value
		Negative 36 (16.7%)	Positive 180 (83.3%)	
Owned	196 (90.8%)	28 (14.3%)	168 (85.7%)	0.00
Rented	20 (9.3%)	8 (40 %)	12 (60%)	
Monthly Income				
Low	214 (99.1%)	34 (94.4%)	180 (100%)	
Medium	2 (0.9%)	2 (5.6%)	-	

4.6 Association between Nutritional Status, Dietary Practices and TB Treatment Outcome

Table 4.4 shows that there was significant association between the body mass index (BMI) and TB treatment outcome ($p=0.01$). It was observed that 27.3% of the participants with negative treatment outcome had low body mass index at the beginning of the treatment, 11.1% had normal BMI, while 33.3% were overweight. Additionally, there was a significant association between eating healthy diets and TB treatment outcome ($p=0.02$). The largest proportion of the patients who developed negative treatment outcome (31.2%) did not consume healthy diets compared to 14.1% of their counterparts. There was no association between the BMI at the end of the TB treatment and treatment outcome.

Table 4.4: Association between Nutritional Status and Dietary Practices and TB Treatment Outcome

Variables	N (%) 216 (100%)	Treatment outcome		p-value
		Yes 36 (16.7%)	No 180 (83.3%)	
BMI at the End of treatment				0.79
Underweight	114 (52.8%)	18 (50.0%)	96 (53.3%)	
Normal	102 (47.2%)	18 (50.0%)	84 (46.6%)	
Body mass index at the beginning				0.01
Underweight-	66 (30.6%)	18 (27.3%)	48 (72.3 %)	
Normal	144 (66.7%)	16 (11.1%)	128 (88.9%)	
Overweight	6 (2.8%)	2 (33.3%)	4 (66.7%)	
Ate healthy diets.				0.02
Yes	184 (85.2%)	26 (14.1%)	158 (85.9%)	
No	32 (14.8%)	10 (31.2%)	22 (68.8 %)	

4.7 Association between Health Seeking Practices and TB Treatment Outcome

A number of health seeking practices were associated with treatment outcome among patients on TB medication. They included distance to clinic to collect TB drugs and cost of travel to collect TB drugs ($p = 0.01$) as shown in Table 4.5. Attitude of staff in the TB clinic ($p = < 0.001$), the reminding factor to take medication ($p = 0.01$), cigarette smoking ($p = 0.01$), and alcohol intake ($p = < 0.001$) were also associated with treatment outcome. Additionally, completion of TB medication ($p = < 0.001$), informing relative on TB medication ($p = 0.01$), presence of comorbidities ($p = 0.02$), presence of clinical signs after treatment ($p = < 0.001$), and adherence to TB medication were associated with TB treatment outcome ($p = < 0.001$).

Table 4.5: Association between Healthcare Seeking Practices and TB Treatment Outcomes

Variables	N (%) 216 (100%)	Treatment outcome		p-value
		Negative 36 (16.7%)	Positive 180 (83.3%)	
Convenient time to collect TB medication				0.16
Morning	159 (73.6%)	31 (86.1%)	128 (71.1%)	
Mid-morning	39 (18.1%)	4 (11.1%)	35 (19.4%)	
Afternoon	18 (8.3%)	1 (2.8%)	17 (9.4%)	
Waiting time at the TB clinic				0.37
Short	21 (9.7%)	2 (5.6%)	19 (10.6%)	
Average	90 (88.0%)	34 (94.4%)	156 (86.7%)	
Long	5 (2.3%)	0 (0.0%)	5 (2.8%)	
Distance to clinic to collect TB drugs				0.01
Near < 2km	136 (63.0%)	16 (11.8.0%)	120 (88.2%)	
Far > 2km	80 (37.0%)	20 (25%)	60 (75%)	
Cost to travel to collect TB drugs				0.01
Affordable	62 (28.7%)	18 (29.0 %)	44 (71.0 %)	
Average	105 (48.6%)	10 (9.5%)	95 (90.5%)	
High	49 (22.7%)	8 (16.3%)	41 (83.7%)	
Attitude of staffs in the TB clinic				0.00
Good	200 (92.6%)	22 (11.0%)	178 (89.0%)	
Poor	16 (7.4%)	14 (87.5%)	2 (12.5%)	
Availability of TB medication				0.097
Available	186 (86.1%)	28 (15.1%)	158 (84.9%)	
Not available	30 (13.9%)	8 (26.7%)	22 (73.3%)	
What remind you to take your medication				0.01
Family member	114 (52.8%)	14 (38.9%)	100 (55.6%)	
Setting alarm	66 (30.6%)	14 (38.9%)	52 (28.9%)	
Lunch	2 (0.2%)	2 (5.6%)	0 (0%)	
Super	28 (13.0%)	4 (11.1%)	24 (13.3%)	
Other	6 (2.8%)	2 (5.6%)	4 (2.2%)	
Cigarette smoker				0.00

Variables	N (%) 216 (100%)	Treatment outcome		p-value
		Negative 36 (16.7%)	Positive 180 (83.3%)	
Yes	46 (21.3%)	16 (34.7%)	30 (65.3%)	0.43
No	170 (78.7%)	20 (11.8%)	150 (88.2%)	
Cigarette smoker				0.00
Heavy smoker	42 (91.3%)	14 (87.5%)	28 (93.3%)	
Light smoker	4 (8.7%)	2 (12.5%)	2 (6.7%)	
Alcohol intake				0.00
Yes	52 (24.1%)	22 (61.1%)	30 (16.7%)	
No	164 (76.0%)	14 (38.9%)	150 (83.3%)	
Alcohol intake				0.00
Heavy drinker	40 (80%)	22 (100%)	18 (64.3%)	
Ligh drinker	10 (20%)	0 (0%)	10 (35.7%)	
Whom do you live with				0.01
Family	178 (82.4%)	24 (13.5%)	154 (86.5%)	
Friend	12 (5.6%)	2 (16.7%)	10 (83.3%)	
Alone	26 (12%)	10 (38.5%)	16 (61.5%)	
Side effect when on TB medication				0.52
Yes	182 (84.3%)	30 (83.3%)	152 (84.4%)	
No	34 (15.7%)	6 (16.7%)	28 (15.6%)	
Completed TB medication				0.00
Yes	190 (88%)	18 (9.5%)	172 (90.5%)	
No	26 (12%)	18 (69.2%)	8 (30.8%)	
Time patients feel better after starting TB medication				0.38
Less than 2 months	186 (86.1%)	30 (83.3%)	156 (86.7%)	
More than 2 months.	30 (13.9%)	6 (16.7%)	24 (13.3%)	
Inform the relatives on TB medication				0.01
Yes	180 (83.3%)	24 (13.3%)	156 (86.7%)	
No	36 (16.7%)	12 (33.3%)	24 (13.3%)	
Where do you collect your medicine				0.11
Dispensary	20 (9.3%)	4 (11.1%)	16 (8.9%)	
Health center	94 (43.5%)	10 (27.8%)	84 (46.7%)	
Main hospital	102 (47.2%)	22 (61.1%)	80 (44.4%)	
Co-morbidities				0.02
Yes	106 (49.1%)	10 (27.8%)	96 (53.4%)	
No	110 (50.9%)	26 (72.2%)	84 (46.7%)	
Receiving treatment for comorbidities				0.03
Yes	104 (48.1%)	10 (27.8%)	94 (52.2%)	
No	112 (51.9%)	26 (72.2%)	86 (47.8%)	
Believe comorbidities affect TB drugs adherence				0.07
Yes	16 (7.4%)	4 (11.1%)	12 (6.7%)	
No	200 (92.6%)	32 (88.9%)	168 (93.3%)	
Clinical signs after treatment				0.00
Yes	52 (24.1)	24 (66.7%)	28 (15.6%)	
No	164 (75.9)	12 (33.4%)	152 (84.5%)	
Adherence to TB medication				0.00
Adhered	146 (67.6%)	8 (22.3%)	138 (76.6%)	
Did not adhere	70 (32.4%)	28 (77.8%)	42 (23.3%)	

4.8 Predictors of Treatment Outcome among Patients on TB Medication

While adjusting for age and sex the study observed significant association between treatment outcome and some predictor variables such as: religion, body mass index (BMI),

TB medication experience, financial treatment support, treatment adherence supporter, and presence of comorbidities as shown in table 4.6. The findings revealed the participants who were non-Christians had significantly lower odds to experience negative treatment outcome compared to Christians (AOR = 0.118, 95% CI: 0.0345 - 0.404, $p = < 0.001$). Similarly, those who were overweight at end line were three times more likely to develop negative treatment outcome compared to their underweight counterparts (AOR = 3.515, 95% CI: 1.139 - 10.844, $p = 0.029$). Patients with negative TB medication experience had higher chance of negative treatment outcome compared to those with positive TB medication experience (AOR=3.080, 95% CI: 1.139-10.844, $p = < 0.001$). Additionally, individuals without treatment adherence supporter and who failed to adhere to medication had significantly higher odds of developing negative treatment outcome compared to their counterparts with AOR=1.396, 95% CI: 1.053-1.825, $p = 0.033$; and AOR = 2.034, 95% CI: 1.002 - 7.488, $p = 0.013$ respectively. On the other hand, participants without comorbidities were less likely to experience negative treatment outcome (AOR = 0.07, 95% CI: 0.010 - 0.495, $p = 0.008$). Healthcare-related factors comprising of poor staff attitude and delayed opening of the TB clinic significantly increased the chances of developing negative treatment outcome (AOR = 0.059, 95% CI: 0.006 - 0.599, $p = 0.017$).

Table 4.6: Multivariate Analysis of Predictors of Treatment Outcome among Participants.

Variable	AoR	95% CI	P-value
Religion			
Christian	Ref		
Non-Christian	0.118	0.034-0.404	< 0.001
Adequate ventilation			
Yes	Ref		
No	0.312	0.090-1.080	0.066
BMI at the end			
Underweight			Ref
Normal	0.372	0.020-6.832	0.506
Overweight	3.515	1.139-10.844	0.029
TB medication experience			
Positive	Ref		
Negative	3.080	1.609-5.895	< 0.001
Treatment adherence supporter			
Household member			Ref
Non household member	1.204	0.740-1.646	0.631
No supporter	1.396	1.053-1.825	0.033
Tobacco and alcohol use			
Yes			Ref
No	2.883	0.295-28.170	0.363
Presence of Comorbidities			
Yes			Ref
No	0.070	0.010-0.495	0.008
Adherence to medication			
Yes			Ref
No	2.034	1.002-7.488	0.013
Healthcare related factors			
Yes	Ref		
No	0.059	0.006-0.599	0.017

AoR refers to adjusted odds ratio, and CI refers to confidence interval, while ref refers to the reference category

4.9 Nutritional Status

The time-series analysis of BMI category scores presented in figure 4.3 showed a progressive improvement in nutritional status in both groups over time. However, the

intervention group demonstrated a more pronounced increase compared to the control group.

