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FROM PLATE TO PATIENT: THE ROLE OF NUTRITION INTERVENTIONS IN DIABETES CONTROL

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Abstract:
Type 2 diabetes mellitus (T2DM) is highly prevalent in Pakistan and is strongly influenced by diet and lifestyle. While clinical pharmacotherapy is well established, rigorous evidence from randomized trials on culturally adapted nutrition interventions in low-resource Pakistani settings is limited. To evaluate whether a structured, culturally adapted nutrition intervention improves glycemic control (primary outcome: HbA1c) compared with standard dietary advice in adults with T2DM attending diabetes clinics in Khyber Pakhtunkhwa. This is a two-arm, parallel-group, randomized controlled trial. A total of 120 adults (30–65 years) with T2DM (baseline HbA1c 7.0–10.0%), on stable glucose-lowering medication for ≥3 months, will be randomized 1:1 to the Intervention or Control arm. The Intervention comprises individualized, culturally adapted meal plans developed with local foods, monthly 45-minute counseling sessions by a clinical nutritionist, printed materials, and weekly WhatsApp follow-up messages; the Control arm receives a single standard diet advice session from clinic staff. Follow-up duration is 6 months. Primary outcome is change in HbA1c from baseline to 6 months. Secondary outcomes include fasting plasma glucose, lipid profile (LDL, HDL, TG), body mass index (BMI), dietary adherence (validated score + 24-hour recalls), medication adherence, and patient satisfaction. Primary analysis follows an intention-to-treat principle. Between-group differences in HbA1c will be analyzed with ANCOVA adjusting for baseline values; repeated measures ANOVA or linear mixed models will assess trajectories over time. A p-value < .05 denotes statistical significance. If effective, the intervention could offer a scalable, culturally congruent model for diabetes care in Pakistan and similar LMIC contexts. To be registered prior to enrolment; ethics approval will be obtained from the relevant institutional review board.

Keywords: *Type 2 Diabetes, Nutrition Intervention, Randomized Controlled Trial, HBA1C, Khyber Pakhtunkhwa, Culturally Adapted Diet.*

Introduction

Type 2 diabetes mellitus (T2DM) has emerged as one of the most pressing public health challenges worldwide. According to the *International Diabetes Federation* (IDF, 2023), approximately 537 million adults are currently living with diabetes globally, and this figure is projected to rise to 643 million by 2030. The burden is particularly alarming in low- and middle-income countries (LMICs), where rapid urbanization, sedentary lifestyles, and dietary transitions toward high-calorie, nutrient-poor foods have accelerated disease prevalence.

Pakistan represents a critical hotspot in this global crisis. The *IDF Diabetes Atlas* ranks Pakistan as the third-highest country in terms of absolute number of adults living with diabetes, with an estimated 33 million cases in 2021 a prevalence rate exceeding 26% among

adults aged 20–79 years. This high prevalence is compounded by low levels of disease awareness, inadequate access to preventive services, and cultural dietary patterns characterized by high consumption of refined carbohydrates, saturated fats, and sugary beverages. Left unchecked, T2DM leads to devastating complications including cardiovascular disease, nephropathy, neuropathy, and retinopathy, significantly diminishing quality of life and imposing substantial economic costs on households and the healthcare system.

Role of Nutrition in Diabetes Management

Dietary management is a cornerstone of T2DM treatment, complementing pharmacotherapy and physical activity. Evidence from multiple randomized controlled trials demonstrates that medical nutrition therapy (MNT) a structured, individualized approach to dietary counseling—can lead to significant reductions in glycated hemoglobin (HbA1c), fasting blood sugar, and lipid levels (Evert et al., 2019; Pastors et al., 2002). The *American Diabetes Association* (ADA) and the *European Association for the Study of Diabetes* (EASD) both recommend that all individuals with T2DM receive individualized nutrition guidance from a trained dietitian.

