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Original Article

Impact of Clinical Pharmacist-led Intervention on Clinical Outcomes, Medication Adherence, and Health-related Quality of Life of Type 2 Diabetic Comorbid Hypertensive Patients: A Randomized Controlled Trial

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Abstract

This study aims to evaluate the impact of a pharmacist-led educational intervention on clinical outcomes, medication adherence, and health-related quality of life (HRQoL) of Type 2 diabetes comorbid hypertensive patients. Ninety-two participants were block-randomized into control (n = 46, usual care) and intervention (n = 46, pharmacist-led education and counseling) groups. Clinical parameters, medication adherence, and HRQoL were assessed at baseline, 3 months, and 6 months. Repeated measures tests and bivariate statistics were used to analyze within-group and between-group differences of outcomes. Seventy-two patients (37 intervention, 35 control) completed the study. The intervention group demonstrated significant reductions in mean glycated hemoglobin (HbA1c) level, systolic and diastolic blood pressure over 6 months ($p < 0.05$), while no significant differences in outcomes were observed among the control group. Altogether, 67.6% of participants in the intervention group attained HbA1c < 7%, and 83.8% achieved optimal blood pressure control and adherence to the prescribed medications. HRQoL health utility score shows marginal but significant improvement in the intervention group. Overall, the pharmacist intervention exhibited small to moderate effects in improving most of these outcomes compared to usual care. The findings revealed that pharmacist-led educational interventions significantly improve clinical outcomes, medication adherence, and HRQoL in diabetic-hypertensive patients. The study recommends routine integration of pharmacists in clinical settings for multidisciplinary care of diabetic-hypertensive patients.

Keywords

Pharmacist intervention, diabetes mellitus, hypertension, medication adherence, health-related quality of life

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Introduction

Diabetes mellitus (DM) has become a major public health concern with its alarming increase in prevalence rates.[1] Globally, more than half a billion adults are living with diabetes, with prevalence reporting higher in low and middle-income countries.[2] Diabetes prevalence in Southeast Asia was 8.8% in 2019, which is projected to increase to 9.7% by 2030.[3] Among the geographic distribution, India had the highest number of deaths (0.25 million) and the second highest in terms of prevalence of diabetes (67.8 million) among countries worldwide.[2] In Nepal, the prevalence of Type 2

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diabetes has been rising steadily over the past decade from 7.75% in 2015 to about 11.24% by 2020, with about 5.7% of the population estimated to have hypertension as a co-morbidity.[4,5] Urban residence, obesity and reduced physical activity are among the factors associated with the increasing prevalence of this chronic disease.[6]

DM remains a major contributor to global morbidity and mortality and is associated with a wide range of complications, including diabetic neuropathy, retinopathy, nephropathy, and more fatal cardiovascular events.[7] Hypertension commonly co-exists among a high proportion (20%–60%) of individuals with diabetes, and this occurrence is influenced by factors such as race, obesity, and age.[8–10] Studies have shown that hypertension is a strong predictor of serious adverse events in people living with diabetes, amplifying the risk of disease-induced cardio-cerebrovascular complications such as coronary arterial diseases, myocardial infarction, and stroke.[11,12] These comorbid conditions may increase patients' susceptibility toward disease-related morbidity affecting their health-related quality of life (HRQoL).[10,13] As such, diabetic-hypertensive patients should regularly take their prescribed medication in order to maintain control over the disease and to achieve the best possible treatment outcomes.[14] Strict glycemic and blood pressure control is the cornerstone for effective disease management and prevention of disease-associated complications. Patients who do not take their medications as prescribed may experience significant worsening of their health condition, treatment failure, complications, hospitalizations, or increased health care costs.[15,16] Pharmacists, being the most accessible healthcare professionals to the general public, could play a vital role in the care of these patients by means of patient education and counseling, identifying drug-related problems, supporting patients' medication management, and optimizing treatment outcomes.[17]

Despite the rising burden of diabetes and hypertension in Nepal, the role of pharmacists in integrated non-communicable disease (NCD) care remains insufficiently defined. The Ministry of Health and Population, Government of Nepal, with support from the World Health Organization (WHO), has set a national target to provide protocol-based treatment services to 1.5 million Nepalese people with hypertension and diabetes by 2025, emphasizing the need to strengthen detection, treatment, follow-up, and monitoring at the primary healthcare level.[18] Current initiatives, however, have largely focused on physician-led screening, implementation of treatment protocol, and training primary healthcare workers, with limited attention toward the pharmaceutical care areas, including medication management, adherence support, follow-up, and pharmacist collaborative care of these patients. Therefore, evaluating a clinical pharmacist-led intervention through a randomized controlled trial may explore the potential role of pharmacists in NCD care, which directly aligns with the goals of Nepal's national NCD priorities. Such evidence could help address a practical gap in the implementation of multidisciplinary, protocol-based care and generate context-specific evidence to support capacity building and development of pharmacist-integrated care models for patients with diabetes and hypertension. To date, experimental trials on pharmacist collaborative care for Type 2 diabetes mellitus (T2DM) comorbid hypertension patients remain scarce in Nepal. Previous studies among newly diagnosed diabetes patients have primarily examined the effects of pharmacist-led intervention on patients' reported outcomes, specifically patient satisfaction and HRQoL. However, these studies did not comprehensively evaluate the impact of such intervention on medication adherence and clinical outcomes such as glycemic control, blood pressure, and other cardiometabolic markers.[19,20] Therefore, this study seeks to address this specific evidence gap by exploring the effectiveness of pharmacist-supervised educational intervention on multiple clinical outcome measures, including adherence and HRQoL. Specifically, the study is guided by the following research questions: first, whether a clinical pharmacist-led educational intervention could influence clinical outcomes, medication adherence, and HRQoL of the diabetic-hypertensive patients as compared to those receiving usual care, and second, which specific outcomes are more responsive to the pharmacist intervention, and what is the magnitude of its effect on these outcomes. Therefore, this prospective, randomized controlled trial aims to provide an inclusive understanding of the impacts of pharmacist collaborative care in the management of patients with co-existing diabetes and hypertension, thereby offering evidence-based strategies to enhance diabetes care and patients' well-being within a low-resource country setting.

Materials and Methods

Study Design

This is a prospective, interventional, parallel arm, randomized controlled trial design, with attempted participant blinding through non-disclosure of group allocation. The study evaluated the effect of pharmacist-led educational intervention on T2DM comorbid hypertension patients. The study included 6 months follow-up period, with assessment conducted at baseline, 3 months, and 6 months after enrollment. The primary objective of this study was to determine the impact of pharmacist-led intervention on primary clinical outcomes, namely, glycemic control and blood pressure regulation, operationally defined as changes in fasting blood sugar (FBS), postprandial blood sugar (PPBS), glycated hemoglobin (HbA1c), systolic blood pressure (SBP), and diastolic blood pressure (DBP), from baseline to 3- and 6-months' follow-up period. Secondary outcomes assessment included changes in secondary clinical parameters, body mass index (BMI), lipid profile, medication management, and HRQoL, among diabetic-hypertensive patients.

Study Settings and Period

The study was conducted on the internal medicine outpatient clinic of Purbanchal University Hospital located in Sundarharaicha municipality, Morang, Koshi Province, Nepal. The study was conducted in outpatients to evaluate the outcomes within a population representative of real-world settings. The participants' recruitment and data collection were performed from August 2023 to July 2024 in the private counseling room setup at the hospital outpatient clinic.

Study Population and Criteria

The study population consisted of outpatients diagnosed with "Type 2 DM comorbid hypertension" and those meeting selection criteria. Inclusion criteria include patients irrespective of gender and aged between 40 and 68 years, who were clinically diagnosed with T2DM, comorbid hypertension, with or without disease-related complications, patients having at least 1 year of medical history of both the disease, and undertaking antidiabetic and antihypertensive medication for at least 6 months, and those patients who voluntarily agreed to participate in the study. Exclusion criteria include patients diagnosed with Type 1 DM, gestational diabetes, and other forms of diabetes, mentally impaired patients, pregnant and critically ill patients requiring hospital admission, patients having tuberculosis, coronavirus, and other forms of highly communicable diseases, and those patients not willing to perform a routine follow-up visit in the hospital.

Participant Recruitment Procedure

On each outpatient clinic day, the healthcare providers were asked to refer patients previously diagnosed with "Type 2 DM comorbid hypertension" for eligibility screening based on inclusion and exclusion criteria. Subsequently, each eligible patient was informed about the study purpose and procedures in their native language and was requested to participate in the study. Written informed consent was obtained from the patients who voluntarily agreed to participate in the study. Upon enrollment, each participant was assigned a unique allocation number in sequential order to ensure systematic tracking. Patients were interviewed for sociodemographic details, and study questionnaires were administered. Blood pressure measurements were carried out using standardized techniques with a calibrated sphygmomanometer, in accordance with established clinical guidelines, and recorded in the outpatients' cards.[21] Additionally, patients were instructed to visit the hospital laboratory on the succeeding day for the collection of FBS and PPBS for relevant biochemical tests. All recruited patients were allowed routine follow-up consultation with a physician and other healthcare providers for drug therapy and advice.

