Peer Reviewed | Open access
Greenresearch © 2026 Issue II Vol.4
International Journal of Pharmacy Practice, Pharmacology and Pharmaceutical Sciences (IJPPPS)

Evaluating the Safety and Efficacy of Herbal–Drug Combinations in Chronic Disease Management

Greenresearch Nigeria

A contributory publication research for Greenresearch Digital Publishing
In affiliation with TES Digital Service Limited for the promotion of African Education under the International Journal of Pharmacy Practice, Pharmacology and Pharmaceutical Sciences (IJPPPS)
Email: Greenresearchng@gmail.com
Phone: +234901 - 951 - 6714

Received: 02.02.2026 | Revised: 28.02.2026 | Accepted: 10.05.2026

Abstract

This study reportedly evaluated the safety and efficacy of herbal–drug combinations in chronic disease management within a low resource healthcare setting. A quantitative comparative design was reportedly used involving 240 patients diagnosed with hypertension, diabetes mellitus, or arthritis, divided equally between herbal–drug combination users and pharmaceutical only users. Clinical efficacy was reportedly assessed using systolic blood pressure, fasting blood glucose, and standardized pain scores, while safety was evaluated based on adverse event incidence. The findings reportedly showed that herbal–drug combinations produced significantly greater clinical improvements, including a 15.0% reduction in systolic blood pressure compared to 9.8% in the drug only group, a 22.8% reduction in blood glucose compared to 14.5%, and a 46.2% reduction in arthritis pain compared to 28.9%. However, adverse events were significantly higher among herbal–drug users, with overall incidence of 60.8% compared to 31.7% in pharmaceutical only users. These findings reportedly indicated that herbal–drug combinations provided enhanced therapeutic efficacy but also increased safety risks. The study reportedly concluded that while herbal–drug combinations could improve clinical outcomes, their use required proper clinical monitoring, patient education, and regulatory oversight to ensure safe and effective integration into chronic disease management.

Keywords: Herbal Medicine, Drug Interactions, Chronic Disease, Therapeutic Safety

Introduction

It was reported that the use of herbal remedies in combination with conventional pharmaceutical treatments had become increasingly common among patients with

chronic diseases in Nigeria and other low-resource healthcare settings. Scholars such as Osemene and Lamikanra (2012) reportedly observed that up to 70% of patients with conditions such as hypertension, diabetes mellitus, and arthritis used at least one herbal preparation concurrently with prescribed medications. This practice was reportedly driven by cultural beliefs, perceived efficacy, affordability, and accessibility of herbal products, and sometimes by dissatisfaction with conventional treatments. The increasing prevalence of herbal–drug combination therapy had reportedly raised critical questions regarding both safety and efficacy, particularly given the potential for pharmacokinetic and pharmacodynamic interactions, adverse effects, and variable quality of herbal preparations.

The central goal of this study was reportedly articulated as evaluating the safety profile and therapeutic efficacy of herbal–drug combinations in the management of chronic diseases, with a focus on quantifying clinical outcomes, identifying adverse interactions, and assessing prescriber and patient awareness of potential risks. The theoretical framework reportedly drew upon two complementary models: the Integrative Health Behavior Model (IHBM), which contextualized patient decision-making in relation to health beliefs, perceived benefits, and cultural practices, and the Risk–Benefit Analysis Framework (RBAF), which helped interpret clinical outcomes in the context of potential therapeutic advantages versus adverse effects (Glasgow et al., 2000; Greenhalgh, 2014). Reportedly, the IHBM provided insights into why patients chose herbal–drug combinations, while the RBAF facilitated assessment of clinical efficacy and safety trade-offs.

It was reported that studies conducted in Nigerian communities highlighted both opportunities and risks associated with herbal–drug use. For example, Osemene and Lamikanra (2012) reportedly noted that commonly used herbs, such as *Garcinia kola*, *Moringa oleifera*, and *Vernonia amygdalina*, were often combined with antihypertensive agents, oral hypoglycemics, and anti-inflammatory drugs. While some studies indicated potential additive or synergistic effects, others reported increased incidence of adverse events, including hepatotoxicity, nephrotoxicity, and unpredictable changes in drug plasma levels. This reportedly emphasized the need for systematic evaluation of safety and efficacy, particularly in settings where pharmacovigilance infrastructure was limited.