However, the majority of existing trials have been conducted in high-income countries (HICs), where healthcare resources, food environments, and patient education levels differ substantially from those in LMICs such as Pakistan. This creates a gap in understanding how nutrition interventions can be effectively adapted to resource-limited settings, where cultural norms, food affordability, and local dietary preferences strongly influence patient adherence.

Cultural Adaptation and Behavioral Adherence

A key barrier to the effectiveness of dietary interventions in Pakistan is the lack of cultural tailoring. Generic diet plans, often modeled after Western nutritional guidelines, may recommend foods that are either unfamiliar, unaffordable, or culturally unacceptable to local populations. Conversely, culturally adapted meal plans—designed to incorporate locally available and affordable foods while meeting nutritional targets—have been shown in other LMICs (e.g., India, Bangladesh) to improve patient adherence and clinical outcomes (Shah et al., 2015). Moreover, in a collectivist cultural context, engaging family members and leveraging community norms may enhance the sustainability of dietary behavior change.

Evidence Gaps

Although small-scale observational studies in Pakistan have suggested potential benefits of nutrition counseling for glycemic control, there is a paucity of high-quality randomized controlled trials assessing the efficacy of structured, culturally adapted dietary interventions in Pakistani adults with T2DM. The absence of such evidence limits policymakers' ability to develop cost-effective, locally relevant guidelines for nutrition therapy as part of routine diabetes care.

Study Rationale

This study seeks to address the evidence gap by evaluating the impact of a structured,

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culturally adapted nutrition intervention—integrating individualized counseling, meal planning, and digital follow-up support—on glycemic control in adults with T2DM in Khyber Pakhtunkhwa, Pakistan. By embedding the intervention within routine clinical care and utilizing culturally familiar foods, the trial aims to test a model that is both clinically effective and operationally feasible in low-resource healthcare settings.

Research Question

Does structured, culturally adapted nutrition intervention lead to greater improvements in HbA1c compared to standard dietary advice among adults with Type 2 diabetes in Pakistan?

Objectives

Primary Objective:

- To evaluate the effect of a structured, culturally adapted nutrition intervention on HbA1c over a six-month period.

Secondary Objectives:

- To assess changes in fasting plasma glucose, lipid profile, and BMI.
- To measure dietary and medication adherence following the intervention.
- To evaluate patient satisfaction and perceived quality of care.

Hypothesis

H_1: Participants receiving the structured, culturally adapted nutrition intervention will experience a significantly greater reduction in HbA1c compared to those receiving standard dietary advice.

Literature Review

Global Burden of Type 2 Diabetes Mellitus

Type 2 diabetes mellitus (T2DM) is a global health emergency, with prevalence increasing in every region of the world. According to the *International Diabetes Federation* (IDF, 2023), T2DM affects approximately 10.5% of the adult population worldwide. The condition is associated with premature mortality, reduced quality of life, and substantial economic costs, particularly in low- and middle-income countries (LMICs) where over 75% of people with diabetes reside. The drivers of this epidemic include unhealthy dietary habits, physical inactivity, and urbanization-related lifestyle changes (Hu, 2011). Without effective interventions, the global health and economic burden of T2DM will continue to rise sharply.

Pathophysiology and the Role of Diet

T2DM is characterized by insulin resistance and progressive beta-cell dysfunction, resulting in hyperglycemia. Diet plays a pivotal role both in the development and management of the condition. Excessive intake of refined carbohydrates, trans fats, and energy-dense foods contributes to insulin resistance and poor glycemic control (Ley et al., 2014). Conversely, dietary modifications such as increased consumption of whole grains, legumes, vegetables, and unsaturated fats are associated with improved insulin sensitivity and reduced cardiovascular risk (Jannasch et al., 2017).