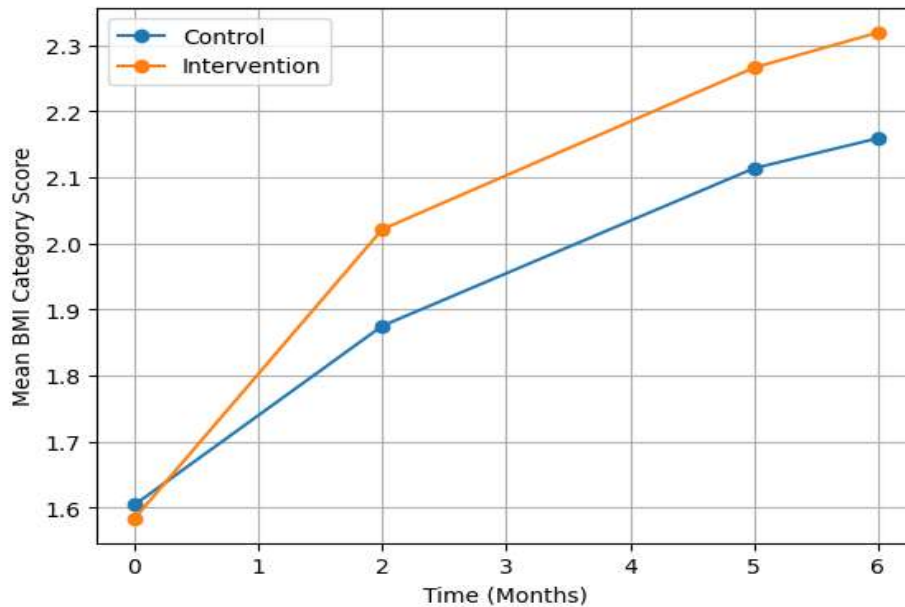


Figure 4.2: BMI time Series Plot Over Critical Treatment Point

Additionally, Table 4.7 showed the nutritional status of the participants at critical points of study that is baseline, 2nd, 5th and 6th months of study. Statistical difference was observed among the participants in control and intervention arms at 2nd month ($p = 0.01$), 4th month ($p = 0.01$), and sixth months of study ($p = 0.001$). However, no statistical difference was observed at baseline

Table 4.7: BMI of the Participants at Baseline, 2nd Month, 5th Month and 6th Month of Study

BMI Cat.	Baseline			2 nd month			5 th month			6 th month		
	Control N (%)	Intervention N (%)	<i>P</i>	Control N (%)	Intervention N (%)	<i>P</i>	Control N (%)	Intervention N (%)	<i>P</i>	Control N (%)	Intervention N (%)	<i>P</i>
			0.98			0.01			0.01			0.001
1	61 (63.5)	62 (64.6)		37 (42.0)	26 (27.7)		17 (19.3)	9 (9.6)		13 (14.8)	4 (4.3)	
2	18 (18.8)	17 (17.7)		32 (36.4)	47 (50.0)		52 (59.1)	60 (63.8)		56 (63.6)	65 (69.1)	
3	11 (11.5)	12 (12.5)		12 (13.6)	14 (14.9)		11 (12.5)	16 (17.0)		11 (12.5)	16 (17.0)	
4	6 (6.3)	5 (5.2)		7 (8.0)	7 (7.4)		8 (9.1)	9 (9.6)		8 (9.1)	9 (9.6)	

The BMI categories are denoted by 1, 2, 3, and 4 representing underweight, normal weight, overweight and obese weight in that order. Cat and *p* refer to category measured with values 1 = underweight, 2 = normal, 3 = overweight, 4 = obese, and *p* value.

Nutrient intake of participants assessed at baseline and endline as shown in Table 4.8. At baseline, energy, protein, and fat intake were comparable between the control and intervention groups. After the intervention, the group that received nutrition education and consumed nutrient dense meal displayed significantly higher energy intake ($p = 0.001$), protein intake ($p < 0.001$), and fat intake ($p < 0.0001$) relative to the control group. Although carbon and fibre consumption did not differ significantly at baseline, the intervention group consumed notably more of both at the endline assessment ($p < 0.001$). Baseline vitamin A-RAE and vitamin C intake were comparable between the control and intervention groups. A marked improvement in the consumption of both vitamins was evident in the intervention group post-intervention, while the control group showed no such change ($p < 0.001$). A similar trend was observed with regards to the intake of minerals such as zinc ($p < 0.001$) and selenium ($p < 0.001$).

Table 4.8: Nutrient Intake of Participants at Baseline and End-Line for both Intervention and Control Groups.

Nutrient	Baseline		p- value	Endline		P-value
	Control	Intervention		Control	Intervention	
Energy (kcal)	1476.57±745.14	1410.82±656.77	0.510	1347.06±477.80	2072.62±680.59	<0.001
Protein (g)	96.42 ± 67.10	81.79 ± 47.76	0.074	87.52±24.36	97.60 ± 52.70	<0.001
Fat (g)	45.99 ± 34.17	45.88 ± 21.86	0.078	43.61 ± 13.32	82.89 ± 23.37	<0.001
Carbo (g)	149.37 ± 86.53	156.63 ± 50.57	0.101	146.23 ± 40.25	221.05 ± 56.86	<0.001
Fibre (g)	39.03 ± 21.80	22.11 ± 10.29	0.098	9.92 ± 8.13	26.12 ± 12.43	<0.001
Vit A-RAE (mcg)	1049.49±690.81	674.11 ± 402.19	0.074	592.97 ± 209.44	809.09 ± 397.78	<0.001
Vitamin C (mg)	171.33 ± 117.99	98.97 ± 62.64	0.231	32.55 ± 35.29	115.61 ± 63.72	<0.001
Zinc (mg)	11.72 ± 10.72	8.08 ± 5.52	0.129	4.00 ± 4.19	9.32 ± 5.26	<0.001
Selenium (mcg)	58.05 ± 54.30	48.82 ± 32.31	0.142	19.31 ± 20.99	31.15 ± 3.11	<0.001

Kcal refers to kilo calories, g refers to grams, mcg refers to micro grams, vit refers to vitamin, RAE refers to retinol equivalent, mg refers to milligram. Carbo represented carbohydrates.

4.10 Difference in Difference (DID) in Nutrient Intake between Intervention and Control Groups at Pre and Post Intervention

The Difference-in-Differences (DID) analysis on the nutrient intake among intervention and control participants revealed significant positive effects for a number of nutrients as shown in Table 4.9. Intervention group was associated with increased intake of energy, protein, carbohydrates, vitamins A, vitamin C, zinc, and selenium, with adjusted odds ratios ranging from 1.49 to 2.14 (p-values < 0.007). These results showed that participants who received the intervention had approximately 1.5 to 2.1 times higher odds of attaining the RDI for the stated nutrients compared to controls. In contrast, fat and fibre intake showed no significant DID between control and intervention groups at both baseline and endline.

Table 4.9: Changes in Outcome Attributable to Intervention between the Control and the Intervention Study Groups at Pre and Post Intervention

Nutritional Indicator	DID Value ($\hat{\beta}$, 95% CI)	OR (95% CI)	p-value
Energy (kcal)	0.67 (0.20, 1.14)	1.95 (1.22, 3.13)	0.003
Protein (g)	0.61 (0.15, 1.07)	1.84 (1.16, 2.91)	0.004
Carbohydrate (g)	0.40 (0.10, 0.70)	1.49 (1.11, 2.01)	0.002
Fat (g)	0.39 (-0.10, 0.88)	1.48 (0.90, 2.41)	0.697
Fibre (g)	0.01 (-0.20, 0.22)	1.01 (0.82, 1.25)	0.443
Vitamin A (mcg)	0.67 (0.20, 1.14)	1.95 (1.22, 3.13)	0.003
Vitamin C (mg)	0.76 (0.30, 1.22)	2.14 (1.35, 3.39)	0.001
Zinc (mg)	0.62 (0.18, 1.06)	1.86 (1.20, 2.89)	0.005
Selenium (mcg)	0.48 (0.12, 0.84)	1.62 (1.13, 2.32)	0.007

DID refers to difference in difference; I^2 refers to I squared statistic; OR refers to odds ratio; CI refers to confidence interval; kcal refers to kilo calories; g refers to grams; mcg refers to micrograms; mg refers to milligram.

4.11 Effect of Nutrient Intake on BMI

Table 4.10 on multi group analysis carried out using structural equation modelling shows the effect of nutrient intake on nutritional status of the participants at different critical

treatment points. The results of the multi group analysis revealed that overall nutrition intake, as represented by the latent variable, significantly and increasingly influenced BMI from the 2nd to the 6th month of TB treatment in both groups. Specifically, in the intervention group, recommended dietary allowances for energy and intakes of protein, carbohydrates, Vitamin A, Vitamin C, Zinc, and Selenium consistently and significantly contributed to an increase in BMI throughout the treatment period. In contrast, for the control group, the protein intake which had a consistent parameter score of -0.54 ($p = 0.005$) at 2nd month, -0.75 ($p = 0.004$) at 5th month, and -0.81 ($p = 0.003$) at 6th month had a negative influence on BMI, while Vitamin C recommended dietary intakes had a consistent significant positive influence on BMI for the same study arm with log odds of 0.52 ($p = 0.03$), 0.67 ($p = 0.031$), and 0.72 ($p = 0.002$) at 2nd, 5th and 6th month of the study. However, fat and fiber intake showed no significant impact on BMI in either group.

Table 4.10: Multi-Group Analysis of the Influence of Nutrition Intake on Body Mass Index at Critical Points of TB Treatment.

Parameter	BMI					
	2 nd month		5 th month		6 th month	
	Estimate	P - value	Estimate	P - value	Estimate	P - value
Latent variable	0.723	< 0.003	0.747	< 0.002	0.912	< 0.001
Structural model						
BMI ~ energy RDA						
Control	0.07	0.327	0.08	0.489	0.10	0.625
Intervention	0.79	0.005*	0.91	0.004*	0.97	0.002*
BMI ~ protein RDI						
Control	- 0.54	0.005*	- 0.75	0.004*	- 0.81	0.003*
Intervention	0.77	0.004*	0.82	0.003*	0.98	0.001*
BMI ~ CHO RDI						
Control	0.06	0.546	0.07	0.578	0.08	0.073
Intervention	0.45	0.005*	0.59	0.032*	0.72	0.002*
BMI ~ Fat RDI						
Control	0.78	0.089	0.81	0.091	0.87	0.093
Intervention	0.55	0.712	0.61	0.933	0.75	0.943
BMI ~ Fibre RDI						
Control	0.10	0.134	0.01	0.879	0.02	0.614
Intervention	0.09	0.175	0.04	0.408	0.03	0.443
BMI ~ VIT A RDI						
Control	0.07	0.210	0.08	0.452	0.09	0.651
Intervention	0.85	0.003*	0.89	0.001*	0.94	0.001*
BMI ~ VIT C RDI						
Control	0.52	0.03*	0.67	0.031*	0.72	0.002*
Intervention	0.85	0.004*	0.91	0.001*	0.98	0.001*
BMI ~ Zinc RDI						
Control	0.053	0.451	0.064	0.723	0.08	0.089
Intervention	0.72	0.004*	0.82	0.003*	0.93	0.001*
BMI ~ Selenium RDI						
Control	0.06	0.430	0.07	0.521	0.079	0.651
Intervention	0.71	0.005*	0.89	0.034*	0.96	0.002*

In this table BMI denotes body mass index, SC denotes sputum conversion, RDI denotes recommended dietary intake, RDA denotes recommended dietary allowance. Time was measured using 2nd, 5th and 6th months. CHO refers to carbohydrates, VIT is vitamin.

4.12 Overall Effect Change on BMI Attributable to Intervention

As shown in Table 4.11 on the DID estimates, the intervention had a significant positive effect on BMI over time. At Month 2, the intervention group showed a 0.72 increase in log odds of BMI improvement (95% CI: 0.15–1.29), corresponding to an adjusted odds ratio (AOR) of 2.06 (95% CI: 1.16–3.64; p = 0.005). This effect strengthened at Month 5,

with a DID estimate of 0.83 (95% CI: 0.17–1.49; AOR: 2.29, 95% CI: 1.19–4.44; p = 0.004), and further at Month 6, reaching 0.87 (95% CI: 0.14–1.60; AOR: 2.39, 95% CI: 1.15–4.95; p = 0.002).

