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Effectiveness of a Collaborative Deprescribing Intervention of Proton Pump Inhibitors: A Randomized Controlled Trial in Pakistan

by

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CERTIFICATE OF APPROVAL

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(Irma Umar)

Abstract

Proton pump inhibitors (PPIs) are widely prescribed, but long-term use is often unnecessary, especially in functional dyspepsia and other acid-related disorders. Structured deprescribing within a multidisciplinary approach can optimize therapy, reduce unnecessary exposure, and maintain symptom control, with patient-centered counseling playing a key role.

This study compared PPIs reduction over six months between intervention and control groups, evaluated gastrointestinal symptoms, adverse events, alternative therapy use, patient adherence, lifestyle compliance, and quality of life EQ-5D-3L. Eligible adults in primary care were randomized to receive standard care or an intervention involving guideline-based assessment, pharmacist counseling, combined decision-making with general practitioners, structured follow-ups, and alternative therapy guidance.

The intervention group demonstrated a higher rate of PPI discontinuation, improved adherence, maintained symptom control, and reported greater satisfaction and quality of life as compared to control group. These findings demonstrated that pharmacist-led counseling and multidisciplinary collaboration using a deprescribing algorithm, such as DROP-IT, can safely optimize PPI use, enhance patient outcomes, and support rational medication management.

Keywords: Proton pump inhibitors, Collaborative Deprescribing, DROP-IT approach, Pharmacist-led intervention, Reflux Disease Questionnaire, Quality of life, General Medication Adherence Scale

Contents

List of Figures

List of Tables

Abbreviations

ADRs	Adverse Drug Reactions
AERS	Adverse Event Reporting System
AGA	American Gastroenterological Association
AKI	Acute Kidney Injury
BCRP	Breast Cancer Resistance Protein
BPA	Best Practice Advice
CAP	Community-Acquired Pneumonia
CKD	Chronic Kidney Diseases
DDD	Defined Daily Dose
DDIs	Drug-Drug Interactions
DROPIT	Document, Review, Optimize, Plan, Implement, Track
EHR	Electronic Health Record
EMA	European Medicines Agency's
EQ-5D-3L	EuroQol Five-Dimension Three-Level
FAERS	FDA, Adverse Event Reporting System
FDA	Food and Drug Administration
GERD	Gastroesophageal Reflux Disease
GMAS	General Medication Adherence Scale
GPs	General Practitioners
HCl	Hydrogen Chloride
IVPPI	Intravenous Proton Pump Inhibitor
NSAIDs	Non-steroidal anti-inflammatory drugs
OPDs	Outpatient Departments
P-gp	P-glycoprotein

PFS	Progression-Free Survival
PPI HD	High-dose PPIs
PPIs	Proton Pump Inhibitors
PSF	Patient Satisfaction Feedback
QOL	Quality of Life
RCTs	Randomized controlled trials
TKIs	Tyrosine Kinase Inhibitors
VAS	Visual Analogue Scale

Chapter 1

Introduction

1.1 Background

Proton pump inhibitors is a pharmaceutical drug that is used to treat heartburn and disorders of the acid. One of the most prescribed drug in inpatient and outpatient care is PPIs [1]. PPIs are seen to produce more long-lasting acid suppression as they can control both basal and food stimulated secretions [2]. Therefore, since they have been discovered by the 1980s, they are being used as the first line therapy for gastroesophageal reflux disease GERD in patients. The United States Food and Drug Administration and the American Gastroenterology Associated strongly recommend the use of PPIs for a limited duration 4 to 8 weeks in treatment of GERD [3]. PPIs should be used long-term, in case of chronic esophagitis or Barrett esophagus or when patients are at high risk of upper gastrointestinal bleeding and who require ongoing NSAID or antiplatelet therapy. For other common indications, it is advised that treatment lasts only from 2 to 12 weeks after which a reevaluation should occur. Despite these restrictions, PPIs rank among the most commonly prescribed and utilized medications worldwide [4]. The chronic use of PPIs can decrease nutrient absorption, especially the decrease in calcium absorption and increasing the chances of fractures. Use of PPIs could increase incidence of gastrointestinal infection e.g. Clostridium difficile

and Campylobacter and community-acquired pneumonia. The gut microbiota is extremely important in enabling the body to resist colonization by foreign enteric pathogens and overgrowth of commensal bacteria [5].