Sample Size and Sampling Techniques

Previous published literature has shown that an effect size of 0.9% reduction in HbA1c with a standard deviation (SD) of 1.4% can be detected with 80% power at the 0.05 level of significance.[22–24] Thus, using the Randomized Controlled Trial (RCT)-specific formula,

$$n = 2\sigma^2 (Z\alpha/2 + Z_\beta)^2/d^2$$

where, σ = SD (1.4), d = effect size (0.9) α = significance level at 0.05, $Z_{\alpha/2}$ value = 1.96, Z_β = 0.84 (80% power).

The calculated sample size for each group is 38. However, 20% of the samples attrition rate was added to the samples, considering the prevalence, to compensate for the loss on follow-up. Thus, a total of 92 patients (46 each, in the control and intervention groups) were enrolled in the study. Consecutive sampling techniques, where every patient meeting the eligibility criteria was enrolled, based on a time capsule frame of 6 months, were used to meet the required sample size.

Randomization Techniques and Procedures

Block randomization techniques were applied to randomize the participants into two parallel arms of control and intervention group to ensure balanced distribution of participants in two arms, until the desired target sample is reached (i.e., Control group [n = 46], intervention group [n = 46]). First, an independent researcher who had no involvement in the trial generated a randomization sequence using a web-based randomization tool. Randomization blocks of sizes 2 and 4 were provided, and each block contained a prespecified allocation sequence corresponding to the enrollment order of participants within that block. The allocation concealment was maintained using a sequentially numbered, sealed, and stapled block-specific envelope prepared by an independent researcher. Each envelope contains the block size and allocation sequence for that block and is kept in the agreed location in the study center. The envelope for a given block was opened only after the required number of eligible participants for that block had completed baseline assessment and had been formally enrolled in the study. Participants within each block were assigned to the intervention or control group according to their chronological enrollment sequence and the allocation order specified in the corresponding envelope. The allocation sequence was not available to the recruiting investigators before participants were enrolled into the block, and subsequent block envelopes remained sealed until the required number of participants for those blocks had been enrolled. To minimize bias, the study patients were kept blinded through non-disclosure of their group allocation and the comparative study hypothesis throughout the study period.

Description of Arms and Intervention

Control Group

Control group patients received routine medical consultations and general advice from their healthcare providers during baseline and follow-up visits. The clinical pharmacist provided only basic counseling to the patients regarding their prescribed medications. Any queries, if asked by the patients, were answered. In other words, "Usual care" was provided to the patients.

Intervention Group

In addition to routine standard care, Patients in the interventional group received two consecutive face-to-face counseling sessions by a clinical pharmacist during the baseline period and the first follow-up period at 3 months in the pharmacist's consultation room. The counseling sessions were based on a prespecified counseling guide that covered key components of diabetes and hypertension education and disease management strategies. Teaching and counseling sessions encompass both non-pharmacological and pharmacological disease management strategies. Non-pharmacological interventions included patient counseling and education on lifestyle modification, healthy dietary habits, physical activity, and stress management techniques. Pharmacological intervention involves counseling with disease-related information, such as diabetes/hypertension signs and symptoms, risk factors, complications, self-monitoring of blood pressure and blood glucose, and appropriate response to hypoglycemia, hypotension, and other warning symptoms. Additionally, patients were informed about their prescribed medications, including drug names, indication, potential adverse effects, potential drug-related problems, and the importance of medication adherence. Evidence-based medication management strategies were emphasized for individuals with non-adherence issues. These include tailored interventions such as individualizing medication regimen to align with individual lifestyle, incorporating cue-based techniques, designing personalized adherence schedules, maintaining medication record, and advising on utilizing mobile-based adherence reminders. These sessions were delivered through verbal communication, supplemented with information leaflets and visual aids such as charts and pictorial diagrams if required. Furthermore, a copy of the educational package was provided to each participant in the interventional group for future reference.

Each counseling session was delivered for approximately 20–40 min. This time duration was set as a predefined counseling window, within which all the essential counseling components could be delivered to the participant as per their clinical and educational needs using the prespecified counseling module presented in Table 1. The minimum time-frame of approximately 20 min was sufficient to deliver the core counseling content to the patient, particularly for those who had adequate prior knowledge of their disease and self-management strat-

Table 1. Patients' Counseling Module Guide.

Steps	Domain	Key Message
1.	Initial assessment	Assess baseline knowledge, current self-care practices, medication use, adherence barriers, and individual blood glucose/BP targets. Tailor counseling while maintaining standardized core content.
2.	Understanding diabetes and hypertension	Explain disease classification, symptoms, asymptomatic disease progression, target ranges, and treatment goals.
3.	Risk factors and complications	Discuss modifiable and non-modifiable risk factors, and Inform about major complications involving the heart, brain, kidneys, eyes, nerves, feet, infections, and sexual health.
4.	Lifestyle modification and management	Reinforce healthy diet, DASH-based principles, salt and sugar reduction, physical activity, weight control, smoking cessation, alcohol limitation, sleep hygiene, and stress management.
5.	Understanding medication, medication safety, and adherence	Assess patients prescription and explain medicine's name, indication, dose, timing, route, adverse effects, storage, refill planning, and tailored adherence strategies. Demonstrate insulin pen administration technique where applicable.
6.	Self-monitoring and record keeping	Inform about home use glucometer/and blood pressure measurement devices, proper techniques of measurement and interpretation of readings, reinforce symptom tracking, and maintenance of glucose and blood pressure measurement logs.
7.	Recognition of emergency symptoms and response	Educate patients about symptoms of hypoglycemia, severe hyperglycemia, hypotension, hypertensive crisis, and emergency response toward the conditions including chest pain, breathlessness, confusion, fainting, visual changes, and neurological symptoms requiring urgent care.
8.	Preventive care and routine screening	Reinforce foot care, eye examination, kidney function monitoring, lipid monitoring, laboratory follow-up, and scheduled clinical review.
9.	Teach-back and patient goal setting	Ask patients to recall key messages, clear doubts, and set achievable self-management goal before leaving the session.
10.	Follow-up and continuity of care	Discuss timing of follow-up telephonic session, encourage appointment keeping, bringing monitoring logs to each visit, encourage shared decision-making, and ongoing communication with healthcare providers.

egies. The counseling sessions were extended up to 40 min for patients during baseline counseling or follow-up sessions in situations where additional counseling was required for the patients due to patients' medication regimen complexity, adherence-related barriers, and addressing patient-specific concerns, or scenarios requiring further clarification. In cases when more than two participants visited the study site on the same day, counseling was provided on an individual basis and in sequential order according to their appointment time or order of arrival. Participants had either waited until the preceding session was completed or were scheduled for a later time on the same day. To maintain consistency and minimize intervention-related variability, all the counseling sessions were delivered by the same clinical pharmacist (researcher) using a specified counseling guide and standardized educational materials. Standardization was carried out through the use of a prespecified counseling module and educational materials, which were content validated by a multidisciplinary team comprising physicians, a nurse, public health professionals, and pharmacists to ensure consistency, accuracy, and clinical relevance of the counseling content. Furthermore, all the counseling sessions were conducted following a patient-centered and respectful approach with consistent interpersonal support to the participants during the process in addressing patients' individual concerns and self-management challenges.

Data Collection Tools and Techniques

Data Collection Procedures

Data were collected at three time points, that is, during baseline, 3 months, and 6 months after enrollment. At each interval, basic demographic characteristics were recorded through structured patient interviews, and standardized questionnaires were administered to obtain patients' reported data. Relevant clinical data, including blood pressure readings, glycemic profiles, and lipid profile test results, were extracted from outpatient prescription cards and patients' laboratory reports, and recorded respectively in patients' profile forms.

Outcome Measures

The outcome measures included both clinical and patient-reported measures, collected at baseline, 3 months, and 6 months. Data were analyzed using mean ± SD for continuous variables and proportion for categorical variables. For continuous measures, within-group and between-group differences were compared between the intervention and control group, whereas for categorical outcomes, the proportion of patients achieving optimal or good outcomes was assessed in each study arm.