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Medical Nutrition Therapy (MNT) in T2DM Management

Medical Nutrition Therapy (MNT) is a structured approach to dietary management delivered by trained nutrition professionals, aimed at achieving individualized treatment goals. The *American Diabetes Association* (ADA) recommends MNT as a first-line intervention for all individuals with T2DM (Evert et al., 2019). MNT has been shown to reduce HbA1c by 0.3–2.0% within 3–6 months, effects comparable to some oral hypoglycemic agents (Pastors et al., 2002). Additionally, MNT can improve lipid profiles, reduce body weight, and enhance quality of life (Franz et al., 2015).

Culturally Adapted Dietary Interventions

Cultural adaptation of dietary interventions involves tailoring recommendations to align with local food availability, preparation methods, and social norms. Research has demonstrated that culturally tailored nutrition programs are more effective in promoting adherence and sustaining long-term behavior change compared to generic dietary advice (Kandula et al., 2015). For example, in South Asian populations, replacing refined rice with whole grains, using lentils and legumes as protein sources, and incorporating traditional spices with anti-inflammatory properties have been effective strategies (Misra et al., 2018).
In LMIC contexts, adaptation also involves addressing barriers such as food affordability, literacy levels, and family-based eating practices. Evidence from India and Bangladesh suggests that interventions integrating culturally relevant meal plans with counseling sessions improve both short-term and long-term glycemic control (Shah et al., 2015; Ali et al., 2019).

Evidence from Randomized Controlled Trials

Several RCTs globally have evaluated nutrition interventions in T2DM management:

- **Look AHEAD (Action for Health in Diabetes) Trial** — A multicenter RCT in the United States demonstrated that intensive lifestyle interventions, including dietary changes and physical activity, significantly improved HbA1c, reduced body weight, and improved cardiovascular risk factors over 4 years (Wing et al., 2013).
- **Diabetes Prevention Program (DPP)** — Showed that dietary modifications and weight loss reduced the incidence of diabetes by 58% in high-risk individuals (Knowler et al., 2002).
- **Indian Diabetes Prevention Program (IDPP)** Demonstrated that lifestyle modification with culturally relevant diet changes reduced diabetes incidence by 28% (Ramachandran et al., 2006).

However, few RCTs have been conducted in Pakistan. One small-scale trial in Lahore found that individualized dietary counseling resulted in a significant reduction in HbA1c over 3 months compared to standard care, but sample size limitations restricted generalizability (Khan et al., 2019).

Digital and Hybrid Nutrition Interventions

The rise of mobile health (mHealth) tools offers opportunities to enhance dietary counseling, especially in rural or resource-limited areas. Studies have shown that supplementing in-person sessions with SMS or WhatsApp reminders improves adherence to dietary plans and

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follow-up attendance (Partridge et al., 2020). In Pakistan, mobile phone penetration is high, making digital supplementation feasible even in low-income populations.

Gaps in the Literature

Despite strong evidence for MNT in high-income settings, there remains a lack of high-quality, large-scale RCTs in Pakistan evaluating the effectiveness of culturally adapted nutrition interventions. Existing studies are often limited by small sample sizes, short follow-up periods, and lack of consideration for socio-cultural factors that influence dietary habits. Furthermore, the integration of digital follow-up support within culturally tailored nutrition interventions has been understudied in the Pakistani context.

Methodology

Study Design

This study is a two-arm, parallel-group, randomized controlled trial (RCT) designed to evaluate the effect of a structured, culturally adapted nutrition intervention on glycemic control in adults with type 2 diabetes mellitus (T2DM). The trial will be conducted in accordance with the *CONSORT* guidelines for randomized trials.

Study Setting

The trial will be implemented in diabetes outpatient clinics at selected public and private hospitals in Khyber Pakhtunkhwa (KP), Pakistan, including tertiary-care and secondary-level facilities. These sites were selected to capture a diverse patient population in both urban and peri-urban areas.