One quarter of the prescribed PPIs were considered inappropriate, either due to the lack of the indication or to excessive high dosing. A well-known strategy in improving medication use and minimizing adverse effects is the process of stopping, reducing dosage or replacing medications that are no longer beneficial or may even be harmful called deprescribing [6].

Minimizing medication-related error is currently a global challenge in patients' safety. Deprescribing is a strategy to minimize the use of multiple medications and improve medication management. This approach, overseen by healthcare professionals, focuses on stopping or reducing medications that cause an adverse effect or are no longer beneficial. While medication deprescribing interventions have demonstrated some favorable results, various challenges can occur during the process. Commonly encountered barriers include clinical uncertainty, withdrawal-related adverse events, and concerns regarding potential negative effects on health-care professional-patient relationships. [7].

Clinical observations have demonstrated that the deprescribing service has notably minimized the consumption of PPIs and lowered medication costs in outpatient care environments, leading to a high rate of successful PPIs deprescribing 80.0% [8]. Despite numerous studies on PPI deprescribing, no universally accepted approach is consistently used in general practice. General practitioners with a clear understanding of appropriate PPI indications and confidence in hospital physicians' prescribing decisions are more likely to discontinue unnecessary medications [9]. It is crucial to stop consumption of PPIs in patients for a long time period if they are not needed. Nevertheless, abrupt cessation may lead to the return of symptoms. A safe strategy for stopping PPIs use is currently being studied, but it has not yet been determined [5]. The global consumption of these medications is high due to their effectiveness, safety, and tolerability. Omeprazole is the second most dispensed drug in England in 2020 with almost $35 million prescriptions being fulfilled at an annual cost of £82 million. In 2019, omeprazole was included

among the top eight most widely prescribed drugs in the United States with more than $52 million prescriptions made. In 2016-2017, should be PPIs spending in the USA reached a level of $19.99 billion [10].

1.2 Global Prescription Trend of PPIs

Proton pump inhibitors are the most widely prescribed drugs in the world, ranking with in top ten medications. Commonly, PPIs are used to prevent the GI ulcers in patients without risk sometime over prescribed to treat functional dyspepsia, preventing stress ulcers in non-ICU patients or in those receiving steroids [11].

Proton pump inhibitors have been used as the drugs of choice for the management of gastric acid-related disorders during the past few decades [12]. This can be expressed through the research which indicates an increase purchase of PPIs. Their widespread use is reflected in their increasing consumption and expenditures worldwide. In the United States, PPIs have been available over the counter since 2003, thus, without physician supervision from perceived safety and efficacy [13].

PPIs are often prescribed inappropriately despite their proven efficacy, leading to polypharmacy and unnecessary medical expenses. Research indicates that many patients use PPIs without a valid prescription or continue treatment beyond the recommended duration, placing an avoidable financial burden on healthcare systems [14, 15]. The necessity to create individual approaches to minimize the unnecessary use of PPIs [16].

1.3 Overuse of PPIs in Pakistan

Used of Proton pump inhibitors has been increasing every 10 years, this increases the risk associated with polypharmacy and other indications. A recent study performed in health care settings in Karachi, Pakistan proved that PPIs as over-prescribed medications. For instance, 47.2% of discharged patients were given

PPIs. In another study of 1,800 patients admitted in medical wards and emergency departments in 24 weeks, 72.6% patients in Lahore were prescribed PPIs [8]. Figure 1 is a visual presentation of for the number of patients being prescribed PPIs in two big cities of Pakistan over the period of 10 years. However, there is limited data on the public's knowledge and behavior on the use of PPIs in developing countries. Inappropriate self-medication and misuse also add to the risk of adverse outcomes [17].