Table 4.11: Effect Changes on BMI Attributable to Intervention. TB Treatment.

Time Point	DID Estimate (β, 95% CI)	AOR (95% CI)	p-value
Month 2	0.72 (0.15, 1.29)	2.06 (1.16, 3.64)	0.005
Month 5	0.83 (0.17, 1.49)	2.29 (1.19, 4.44)	0.004
Month 6	0.87 (0.14, 1.60)	2.39 (1.15, 4.95)	0.002

In this table BMI denotes body mass index, DID denotes difference in difference, AOR refers to adjusted odds ratio, CI refers to confidence interval, and β refers to beta.

4.13 Negative Sputum Conversion at Different Critical Treatment Point

The absolute risks for sputum smear conversion rate for the intervention group were over 90% at the 2nd, 5th and 6th months of follow-up for the intervention arm. While for the control group, the absolute risks for conversion rate were relatively low at all follow-up critical points with a cumulative smear conversion for the study duration settling at 85.2% as shown in figure 4.2.

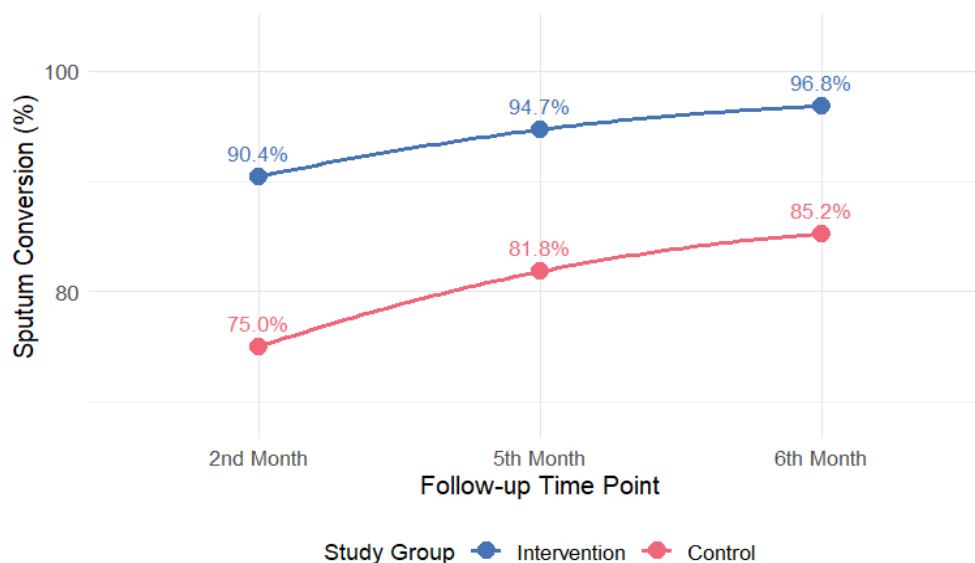


Figure 4.3: Negative Sputum Conversion at Different Critical Treatment Point

4.14 Relationship between Nutritional Status and Sputum Conversion

The results showed that the intervention arm had significant association between body mass index and sputum conversion at all the three time points as shown in Table 4.12. A BMI of 29.51 ($p < 0.000$) was observed at 2nd month; 30.85 ($p < 0.001$) at 5th month and 35.19 ($p < 0.001$) at 6th month. On the contrary, the control arm displayed significant associations only at the 5th and 6th months of study with BMI of 18.10 ($p = 0.005$) and 18.70 ($p = 0.006$).

Table 4.12: Association between Nutritional Status and Sputum Conversion on TB Medication between the Control and Intervention Group

Variable	Intervention		Control	
	χ^2	P value	χ^2	P value
BMI ~ SC2	29.51	0.000	12.28	0.060
BMI ~ SC5	30.85	0.000	18.10	0.005
BMI ~ SC6	35.19	0.000	18.70	0.006

SC2, SC5, and SC6 refers to sputum conversion at second month, fifth month and sixth month of study, χ^2 refers to chi square.

4.15 Association between Nutritional Intake and Sputum Conversion

The results on the association between nutritional intake and sputum conversion at the second month of treatment are presented in Table 4.13. The results showed that all the nutrients studied were significantly associated with nutrient intake among the participants in the intervention group with the exception of fats and fibre with $p > 0.05$. In contrast, the control group showed non-significant associations with only intake of Vitamin A ($p = 0.036$) showing significant association with sputum conversion.

Table 4.13: Association between Nutrient Intake and Sputum Conversion at Second Month of TB Medication.

Variable	Intervention		Control	
	χ^2	P value	χ^2	P value
SC~ energy	11.68	0.002	1.83	0.176
SC~ protein	9.59	0.002	0.38	0.537
SC~ fat	3.99	0.056	1.22	2.680
SC~ fibre	4.23	0.071	0.24	0.621
SC~ carbohydrates	5.11	0.024	0.13	0.712
SC~ vitamin A	9.63	0.002	4.39	0.036
SC~ vitamin C	10.27	0.001	0.24	0.622
SC~ zinc	7.14	0.005	2.57	0.109
SC~ selenium	4.35	0.037	0.97	0.325

SC refers to sputum conversion and χ^2 refers to chi square.

4.16 Association between Nutrient Intake and Sputum Conversion at Fifth Month of TB Medication

The results demonstrated significant associations between sputum conversion and nutrient intakes of energy ($p = 0.012$), protein ($p = 0.002$), carbohydrates ($p = 0.009$), vitamins A ($p = 0.001$) and C ($p = 0.002$), zinc ($p = 0.004$), and selenium ($p = 0.012$) for the intervention group as shown in Table 4.14. In contrast, there was no significant associations between nutrient intake and sputum conversion in the control arm.

Table 4.14: Association between Nutrient Intake and Sputum Conversion at fifth Month of TB Medication.

Variable	Intervention		Control	
	χ^2	P value	χ^2	P value
SC~ energy	10.26	0.012	2.23	0.957
SC~ protein	11.83	0.002	3.03	0.857
SC~ fat	3.11	0.059	1.27	0.869
SC~ fibre	3.94	0.081	0.06	1.544
SC~ carbohydrates	6.91	0.009	0.62	0.430
SC~ vitamin A	11.63	0.001	2.05	0.152
SC~ vitamin C	9.69	0.002	1.79	0.181
SC~ zinc	8.48	0.004	3.70	0.054
SC~ selenium	6.26	0.012	1.22	0.648

SC refer to sputum conversion while χ^2 refers to chi square.

4.17 Association between Nutrient Intake and Sputum Conversion at Sixth Month of TB Medication

The Table 4.15 presents the results of a Chi-square analysis showing the relationship between nutrient intake and sputum conversion in the two groups. The results showed that in the intervention arm there was significant associations between sputum conversion and nutrient intakes of energy ($p = <0.001$), protein ($p = 0.001$), carbohydrates ($p = 0.003$), vitamins A ($p = 0.001$) and C ($p = 0.003$), zinc ($p = 0.002$), and selenium ($p = 0.004$).

However, in the control arm, there was no significant associations between sputum conversion and nutrient intake.

Table 4.15: Association between Nutrient Intake and Sputum Conversion at Sixth Month of TB Medication

Variable	Intervention		Control	
	χ^2	P value	χ^2	P value
SC~ energy	15.51	0.000	3.24	0.62
SC~ protein	12.12	0.001	4.01	0.94
SC~ fat	5.16	0.051	0.05	0.829
SC~ fibre	4.23	0.073	0.06	0.813
SC~ carbohydrates	8.16	0.003	2.47	0.116
SC~ vitamin A	12.26	0.001	0.05	0.829
SC~ vitamin C	10.16	0.003	2.91	0.930
SC~ zinc	9.45	0.002	2.97	0.16
SC~ selenium	8.12	0.004	1.82	0.919

SC refer to sputum conversion while χ^2 refers to chi square.

4.18 Multi-Group Analysis Showing the Effects of Various Nutrient Intakes on Sputum Conversion at Critical TB Treatment Time Points

The results of structural equation model analysis on the relationship between dietary intake and sputum conversion rates for both intervention and control study arms are presented in Table 4.16. In this model the lantern variables were sputum conversion at 2nd month, 5th month and 6th month. Other than higher fat intake which was significantly associated with beneficial effects on sputum conversion with parameter estimate of 0.15 ($p = 0.026$) at second month among the participants in the control group, there was no any other nutrient which showed such association at any of the critical treatment time points. However, this was not the case for intervention study arm which showed that energy, protein, carbohydrates, Vitamin A, Vitamin C, zinc and selenium were significantly associated with sputum conversion at least at one critical TB treatment time point. Higher energy intake was associated with significant positive estimates for sputum conversion at all-time points, that is 2nd month: 0.76 ($p = 0.007$), 5th month: 0.86 ($p = 0.006$), and 6th

month: 0.91 ($p = 0.003$). Beneficial effect of protein intake on sputum conversion was observed with strong positive estimates of 0.67 ($p = 0.004$), 0.76 ($p = 0.004$), and 0.95 ($p = 0.001$) at 2nd month, 5th month and 6th month respectively. Higher intake of carbohydrate was associated with significant estimates at 5th and 6th month of treatment. Specifically, the estimate scores were 0.17 ($p = 0.004$) at 5th month and 0.47 ($p = 0.002$) at 6th month of treatment. Beneficial effect of Vitamin A was observed across the three treatment points with significant positive estimates of 0.75 ($p = 0.003$), 0.81 ($p = 0.002$), and 0.88 ($p = 0.001$) observed at 2nd month, 5th month and 6th month of treatment in that order. Additionally, a positive significant effect was observed for Vitamin C with positive estimates values of 0.80 ($p = 0.001$) at 2nd month, 0.89 ($p = 0.001$) at 5th month and 0.01 ($p = 0.001$) at 6th month of treatment. Beneficial effects were also recorded for both zinc and selenium at all the three treatment points, that is, 0.67 ($p = 0.005$), 0.78 ($p = 0.004$) and 0.82 ($p = 0.002$) for zinc, and 0.53 ($p = 0.007$), 0.75 ($p = 0.004$) and 0.79 ($p = 0.005$) for selenium respectively. Fiber and fat estimates were not significant.

Table 4.16: Multi-Group Analysis of the Effects of Nutritional Status and Nutrient Intake on Sputum Conversion at Critical Points of TB Treatment

Parameter	Sputum conversion					
	2 nd month		5 th month		6 th month	
	Estimate	P – value	Estimate	P - value	Estimate	P – value
Latent variable	0.827	< 0.001	0.798	< 0.001	0.821	< 0.001
Structural model						
SC ~ energy RDA						
Control	0.06	0.276	0.08	0.433	0.09	0.528
Intervention	0.76	0.007*	0.86	0.006*	0.91	0.003*
SC ~ protein RDI						
Control	0.06	0.593	0.09	0.714	0.12	0.881
Intervention	0.67	0.004*	0.76	0.004*	0.95	0.001*
SC ~ CHO RDI						
Control	0.04	0.479	0.05	0.064	0.07	0.069
Intervention	0.07	0.139	0.17	0.004	0.47	0.002*
SC ~ Fat RDI						
Control	0.06	0.026	0.081	0.876	0.083	0.894
Intervention	0.45	0.697	0.57	0.928	0.058	0.928
SC ~ Fibre RDI						
Control	0.10	0.134	0.01	0.879	0.02	0.614
Intervention	0.09	0.175	0.04	0.408	0.03	0.443
SC ~ VIT A RDI						
Control	0.08	0.191	0.09	0.603	0.98	0.764
Intervention	0.75	0.003*	0.81	0.002*	0.88	0.001*
SC ~ VIT C RDI						
Control	0.04	0.576	0.06	0.094	0.07	0.099
Intervention	0.80	0.001*	0.89	0.001*	0.096	0.000*
SC ~ Zinc RDI						
Control	0.048	0.447	0.057	0.693	0.07	0.081
Intervention	0.67	0.005*	0.78	0.004*	0.87	0.002*
SC ~ Selenium RDI						
Control	0.05	0.270	0.08	0.292	0.089	0.295
Intervention	0.53	0.007*	0.75	0.004*	0.79	0.005*

SC refer to sputum conversion, RDI: recommended dietary intake, RDA: recommended dietary allowance, VIT: vitamin, CHO: carbohydrates, * refers to significantly different value at $p < 0.05$.