Study Population

Inclusion Criteria

- Adults aged **30–65 years**.
- Diagnosed with T2DM for at least 1 year.
- Baseline HbA1c between **7.0% and 10.0%**.
- On stable doses of oral glucose-lowering medication for ≥3 months.
- Willingness to provide written informed consent and participate in follow-up.

Exclusion Criteria

- Type 1 diabetes or gestational diabetes.
- Pregnant or lactating women.
- History of severe comorbidities (e.g., end-stage renal disease, advanced cardiovascular disease, active malignancy).
- Cognitive impairment or psychiatric disorders that may hinder participation.
- Participation in another clinical trial within the last 6 months.

Sample Size

The sample size was calculated to detect a minimum clinically significant difference in HbA1c of 0.5% between intervention and control groups, assuming a standard deviation of 0.8%, power of 80%, and a two-sided alpha of 0.05. Using the formula for comparing two means, the required sample size is 54 participants per group. Allowing for 10% attrition, a total of

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120 participants will be enrolled (60 per arm).

Randomization and Allocation

Participants will be randomized in a 1:1 ratio to the intervention or control group using computer-generated block randomization (block sizes of 4 and 6) to maintain allocation concealment. Sequentially numbered, opaque, sealed envelopes (SNOSE) will be used for allocation concealment, prepared by a statistician not involved in patient recruitment or assessment.

Blinding

Due to the nature of the intervention, participants and nutritionists cannot be blinded to group allocation. However, laboratory technicians analyzing biochemical outcomes and statisticians conducting data analysis will be blinded.

Intervention

Intervention Group:

- **Initial Session:** 45–60-minute individualized counseling session by a registered clinical nutritionist.
- **Culturally Adapted Meal Plan:** Developed using locally available and affordable foods (e.g., whole wheat roti, brown rice, lentils, seasonal vegetables).
- **Printed Diet Guide:** Including portion sizes, healthy cooking methods, and meal frequency.
- **Follow-Up:** Monthly in-person counseling sessions (45 minutes each).
- **Digital Support:** Weekly WhatsApp reminders with meal suggestions, motivational messages, and adherence checks.

Control Group:

- One-time **standard dietary advice** provided by clinic physician at baseline, based on Pakistan Diabetes Society recommendations, without individualized follow-up.

Follow-Up Duration

Total follow-up period: **6 months**, with data collection at **baseline, 3 months, and 6 months**.

Outcome Measures

Primary Outcome:

- Change in HbA1c from baseline to 6 months.

Secondary Outcomes:

- Fasting blood sugar (FBS).
- Lipid profile: total cholesterol, LDL-C, HDL-C, triglycerides.
- Body Mass Index (BMI) and waist circumference.
- Dietary adherence score (validated food frequency questionnaire + 24-hour dietary recall).
- Medication adherence (Morisky Medication Adherence Scale-8).
- Patient satisfaction score (Likert scale).

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Data Collection Procedures

- **Anthropometry:** Standardized measurement protocols for weight, height, and waist circumference.
- **Biochemical Tests:** FBS, HbA1c, and lipid profile measured at accredited laboratories.
- **Questionnaires:** Administered by trained data collectors using structured formats in

Statistical Analysis Plan

- **Primary analysis:** Intention-to-treat (ITT) principle.
- Between-group differences in HbA1c change: ANCOVA, adjusting for baseline HbA1c.
- Within-group changes over time: repeated measures ANOVA or linear mixed-effects models.
- Secondary outcomes: Independent t-tests or Mann–Whitney U tests for continuous variables; chi-square tests for categorical variables.
- Statistical significance set at $p < 0.05$.
- Data analyzed using SPSS v27.

Ethical Considerations

- Approval from Institutional Review Board (IRB) of participating institutions.
- Written informed consent obtained from all participants.
- Confidentiality ensured through anonymized data storage and restricted access.
- Participants in the control group will receive the printed culturally adapted meal plan at study completion.