1. Clinical measures: The key clinical parameters were extracted from patients' prescription records and laboratory reports to objectively assess the intervention effects. These included:
   - Glycemic control: Assessed in terms of FBS level, PPBS levels (mm/dL), and HbA1c in percent. An HbA1c level < 7% was considered an optimal glycemic control category.
   - Blood pressure: Assessed in terms of SBP and DBP (mmHg), reading through prescription cards. Patients with SBP/DBP <140/90 mmHg were considered the optimal target threshold category.
   - Lipid profile: Assessed through fasting blood serum level of total cholesterol (TC), low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), and triglycerides (TG) levels measured in mg/dL.
   - BMI: Calculated from measured weight and height (kg/m^2).
2. Patients reported outcome measures
   a. Medication adherence

      Patient's medication adherence was measured using the Novel General Medication Adherence scale (GMAS), a tool originally developed by Naqvi et al. at Pakistan[25] and subsequently translated, adapted, and validated for use in the Nepalese context by Shrestha et al.[26] GMAS questionnaires consist of 11 items rated on a 4-point Likert scale (0–3), yielding a total score between 0 and 33. The tool comprises questionnaires divided into three domains, namely, patients' behavior-related non-adherence (PBNA) (5 items, score range 0–15), additional disease and pill burden related (ADPB) (4 items, score range 0–12), and cost-related non-adherence (CRNA; two items, score range 0–6), respectively. A patient with a total score ≥ 30 was classified as the "highly adherent" category. For analysis, both total and subscale scores were used in mean-based comparisons, while dichotomized categories were used in proportion-based analysis.

   b. HRQoL

      HRQoL was measured using the Nepali version of the European Quality of Life-5 Dimension-5 Levels (EQ-5D-5L) questionnaire, developed by the EuroQoL research foundation.[27] The EQ-5D-5L questionnaire assesses HRQoL in five dimensions, namely, mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five levels to describe the severity (1 = no problem to 5 = extreme problems/unable). This descriptive system allows classification up to 3,125 unique health states. Each participant's response was converted into a five-digit health state, which was translated into EQ-5D-5L index score using the India-specific value set (a standardized set of weights to the patient's responses across the five dimensions) developed by Jyani et al.[28]

This value set was selected due to the sociocultural similarities between India and Nepal and the absence of a standardized value set for Nepal. The health utility-based EQ-5D index score ranges from values less than 0 (indicating a health state worse than death) to 1 (representing "full health"). In this study, the calculated index score was used to evaluate the mean change within groups. Additionally, an index score ≥ 0.80 was applied as a threshold to categorize a patient as having "good" HRQoL for proportion-based analysis.

Follow-up and Monitoring

Participants were followed up to 6 months post-enrollment to assess the impact of the intervention. Throughout the trial period, Participants were notified about the respective follow-up visit dates through telephonic reminders. For participants in the intervention groups, additional telephonic reminders were provided every 6–8 weeks to reinforce the counseling session. Upon completion of all scheduled follow-up visits, participants were informed that their study participation had been completed and that no further study-specific follow-up was required. As part of the post-study procedure, participants in both groups were advised to continue disease management through routine outpatient follow-up with their treating physician and other healthcare providers at the hospital. Following study completion, participants continued to receive usual clinical care and medication-related services through standard hospital practice; however, no study-specific intervention, education, or counseling support was provided to the participants beyond the prespecified follow-up period. All data were securely stored in the lock cabinet to maintain confidentiality. The study was monitored by an independent data safety and monitoring board to ensure the safety and integrity of the trial.

Statistical Methods

The data was analyzed using IBM SPSS Statistics for Windows, version 26. The primary analysis was conducted following a per-protocol approach, including only participants who completed the study with complete baseline and follow-up outcome data. Participants lost to follow-up were not included in the outcome analysis. Reasons for loss to follow-up were documented and are presented in the participant flow diagram. Descriptive statistics such as mean, frequency, and percentage were used to summarize the data. The chi-squared test was performed to assess the statistical relations for categorical variables between groups. For continuous variables, the normality of data distribution was examined using the Shapiro–Wilk test and histogram. Bivariate and repeated measures analysis was conducted using appropriate statistical tests based on data distribution: paired sample *t*-test and Wilcoxon signed-ranked test for within-group comparison, and independent sample *t*-test or Mann–Whitney *U* test was used for between-group comparisons. The strengths of the intervention's effect across all outcome measures over 6 months were evaluated using the rank biserial correlation coefficient (r) derived from the formula $r = Z/\sqrt{N}$, where Z is the standardized test statistic, and N is the total sample size. Effect size was interpreted according to Cohen's guidelines as 0.1−<0.3 small, 0.3−0.5 moderate, >0.5 large effects, respectively. Additionally, the main effect of intervention on blood pressure and HbA1c value was also assessed by computing the partial eta square value derived from repeated-measure ANOVA, as these variables were normally distributed. $p < 0.05$ was considered statistically significant. In this study, pharmacist-related characteristics were not analyzed as predictors of outcomes because all intervention sessions were delivered by a single clinical pharmacist, which precludes between-provider comparisons. Furthermore, consultation duration was not investigated as an independent predictor because the intervention was delivered longitudinally across multiple in-person counseling sessions and telephonic follow-up contacts, and the counseling time was not prospectively recorded as a predefined standardized variable.

Ethical Consideration

The study proposal was reviewed and approved by the ethical review board of Nepal Health Research Council (Approval ref no: 1050, Proposal ID 382/2022 PhD). The study was registered in the US clinical trial registry (clinicaltrials.gov, Identifier number: NCT05707481). Written informed consent was obtained from all participants before enrollment. Participants were informed of their right to withdraw from the study at any time without affecting their standard care. Participants' rights to autonomy, confidentiality, and freedom from harm were assured.

Results

Participants Flow and Baseline Characteristics

A total of 157 patients were assessed for eligibility, of which 92 patients met the inclusion criteria and were randomized into the intervention group (n = 46) and the control group (n = 46). During the 6-month follow-up period, 20 participants (11 in the control group and 9 in the intervention group) were lost to follow-up, resulting in an overall attrition rate of 21.7%. Altogether, 72 participants (35 in the control and 37 in the intervention group) completed the 6-month follow-up study and were included for the final analysis. The consort flow diagram of the participants is provided in Figure 1.

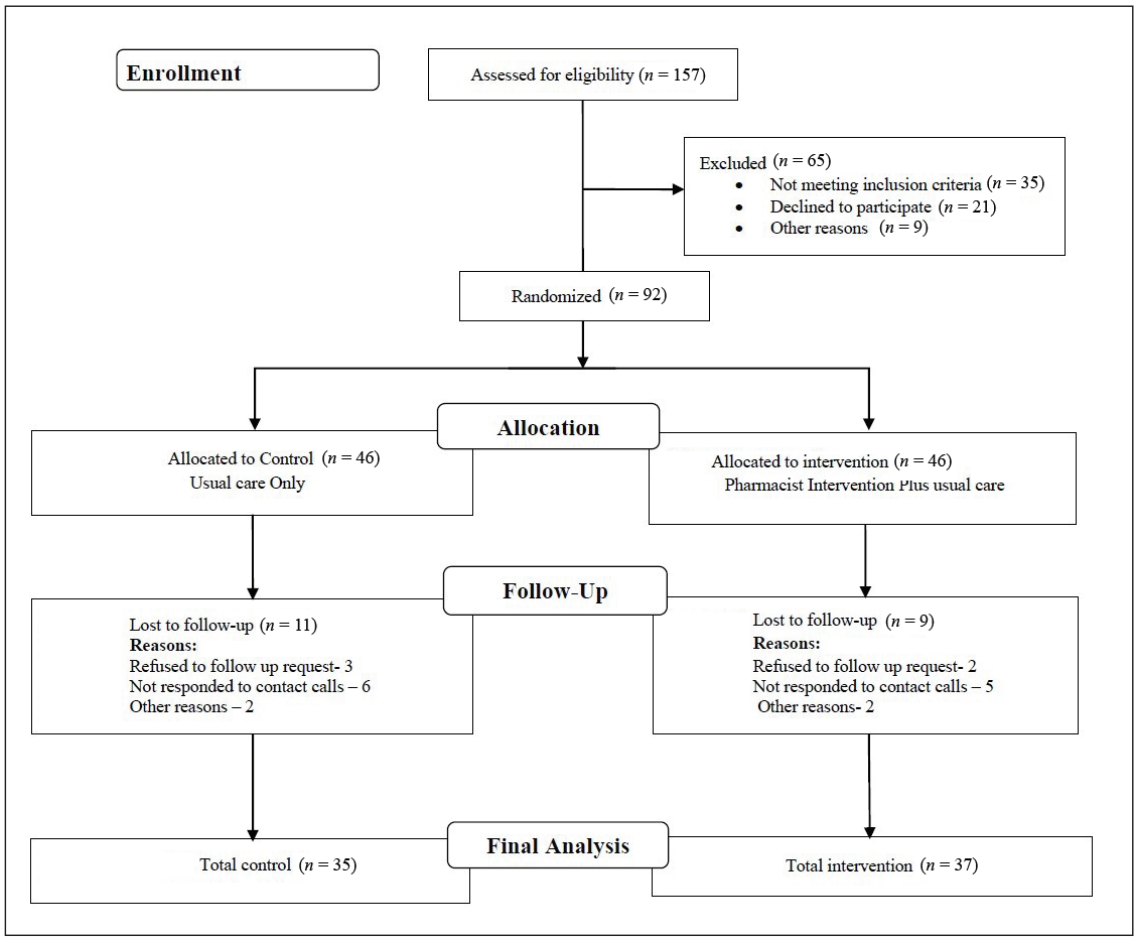

Figure 1. Consort Flow Diagram of Study Participants.

At baseline, the intervention and control groups were comparable across all sociodemographic, clinical, and patient-reported outcomes measures, with no statistically significant differences observed across measured variables ($p > 0.05$). Specifically, the groups demonstrated similar participant characteristics, including the mean age (control: 53.80 years, SD = 7.54; intervention: 53.65 years, SD = 7.05; $p = 0.995$) and the proportion of female participants (control: (42.9%); intervention (40.5%), $p = 0.842$). Similarly, there were no significant differences in education attainments, employment status, lifestyle behaviors (smoking and alcohol use), disease history, family history, or prescribed antidiabetic and antihypertensive medications between control and intervention groups at the baseline (Table 2).