Reportedly, the challenge of monitoring herbal–drug interactions was compounded by variability in herbal product composition, lack of standardization, and limited documentation of dosage. Patients reportedly often did not disclose herbal use to healthcare providers, creating further risk. Scholars such as Ekor (2014) reportedly argued that unmonitored herbal–drug combinations could undermine treatment outcomes, exacerbate chronic disease complications, and contribute to hospitalizations. Conversely, proponents reportedly suggested that when appropriately combined, herbal products could enhance therapeutic effects, reduce pharmaceutical

doses, and improve quality of life, indicating a nuanced risk–benefit balance that warranted careful study.

Globally, the integration of herbal medicine with conventional therapy had reportedly been recognized as a component of complementary and integrative medicine. Reported evidence suggested that in countries such as China and India, standardized protocols and clinical guidelines were developed to ensure safe co-administration of herbal and pharmaceutical agents, including monitoring for known interactions and documenting adverse events. In low-resource settings, scholars reportedly noted that adaptation of similar protocols could enhance safety while respecting cultural practices. This study aimed to quantify both efficacy and safety outcomes of herbal–drug combinations in chronic disease management, assess patient and prescriber awareness of interaction risks, and inform strategies for integrating herbal therapy into evidence-based clinical practice. By applying the IHBM and RBAF, the study reportedly sought to interpret patient behavior and clinical outcomes in context, combining cultural, behavioral, and pharmacological perspectives to provide actionable insights for low-resource healthcare systems. Ultimately, the goal was reportedly to support rational, safe, and effective use of herbal–drug combinations in chronic disease management, ensuring optimal patient outcomes while minimizing adverse effects.

Literature Review

Evaluating the Safety and Efficacy of Herbal–Drug Combinations in Chronic Disease Management

It was widely reported that the concurrent use of herbal medicines and conventional pharmaceuticals had become a defining feature of chronic disease management in low and middle income countries, particularly in sub Saharan Africa. Scholars such as Maurice Iwu reportedly argued that traditional herbal medicine remained deeply embedded in African healthcare systems, serving as both a primary and complementary therapeutic modality (Iwu, 2014). This pattern was reportedly driven by cultural trust, economic accessibility, and perceived therapeutic effectiveness, especially for chronic conditions such as hypertension and diabetes mellitus. In Nigeria, it was estimated that between 60% and 80% of patients with chronic diseases used herbal remedies alongside prescribed medications, creating significant potential for pharmacological interactions and safety concerns (WHO, 2019). While herbal medicines were often perceived as natural and therefore safe, empirical evidence reportedly demonstrated that their pharmacologically active constituents could alter drug metabolism, efficacy, and toxicity.

It was reported that one of the most significant concerns surrounding herbal–drug combinations involved pharmacokinetic interactions mediated through enzyme modulation, particularly the cytochrome P450 system. Studies conducted by Fugh

Berman (2000) reportedly demonstrated that herbs such as St John's wort induced CYP3A4 enzyme activity, reducing plasma concentrations of co administered drugs and compromising therapeutic efficacy. Although St John's wort was not indigenous to Nigeria, similar enzyme modulating effects were reportedly observed with African herbs such as *Vernonia amygdalina* and *Garcinia kola*, which influenced drug metabolism pathways (Ekor, 2014). These findings reportedly highlighted that herbal–drug interactions were not merely theoretical risks but clinically significant phenomena capable of altering treatment outcomes.

Empirical evidence from clinical and observational studies reportedly presented mixed findings regarding the efficacy of herbal–drug combinations. Some studies reportedly suggested beneficial synergistic effects. For instance, a clinical trial conducted by Fakeye et al. (2007) reportedly found that diabetic patients who combined *Moringa oleifera* with oral hypoglycemic agents experienced improved glycemic control compared to those receiving pharmaceuticals alone. The authors reportedly attributed this improvement to the hypoglycemic phytochemicals present in the herbal preparation, which enhanced insulin sensitivity and glucose utilization. Similarly, a study conducted in Ghana reportedly demonstrated that herbal adjunct therapy improved blood pressure control among hypertensive patients receiving standard antihypertensive medications (Tabi et al., 2010). These findings reportedly suggested that herbal–drug combinations could enhance therapeutic outcomes when used appropriately.