Expected Results

Based on evidence from similar randomized controlled trials in other LMIC settings, it is anticipated that participants in the intervention group will demonstrate significantly greater improvements in glycemic control compared to the control group at 6 months.

Primary Outcome Expectation:

- Mean reduction in HbA1c in the intervention group is expected to be 0.8–1.0% versus 0.3–0.4% in the control group.
- Between-group difference expected to be statistically significant ($p < 0.05$).

Secondary Outcome Expectations:

- **Fasting Plasma Glucose (FPG):** Reduction of 20–30 mg/dL in the intervention group compared to 10–12 mg/dL in control.
- **BMI:** Reduction of 0.5–1.0 kg/m² in the intervention group; minimal change in control.
- **Lipid Profile:** LDL-C decrease of 8–12 mg/dL and triglyceride reduction of 15–20 mg/dL in intervention group; smaller changes in control.
- **Dietary Adherence:** Higher adherence scores (≥80% compliance) in the intervention group compared to control (~60%).
- **Medication Adherence:** Slight improvement in intervention group due to increased patient engagement.
- **Patient Satisfaction:** Higher mean satisfaction scores in the intervention group.

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If confirmed, these findings would support the integration of culturally adapted nutrition interventions into standard diabetes care protocols in Pakistan.

Table 1. Baseline Characteristics of Participants (n = 120)

Variable	Intervention (n=60) Mean ± SD / n (%)	Control (n=60) Mean ± SD / n (%)	p-value
Age (years)	51.2 ± 8.1	50.8 ± 7.9	0.78
Gender (Male)	28 (46.7%)	30 (50.0%)	0.71
Duration of Diabetes (yrs)	6.8 ± 3.2	6.6 ± 3.5	0.82
HbA1c (%)	8.3 ± 0.7	8.2 ± 0.8	0.54
Fasting Plasma Glucose (mg/dL)	162.4 ± 28.6	160.1 ± 29.2	0.66
BMI (kg/m²)	27.6 ± 3.1	27.4 ± 3.2	0.81
LDL-C (mg/dL)	115.2 ± 18.4	113.8 ± 17.6	0.69
Triglycerides (mg/dL)	154.6 ± 32.1	152.3 ± 31.7	0.74

Table 2. Changes in Primary and Secondary Outcomes Over 6 Months

Outcome Variable	Baseline Mean ± SD	3 Months Mean ± SD	6 Months Mean ± SD	Change from Baseline (6 Months)	p-value (Intervention vs Control)
HbA1c (%)	8.3 ± 0.7	7.7 ± 0.6	7.4 ± 0.6	-0.9	0.01
FPG (mg/dL)	162.4 ± 28.6	145.8 ± 24.2	140.5 ± 23.1	-21.9	0.02
BMI (kg/m²)	27.6 ± 3.1	27.2 ± 3.0	26.9 ± 3.0	-0.7	0.03
LDL-C (mg/dL)	115.2 ± 18.4	110.1 ± 17.2	107.3 ± 16.9	-7.9	0.04
Triglycerides (mg/dL)	154.6 ± 32.1	148.3 ± 30.4	142.9 ± 28.7	-11.7	0.05
Dietary Adherence (%)	62.5 ± 12.0	75.4 ± 10.8	82.6 ± 9.4	+20.1	<0.001
Patient Satisfaction	3.5 ± 0.8	4.1 ± 0.7	4.4 ± 0.6	+0.9	<0.001

Note: Data are placeholders for illustration; actual results will be inserted post-trial.

Discussion

Principal Findings

This randomized controlled trial is expected to demonstrate that a structured, culturally adapted nutrition intervention significantly improves glycemic control in adults with type 2 diabetes mellitus (T2DM) compared to standard dietary advice. The anticipated reduction in HbA1c of approximately 0.8–1.0% in the intervention group aligns with findings from similar interventions in other LMICs and exceeds the minimal clinically important difference for glycemic control (UKPDS, 1998). Improvements are also expected in fasting plasma glucose, lipid profile, BMI, dietary adherence, and patient satisfaction, suggesting that nutrition

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interventions can exert comprehensive metabolic benefits when appropriately adapted to the cultural context.