Furthermore, participants' baseline clinical measures, such as glycemic profile (FBS, PPBS, HbA1c), blood pressure (SBP, DBP), BMI, lipid profile (TC, TG, LDL, HDL), also showed no significant differences between control and intervention groups. Likewise, medication adherence (GMAS scores) and HRQoL (EQ-5D-5L index score) were also comparable between the groups at baseline ($p > 0.05$) (Table 3).

Within-group Comparison of Outcomes Between Control and Intervention Groups (Baseline-follow-up)

The within-group changes in each outcome measure from baseline to follow-up are detailed separately in Table 4 for the control group and Table 5 for the intervention group. The findings revealed that the intervention group demonstrated significant improvements in glycemic control over the 6-month study period, with sustained reductions in post-prandial blood glucose (PPBS: mean difference [MD] = −52.11 mg/dL, $p < 0.001$ at 3 months; MD = −43.32 mg/dL, $p < 0.001$ at 6 months) and HbA1c (MD = −0.75%, $p = 0.005$ at 3 months; MD = −0.66%, $p = 0.021$ at 6 months) levels. Similarly, there was a significant reduction in SBP (MD = −7.08 mmHg, $p < 0.001$) and DBP (MD = −3.51 mmHg, $p = 0.005$) at 3 months, which further improved by 6 months (SBP: MD = −11.11 mmHg, $p < 0.001$; DBP: MD = −4.45 mmHg, $p = 0.002$). Additionally, the intervention group achieved notable declines in LDL cholesterol at 3 months (MD = −13.57 mg/dL, $p = 0.002$) and 6 months (MD = −11.05 mg/dL, $p = 0.006$), along with reduced TG (MD = −37.64 mg/dL, $p = 0.030$) at 6 months, with a modest decrease in BMI (MD = −0.29 kg/m², $p = 0.020$)

Table 2. Baseline Comparison of Sociodemographic Characteristics of Participants Included in the Final Analysis.

Participants Characteristic		Control Group *n* (%) *N* = 35	Intervention Group *n* (%) *N* = 37	*p* Value
Age (years)*	Mean ± SD	53.80 ± 7.54	53.65 ± 7.05	0.995
Gender	Male	20 (57.14)	22 (59.46)	
	Female	15 (42.86)	15 (40.54)	0.842
Education	Below secondary	16 (45.71)	14 (37.84)	
	Secondary and above	19 (54.29)	23 (62.16)	0.498
Employment status	Unemployed	18 (51.43)	15 (40.54)	
	Employed	17 (48.57)	22 (59.46)	0.354
Current smoking	Yes	10 (28.57)	10 (27.03)	
	No	25 (71.43)	27 (72.97)	0.884
Current alcoholic	Yes	10 (28.57)	5 (13.51)	
	No	25 (71.43)	32 (86.49)	0.116
DM history	1–3 years	5 (14.29)	6 (16.22)	
	3–5 years	8 (22.86)	11 (29.73)	0.433
	5–10 years	9 (25.71)	4 (10.81)	
	>10 years	13 (37.14)	16 (43.24)	
HTN history	1–3 years	15 (42.86)	13 (35.13)	
	3–5 years	6 (17.14)	10 (27.03)	0.331
	5–10 years	8 (22.86)	4 (10.81)	
	>10 years	6 (17.14)	10 (27.03)	
DM family history	Present	17 (48.57)	25 (67.57)	0.102
	Absent	18 (51.4)	12 (32.43)	
HTN family history	Present	17 (48.57)	24 (64.87)	
	Absent	18 (51.42)	13 (35.13)	0.163
Medication prescribed antidiabetic	Biguanides	33 (94.28)	35 (94.59)	0.954
	Sulphonylureas	21 (60)	17 (45.95)	0.611
	Dipeptidyl peptidase (DPP-4) inhibitor	10 (28.57)	12 (32.43)	0.722
	Others	10 (28.57)	10 (27.03)	0.884
Antihypertensive	Angiotensin receptor blocker	27 (77.14)	31 (83.78)	0.477
	Calcium channel blocker	16 (45.71)	19 (51.35)	0.632
	Others	9 (25.71)	5 (13.51)	0.191
Others	Antilipidemic drugs	18 (51.42)	14 (37.84)	0.246

Notes: *p* value calculated using Pearson chi-square test for categorical variables.
*Independent sample Mann–Whitney *U* test for continuous variables.

(Table 5). Whereas the control group exhibited a marginal reduction in HDL (MD = −3.72 mg/dL, $p = 0.025$) level at 6 months, with no significant changes in other clinical parameters at 3 months and 6 months follow-up period (Table 4).

Similarly, general medication adherence subscale scores among the intervention group were significantly improved across all domains, especially in the PBNA domain (MD = +1.24, $p < 0.001$), and the ADPB-related domain (MD = +0.59, $p = 0.012$), resulting in improved overall medication adherence scores (MD = +2.16, $p < 0.001$) (Table 5). In contrast, control group participants showed no statistically significant changes in PBNA or overall adherence scores, but exhibited ADPB-related adherence challenges, as reflected by a significant decline in ADPB domain scores at 6 months (MD = −0.58, $p = 0.006$) (Table 4). Item-level analysis revealed that improvements in participants medication taking behaviors were particularly evident among interventional group in specific PBNA and ADPB domain items, marked by improved patients' medication recalls ($p < 0.001$), fewer instances of discontinuing medication when feeling well ($p < 0.002$), avoiding self-cessation of medication without consultations ($p < 0.017$), and improved management of complex medication regimens ($p < 0.004$). Whereas, in the control group patients, there was a slight but significant decrease in the tendency to stop medication due to side effects (e.g., gastric discomfort). However, the tendency to miss doses following disease progression or the addition of new medicines was increased ($p = 0.005$) (Table 6).

In terms of HRQoL, intervention group showed weak but statistically significant improvements in the EQ-5D-5L index score at 3 months (MD = +0.047, $p = 0.002$) and 6 months (MD = +0.059, $p < 0.001$), indicating the intervention's beneficial effects on HRQoL (Table 5), While control group exhibited no any statistically significant improvements in HRQoL (EQ-5D-5L index score) (Table 4). These findings are further supported by the distribution of participants' responses to individual EQ-5D-5L items questionnaires, presented in Table 7. The proportion of participants reporting no problems in the intervention group increased notably from baseline to final follow-up in most domains, particularly in

Table 3. Baseline Comparison of Clinical Characteristics, Medication Adherence (GMAS), and Health-related Quality of Life (EQ-5D-5L) Index Scores of Participants Included in the Final Analysis.

Participants Characteristics		Control Group *n* (%) *N* = 35 Mean ± SD	Intervention Group *n* (%) *N* = 37 Mean ± SD	*p* Value
Glycemic profile	FBS (mg/dL)	128.23 ± 58.70	130.22 ± 38.80	0.316[a]
	PPBS (mg/dL)	217.69 ± 98.09	231.73 ± 80.04	0.274[a]
	A1C (%)	7.09 ± 1.71	7.39 ± 1.47	0.426[b]
Blood pressure (BP)	SBP (mmHg)	134.14 ± 15.08	136.46 ± 14.16	0.504[b]
	DBP (mmHg)	84.51 ± 9.68	86.86 ± 9.91	0.313[b]
Body mass index	BMI	26.05 ± 3.23	25.71 ± 3.16	0.659[b]
Lipid profile	TC (mg/dL)	169.71 ± 49.23	167.84 ± 44.54	0.866[b]
	TG (mg/dL)	229.63 ± 115.05	218.70 ± 120.36	0.454[a]
	HDL (mg/dL)	52.14 ± 12.51	53.02 ± 12.76	0.731[a]
	LDL (mg/dL)	102.05 ± 35.77	101.32 ± 32.26	0.826[a]
Medication adherence (GMAS score)	PBNA	13.08 ± 1.73	13.08 ± 1.55	0.693[a]
	ADPB	10.20 ± 1.27	10.16 ± 1.06	0.579[a]
	CRNA	5.54 ± 0.74	5.43 ± 0.76	0.453[a]
	Overall	28.82 ± 3.10	28.67 ± 2.67	0.566[a]
HRQoL	EQ-5D-5L index score	0.882 ± 0.15	0.880 ± 0.09	0.470[a]

Notes: SD: Standard deviation, BMI: Body mass index, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, FBS: Fasting blood sugar, PPBS: Post-prandial blood sugar, A1C, Glycated hemoglobin, GMAS: General medication adherence scale, PBNA: Patients' behavior-related non-adherence, ADPB: Additional disease and pill burden, CRNA: Cost-related non-adherence, HRQoL: Health-related quality of life, EQ-5D index score: Euro quality of life, EQ-5D-5L: European quality of life-5 dimension-5 levels.

p Value calculated using.

[a]independent-samples Mann–Whitney *U* test.