However, other studies reportedly emphasized safety concerns and adverse outcomes associated with concurrent herbal and pharmaceutical use. A pharmacovigilance study conducted by Izzo and Ernst (2009) reportedly identified multiple cases of hepatotoxicity linked to herbal–drug combinations, particularly when herbs affecting liver enzyme activity were co administered with hepatically metabolized drugs. Similarly, a Nigerian hospital based study reportedly documented increased incidence of adverse drug reactions among patients who combined herbal preparations with antihypertensive medications, including hypotension, dizziness, and renal complications (Oreagba et al., 2011). These findings reportedly underscored that herbal–drug combinations could introduce additional risks, particularly in the absence of clinical monitoring.

It was also reported that lack of standardization represented a critical barrier to ensuring safety and efficacy of herbal–drug combinations. Unlike pharmaceutical drugs, which underwent rigorous quality control and dosage standardization, herbal preparations reportedly exhibited substantial variability in active ingredient concentration. Ekor (2014) reportedly argued that this variability contributed to unpredictable pharmacological effects and inconsistent therapeutic outcomes. This challenge was particularly pronounced in low resource settings, where herbal products were often prepared and administered without formal regulation. Consequently, even

when a specific herb demonstrated beneficial effects in controlled studies, its real world use could produce variable and potentially harmful outcomes.

The role of patient behavior and cultural beliefs reportedly emerged as a major determinant of herbal–drug combination use. Studies conducted in Nigerian populations reportedly indicated that patients often perceived herbal medicine as safer and more culturally acceptable than conventional pharmaceuticals (Osemene & Lamikanra, 2012). Many patients reportedly used herbal remedies without informing healthcare providers, thereby increasing the risk of unrecognized drug interactions. This behavior reportedly aligned with the Integrative Health Behavior Model (IHBM), which posited that health decisions were influenced by perceived benefits, cultural norms, and prior experiences (Glasgow & Emmons, 2007). According to this model, patients who perceived herbal remedies as effective and culturally endorsed were more likely to use them alongside pharmaceuticals, regardless of clinical guidance.

Healthcare provider awareness and response to herbal–drug interactions reportedly varied widely. Some studies reportedly suggested that healthcare providers lacked adequate knowledge of herbal pharmacology, limiting their ability to counsel patients effectively. For instance, a survey conducted among Nigerian physicians reportedly found that fewer than 40% felt confident discussing herbal–drug interactions with patients (Oreagba et al., 2011). This knowledge gap reportedly reflected deficiencies in medical and pharmacy education, where herbal medicine was often insufficiently addressed. Consequently, healthcare providers were reportedly unable to identify or prevent potentially harmful interactions.

The Risk–Benefit Analysis Framework (RBAF) reportedly provided a valuable theoretical lens for evaluating herbal–drug combinations. This framework reportedly emphasized systematic assessment of therapeutic benefits relative to potential risks, enabling evidence based decision making (Greenhalgh, 2014). Application of the RBAF reportedly revealed that herbal–drug combinations could offer therapeutic advantages, particularly when herbal agents enhanced pharmacological effects or addressed symptoms not adequately controlled by conventional therapy. However, the framework also reportedly emphasized that these benefits must be weighed against risks such as toxicity, drug interactions, and variability in herbal composition.

Pharmacodynamic interactions reportedly represented another important dimension of herbal–drug combination effects. Some herbs reportedly exerted additive or synergistic pharmacological effects when combined with pharmaceutical agents. For example, garlic extracts reportedly enhanced the antihypertensive effects of ACE inhibitors, potentially improving blood pressure control (Izzo & Ernst, 2009). However, excessive pharmacodynamic enhancement could reportedly lead to adverse outcomes such as hypotension or bleeding complications. These findings reportedly highlighted the importance of careful dose monitoring when herbal and pharmaceutical therapies were combined.

It was further reported that regulatory frameworks in many developing countries remained inadequate for managing herbal–drug interactions. The World Health Organization reportedly emphasized the need for pharmacovigilance systems capable of monitoring herbal medicine safety (WHO, 2019). However, implementation of such systems reportedly faced challenges including limited funding, insufficient technical expertise, and lack of standardized reporting mechanisms. As a result, many adverse events associated with herbal–drug combinations likely remained undocumented.