4.19 Effect changes between Control and Intervention on Sputum Conversion at Critical Time Points of TB Treatment

The DID analysis presented in Table 4.17 revealed that the intervention had a positive effect on the SC among participants at months 2, 5, and 6 compared to controls. The net

effect changes attributable to the intervention ranged from 1.95 at month 2, 2.05 at month 5, and 2.20 at month 6, indicating nearly twofold increased odds of improved nutrient status attributable to the intervention.

Table 4.17: Changes in SC Outcome Attributable to Intervention between the Control and the Intervention Study Groups at Pre and Post Intervention

Time Point	Group	DID Estimate (β, 95% CI)	AOR (95% CI)	p-value
Month 2	Intervention	0.67 (0.20, 1.14)	1.95 (1.22, 3.13)	0.003
Month 5	Intervention	0.72 (0.25, 1.19)	2.05 (1.28, 3.29)	0.002
Month 6	Intervention	0.79 (0.31, 1.27)	2.20 (1.36, 3.56)	0.001

DID refers to difference in difference; CI refers to confidence interval; AOR refers to adjusted odds ratio while β refers to beta.

4.20 Association between Nutritional Intake and Clinical Sign Score

Table 4.18 presents the association between clinical sign scores and nutritional intake at the second month of TB medication. The intervention group reported significant associations, as reflected in energy ($p = 0.032$), protein ($p = 0.042$), fat ($p = 0.045$), carbohydrates ($p = 0.002$), vitamin A ($p = 0.002$), vitamin C ($p = 0.042$), zinc ($p = 0.027$), and selenium ($p = 0.002$). However, the control group indicated an association only with vitamin A intake ($p = 0.032$).

Table 4.18: Association between Nutrient Intake and Clinical Sign Score at Second Month of TB Medication

Variable	Intervention		Control	
	χ^2	P value	χ^2	P value
CSS~ energy	7.28	0.032	3.45	0.050
CSS ~ protein	6.99	0.041	1.26	0.531
CSS ~ fat	4.06	0.045	3.76	0.152
CSS ~ fibre	1.73	0.420	0.16	0.924
CSS ~carbohydrates	10.34	0.002	2.05	0.359
CSS ~ vitamin A	8.36	0.002	4.53	0.045
CSS ~ vitamin C	5.44	0.042	4.35	0.114
CSS ~ zinc	6.48	0.027	3.35	0.187
CSS ~ selenium	8.61	0.002	0.89	0.641

CSS refers to clinical signs score while χ^2 refers to chi square.

4.20 Association between Nutrient Intake and Clinical Sign Score at Fifth Month of TB Medication

At the fifth month of TB medication, a significant association between clinical sign scores and nutrient intake was evident in the intervention group, with energy ($p = 0.002$), protein ($p = 0.002$), fat ($p = 0.002$), carbohydrates ($p = 0.002$), vitamin A ($p = 0.002$), vitamin C ($p = 0.002$), zinc ($p = 0.002$), and selenium ($p = 0.002$) as shown in Table 4.19. The control group showed a significant association between clinical sign scores and energy intake ($p = 0.040$), carbohydrates intake ($p = 0.045$), and vitamin C intake ($p = 0.042$).

Table 4.19: Association between Nutrient Intake and Clinical Sign Score at Fifth Month of TB Medication

Variable	Intervention		Control	
	χ^2	P value	χ^2	P value
CSS ~ energy	9.68	0.002	4.48	0.040
CSS ~ protein	7.85	0.031	3.07	0.215
CSS ~ fat	5.36	0.035	2.14	0.151
CSS ~ fibre	2.98	0.312	1.12	0.572
CSS ~ carbohydrates	12.56	0.001	6.18	0.045

CSS ~ vitamin A	11.36	0.001	1.59	0.450
CSS ~ vitamin C	8.24	0.024	5.05	0.042
CSS~ zinc	8.98	0.025	4.216	0.127
CSS ~ selenium	9.73	0.002	1.518	0.372

CSS refers to clinical signs score while χ^2 refers to chi square.

4.21 Association between Nutrient Intake and Clinical Sign Score at Sixth Month of TB Medication

At the sixth month of TB medication, a significant association was observed in the intervention group between clinical sign scores and nutrient intake, particularly with energy ($p = 0.002$), protein ($p = 0.025$), fat ($p = 0.030$), carbohydrates ($p = 0.001$), vitamin A ($p = 0.001$), vitamin C ($p = 0.020$), zinc ($p = 0.017$), and selenium ($p = 0.014$). Similarly, in the control group, a significant association was noted between clinical sign scores and energy intake ($p = 0.033$) as well as carbohydrates intake ($p = 0.032$), as shown in Table 4.20.

Table 4.20: Association between Nutrient Intake and Clinical Sign Score at Sixth Month of TB Medication

Variable	Intervention		Control	
	χ^2	P value	χ^2	P value
CSS~ energy	9.98	0.002	6.13	0.033
CSS ~ protein	9.73	0.025	3.73	0.193
CSS ~ fat	5.49	0.030	3.90	0.092
CSS ~ fibre	3.73	0.238	2.51	0.321
CSS ~ carbohydrates	13.49	0.001	7.06	0.032
CSS ~ vitamin A	12.34	0.001	5.37	0.068
CSS ~ vitamin C	9.34	0.020	5.37	0.068
CSS ~ zinc	9.76	0.017	6.10	0.081
CSS ~ selenium	10.90	0.014	2.193	0.908

CSS refers to clinical signs score while χ^2 refers to chi square.

4.22 Multi-Group Analysis Showing the Effects of Various Nutrient Intakes on Clinical Sign Score at Critical TB Treatment Time Points

The association between nutrient intake and BMI was significant at the 2nd, 5th, and 6th months of assessment in both the intervention and control groups as shown in Table 4.21. However, a significant association was observed only in the intervention group for energy RDA, protein RDI, carbohydrate RDI, vitamin C, vitamin A, zinc, and selenium. The results of the structural equation model analysis on the relationship between dietary intake and clinical sign scores in the intervention and control study arms. In this analysis, the latent variables were the clinical sign scores at the 2nd, 5th, and 6th months.

Table 4.21: Multi-Group Analysis of the Effects of Nutritional Status and Nutrient Intake on Clinical Sign Scores at Critical Points of TB Treatment

Parameter	Clinical sign scores					
	2 nd month		5 th month		6 th month	
	Estimate	P - value	Estimate	P - value	Estimate	P - value
Latent variable	0.827	< 0.001	0.798	< 0.001	0.821	< 0.001
Structural model						
CSS ~ energy RDA						
Control	0.01	0.933	0.15	0.142	-0.070	0.559
Intervention	0.69	0.041*	0.73	0.039*	0.83	0.034*
CSS ~ protein RDI						
Control	0.28	0.095	0.043	0.735	0.07	0.0635
Intervention	0.56	0.03*	0.61	0.029*	0.88	0.002*
CSS ~ CHO RDI						
Control	0.19	0.15	0.05	0.53	0.19	0.166
Intervention	0.47	0.003*	0.69	0.003*	0.81	0.002*
CSS ~ Fat RDI						
Control	0.148	0.402	0.134	0.242	0.028	0.817
Intervention	0.24	0.070	0.28	0.066	0.32	0.081
CSS ~ Fibre RDI						
Control	0.15	0.438	0.054	0.028	0.055	0.647
Intervention	0.19	0.081	0.24	0.084	0.39	0.07
CSS ~ VIT A RDI						
Control	0.319	0.056	0.052	0.676	0.005	0.976
Intervention	0.71	0.041*	0.85	0.032*	0.91	0.002*
CSS ~ VIT C RDI						
Control	0.19	0.308	0.109	0.342	0.167	0.171
Intervention	0.76	0.003*	0.87	0.002*	0.93	0.002*
CSS ~ Zinc RDI						
Control	0.151	0.314	0.047	0.673	0.169	0.218
Intervention	0.62	0.045*	0.71	0.040*	0.82	0.030*
CSS ~ Selenium RDI						
Control	0.24	0.983	0.28	0.947	0.033	0.770
Intervention	0.65	0.034*	0.69	0.025*	0.87	0.002*

CSS refers to clinical sign score, RDI refers to recommended dietary intake, while RDA refers to recommended dietary allowance. VIT refers to vitamin, CHO refers to carbohydrates, and * refers to a statistically significant value at $p < 0.05$.

4.23 Effect Changes between Control and Intervention on CSS at Critical Time Points of TB Treatment

The DID analysis presented in Table 4.22 revealed that the intervention significantly improved clinical signs score outcomes over time compared to the control group. At Month 2, the intervention group showed a DID estimate of 0.68 (95% CI: 0.02 to 1.34), corresponding to an adjusted odds ratio (AOR) of 1.98 (95% CI: 1.02 to 3.82; $p = 0.041$),

indicating nearly double the odds of improvement. This positive effect persisted at Month 5 with a DID of 0.58 (95% CI: 0.03 to 1.13) and an AOR of 1.79 (95% CI: 1.03 to 3.10; $p = 0.039$). By Month 6, the intervention effect was further enhanced. It had a DID estimate of 0.90 (95% CI: 0.25 to 1.55) and an AOR of 2.46 (95% CI: 1.29 to 4.71; $p = 0.034$) which was more than twice the odds of clinical signs score improvement relative to controls.

Table 4.22: Effect Changes between Control and Intervention ON CSS at Critical Time Points of TB Treatment

Time Point	DID Estimate (β, 95% CI)	AOR (95% CI)	p-value
Month 2	0.68 (0.02, 1.34)	1.98 (1.02, 3.82)	0.041
Month 5	0.58 (0.03, 1.13)	1.79 (1.03, 3.10)	0.039
Month 6	0.90 (0.25, 1.55)	2.46 (1.29, 4.71)	0.034

DID refers to difference in difference; AOR refers to adjusted odds ratio while β refers to beta.

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Practices Associated with Treatment Outcome among TB Patients

The research identified various socio-demographic, health seeking behaviors and health system factors that were important in determining TB treatment outcome. Low BMI at the onset of treatment, poor dietary habits, long distances and high transport costs to TB clinics, unfavorable attitudes of medical staff, lack of supporters of treatment adherence, comorbidities, tobacco smoking, alcohol consumption, and non-compliance with taking TB medication contributed to negative treatment outcomes. The results were in concurrence with a study which reported low BMI in patients with TB was attributable to nearly double the risk of negative treatment outcome (Muhamad, 2011). Among patients who did not achieve positive outcome in the current study, the majority of them were underweight at the time of enrollment which is consistent with the findings of a study by (Ejemot-Nwadiaro et al., 2020), who reported a more than threefold likelihood of occurrence of treatment failure among underweight TB patients. The findings therefore support the existing knowledge of the role of malnutrition in weakening cell-mediated immunity (Morales et al., 2024). Low cell-mediated immunity is associated with poor outcomes among patients on medication (Chowdhury et al., 2018). The association between insufficient dietary intake and negative treatment outcomes could further suggest that attaining RDA for essential nutrients for patients on medication is important. Patients who met their RDA for vitamin A and zinc intakes were shown to have faster recovery rates during treatment of infectious diseases (Inthavong et al., 2025).