[b]independent-samples *t*-test.

$p < 0.05$ was considered statistically significant.

Table 4. Within-group Changes in Outcome Measures from Baseline to Follow-up in the Control Group.

		Control Group (*N* = 35)						
Outcomes		Baseline Mean ± SD	Follow-up at 3 Months Mean ± SD	Mean diff.	*p* Value	Follow-up at 6 Months Mean ± SD	Mean diff	*p* Value
Glycemic profile	FBS (mg/dL)	128.23 ± 58.70	124.49 ± 60.59	−3.74[a]	0.948[‡]	124.95 ± 29.80	−3.28[a]	0.363[a‡]
							0.46[b]	0.164[b‡]
	PPBS (mg/dL)	217.69 ± 98.09	202.17 ± 79.98	−15.52[a]	0.635[‡]	225.03 ± 74.88	7.34[a]	0.408[a‡]
							22.88[b]	0.087[b‡]
	A1C (%)	7.09 ± 1.71	7.03 ± 1.81	−0.06[a]	0.782[†]	7.41 ± 1.19	0.32[a]	0.193[a†]
							0.38[b]	0.146[b†]
Blood pressure	SBP (mmHg)	134.14 ± 15.08	132.80 ± 12.68	−1.34[a]	0.543[†]	131.77 ± 12.32	−2.37[a]	0.354[a†]
							−1.03[b]	0.640[b†]
	DBP (mmHg)	84.51 ± 9.68	84.94 ± 6.47	0.43[a]	0.755[†]	84.89 ± 7.44	0.38[a]	0.845[a†]
							−0.05[b]	0.965[b†]
Body mass index	BMI	26.05 ± 3.23	26.15 ± 3.23	0.10[a]	0.212[†]	26.17 ± 3.24	0.12[a]	0.236[a†]
							0.02[b]	0.813[b†]
Lipid profile	TC (mg/dL)	169.71 ± 49.23	172.49 ± 48.68	2.77[a]	0.745[†]	156.46 ± 41.90	−13.25[a]	0.083[a†]
							−16.03[b]	0.065[b†]
	TG (mg/dL)	229.63 ± 115.05	211.60 ± 99.07	−18.02[a]	0.298[†]	209.00 ± 102.7	−20.63[a]	0.309[a†]
							−2.60[b]	0.844[b†]
	HDL (mg/dL)	52.14 ± 12.51	51.14 ± 11.88	−1[a]	0.358[†]	48.42 ± 10.53	−3.72[a]	0.025[a†]
							−2.72[b]	0.031[b†]
	LDL (mg/dL)	102.05 ± 35.77	105.05 ± 42.95	3[a]	0.638[‡]	98.00 ± 33.04	−4.05[a]	0.669[a‡]
							−7.05[b]	0.270[b‡]

(Table 4 continued)

(Table 4 continued)

Outcomes		Control Group (*N* = 35)						
		Baseline Mean ± SD	Follow-up at 3 Months Mean ± SD	Mean diff.	*p* Value	Follow-up at 6 Months Mean ± SD	Mean diff	*p* Value
Medication adherence (GMAS)	PBNA	13.08 ± 1.73	13.05 ± 1.39	−0.03[a]	0.621[‡]	13.45 ± 1.54	0.37[a] 0.40[b]	0.197[a‡] 0.109[b‡]
	ADPB	10.20 ± 1.27	9.94 ± 1.13	−0.26[a]	0.266[‡]	9.62 ± 1.05	−0.58[a] −0.32[b]	0.006[a‡] 0.160[b‡]
	CRNA	5.54 ± 0.74	5.57 ± 0.81	0.03[a]	0.813[‡]	5.45 ± 0.78	−0.09[a] −0.12[b]	0.366[a‡] 0.475[b‡]
	Overall	28.82 ± 3.10	28.60 ± 2.69	−0.22[a]	0.567[†]	28.54 ± 2.88	−0.28[a] −0.06[b]	0.419[a†] 0.886[b†]
HRQoL	EQ-5D-5L index score	0.882 ± 0.15	0.895 ± 0.15	0.013[a]	0.236[‡]	0.894 ± 0.11	0.012[a] 0.001[b]	0.336[a‡] 0.676[b‡]

Notes: SD: Standard deviation, FBS: Fasting blood sugar, PPBS: Post-prandial blood sugar, A1C: Glycated hemoglobin, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, BMI: Body mass index, TC: Total cholesterol, TG: Triglycerides, LDL: Low-density lipoprotein cholesterol, HDL: High-density lipoprotein cholesterol (HDL), PBNA: Patients' behavior-related non-adherence, ADPB: Additional disease and pill burden, CRNA: Cost-related non-adherence, GMAS: General medication adherence scale, HRQoL: Health-related quality of life, EQ-5D index score: Euro quality of life utility-based index value.

[†]*p* value calculated by paired sample *t*-test.

[‡]*p* Value calculated using Wilcoxon signed rank test.

[a]Indicates as compared to baseline,.

[b]indicates as compared to 1st follow-up period at 3 months.

$p < 0.05$ represent statistically significant results.

Table 5. Within-group Changes in Outcome Measures from Baseline to Follow-up in the Intervention Group.

Outcomes Category		Intervention Group (*N* = 37)						
		Baseline Mean ± SD	Follow-up at 3 Months Mean ± SD	Mean Diff.	*p* Value	Follow-up at 6 Months Mean ± SD	Mean Diff.	*p* Value
Glycemic profile	FBS (mg/dL)	130.22 ± 38.80	120.14 ± 31.58	−10.08[a]	0.053[‡]	116.68 ± 26.13	−13.54[a] −3.46[b]	0.080[a‡] 0.757[b‡]
	PPBS (mg/dL)	231.73 ± 80.04	179.62 ± 47.82	−52.11[a]	<0.001[‡]	188.41 ± 55.25	−43.32[a] 8.79[b]	<0.001[a‡] 0.534[b‡]
	A1C (%)	7.39 ± 1.47	6.64 ± 1.12	−0.75[a]	0.005[†]	6.73 ± 0.89	−0.66[a] 0.09[b]	0.021[a†] 0.537[b†]
Blood pressure	SBP (mmHg)	136.46 ± 14.16	129.38 ± 9.59	−7.08[a]	<0.001[†]	125.35 ± 9.87	−11.11[a] −4.03[b]	<0.001[a†] 0.018[b†]
	DBP (mmHg)	86.86 ± 9.91	83.35 ± 7.22	−3.51[a]	0.005[†]	82.41 ± 6.53	−4.45[a] −0.94[b]	0.002[a†] 0.427[b†]
Body mass index	BMI	25.71 ± 3.16	25.51 ± 3.08	−0.23[a]	0.023[†]	25.42 ± 2.96	−0.29[a] −0.09[b]	0.020[a†] 0.256[b†]
Lipid profile	TC (mg/dL)	167.84 ± 44.54	161.24 ± 41.11	−6.6[a]	0.213[‡]	162.24 ± 41.75	−5.6[a] −1.0[b]	0.499[a‡] 0.875[†b]
	TG (mg/dL)	218.70 ± 120.36	202.46 ± 90.96	−16.24[a]	0.236[‡]	181.05 ± 96.89	−37.64[a] −21.40[b]	0.030[a‡] 0.253[†b]
	HDL (mg/dL)	53.02 ± 12.76	54.24 ± 10.21	1.22[a]	0.421[†]	56.23 ± 17.09	3.21[a] 1.99[b]	0.229[a†] 0.373[b†]
	LDL (mg/dL)	101.32 ± 32.26	87.75 ± 26.16	−13.57[a]	0.002[‡]	90.27 ± 24.34	−11.05[a] −2.52[b]	0.006[a‡] 0.160[b‡]
Medication adherence (GMAS)	PBNA	13.08 ± 1.55	14.08 ± 0.82	1[a]	<0.001[‡]	14.32 ± 0.88	1.24[a] 0.24[b]	<0.001[a‡] 0.137[b‡]
	ADPB	10.16 ± 1.06	10.70 ± 0.96	0.54[a]	0.025[‡]	10.75 ± 0.98	0.59[a] 0.05[b]	0.012[a‡] 0.741[b‡]

(Table 5 continued)

(Table 5 continued)

Outcomes Category		Intervention Group (*N* = 37)						
		Baseline Mean ± SD	Follow-up at 3 Months Mean ± SD	Mean Diff.	*p* Value	Follow-up at 6 Months Mean ± SD	Mean Diff.	*p* Value
	CRNA	5.43 ± 0.76	5.78 ± 0.41	0.35[a]	0.009‡	5.75 ± 0.59	0.32[a]	0.074[a]‡
							0.03[b]	0.776[b]‡
	Overall	28.67 ± 2.67	30.54 ± 1.62	1.87[a]	<0.001†	30.83 ± 1.70	2.16[a]	<0.001[a]†
							0.29[b]	0.289[b]†
HRQoL	EQ-5D-5L index score	0.880 ± 0.09	0.927 ± 0.12	0.047[a]	0.002‡	0.939 ± 0.06	0.059[a]	<0.001[a]‡
							0.012[b]	0.696[b]‡

Notes: SD: Standard deviation, FBS: Fasting blood sugar, PPBS: Post-prandial blood sugar, A1C: Glycated hemoglobin; SBP: Systolic blood pressure, DBP: Diastolic blood pressure, BMI: Body mass index, TC: Total cholesterol, TG: Triglycerides, LDL: Low-density lipoprotein cholesterol, HDL: High-density lipoprotein cholesterol (HDL), PBNA: Patients' behavior-related non-adherence, ADPB: Additional disease and pill burden, CRNA: Cost-related non-adherence, GMAS: General medication adherence scale, HRQoL: Health-related quality of life, EQ-5D-5L index score: European quality of life-5 dimension-5 levels based-index value.