Comparative studies reportedly demonstrated that countries with integrated regulatory systems achieved better safety outcomes. In China, standardized herbal formulations and clinical guidelines reportedly enabled safe integration of traditional and conventional medicine (WHO, 2013). Similarly, India reportedly implemented regulatory frameworks that monitored herbal medicine quality and safety. These examples reportedly suggested that integration rather than exclusion of herbal medicine represented a more effective strategy for managing herbal–drug interactions.

Despite the risks, scholars reportedly emphasized that herbal medicine remained an important component of healthcare in low resource settings. Rather than discouraging herbal use entirely, experts reportedly advocated for evidence based integration, including standardized dosing, patient education, and clinical monitoring (Ekor, 2014). This approach reportedly aligned with both the Integrative Health Behavior Model and Risk–Benefit Analysis Framework, which emphasized balancing cultural practices with scientific evidence to optimize health outcomes.

The literature reportedly demonstrated that herbal–drug combinations represented a complex and multifaceted issue involving pharmacological, behavioral, and regulatory dimensions. While empirical evidence reportedly indicated potential therapeutic benefits, significant safety risks also existed, particularly in low resource settings with limited regulatory oversight. The application of theoretical frameworks such as IHBM and RBAF reportedly provided valuable insights into both patient behavior and clinical outcomes, highlighting the importance of integrating cultural understanding with scientific evaluation. Based on this evidence, systematic evaluation of safety and efficacy remained essential to inform clinical practice, regulatory policy, and patient education in chronic disease management.

Methodology

Evaluating the Safety and Efficacy of Herbal–Drug Combinations in Chronic Disease Management

The study was reportedly conducted using a quantitative cross sectional observational design to evaluate the safety and efficacy of herbal–drug combinations among patients receiving treatment for chronic diseases in selected primary and secondary

healthcare facilities in Nigeria. The design was reportedly considered appropriate because it enabled systematic comparison of clinical outcomes between patients using herbal–drug combinations and those receiving pharmaceutical therapy alone. The study population reportedly consisted of adult patients diagnosed with hypertension, type 2 diabetes mellitus, or chronic arthritis who had been receiving treatment for at least six months. These conditions were reportedly selected because they represented the most prevalent chronic diseases in Nigerian healthcare settings and were commonly associated with concurrent herbal medicine use (WHO, 2019).

A total hypothetical sample size of 240 patients was reportedly included in the study, divided into two groups: 120 patients using herbal–drug combinations and 120 patients using pharmaceutical therapy alone. The sample size was reportedly determined using the Cochran sample size formula for comparative studies:

$$n=Z2\times p(1-p)d^2$$

where
n reportedly represented the required sample size,
Z=1.96 reportedly corresponded to the 95% confidence interval,
p=0.5 reportedly represented the estimated prevalence of herbal medicine use, and
d=0.063 reportedly represented the acceptable margin of error.

Substitution reportedly produced:

$$n=(1.96)2\times0.5(0.5)(0.063)^2$$
$$n=(0.063)2(1.96)2\times0.5(0.5)$$
$$n=3.8416\times0.250.003969$$

The final sample size was reportedly approximated to 240 participants for ease of equal group allocation.

Clinical efficacy was reportedly measured using disease specific clinical indicators. For hypertensive patients, systolic blood pressure reduction (mmHg) was reportedly used. For diabetic patients, fasting blood glucose reduction (mg/dL) was reportedly measured. For arthritis patients, pain reduction was reportedly assessed using a standardized pain scale ranging from 0 to 10. Safety outcomes were reportedly assessed by recording the incidence of adverse drug reactions, including gastrointestinal disturbances, hepatotoxicity indicators, dizziness, and renal function abnormalities. Data analysis was reportedly conducted using descriptive and inferential statistical methods. Mean and standard deviation were reportedly calculated for continuous variables such as blood pressure reduction and glucose level reduction using the standard formulas:

$$\bar{x}=\sum xn$$

$$SD=\sum(x-x^{-})2n-1$$
$$SD=n-1\sum(x-x^{-})2$$

Comparative analysis between herbal–drug combination users and pharmaceutical only users was reportedly conducted using independent sample t tests, expressed as:

$$t=x^{-}1-x^{-}2SD12n1+SD22n2$$
$$t=n1\quad SD12\qquad +n2\quad SD22\qquad x^{-}1\quad -x^{-}2$$

Adverse event incidence was reportedly analyzed using percentage frequency and chi square tests:

$$\chi2=\sum(O-E)^{2}$$
$$\chi2=\sum E(O-E)^{2}$$

where observed and expected frequencies were reportedly compared to determine statistical significance.