Beyond individual factors, health system issues also demonstrated strong predictive value. Notably, poor staff attitude stood out. This observation was consistent with those reported by and (Muthoni et al., 2023; Tachfouti et al., 2012) who documented how negative

provider-patient interactions reduce treatment adherence and trust. Similarly, travel distances greater than 2 km and elevated costs significantly raised the likelihood of negative treatment outcome. Indeed, studies by (Dlangalala et al. 2024) observed the need of patients with TB to be linked to clinics within their area of residence since geographic accessibility is associated with good health-seeking behaviors (Wu et al., 2022).

One of the most striking findings in the study was that being overweight at end of treatment significantly increased the odds of negative outcomes. This was a deviation from previous paradigms that emphasized underweight status. Studies have associated overweight with comorbidities such as diabetes and metabolic syndromes (Bozkurt et al., 2016). Further studies like those conducted by Inzucchi et al. (2012) documented that metabolic syndrome and diabetes are increasingly complicating TB management. These comorbid metabolic disorders may impair immune response and alter the pharmacokinetics of anti-TB drugs, reducing treatment efficacy. However, such discrepancies could also be due to unknown factors like HIV status or underlying inflammation, or the relatively short follow-up period in the current study, which may have limited detection of meaningful BMI changes. Importantly, the current study also revealed that BMI at the end of treatment had a significant association with outcomes, aligning with previous research that reported BMI gain during therapy as a strong recovery marker (Montalvo et al., 2018).

Additionally, alcohol consumption and smoking in the study were significantly associated with poor treatment outcomes. This was in agreement with other studies which reported that tobacco and alcohol use exacerbate TB progression and compromise treatment adherence (Ismail et al., 2023). Lastly, the presence of comorbidities and absence of adherence supporters were strong negative predictors, confirming earlier reports that TB care must integrate comorbidity screening and foster patient-centered support structures (Lottaine, et al., 2025).

5.1.2 Adherence to RDI among TB Patients

The nutrition education intervention improved adherence to RDIs for energy, protein, carbohydrates, vitamins A and C, zinc, and selenium. Though there are limited studies linking recommended nutrient intakes to treatment outcomes among TB patients, previous studies have generally shown that dietary supplementation for TB patients is important in preventing treatment failure and development of MDR – TB (Mendes et al., 2025). Additionally, studies by (Sinha et al. (2025) reported that targeted nutrition counseling increased protein intake by 25% and micronutrient consumption by 18% among TB patients within three months. Similarly, Livingstone et al. (2023) illustrated that intensive nutrition education combined with culturally appropriate dietary guidance enhanced patients' vitamin A and zinc intake significantly, which is consistent with the observations in the current study. The current findings therefore do not directly concur or differ with existing studies but rather fill a critical evidence gap by demonstrating that achieving recommended dietary intakes, even without supplementation, can be associated with improved nutritional and clinical outcomes. Thus, the study is contributory to emerging evidence rather than strictly comparative.

While the intervention positively impacted macronutrients and critical micronutrients essential for immune function, fat and fiber intakes remained without positive improvement. This aligned with Koethe & Reyn. (2016) who noted that traditional rural diets in East Africa are often low in fat-rich and high-fiber foods due to limited availability and affordability. The non-supplementary nature of the intervention in the current study, and the focus on education without material food support may have limited the ability to change the intake of these nutrients (Hu et al., 2022). This is supported by supplementation trials in similar populations, such as those conducted by Grobler et al. (2016) which reported increased fat intake following intervention. This finding could be an indication that nutrition education alone might not be sufficient to influence the intake of nutrients but require access to specific food sources.

Another salient finding was the significant improvement observed in vitamin A and C intake. This finding is in agreement with studies that report improved micronutrient intake following targeted dietary counselling (Degefa et al., 2021). These vitamins play critical roles in maintaining the integrity and function of mucosal barriers and antioxidant defenses, which are also important in TB pathogenesis (Wagnew et al., 2022). The study's success in improving these intakes suggested that counseling focused on nutrient-dense local foods could effectively enhance micronutrient status without the need for supplements. This interpretation partially agrees with studies supporting food-based approaches, but contrasts with those that emphasize supplementation as the primary strategy for micronutrient improvement (Campa et al., 2017). Furthermore, selenium and zinc intake also improved significantly in the intervention arm. These trace elements are reported to modulate immune responses and antioxidant capacity during TB infection, and there has been correlated with delayed sputum conversion and poorer outcomes (Calderwood et al., 2021). Thus, the present results are in agreement with studies that emphasize the role of these micronutrients in TB progression and recovery.

5.1.3 Effect of Nutrition Education Intervention on Sputum Smear Conversion

The study revealed that the intervention doubled the likelihood of sputum conversion at every key point of treatment. This finding is consistent with prior studies that showed the positive effect of nutrition support on TB treatment outcomes (Sinha et al., 2025). One of these studies reported that nutrition support increased sputum conversion rates by almost 80 per cent (Calderwood et al., 2021). However, the design adopted in these studies, did not allow longitudinal follow up of the sputum conversion, but when the design allowed, it was limited to single time point unlike in the current study which observed sputum conversion ta multiple time points (Gamachu et al., 2022). The consistent results observed at multiple treatment milestones strengthened the argument that sustained dietary improvements translate to progressive mycobacterial clearance (Yang et al., 2025). This observation is consistent with longitudinal studies that emphasize sustained nutritional improvement as a driver of treatment success (Morales et al., 2024). The findings also identified the specific nutrients most strongly associated with sputum conversion. They

included energy, protein, carbohydrates, vitamins A and C, zinc, and selenium. These findings align with biological evidence that these nutrients modulate immune effectors that are critical in macrophage activation and pathogen killing (Dow et al., 2021). Therefore, the results concurred with mechanistic studies on nutrient-immune interactions.

Although numerous past studies have revealed that nutrition counselling without food supplementation can have limited effect, our outcome indicated that well-prepared, context-oriented education can elicit clinically important changes on its own. This finding therefore partially contradicted earlier studies that reported limited impact of education – only interventions, while aligning with more recent evidence emphasizing the importance of context-specific and behaviorally informed approaches (Ayakaka et al., 2017). This can be an indicator of a good behavioral change message, follow-up, and culturally acceptable dietary advice tailored to the individual needs (Ickes et al., 2022). In addition, the similarity of the baseline nutrient intake between the intervention and control groups strengthened the inference that differences observed during the follow-up period was associated with intervention and not confounding factors. This observation is consistent with principles of control study design and supports the internal validity of the findings (Chagoma et al., 2025). Therefore, the evidence confirms that nutrition education could be a critical complement to pharmacological treatment of TB, accelerating sputum conversion and possibly reducing the risk of transmission.

5.1.4 Effects of Nutrition Education Intervention on Clinical Sign Scores among TB Patients

The odds of clinical symptoms improvement nearly doubled after 2 months and more than doubled by 6 months of the intervention. These gains not only indicated microbiological clearance but also both subjective and objective resolution of morbidity related to TB (Scriba et al., 2017). The gradual increase in these effects supports the cumulative positive impacts of better nutrition on patient recovery. Research also noted that education on nutrition had the effect of alleviating symptoms reported by the patients and improving

their physical functioning during treatment. Our results also aligned with the findings of mechanistic studies, which reported that micronutrients commonly found in the intervention group (vitamins A and C, zinc, and selenium) are essential cofactors in immune system modulation as well as tissue repair (Gombart et al., 2020).

The absence of significant change in fat and fiber intake, despite continued clinical improvement aligned with growing recognition that immune-modulatory micronutrients may have more direct effects on disease symptomatology than general macronutrient quality alone (Campa et al., 2017). The study also demonstrated significant correlations between improved nutrient intake and clinical scores at multiple time points. Further reinforcing the importance of sustained nutritional adherence. These benefits likely contributed to reduced inflammation, enhanced appetite, and weight gain, helping to break cycles of malnutrition and disease.

There are some potential limitations that should be considered when interpreting the findings of the study. First, the study adopted a quasi-experimental design with pre-post-test. This design is limited with its non-randomized allocation of participants which limits the ability to fully attribute observed effects to the intervention, as participants were not assigned by chance. Thus, the unmeasured differences between groups may have influenced outcomes despite apparent baseline similarities. Second, dietary intake was assessed using a food frequency questionnaire, which is subject to recall and reporting bias and may not reflect actual nutrient status as accurately as biochemical markers. Third, the analysis involved multiple comparisons across nutrients and outcomes, increasing the risk of type I error (false positives), and thus some statistically significant findings should be interpreted with caution. Finally, the generalizability of the results may be limited to similar county-level settings with comparable socio-demographic and health system characteristics, and may not extend to populations with different contexts.

5.2 Conclusion

The study found that treatment outcomes were shaped by a combination of healthcare access, behavioral, and baseline clinical factors. Patients experiencing access barriers related to long distance and high cost, lacking adherence support, or engaging in substance use were significantly more likely to have poor outcomes. They were also more likely to have low baseline BMI and comorbidities ($p < 0.01$). Multivariate analysis confirmed these as independent predictors of treatment outcome. These findings indicated that both structural and individual-level factors played a critical role in determining treatment success among TB patients on medication.

The nutrition education intervention produced clear improvements in dietary quality, particularly in the intake of energy, protein, carbohydrates, and key immune-supportive micronutrients. Adherence to recommended dietary intake improved significantly (AOR = 1.84–2.14, $p < 0.01$), and this was accompanied by progressive increases in BMI at the 2nd, 5th, and 6th months ($p = 0.01, 0.01, \text{ and } 0.001$, respectively). However, improvements were not uniform across all nutrients.

Patients exposed to the intervention achieved faster and more consistent sputum conversion across treatment milestones, with conversion rates exceeding 90% compared to 85.2% in the control group ($p < 0.01$). Improved intake of macronutrients and micronutrients showed significant positive associations with bacteriological clearance, including energy ($\beta = 0.76\text{--}0.91$), protein ($\beta = 0.67\text{--}0.95$), carbohydrates ($\beta = 0.17\text{--}0.47$), vitamin A ($\beta = 0.75\text{--}0.88$), vitamin C ($\beta = 0.80\text{--}0.89$), zinc ($\beta = 0.67\text{--}0.82$), and selenium ($\beta = 0.53\text{--}0.79$), all $p < 0.01$. These findings support the role of nutrition in enhancing treatment response and reducing duration of infectivity among TB patients on medication.

The intervention group showed greater and sustained improvement in clinical signs over time, including reductions in key TB-related symptoms. Odds of clinical improvement were significantly higher at the 2nd, 5th, and 6th months (AOR = 1.98, 1.79, and 2.46, respectively; $p < 0.05$). These improvements aligned with enhanced nutritional intake,

indicating a link between dietary adequacy and symptomatic recovery. The consistency of effect across multiple time points suggested that the intervention supported overall clinical progression during treatment.