Comparison with Existing Literature

The projected effect sizes are consistent with prior global trials. For example, the *Look AHEAD* trial reported HbA1c reductions of 0.6–0.9% following intensive lifestyle interventions (Wing et al., 2013). Similarly, the *Indian Diabetes Prevention Program* demonstrated a 28% reduction in diabetes incidence with culturally relevant dietary counseling (Ramachandran et al., 2006).

Our trial extends these findings by integrating a low-cost digital follow-up component (weekly WhatsApp messages), which has shown promise in enhancing adherence in resource-limited settings (Partridge et al., 2020). This hybrid model could be particularly relevant in Pakistan, where mobile penetration exceeds 85% and healthcare resources are constrained.

Mechanisms of Action

The anticipated improvements may result from several synergistic mechanisms:

1. **Nutritional Composition:** Increased fiber intake, improved glycemic load, and reduced saturated fat may enhance insulin sensitivity.
2. **Behavioral Adherence:** Regular follow-up and culturally tailored materials may improve patient motivation and consistency.
3. **Family and Social Engagement:** In collectivist cultures, involving family members in dietary planning can reinforce healthy behaviors at the household level.

These mechanisms underscore the importance of cultural congruence in dietary interventions a factor often underemphasized in generic guidelines.

Policy and Practice Implications

If the intervention proves effective, it could be integrated into existing diabetes care pathways in Pakistan with minimal additional cost. The intervention model is designed to be scalable, requiring only basic nutritionist training, culturally adapted educational materials, and the use of widely available digital communication tools. This aligns with WHO's recommendations for task-shifting and community-based non-communicable disease (NCD) management in LMICs.

Strengths and Limitations

Strengths of this trial include:

- **Randomized controlled design** ensuring robust causal inference.
- **Cultural adaptation** of dietary recommendations for higher adherence.
- **Integration of digital support**, increasing scalability.
- **Multiple outcome measures** capturing metabolic, behavioral, and patient-reported impacts.

Limitations:

- The open-label nature of the intervention introduces the potential for performance bias.
- The 6-month follow-up limits conclusions about long-term sustainability.
- Results may not be generalizable to rural populations without mobile access.
- Dietary adherence is partly self-reported, which could introduce recall bias.

Future Research

Future work should:

- Extend follow-up to assess long-term sustainability of dietary changes.
- Evaluate cost-effectiveness for large-scale implementation.
- Investigate the impact of similar culturally adapted interventions in rural and underserved populations.
- Explore integration with other lifestyle interventions, such as structured physical

Conclusion

- This randomized controlled trial aims to address a critical evidence gap in the management of type 2 diabetes mellitus in Pakistan by evaluating the efficacy of a structured, culturally adapted nutrition intervention. Drawing on global evidence and local dietary patterns, the intervention is designed to improve glycemic control, enhance dietary adherence, and promote overall metabolic health in a way that is feasible and affordable within the country's healthcare system.
- The expected findings — including a clinically significant reduction in HbA1c, improved lipid profile, modest weight loss, and higher patient satisfaction — would underscore the potential of culturally tailored dietary counseling as a cornerstone of diabetes care in low- and middle-income settings. By integrating digital follow-up through widely accessible mobile platforms, this approach could be scaled nationally at relatively low cost.
- Ultimately, implementing such evidence-based, culturally sensitive nutrition interventions could contribute substantially to reducing the burden of diabetes-related morbidity and mortality in Pakistan. These results will provide policymakers, clinicians, and public health practitioners with actionable strategies to integrate nutrition therapy into routine care, thereby improving health outcomes and quality of life for millions of individuals living with diabetes.

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