†*p* Value calculated by paired sample *t*-test. ‡*p* Value calculated using the Wilcoxon signed rank test.

$p < 0.05$ represents statistically significant results.

[a]indicates as compared to baseline.

[b]indicates as compared to follow-up period at 3 months.

$p < 0.05$ represents statistically significant results.

Table 6. Comparison of Baseline and Follow-up Mean Scores for Individual General Medication Adherence Scale (GMAS) Items in the Intervention and Control Groups.

Construct	GMAS Measuring Item Description	Group	Baseline	Follow-Up 1 At 3 Months	Follow-Up 2 At 6 Months	*p* Value
PBNA	Do you have difficulty remembering to take your medications?	Intervention	2.46 ± 0.50	2.70 ± 0.46	2.92 ± 0.27	<0.001
		Control	2.57 ± 0.73	2.54 ± 0.65	2.63 ± 0.54	0.689
	Do you forget to take your medication due to your busy schedule, traveling, meetings, events at home, parties, marriage, religious celebrations, etc.?	Intervention	2.38 ± 0.54	2.57 ± 0.50	2.59 ± 0.49	0.131
		Control	2.49 ± 0.65	2.40 ± 0.54	2.37 ± 0.55	0.368
	Do you discontinue your medication when you feel well?	Intervention	2.73 ± 0.50	3 ± 0.0	2.95 ± 0.22	0.002
		Control	2.80 ± 0.40	2.86 ± 0.43	2.89 ± 0.32	0.572
	Do you stop taking medications when you feel adverse effects such as gastric discomfort, etc.?	Intervention	2.78 ± 0.41	2.89 ± 0.31	2.95 ± 0.23	0.078
		Control	2.40 ± 0.77	2.46 ± 0.56	2.74 ± 0.50	0.005
	Do you stop taking medications without informing the doctor?	Intervention	2.73 ± 0.74	2.92 ± 0.27	2.92 ± 0.28	0.017
		Control	2.83 ± 0.38	2.83 ± 0.38	2.83 ± 0.45	0.999
ADPB	Do you discontinue your medicines due to other medicines that you have to take for your additional disease?	Intervention	2.78 ± 0.47	2.86 ± 0.34	2.92 ± 0.27	0.178
		Control	2.80 ± 0.47	2.73 ± 0.44	2.83 ± 0.45	0.510
	Do you find it is a hassle to remember your medications due to medication regime complexity?	Intervention	2.14 ± 0.53	2.49 ± 0.50	2.35 ± 0.48	0.004
		Control	2.34 ± 0.59	2.37 ± 0.54	2.17 ± 0.51	0.102
	During the last month, had there been any occasion when you missed your medicines due to progression of disease and addition of new medicines?	Intervention	2.62 ± 0.49	2.68 ± 0.47	2.68 ± 0.47	0.819
		Control	2.49 ± 0.50	2.49 ± 0.50	2.46 ± 0.50	0.005
	Do you alter medication regimen, dose and frequency by yourself?	Intervention	2.62 ± 0.49	2.68 ± 0.47	2.81 ± 0.39	0.183
		Control	2.83 ± 0.38	2.89 ± 0.32	2.83 ± 0.38	0.961

(Table 6 continued)

(Table 6 continued)

Construct	GMAS Measuring Item Description	Group	Baseline	Follow-Up 1 At 3 Months	Follow-Up 2 At 6 Months	*p* Value
CRNA	Do you discontinue these medications because they are not worth of the money you spent on them?	Intervention	2.81 ± 0.46	2.95 ± 0.22	2.95 ± 0.23	0.113
		Control	2.83 ± 0.38	2.89 ± 0.32	2.83 ± 0.38	0.641
	Do you find it difficult to buy your medicines because they are expensive?	Intervention	2.62 ± 0.83	2.84 ± 0.83	2.81 ± 0.83	0.058
		Control	2.71 ± 0.57	2.69 ± 0.63	2.63 ± 0.59	0.662
Overall GMAS mean score		Intervention	28.67 ± 2.67	30.54 ± 1.62	30.83 ± 1.70	<0.001
		Control	28.82 ± 3.10	28.60 ± 2.69	28.54 ± 2.88	0.449

Notes: PBNA: Patients' behavior-related non-adherence, ADPB: Additional disease and pill burden, CRNA: Cost-related non-adherence, GMAS: General medication adherence scale.

p value calculated using the Friedman test for repeated measures ANOVA.

$p < 0.05$ indicates statistically significant.

Table 7. Participants' Response to EQ-5D-5L Questionnaire Items from Baseline to Follow-up in the Control and Intervention Groups.

	Response *n* (%)					
	Control Group (*N* = 35)			Intervention Group (*N* = 37)		
EQ-5D-5L Items	Baseline	Follow-up at 3 Months	Follow-up at 6 Months	Baseline	Follow-up at 3 Months	Follow-up at 6 Months
Mobility						
No problem	24 (68.5)	27 (77.1)	28 (80)	21 (56.8)	31 (83.8)	31 (83.8)
Slight problem	9 (25.7)	6 (17.1)	3 (8.6)	14 (37.8)	5 (13.5)	6 (16.2)
Moderate problem	1 (2.9)	1 (2.9)	4 (11.4)	2 (5.4)	1 (2.7)	0(0)
Severe problem	1 (2.9)	1 (2.9)	0 (0)	0 (0)	0 (0)	0 (0)
Extreme problem	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Self-care						
No problem	30 (85.7)	32 (91.4)	31 (88.5)	31 (83.8)	35 (94.6)	36 (97.3)
Slight problem	1 (2.9)	3 (8.6)	3 (8.6)	6 (16.2)	1 (2.7)	1 (2.7)
Moderate problem	4 (11.4)	0 (0)	1 (2.9)	0 (0)	1 (2.7)	0 (0)
Severe problem	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Extreme problem	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Usual Activity						
No problem	26 (74.2)	25 (71.4)	25 (71.4)	21 (56.8)	32 (86.5)	29 (78.4)
Slight problem	7 (20)	9 (25.7)	8 (22.9)	15 (40.5)	4 (10.8)	8 (21.6)
Moderate problem	1 (2.9)	1 (2.9)	2 (5.7)	1 (2.7)	1 (2.7)	0 (0)
Severe problem	1 (2.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Extreme problem	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pain/Discomfort						
No problem	15 (42.9)	15 (42.9)	11 (31.4)	11 (29.7)	15 (40.5)	19 (51.4)
Slight problem	14 (40)	16 (45.7)	18 (51.5)	19 (51.4)	21 (56.8)	17 (45.9)
Moderate problem	6 (17.1)	4 (11.4)	6 (17.1)	7 (18.9)	1 (2.7)	1 (2.7)
Severe problem	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Extreme problem	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Anxiety/Depression						
No problem	16 (45.7)	13 (37.1)	10 (28.6)	14 (37.8)	22 (59.5)	16 (43.3)
Slight problem	12 (34.3)	16 (45.7)	20 (57.1)	18 (48.6)	12 (32.4)	17 (45.9)
Moderate problem	7 (20)	6 (17.1)	5 (14.3)	5 (13.5)	2 (5.4)	4 (10.8)
Severe problem	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.7)	0 (0)
Extreme problem	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

mobility (56.8%–83.8%), usual activities (56.8%–78.4%), pain/discomfort (29.7%–51.4%), and anxiety/depression (37.8%–43.3%). In contrast, patients in the control group showed minimal improvement for mobility and self-care, while there was an increased frequency of patients reporting at least "some problems," particularly in the domains of pain/discomfort and anxiety/depression over time.

Between-group Comparison of Difference in Outcomes Among Control and Intervention Groups (Baseline-follow-up)

At 6 months follow-up period, the intervention group achieved superior reduction in outcomes with higher median (q1, q3) difference as compared from baseline, with moderate effect sizes for PPBS (−33 (−86, −3) vs. 14 (−43, 58), $p = 0.003$, $r = 0.34$), HbA1c (−0.7 (−1.8, 0.4) vs. 0.4 (−0.2, 1.1), $p = 0.007$, $r = 0.32$), SBP (−10 (−16.5, −4) vs. −5 (−10, 5), $p = 0.007$, $r = 0.32$). Repeated measures ANOVA confirmed significant time-by-group interactions for HbA1c ($F = 4.755$, $p = 0.010$, $\eta p^2 = 0.064$), SBP ($F = 4.668$, $p = 0.011$, $\eta p^2 = 0.063$), and DBP ($F = 3.451$, $p = 0.034$, $\eta p^2 = 0.047$), indicating sustained intervention effects over time among intervention groups. Similarly, statistically significant improvements ($p < 0.05$) across all domains of medication adherence within the intervention group were observed, with moderate effect sizes ($r \approx 0.3–0.5$). while health utility-based index scores showed only a marginal increase in the intervention group (median [Q1, Q3] = 0.067 [−0.005, 0.13]), with a small but statistically significant intervention effect ($p = 0.026$, $r = 0.26$) (Table 8).