A key limitation to this study was that the non-randomized design and reliance on self-reported dietary measures likely introduced bias and limited causal interpretation. These findings showed that nutrition education, when grounded in context-specific practices, can strengthen TB treatment response by improving dietary behavior and supporting recovery.

5.3 Recommendations

From the findings of this study, we recommend the following;

1. The Public Health office in Kericho County should identify context specific factors associated with negative treatment outcomes among patients with TB in the region to enable targeted intervention.
2. The Public Health Office in Kericho County should introduce individualized nutrition education programs for TB patients to enhance adherence to nutrient-dense meal which is rich in energy, protein, vitamins A and C, zinc, and selenium.
3. The Public Health Office in Kericho County in collaboration with the Nutrition Department should strengthen nutritional support and monitoring among TB patients to accelerate sputum smear conversion during the treatment period.
4. Longitudinal research to assess the sustained effects of nutrition education interventions on the improvement and stability of clinical signs.

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APPENDICES

Appendix I: Consent Forms

Greetings,

My name is Collins Kirui. I am a practicing clinical officer and currently I am a student pursuing PhD at Jomo Kenyatta University of Agriculture and Technology. I am conducting a study on 'The potential of positive deviance nutrition intervention on management of treatment failure among patients with active TB in Kericho County'. This study is basically to assess the patients with active TB, recruit them in a six-month intervention and further three months follow up period. The intervention will include two health and nutrition education sessions every month and a positive deviant meal prepared based on the skills learnt during the nutrition education sessions. Your sputum, weight and height measurements will be taken periodically during the intervention period.

I am requesting you to take part as a study participant. Before you take you part in the study I am requesting you to read out the consent form and make an inform choice either to agree or disagree to join the study. To participate in the study is volunteer therefore you can choose to take part or not to take part in the study. The members who will participate in study will have any gain any recompence in the study period. Taking part in the research will not affect in anyway the services you're offered in the hospital. All the information you'll give will be treated with utmost confidentiality and your name will not be written anywhere in the form, instead will use coded numbers to identify the forms. In case you would like to be issued with the report of this research you're requested to indicate your mobile number If you accept to participate in the study, you'll be requested to sign before a witness or to insert your thumb print in the space below the form. This is an indication that you've made your own choice to participate and that you've not been coerced or forced. If you come across unfamiliar word(s) or statements that you don't understand as you fill in the form don't hesitate to ask for explanation.

All the participants in this study will be patients with active TB identified through positive deviance inquiry process. If you consent to participate in the study, you'll be asked a range of questions about TB disease and your dietary practices. You'll also be asked how you've been feeling in the last one week.

There is no risk associated with your participation in this study because no drugs or blood samples are taken as part of the study apart from the sputum, weight and height measurements. No bus or motorcycle costs will be refunded in the study because the intervention will be carried out during your usual clinic visits. Additionally, the findings of the study may be of use to policy makers to improve on maternal mental health.

I, participant number have read/have been read to all the information that I need to enable me to understand what the study entails. I therefore, from an informed consent willfully accept to participate in the study.

.....

Sign/thumb

Date

In case of further information or any question(s) the following can be contacted

Collins Kirui,

Phone no: 0723457612/0782442171

Supervisors

Name.....

Title.....

Department/organization.....

Phone number.....

Appendix II: Questionnaires

Section A: Social Demographic Information

1. Participant no

2. Age in years:

a) 18 – 25 []

b) 26 – 33 []

c) 34 – 41 []

d) 42 – 49 []

e) 50 – 57 []

f) 58 – 65 []

f) 66 – 73 []

g) Above 73 []

3. Religion

a) Christian []

b) Islam []

c) Others

4. Gender: a) Male []

b) Female []

5. Education: a) None []

b) Primary []

c) Secondary []

d) Tertiary []

6. Marital status: a) married []

b) Single []

c) Separated []

d) Divorced []

d) Widow/widower []

7. Occupation

a). Formal []

b). Informal []

c). Farmers []

e). Others []

8. House family live in

a). Own []

b). Rent []

c). Others []

9. Monthly Income in Kshs.

a) < 10,000 []

b) 10, 000-20,000 []

c). 20,000-50,000 []

d). >50,000 []

SECTION B: Nutritional Status

10. Anthropometric measurements

a. Weight

b. Height

Food Consumption Frequency questionnaires

11. (a) Over the past 7 days, how often did you eat vegetable such as kales, cabbages, traditional

vegetables?

a) Once a day

b) 2-3 times in a day

c) 1-2 times in a week

d) 3-4 times in a week

e) 5-6 times in a week

11. (b). Every time you ate vegetables, how much did you usually take?

a) Less than $\frac{3}{4}$ cup (250 mls)

b) . -1. cup (250 mls)

c) More than 1. mls)

12. (a) Over the past 7 days, how often did you eat cereals such as rice, ugali, mashed potatoes

and arrow roots

a) 1 time per day

b) 2-3 times per day

c) 1-2 times per week

d) 5-6 times per week

12. (b) Each time you eat cereals such as rice, ugali, mashed potatoes and arrow roots, how much

did you usually eat?

i) Less than $\frac{3}{4}$ cup (250 mls)

ii) . -1 . cup (250 mls)

iii) More than 1 . mls)

13. (a) Over the past 7 days, how often did you eat food such as meat, poultry and fish?

- a) 1 time per day
- b) 2-3 times per day
- c) 1-2 times per week
- d) 5-6 times per week

13. (b) Every time you eat poultry, meat or fish, how much do you normally eat?

- a) Less than $\frac{3}{4}$ cup (250 mls)
- b) 1. cup (250 mls)
- c) More than 1. cups (250 mls)

14. (a) For the past seven (7) days, how often did you consume legumes such as beans (lentils,

peas, baked beans kidney beans and soybeans

- a) Once in a day
- b) 2-3 times in a day
- c) 1-2 times in a week
- d) 3-4 times in a week
- e) 5-6 times in a week

14. (b). Each time you eat legumes, how much do you usually eat?

- a) Less than $\frac{3}{4}$ cup (250 mls)

b) . -1cup (250 mls)

c) More than 1(250 mls)

15. (a) Over the past 7 days, which fat were usually added to your vegetables, meat, poultry or

legumes such food during cooking? (Please tick where it applies)

a) Margarine (including low fat)

b) Butter (including low fat)

c) Corn oil

d) Solid vegetable fat

e) Other kinds of oils

15. (b) If you can remember again about all the vegetables and other cooked food you consumed

in the past 7 days, how often fat, sauce or dressing added after cooking or added at the table?

a) Once in a day

b) 2-3 times in a day

c) 1-2 times in a week

d) 3-4 times in a week

e) 5-6 times in a week

16. (a) If margarine, butter, or bacon fat was added to cooked vegetables after cooking or at the

table, how much did you add?

- a) Did not usually add
- b) Less than one teaspoon
- c) 1 to 3 teaspoons
- d) More than 3 teaspoons 74

If you can reflect on all the meat, poultry, and fish you took in the past 7 days and how they were

cooked.

16. (b) How regularly was butter, margarine, Oil, or other fat used to fry, saute or marinate any

meat, fish, poultry you ate?

- a) Once a day
- b) 2-3 times in a day
- c) 1-2 times in a week
- d) 3-4 times in a week
- e) 5-6 times in a week

The next questions ask about your intake of bread. We shall begin by asking you about bread you

eat as part of sandwiches only. Then we will ask about all other bread you eat.

17. (a) How regularly did you eat rolls or breads as part of sandwiches (together with samosa and

hot dog)

a) Once a day

b) 2-3 times in a day

c) 1-2 times in a week

d) 5-6 times in a week

17. (b). Every time you consumed breads or rolls as part of your sandwiches how many did you

usually eat?

a) 1 slice or . roll

b) 2 slices or 1 roll

c) More than 2 slices

18. (a) Over the past 7 days, how often did you drink fresh milk, sour milk, mala or yoghurt?

a) Once a day

b) 2-3 times in a day

c) 1-2 times in a week

d) 3-4 times in a week

e) 5-6 times in a week

f) Never

18. (b). Each time you drink fresh milk, sour milk, mala or yoghurt, how much do you drink?

a) Less than (250 mls) half a cup

b) Half to 1 cup

c) More than 1 cup

19. (a) How regularly do you add honey or sugar to the tea, coffee or porridge?

a) 1-3 times in a day

b) 2-4 times in a week

c) 5-6 times in a week

d) 1 time in a day

e) 2-4 times in a day

f) Never

19. (b). Every time honey or sugar was added to the foods you ate, how much was normally

added?

a) < than 1 teaspoon

b) 1 to 3 teaspoons

c) > than 3 teaspoons

SECTION C: Sputum conversion Results.

20. What is the sputum conversion at critical time point laboratory results:

a. Positive []

b. Negative []

SECTION D: Clinical Signs score of Tuberculosis

21. Clinical sign of tuberculosis at critical time point

Persistent cough	Yes []	No []
Loss of appetite	Yes []	No []
Lack of energy	Yes []	No []
Blood in sputum	Yes []	No []
Weight loss	Yes []	No []
Chest pain	Yes []	No []
Sweating at night	Yes []	No []

SECTION E: NUTRITION AND HEALTHCARE SEEKING PRACTICES

Health Care System Related

22. What would be the most convenient TB clinic opening time for you?

a) <8.00 a.m. – 5.00 p.m. [] c) 8.00 a.m. – 5.00 p.m. []

b) 8.00 a.m. – >5.00 p.m. [] d) < 8.00 a.m. – >5.00 p.m. []

23. How long do you wait at the clinic before being attended.

a) < 1 hour [] b) 1 – 2 hours [] c) 3 hours []

24. How long (distance) do you travel to collect drugs (kms).

a) < 5 [] b) 5 – 10 [] c) 11 – 15 []

d) 8 – 20 [] e) > 20 []

25. How much does it cost to reach the facility (Kshs?)

a) Nothing [] b) <Ksh 20 [] c) Ksh 20 – 40 [] d) >Ksh. 40 []

26. How do you rate the staff attitude where you collect drugs?

a) Very friendly [] b) Friendly [] c) Indifferent []

d) Unfriendly [] e) Very unfriendly []

27. Were you told the importance of taking drugs regularly and to completion?

a) Yes [] b) No []

28. What drugs are you supposed to take daily?

a) Isoniazid [] c) Rifampicin []

c) Pyrazinamide [] d) Ethambutol []

29. When you go to pick drugs, what would you say about the availability of

Medicines?

a) Always available []

b) Sometimes not available []

30. What do you know about symptoms of TB? (Tick all the ones applicable)

a) Coughing [] Yes [] No

b) Night sweat [] Yes [] No

c) Loss of weight [] Yes [] No

d) Chest pain [] Yes [] No

31. TB drugs should be taken until

a) 6 months [] Yes [] No

b) One feels better then stop on your own [] Yes [] No

c) 6 months completed and health workers tell you to stop. [] Yes [] No

Patient-Related Factors

32. Have you smoked cigarettes in the last 6 months?

- a) Yes []
- b) No []
- c) Cannot recall []

33. Did you drink alcohol in the last 6 months?

- a) Yes []
- b) No []
- c) Cannot recall []

34. TB can be cured if treatment is taken daily for the correct treatment duration

- a) Yes []
- b) No []

Default Factors

35. Whom do you live with?

- a) Family []
- b) Friend []
- c) Alone []
- d) Others

36. How many other people live with you?

- a) 0 []
- b) 1 – 3 []
- c) 4 – 6 []
- d) >4 []

37. How big is your dwelling home (No. of bedrooms)

- a) 1 – 2 []

SAb) 3 – 4 []

c) > 5 []

38. How long have you stayed in your current dwelling/home.

a) < 3 months []

b) 3 – 12 months []

c) > 12 months []

Disease and Medicine Related Factors

39. Do you experience any side effect when you were taking TB Treatment?

a) Yes []

b) No []

40. If yes, which side effects? (Tick all applicable)

a) Diarrhoea and vomiting []

b) Skin rashes []

c) Headache and dizziness []

d) Numb feet and hands []

e) Yellow eyes [] f) others []

41. From starting to take drugs, how long did you take before feeling better (month)

a) < 2 []

b) 2 – 4 []

c) 5 – 6 []

d) Didn't feel healthy []

42. Did you complete your TB Treatment?

a) Yes []

b) No []

Stigma and Discrimination

43. Did you inform your family/friends that you are on TB Treatment?

a) Yes []

b) No []

44. If No, why?

a) Fear of being isolated by friends and relative []

b) No one to visit []

45. Where do you collect your medicine?

a) Main hospital []

b) Dispensary []

c) Outside this area []

46. If (c) above, why?

a) Shortage []

b) Distance []

c) Other reasons.....