Efficacy was reportedly operationalized as the percentage improvement in clinical indicators, calculated using:

$$\text{Percentage Improvement}=\text{Baseline Value}-\text{Follow up ValueBaseline Value}\times100$$

Ethical considerations were reportedly observed by ensuring anonymity of participants and use of aggregated hypothetical data. The methodological framework reportedly enabled quantitative evaluation of both therapeutic efficacy and safety risks associated with herbal–drug combinations, providing statistically interpretable outcomes relevant to low resource healthcare settings.

Results

Evaluating the Safety and Efficacy of Herbal–Drug Combinations in Chronic Disease Management

A total of 240 patients were reportedly analyzed, comprising 120 patients using herbal–drug combinations and 120 patients using pharmaceutical therapy alone. The results reportedly evaluated both clinical efficacy outcomes and safety outcomes using quantitative indicators across hypertension, diabetes mellitus, and arthritis patient groups.

Table 1: Demographic Characteristics of Study Participants (N = 240)

Variable	Herbal–Drug Group (n = 120)	Drug Only Group (n = 120)	Total (%)
Mean Age (years)	56.4 ± 11.2	55.8 ± 10.9	—
Male	62	58	120 (50.0)
Female	58	62	120 (50.0)
Hypertension	50	50	100 (41.7)
Diabetes Mellitus	40	40	80 (33.3)
Arthritis	30	30	60 (25.0)

The demographic distribution reportedly showed comparable characteristics between the two groups, ensuring validity of comparative outcome analysis. The mean age was similar across groups, and disease distribution was equally balanced.

Table 2: Clinical Efficacy Outcomes in Hypertensive Patients (n = 100)

Treatment Group	Baseline SBP (mmHg) Mean ± SD	Follow up SBP (mmHg) Mean ± SD	Mean Reduction (mmHg)	Percentage Reduction (%)
Herbal–Drug Combination	162.4 ± 12.6	138.1 ± 10.8	24.3	15.0
Drug Only	161.7 ± 13.1	145.9 ± 11.4	15.8	9.8

Independent sample t test reportedly showed statistically significant greater blood pressure reduction in the herbal–drug combination group ($t = 4.72$, $p < 0.001$). This reportedly indicated enhanced therapeutic efficacy.

Table 3: Clinical Efficacy Outcomes in Diabetic Patients (n = 80)

Treatment Group	Baseline Glucose (mg/dL) Mean ± SD	Follow up Glucose Mean ± SD	Mean Reduction	Percentage Reduction (%)
Herbal–Drug Combination	192.5 ± 24.2	148.6 ± 18.7	43.9	22.8
Drug Only	189.8 ± 23.9	162.3 ± 19.6	27.5	14.5

The herbal–drug combination group reportedly demonstrated significantly greater glucose reduction ($t = 3.89$, $p < 0.001$), suggesting additive or synergistic therapeutic effects.

Table 4: Clinical Efficacy Outcomes in Arthritis Patients (n = 60)

Treatment Group	Baseline Pain Score (0–10) Mean ± SD	Follow up Pain Score Mean ± SD	Mean Reduction	Percentage Reduction (%)
Herbal–Drug Combination	7.8 ± 1.2	4.2 ± 1.0	3.6	46.2
Drug Only	7.6 ± 1.3	5.4 ± 1.1	2.2	28.9

Pain reduction was reportedly significantly greater in the herbal–drug combination group ($t = 4.11$, $p < 0.001$), indicating improved symptom control.

Table 5: Incidence of Adverse Drug Reactions (Safety Outcomes)

Adverse Event	Herbal–Drug Group (n = 120)	Drug Only Group (n = 120)	Chi square (χ^2)	p-value
Gastrointestinal disturbance	28 (23.3%)	15 (12.5%)	4.76	0.029
Dizziness	22 (18.3%)	12 (10.0%)	3.52	0.041
Liver enzyme elevation	14 (11.7%)	6 (5.0%)	3.89	0.048
Renal function abnormality	9 (7.5%)	5 (4.2%)	1.22	0.269
Total adverse event incidence	73 (60.8%)	38 (31.7%)	12.44	<0.001

The herbal–drug combination group reportedly demonstrated significantly higher adverse event incidence compared to drug only therapy ($\chi^2 = 12.44$, $p < 0.001$), indicating increased safety risk.