Proportion of Patients Achieving Optimal Outcomes Between Groups (Baseline End of Trial)

Table 9 shows the proportion of patients achieving optimal outcome levels during baseline and at the end of the trial between control and intervention groups. While there were no statistically significant differences between patients' proportions during baseline, a significantly higher proportion

Table 8. Between-groups Comparison of Change in Outcome Measures Among Control and Intervention Groups Compared to Baseline.

		After 3 Months			After 6 Months			
		Control (*N* = 35)	Intervention (*N* = 37)		Control (*N* = 35)	Intervention (*N* = 37)		
Outcomes Category		Median (q1, q3) Change	Median (q1, q3) Change	*p* Value	Median (q1, q3) Change	Median (q1, q3) Change	*p* Value	Effect Size (*r*)
Glycemic profile	FBS (mg/dL)	2 (−20, 14)	−10 (−23.5,9)	0.215	4 (− 8, 20)	−12 (−46.5, 16.5)	0.073	0.21
	PPBS (mg/dL)	−8 (−49, 43)	−25 (− 122,1)	0.047	14 (−43, 58)	−33 (−86, −3)	0.003	0.34
	HbA1c (%)	0 (− 1.2, 0.7)	−1 (−1.6, 0.2)	0.049	0.4 (−0.2, 1.1)	−0.7 (−1.8, 0.4)	0.007	0.32
Blood pressure	SBP (mmHg)	0 (−10, 9)	−5 (−12.5, 0.5)	0.052	−5 (−10, 5)	−10 (−16.5, −4)	0.007	0.32
	DBP (mmHg)	0 (−5, 5)	−4 (−8.5, 0)	0.015	0 (−7, 7)	−5 (−10.5, 1)	0.044	0.24
Body mass index	BMI	0 (− 0.44, 0.17)	−0.36 (−0.44, 0.14)	0.004	0 (−0.53, 0.36)	−0.35 (−0.79, 0.30)	0.009	0.30
Lipid profile	TC (mg/dL)	2 (−26, 33)	−8 (−26.5, 10)	0.389	−15 (−43, 15)	−5 (−19, 21.5)	0.265	0.13
	TG (mg/dL)	−5 (−69, 49)	−11 (−41, 24)	0.866	−7 (−72, 44)	−20 (−91, 12)	0.461	0.08
	HDL (mg/dL)	−1 (−5, 4)	−1 (−5, 6.5)	0.276	−4 (−8, 2)	3 (−7.5, 12.5)	0.071	0.21
	LDL (mg/dL)	0 (−18, 23)	−11 (−28.5, 2)	0.027	−5 (−13, 18)	−7 (−15, 2.5)	0.279	0.12
Medication adherence (GMAS)	PBNA	0 (−1, 0)	1 (0, 2)	<0.001	0 (−1, 1)	1 (0, 2)	0.016	0.28
	ADPB	0 (−1, 1)	0 (0, 1)	0.022	0 (−2, 0)	0 (0, 1)	0.001	0.38
	CRNA	0 (0, 0)	0 (0, 1)	0.074	0 (0 ,0)	0 (0,1)	0.012	0.29
	Overall	1 (−1, 1)	2 (0,4)	<0.001	0 (−2, 1)	2 (0, 4)	<0.001	0.43
HRQoL	EQ-5D-5L index score	0 (−0.017, 0.046)	0 (−0.048, 0.062)	0.048	0.049 (0, 0.109)	0.067 (−0.005, 0.13)	0.026	0.26

Notes: FBS: Fasting blood Sugar, PPBS: Post-prandial blood sugar, A1C: Glycated hemoglobin; SBP: Systolic blood pressure, DBP: Diastolic blood pressure, BMI: Body mass index, TC: Total cholesterol, TG: Triglycerides, LDL: Low-density lipoprotein cholesterol, HDL: High-density lipoprotein cholesterol (HDL), PBNA: Patients' behavior-related non-adherence, ADPB: Additional disease and pill burden, CRNA: Cost-related non-adherence, GMAS: General medication adherence scale, HRQoL: Health-related quality of life, EQ-5D-5L index score: European quality of life-5 dimension-5 levels based-index value.

p value calculated by the independent-samples Mann–Whitney *U* test.

p <0.05 represents statistically significant results.

Rank biserial correlation coefficient effect size *r* value interpretation: 0.1 to <0.3 indicates a small effect.

r value 0.3−0.5 indicates a moderate effect.

r > 0.5 indicates a large effect.

Table 9. Proportion of Patients with Optimal Outcomes Level During Baseline and End of Trial.

Outcomes	Groups	Baseline *n* (%)	*p* Value	End of Trial *n* (%)	OR (95% CI)	*p* Value
HbA1c (<7%)	Control (*N* = 35)	18 (51.4)	0.814	12 (34.3)	3.99 (1.49–10.64)	0.005
	Intervention (*N* = 37)	18 (48.6)		25 (67.6)		
Blood pressure (<140/90)	Control (*N* = 35)	18 (51.4)	0.824	19 (54.3)	4.35 (1.45–13.05)	0.007
	Intervention (*N* = 37)	20 (54.1)		31 (83.8)		
High medication adherence (GMAS score ≥30)	Control (*N* = 35)	17 (48.6)	0.493	13 (37.1)	8.74 (2.88–26.55)	<0.001
	Intervention (*N* = 37)	15 (40.5)		31 (83.8)		
High HRQoL (EQ- 5D-5L index score ≥ 0.80)	Control (*N* = 35)	29 (82.9)	0.313	30 (85.7)	2.91 (0.53–16.13)	0.254
	Intervention (*N* = 37)	27 (72.9)		35 (94.6)		

Notes: HbA1c: Glycated hemoglobin, GMAS: General medication adherence score, HRQoL: Health-related quality of life, EQ-5D-5L index score: European quality of life-5 dimension-5 levels index value.
p value calculated using the Pearson chi-square test or Fisher's exact test.

of intervention group patients achieved optimal glycemic targets (HbA1c <7%: 67.6% vs. 34.3%; $p = 0.005$) and blood pressure control (83.8% vs. 54.3%; $p = 0.007$) compared to the usual care group, after 6 months. Similarly, a high adherence level (GMAS score ≥ 30) was attained by a significantly higher proportion of the patients in the intervention group (83.8%) than the control group, which was statistically significant. However, group differences in those achieving a higher HRQoL health utility score (≥0.80) were non-significant between control and intervention groups ($p = 0.254$), likely due to high baseline ceiling effects among the control group.

Discussion

This study revealed that the pharmacist-led educational intervention could have a substantial influence on improving clinical, behavioral, and HRQoL outcomes in patients with comorbid diabetes and hypertension. Our findings contribute to the growing body of literature supporting the expanded role of pharmacists in chronic disease management, particularly for patients with cardiometabolic conditions.

The baseline comparability between groups across all measures of demographic and clinical characteristics ($p > 0.05$) shows a balanced distribution of the participants between control and intervention groups, strengthening internal validity, while real-world follow-up settings enhanced external validity of our study.[29] In our study, there is a noticeable decrease in PPBS alongside reductions in HbA1c, with 67.6% participants achieving optimal glycemic control (HbA1c < 7%) in the intervention group. These findings were not only statistically significant but also clinically meaningful, as previous studies have revealed that even modest reductions in HbA1c could significantly decrease diabetes-related complications.[30] Similar to our findings, studies in Jordan, Nigeria, and Brazil have reported a decrease in HbA1c level by 0.8%–0.6% in the intervention group with a mean increase in HbA1c ranging from 0.1% to 0.7% from baseline in usual care groups.[31–33] Numerous studies have shown that pharmacist intervention on Type 2 diabetes could lead to a significant reduction of HbA1c, with differences in change of outcomes ranging between −0.18% and −2.1%.[34] However, the HbA1c reduction in our study was lower than that conducted in Malaysia (−1.19%),[22] England (−1.6%),[24] and Pakistan (−0.91%).[35] This might be attributed to the small baseline HbA1c value among study groups in our study. Similarly, blood pressure was significantly reduced among the intervention group compared to usual care, which aligns with the findings reported in the meta-analysis by Alshehri et al.[36] The current guidelines recommend an optimal target of SBP/DBP less than 140/90 to reduce the cardio-cerebrovascular complications associated with diabetes.[37] In our study, optimal target blood pressure was achieved by a high proportion of patients in the intervention group compared to the control group (83.8% vs. 54.3%). Pousinho et al. in their systematic review and meta-analysis, reported that pharmacist intervention among diabetes patients shows greater improvements of blood pressure with between-group difference of −3.3 to −23.5 mmHg in systolic and −0.21 to −9.1 mmHg in DBP.[34] The reduction of blood pressure in diabetic patients is particularly important as the study has demonstrated that even modest reductions of 5–10 mmHg in SBP can reduce cardiovascular risk by 10%–20%.[38,39] The between-group analyses depicted small to moderate effect sizes ($r = 0.24–0.34$) for key outcomes, with a significantly higher proportion of patients achieving treatment targets in the intervention group. These findings support the critical role of clinical pharmacists in diabetes management, which was comparable to other effective behavioral interventions studies.[34,40] Furthermore, the intervention group participants were associated with a reduction of BMI (−0.29 kg/m²) in our study, which was in line with a study conducted by Degeeter et al.[41] However, the study conducted