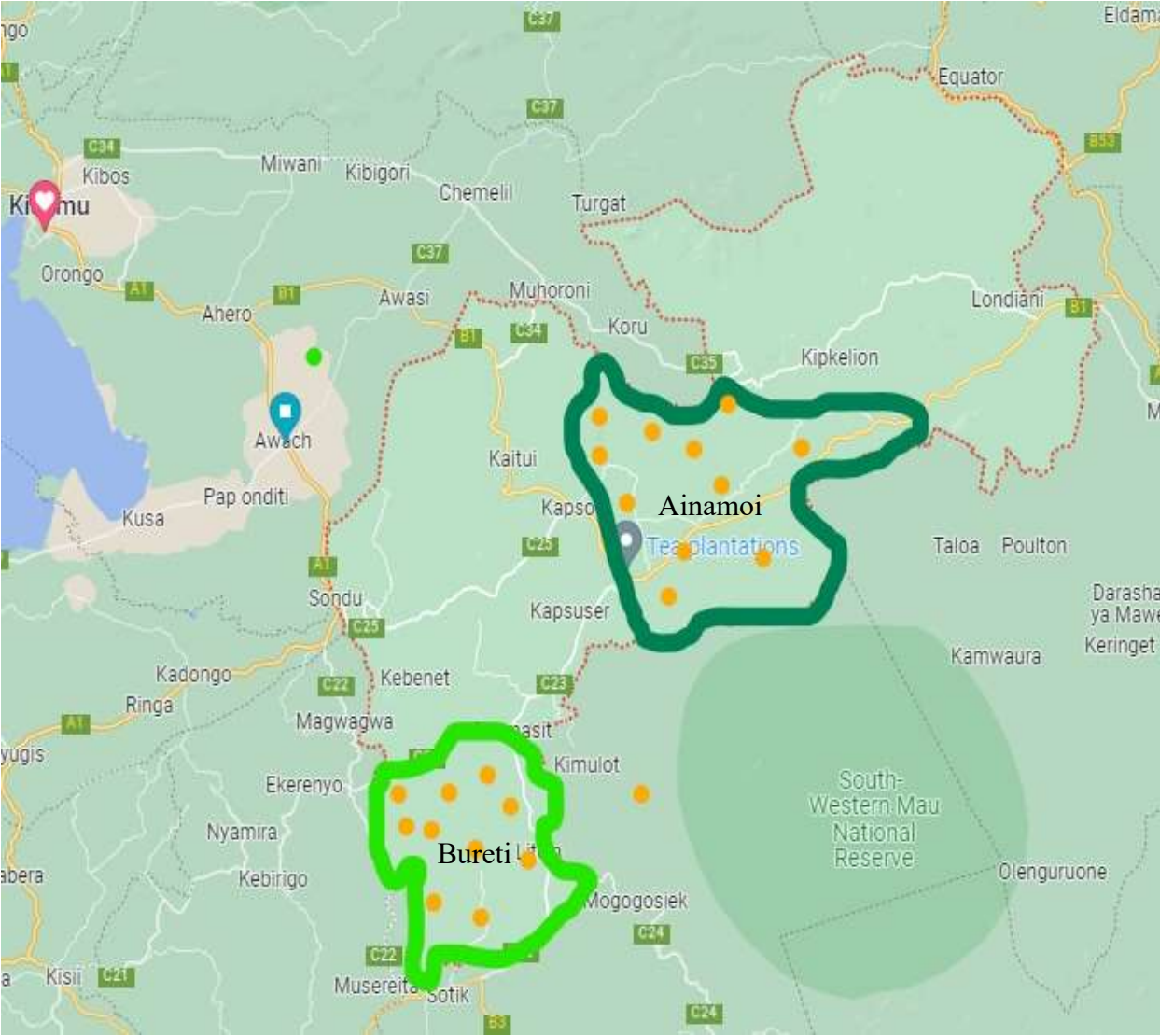
Co morbidities

47. Do you have any of the following diseases (write yes or no in the column provided?)

PROBLEM	Do you have the problem?		Do you receive the treatment?		Does it limit your activities?	
	No	Yes	No	Yes	No	Yes
Heart diseases						
High blood pressure						
Lung diseases						
Diabetes mellitus						
HIV disease						
Ulcers.						
Kidney disease						
Liver disease						
Anaemia						
Cancer						


Depression
Other medical
problem (write it
down)

Appendix III: Map



Appendix IV: Approval Forms

IREC Approval form


OFFICE OF THE DIRECTOR OF GRADUATE STUDIES AND RESEARCH
UNIVERSITY OF EASTERN AFRICA, BARATON
P.O. BOX 2500-30100, Eldoret, Kenya, East Africa

B0207122022 December 7, 2022

TO: Kirui Collins Kipkosgei
Department of Environmental Health and Disease Control
School of Public Health
Jomo Kenyatta University of Agriculture and Technology (JKUAT)

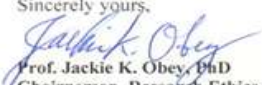
Dear Collins,

RE: The Potential of Positive Deviance Nutrition Intervention in Prevention of Treatment Failure among Patients with Active Tuberculosis in Kericho County
This is to inform you that the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton has reviewed and approved your above research proposal. Your application approval number is UEAB/ISERC/02/12/2022. The approval period is 7th December 2022 – 7th December, 2023.


This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) <https://oris.nacosti.go.ke> and also obtain other clearances needed.

Sincerely yours,

Prof. Jackie K. Obey, PhD
Chairperson, Research Ethics Committee

A SEVENTH-DAY ADVENTIST INSTITUTION OF HIGHER LEARNING
CHARTERED 1991



University of Eastern Africa, Baraton
07 DEC 2022
P.O. BOX 2500, ELDORET
Research Ethics Committee

NACOSTI Research Licence

REPUBLIC OF KENYA
NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION

Ref No: **619774**

RESEARCH LICENSE



2019 WEEK


This is to Certify that Mr., Kipkosgei Kirui Collins of Jomo Kenyatta University of Agriculture and Technology, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Kericho on the topic: THE POTENTIAL OF POSITIVE DEVIANCE NUTRITION INTERVENTION IN PREVENTION OF TREATMENT FAILURE AMONG PATIENTS WITH ACTIVE TUBERCULOSIS IN KERICHO COUNTY for the period ending : 09/February/2024.

License No: **NACOSTI/P/23/23219**

Applicant Identification Number: **619774**

Director General
NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION

Verification QR Code



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See overleaf for conditions

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013 (Rev. 2014)
Legal Notice No. 108: The Science, Technology and Innovation (Research Licensing) Regulations, 2014

The National Commission for Science, Technology and Innovation, hereafter referred to as the Commission, was established under the Science, Technology and Innovation Act 2013 (Revised 2014) herein after referred to as the Act. The objective of the Commission shall be to regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto.

CONDITIONS OF THE RESEARCH LICENSE

1. The License is granted subject to provisions of the Constitution of Kenya, the Science, Technology and Innovation Act, and other relevant laws, policies and regulations. Accordingly, the licensee shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under the Act, or prescribed by provisions of International treaties of which Kenya is a signatory to
2. The research and its related activities as well as outcomes shall be beneficial to the country and shall not in any way:
 - i. Endanger national security
 - ii. Adversely affect the lives of Kenyans
 - iii. Be in contravention of Kenya's international obligations including Biological Weapons Convention (BWC), Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO), Chemical, Biological, Radiological and Nuclear (CBRN).
 - iv. Result in exploitation of intellectual property rights of communities in Kenya
 - v. Adversely affect the environment
 - vi. Adversely affect the rights of communities
 - vii. Endanger public safety and national cohesion
 - viii. Plagiarize someone else's work
3. The License is valid for the proposed research, location and specified period.
4. The license any rights thereunder are non-transferable
5. The Commission reserves the right to cancel the research at any time during the research period if in the opinion of the Commission the research is not implemented in conformity with the provisions of the Act or any other written law.
6. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research.
7. Excavation, filming, movement, and collection of specimens are subject to further necessary clearance from relevant Government Agencies.
8. The License does not give authority to transfer research materials.
9. The Commission may monitor and evaluate the licensed research project for the purpose of assessing and evaluating compliance with the conditions of the License.
10. The Licensee shall submit one hard copy, and upload a soft copy of their final report (thesis) onto a platform designated by the Commission within one year of completion of the research.
11. The Commission reserves the right to modify the conditions of the License including cancellation without prior notice.
12. Research, findings and information regarding research systems shall be stored or disseminated, utilized or applied in such a manner as may be prescribed by the Commission from time to time.
13. The Licensee shall disclose to the Commission, the relevant Institutional Scientific and Ethical Review Committee, and the relevant national agencies any inventions and discoveries that are of National strategic importance.
14. The Commission shall have powers to acquire from any person the right in, or to, any scientific innovation, invention or patent of strategic importance to the country.
15. Relevant Institutional Scientific and Ethical Review Committee shall monitor and evaluate the research periodically, and make a report of its findings to the Commission for necessary action.

National Commission for Science, Technology and
Innovation(NACOSTI),
Off Waiyaki Way, Upper Kabete,
P. O. Box 30623 - 00100 Nairobi, KENYA
Telephone: 020 4007000, 0713788787, 0735404245
E-mail: dg@nacosti.go.ke
Website: www.nacosti.go.ke

Appendix V: letter of Introduction

Patient Number.....

Name of the enumerator.....

Date of interview.....

Dear Sir/Madam

My Name is Kirui Collins Kipkosgei, a student pursuing a course that will award of a Ph.D. in Public Health at Jomo Kenyatta University of Agriculture and Technology. The research topic of current study I am undertaking is on potential of positive deviance nutrition intervention among patient with active Tuberculosis in Kericho county, Kenya.

The questionnaire has been designed to collect the information that will assist in achieving the goals of this research study and I'm in the process of collecting the data required for the study. You are kindly requested to respond to the questionnaire. I shall be very grateful if you will kindly spend part of your time participating in this study a by responding to the questions in the questionnaire and participate in the follow up till completion of medication

Please note that you are free to stop the interview at any time if you feel uncomfortable. The information that you will provide will be treated with the utmost confidentiality and will only be used for the purpose of this research study. Your cooperation will be highly appreciated.