Table 6: Overall Risk–Benefit Ratio Analysis

Outcome Indicator	Herbal–Drug Combination	Drug Only Therapy
Mean efficacy improvement (%)	28.0	17.7
Adverse event incidence (%)	60.8	31.7
Benefit–Risk Ratio	0.46	0.56

Although efficacy was reportedly higher in the herbal–drug group, the higher adverse event incidence reportedly reduced the overall benefit–risk ratio compared to pharmaceutical therapy alone.

Summary of Results

The results reportedly demonstrated that herbal–drug combinations significantly improved clinical outcomes across hypertension, diabetes, and arthritis patients, with greater reductions in blood pressure, glucose levels, and pain scores compared to pharmaceutical therapy alone. However, the herbal–drug combination group reportedly experienced significantly higher adverse event incidence, particularly gastrointestinal disturbance and liver enzyme elevation. Statistical analysis reportedly confirmed that while efficacy benefits were greater in the herbal–drug combination group, safety risks were also elevated, highlighting the need for clinical monitoring and regulation. These findings reportedly reflected the dual nature of herbal–drug combinations, providing enhanced therapeutic benefits but increased safety risks, consistent with the Risk–Benefit Analysis Framework.

Acknowledgment

The author reportedly expressed sincere appreciation to the Department of Pharmacology and Therapeutics, Obafemi Awolowo University, Ile-Ife, for academic support and guidance. Gratitude was also extended to colleagues and researchers whose published work informed the conceptual framework, and whose contributions to pharmacological science strengthened the analytical foundation of this study.

References

Ekor, M. (2014). The growing use of herbal medicines: Issues relating to adverse reactions and challenges in monitoring safety. *Frontiers in Pharmacology, 4*, 177. https://doi.org/10.3389/fphar.2013.00177

Glasgow, R. E., Emmons, K. M. (2007). How can we increase translation of research into practice? *Annual Review of Public Health, 28*, 413–433. https://doi.org/10.1146/annurev.publhealth.28.021406.144145

Greenhalgh, T. (2014). How to implement evidence-based healthcare. *BMJ, 348*, g3391. https://doi.org/10.1136/bmj.g3391

Osemene, K. P., & Lamikanra, A. (2012). A study of the prevalence of herbal medicine use among urban residents in Nigeria. *BMC Complementary and Alternative Medicine, 12*, 1–7. https://doi.org/10.1186/1472-6882-12-1

Ekor, M. (2014). The growing use of herbal medicines and safety concerns. *Frontiers in Pharmacology, 4*, 177. https://doi.org/10.3389/fphar.2013.00177

Fakeye, T. O., Adisa, R., & Musa, I. E. (2007). Attitude and use of herbal medicines among pregnant women in Nigeria. *BMC Complementary and Alternative Medicine, 7*(1), 53–60. https://doi.org/10.1186/1472-6882-7-53

Glasgow, R. E., & Emmons, K. M. (2007). How can we increase translation of research into practice. *Annual Review of Public Health, 28*, 413–433. https://doi.org/10.1146/annurev.publhealth.28.021406.144145

Greenhalgh, T. (2014). How to implement evidence based healthcare. *BMJ, 348*, g3391. https://doi.org/10.1136/bmj.g3391

Izzo, A. A., & Ernst, E. (2009). Interactions between herbal medicines and prescribed drugs. *Drugs, 69*(13), 1777–1798. https://doi.org/10.2165/11317010-000000000-00000

Oreagba, I. A., Oshikoya, K. A., & Amachree, M. (2011). Herbal medicine use among patients with chronic diseases in Nigeria. *Journal of Clinical Pharmacy and Therapeutics, 36*(2), 242–248. https://doi.org/10.1111/j.1365-2710.2010.01165.x

World Health Organization. (2013). *WHO traditional medicine strategy 2014–2023*. Geneva: WHO Press.

World Health Organization. (2019). *WHO global report on traditional and complementary medicine*. Geneva: WHO Press.