by the Look AHEAD research group revealed that the intensive lifestyle interventions, such as physical activity and calorie restriction, could potentially result in greater weight management effects as compared to those receiving diabetes support and education alone.[42] The reductions in LDL and TG levels observed within the intervention group suggest that the intervention may have contributed to improvements in multiple cardiovascular risk factors simultaneously. These findings were in line with findings of some similar previous trials.[22,34,43] In contrast, the control group patients exhibited a decline in HDL levels at 6 months compared to baseline. Studies have shown that diabetes tends to have a detrimental effect on HDL levels.[44] However, the study has revealed that adherence to healthy lifestyle-related factors is associated with improved cardiometabolic risk markers in people with diabetes.[45] In our study, although the control group patients received routine care, they may have experienced limited reinforcement regarding lifestyle modifications, diet management, physical activity, and a disease-specific self-management guide, which may have limited participant adoption of healthy lifestyle behaviors that may have contributed to this finding. The lipid reduction is particularly important given the fact that elevated lipid levels pose a high cardiovascular risk in diabetic-hypertensive patients.[46] These effects on glycemic management, blood pressure control, and other clinical outcomes may be attributed to our tailored education and counseling addressing both behavioral and clinical aspects of disease management, leading to collaborative goal settings for adoption of a healthy lifestyle and improved adherence behavior, which may have resulted in improved glycemic and blood pressure control in patients among intervention groups. These findings are consistent with the recommendations of the American Diabetes Association (ADA) Standards of Care in Diabetes and the opinion statement of the Ambulatory Care Practice and Research Network of the American College of Clinical Pharmacy, which emphasize the importance of diabetes self-management education, lifestyle and behavioral interventions, and the integral role of clinical pharmacists within collaborative, team-based care models in optimizing patient outcomes.[47,48]

Literature has shown that pharmacist collaborative care could better support patients to take their medication as prescribed and comply with diabetes and cardiovascular guidelines, leading to improved clinical outcomes.[48,49] In our study, improvements in patients' medication management behaviors were observed across all domains in the intervention group over the follow-up period, with 83.8% of patients taking their medication consistently and appropriately by the end of the trial. The results concides with findings from similar trials conducted in Ethiopia and Pakistan, where 61%–95% of patients in the intervention group achieved the respective studies criteria for good or high medication adherence levels following pharmacist intervention.[50,51] This suggests that our intervention may have supported patients in following their treatment plans by addressing specific challenges and barriers faced by the patients through patient-tailored interventions.[52,53] Consistent with our study findings, numerous previous trials have demonstrated that pharmacist intervention supports people with diabetes in managing their medication regimen more effectively.[22,54,55] Taking medication as directed is imperative in managing diabetes, as patients' failure to keep up with their medication schedule has been linked to unfavorable clinical outcomes, including suboptimal glycemic control and increased risk of complications.[15]

Similarly, the increase in the HRQoL EQ-5D index score was modest (EQ-5D-5L: +0.04) but statistically significant, suggesting a small improvement in HRQoL among intervention groups within the short study duration. These findings are consistent with findings of previous trials.[20,51,54,56] This may be attributed to optimized medication use alongside improved clinical outcomes, which could have positively influenced patients' subjective well-being and quality of life. The difference in the proportion of patients attaining a high HRQoL level at the end of the study was not statistically significant between the intervention and control groups (94.6% vs. 85.7%), possibly due to a baseline ceiling effect among the control group, which is consistent with findings in a previous study.[22,57]

Strengths and Limitations

In Nepal, to our knowledge, this is the first experimental trial to evaluate the impact of pharmacist-led educational interventions on clinical outcomes in patients with diabetes and comorbid hypertension. The findings provide significant evidence to support the integration of clinical pharmacists into multidisciplinary healthcare teams for improving chronic disease management by means of patient-centered pharmaceutical care services. However, the study has several limitations. First, the single-center study design and inclusion of participants aged up to 68 years may limit the generalizability of the findings, particularly to older patients with diabetes and hypertension. Second, the use of self-reported adherence and HRQoL measures may be subjected to participants' recall and social desirability bias. Third, the final analyzed sample was smaller than the initially analyzed per-group sample size due to participant attrition during follow-up, and the per-protocol analysis approach, which included only participants with complete follow-up data, may have introduced attrition bias and reduced the statistical power of the study; therefore, findings should be interpreted cautiously. Fourth, although participants were not informed of group allocation or the comparative study hypothesis, the nature of the pharmacist-led counseling intervention may have allowed participants to infer allocation prediction. In addition, neither the intervention pharmacist nor the outcome assessors were blinded; thus, the pragmatic open-label nature of the trial may have introduced expectation, performance, or assessment bias,

particularly for patient-reported outcomes. Fifth, although efforts were made to ensure a consistent counseling approach, empathy during the pharmacist-led counseling was not formally assessed using a validated scale, and the study could not objectively confirm uniformity in the level of empathy expressed across participants. Similarly, the multicomponent nature of the intervention precluded assessment of the independent effects of individual counseling components on outcomes. In addition, all intervention sessions were delivered by a single clinical pharmacist, thereby preventing assessment of provider-related effects on outcomes, which may limit study generalizability. Similarly, consultation duration was not prospectively recorded in a standardized manner across repeated in-person counseling sessions and telephonic follow-up contacts. Therefore, the potential intervention–response effect of counseling time on outcomes could not be assessed. Likewise, the study did not introduce post-study educational or counseling support to the control group participants after completion of follow-up. Finally, the 6-month follow-up period may not be adequate to determine the long-term sustainability of the observed effect. Future studies should include multicenter designs with larger samples, age-appropriate assessments for geriatric populations, and consider post-study educational support to provide equitable access to self-management information and reinforce disease-related care for all the participants in the study.

Conclusion

The study suggests that clinical pharmacist-led educational intervention may improve glycemic control, blood pressure management, medication adherence, and HRQoL in patients with comorbid diabetes and hypertension. Pharmacist intervention by means of pharmaceutical care, structured education, and patient counseling focused on multiple components such as disease awareness, medication management, lifestyle modification, self-monitoring, and tailored adherence strategies may have supported diabetes care and improved treatment outcomes among the interventional group participants than those receiving usual care, in the hospital outpatient settings. Consequently, the study recommends that integrating clinical pharmacists into outpatient diabetes care teams may be a promising strategy to support optimized care, improve health outcomes, and well-being for patients with diabetes and hypertension.

Recommendation for Policy and Implication for Practice

The study recommends that healthcare institutions and policymakers should formally integrate clinical pharmacists as essential members of multidisciplinary diabetes care teams in all clinical settings through collaborative practice agreements. Those agreements should empower pharmacists to optimize patients' medication regimen, address adherence barriers, and deliver patient-centered education and counseling support. Clinicians are encouraged to move beyond siloed care and are encouraged to adopt proactive, team-based care models that leverage pharmacists, nurses, and other diabetic care practitioners' expertise for collaborative care to meet the complex therapeutic and self-management needs of individuals with diabetes. Furthermore, the study highlights the need for co-management frameworks within the collaborative care models, emphasizing the development of standardized referral pathways to efficiently identify high-risk patients who would benefit most from pharmacist-led intervention.

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Authors' Contribution

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agreed to be accountable for all aspects of the work. All the authors are eligible to be an author as per the International Committee of Medical Journal Editors (ICMJE) requirements/guidelines.

Consent to Participate

All participants provided written informed consent prior to the enrollment in the study.

Consent for Publication

Not applicable.

Data Availability Statement

The data underlying this article will be shared upon reasonable request to the corresponding author.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval

The study proposal was reviewed and approved by the ethical review board of Nepal Health Research Council (Approval

ref no: 1050, Proposal ID 382/2022 PhD). The study was registered in the US clinical trial registry (clinicaltrials.gov, Identifier number: NCT05707481).

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Informed Consent

Written informed consent was obtained from all participants before enrollment. Participants were informed of their right to withdraw from the study at any time without affecting their standard care. Participants' rights to autonomy, confidentiality, and freedom from harm were assured.

Use of Artificial Intelligence-assisted Tools

AI-assisted language support tools were used solely to improve language clarity and correct grammar. No AI tools were used for data generation, data analysis, interpretation, scientific content development, or image manipulation. All authors critically reviewed and revised the manuscript to ensure its accuracy, integrity, and scientific rigor of its content.

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