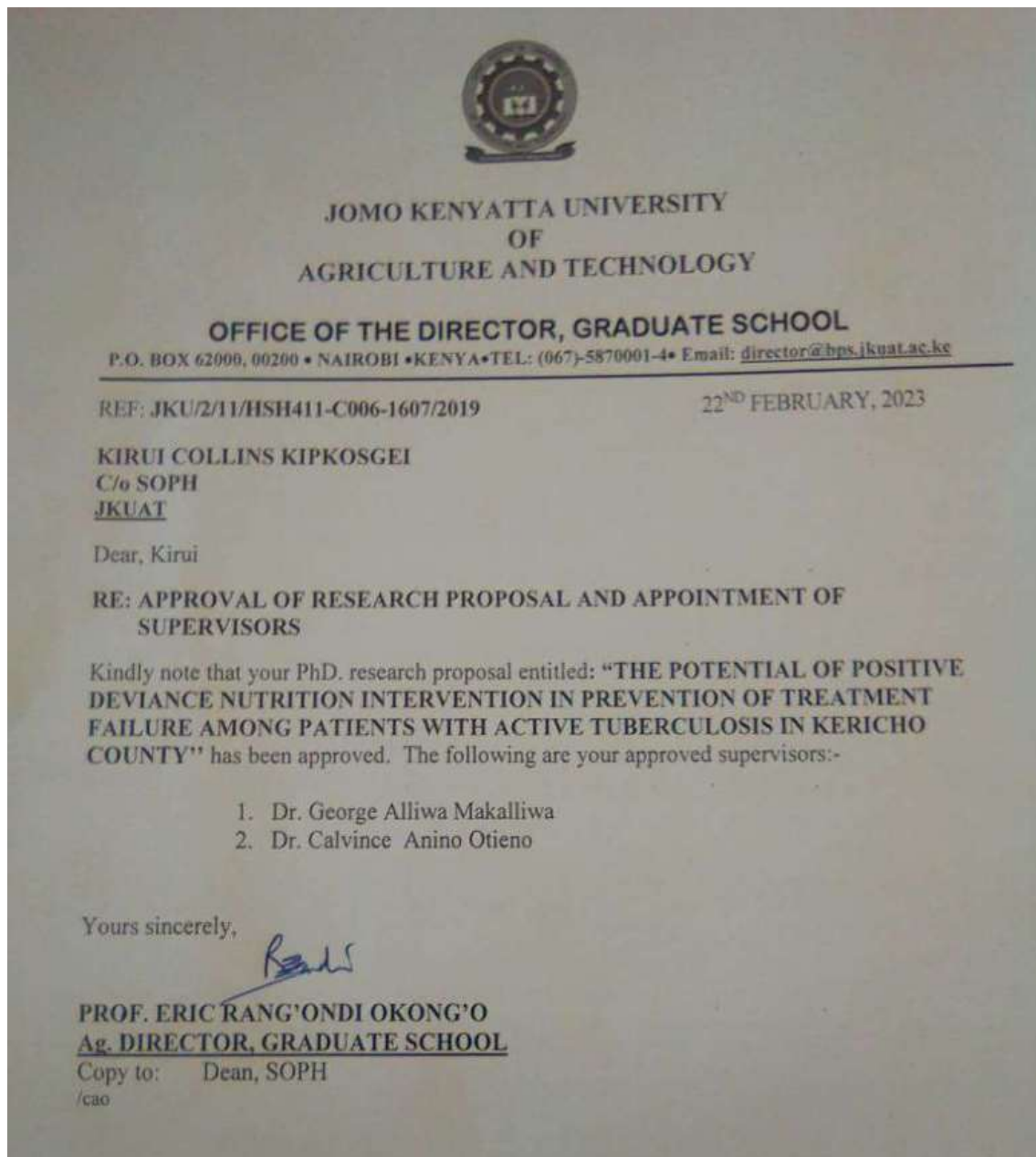
Thank you very much in advance,

Yours faithfully,

Kirui Collins Kipkosgei

REG NO HSH411-C006-1607/2019.

Appendix VI: Supervisors Approval



Appendix VII: Model Diagnostics

7.1 Goodness-of-Fit Tests

Table 7.1: Hosmer–Lemeshow Goodness-of-Fit Test for Logistic Regression Models

Model	χ^2	df	p-value	Interpretation
Sputum conversion model	6.21	8	0.62	Good fit
Clinical sign score model	7.05	8	0.53	Good fit

Interpretation

The Hosmer–Lemeshow test evaluated whether observed and predicted probabilities differ significantly. A p-value > 0.05 indicated that the model fitted the data adequately.

Table 7.2: Model fit Statistics

Model	AIC	BIC	Nagelkerke R ²
Sputum conversion model	182.4	210.7	0.32
Clinical sign score model	195.6	224.1	0.28

Interpretation

- Lower AIC/BIC values indicated better model fit
- Nagelkerke R² showed moderated explanatory power

7.2 Multicollinearity Diagnostics

Table 7.3: Variance Inflation Factors (VIF)

Variable	VIF
Age	1.32
Sex	1.21
BMI	2.14
Alcohol Use	1.87
Tobacco Use	1.76
Nutritional Intake	2.45

Interpretation

All VIF values were below 5, indicating no significant multicollinearity among predictor variables.

7.3 Residual diagnostics

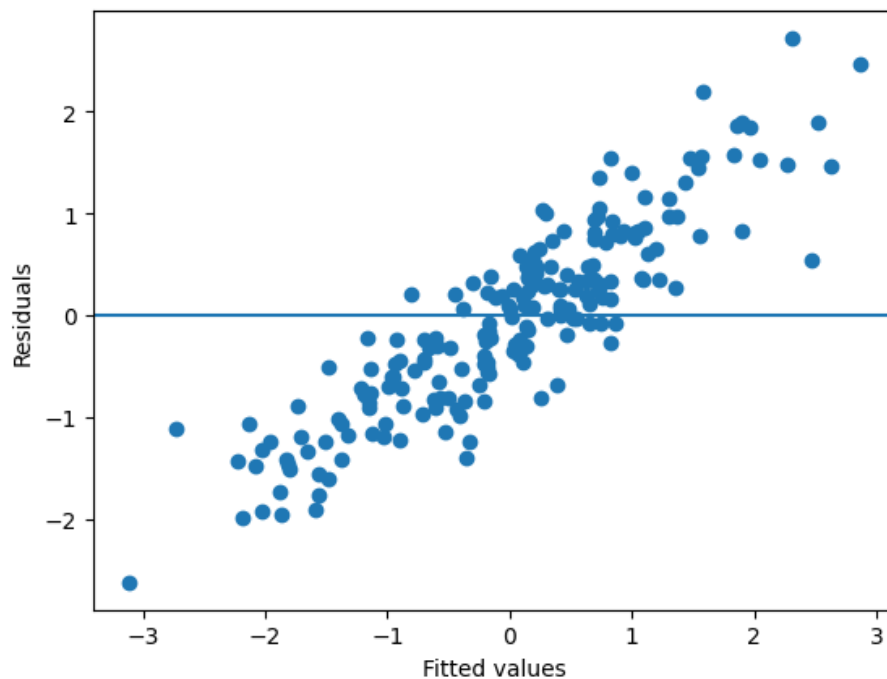


Figure 7.1: Residuals vs Fitted Values Plot

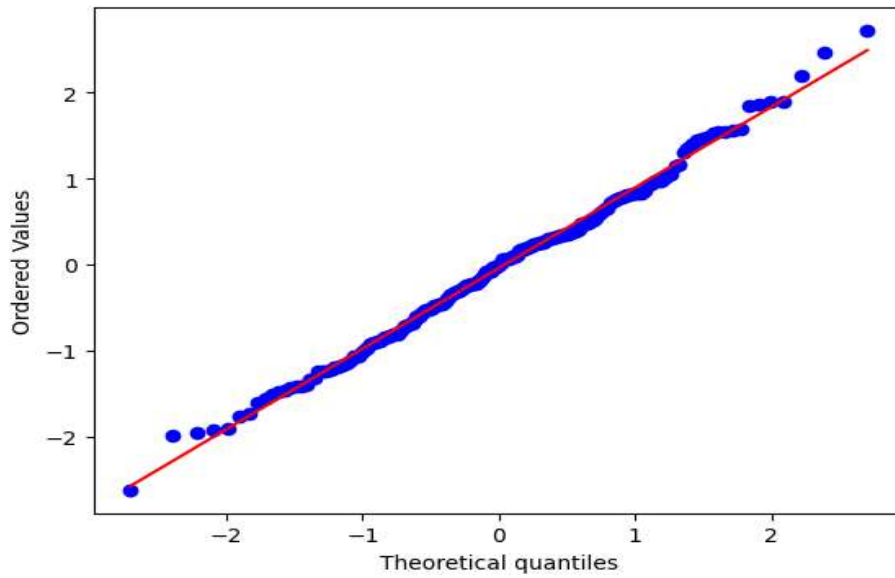


Figure 7.2: Normal Q–Q plot of residuals

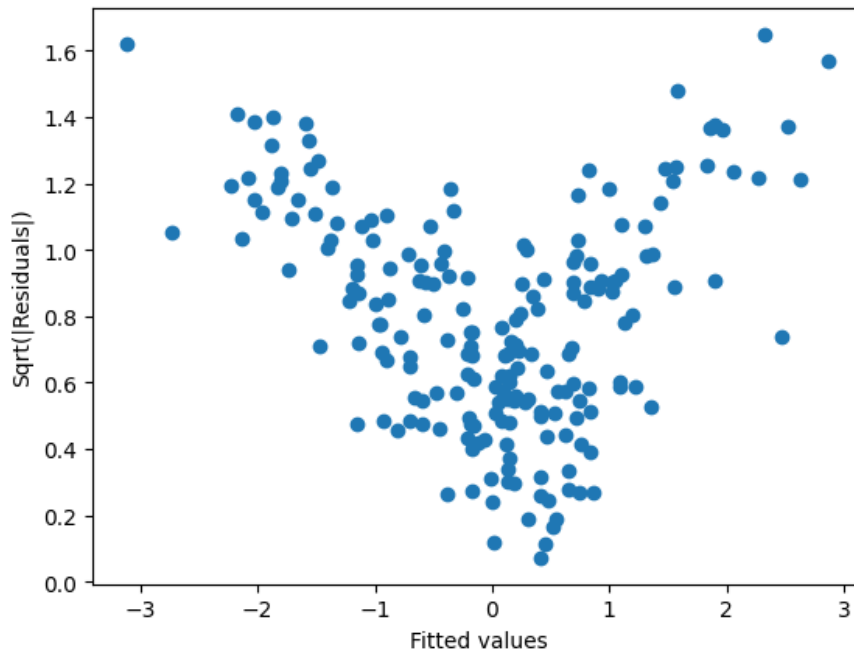


Figure 7.3: Scale–Location plot

Interpretation

- Residuals were randomly distributed around zero
- No clear patterns indicated model misspecification
- Q–Q plots suggested approximate normality for continuous outcomes

7.4 Influence and Outlier Diagnostics

Table 7.4: Leverage and Cook’s Distance

Observation	Leverage	Cook’s distance
Max value	0.18	0.32

Interpretation

No observations exceeded critical thresholds (Cook’s $D < 1$) which was an indication that there were no influential outliers affecting model estimates.

7.5 Random effects and clustering diagnostics

Table 7.5: Variance Components and ICC

Outcome	Between-cluster variance	Within-cluster variance	ICC
BMI	0.50	4.50	0.10
Sputum conversion	0.30	3.29	0.08

Interpretation

The ICC values indicated moderate clustering at the health facility level, justifying the use of mixed-effects models.

7.6 Model specification checks

- Functional form of continuous variables was assessed and found appropriate

- Interaction terms (intervention \times time) were included in DID models