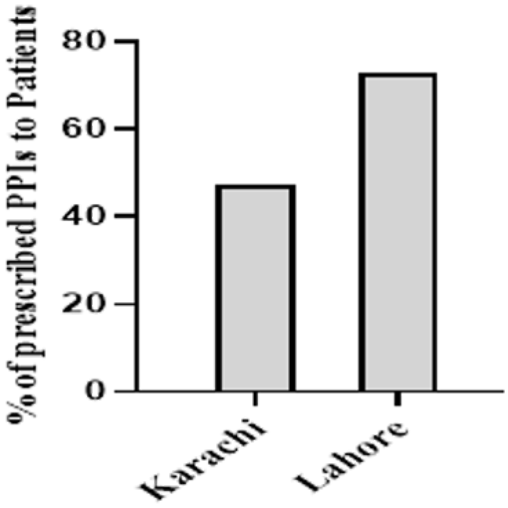

FIGURE 1.1: Consumption of PPIs in Pakistan [8].

1.4 Need for Deprescribing for Minimizing Over Consumption of Proton Pump Inhibitors in Pakistan

The term used deprescribing is a process of reducing or stopping a medication that may not be necessary or may cause of harm with the aimed of managing of symptoms and optimizing overall medication [18]. Polypharmacy, inappropriate long-term use of medications, and the absence of the organized practice of medication reviews all contribute to the necessity of deprescribing in Pakistan, where the prevalence of polypharmacy and inappropriate use of medication increases.

Extensive use of medications over a long period by patients without periodic re-assessment contributes to the risk of adverse drug reactions, medication burdens, and unjustified healthcare expenditures [19]. Therefore, deprescribing interventions are needed to promoted the rational use of drugs, enhance patient safety, and maximize treatment outcomes in the Pakistani healthcare system. This is a special concern in the case of proton pump inhibitors that are commonly prescribed and for long term even when no longer clinically necessary. Possible side effects of prolonged use of PPIs, impaired nutrient absorption, increased risk of fractures, enteric infections and gut microbiota changes [5]. In Pakistan, the deprescribing of PPIs could play an important role in reducing inappropriate medication use and improving overall patient health.

1.5 Structured Collaborative Approach for Deprescribing Proton Pump Inhibitors

A structured deprescribing approach involves collaborative efforts between pharmacists and general practitioners to safely reduced or discontinued inappropriate proton pump inhibitors therapy in patients. In this process, pharmacists first consult with patients about their existing proton pump inhibitor medication. They provide patients with brochures that include information about the risks of proton pump inhibitor medication and its benefits. They also provide a patient with a medication profile that includes important details, such as any possible drug interactions that may arise.

This information is shared with the general practitioner, who examines the medication regimen of the patient and develops an appropriate plan for deprescribing proton pump inhibitor medication with the help of appropriate guidelines. Once a plan is developed, pharmacists monitor patients by consulting with them. They also provide patients with appropriate advice about using medications that can provide relief from any possible rebound effect. They also provide advice about non-pharmacological methods of managing symptoms. In this way, a structured

approach to deprescribing proton pump inhibitor medication promotes appropriate communication between pharmacists and physicians, as well as the safe deprescribing of medication [7].

1.6 Justification for the Study

Although PPIs are highly effective in treating acid-related disorders, their inappropriate and long-term use has become a global concern. Irrational prescribing contributes to rising healthcare costs, unnecessary polypharmacy, and long-term risks such as hypomagnesemia, vitamin B12 deficiency, osteoporosis, and Clostridioides difficile infections.

In Pakistan, inappropriate PPIs use is widespread, structured deprescribing programs are lacking, and physician-pharmacist collaboration remains suboptimal.

Therefore, evaluating collaborative deprescribing interventions is essential to improve prescribing practices, enhance patient safety, reduce the healthcare burden, and address a critical evidence gap, while generating local evidence to inform national policies on the rational use of medicines.

1.7 Significance of Study

This study on inappropriate prescribing practices will have a direct impact on patient health and the healthcare system in Pakistan. This study will also have the potential to assess the effectiveness of the collaborative deprescribing intervention between pharmacists and physicians. This study will also have the potential to reduce the unnecessary drug burden on the population, drug-related problems, and costs on the healthcare system, resulting in an improved quality of life. In a resource-constrained country like Pakistan, its important to optimized pharmacotherapy in order to ensure the efficiency of the healthcare system. This study will also have the potential to highlight the importance of clinical pharmacists

as active members of the multidisciplinary team, which will also have a positive impact on the infrastructure of the country. Deprescribing is an effective strategy in reducing the inappropriate drug burden in the population worldwide.

However, there is a lack of evidence in South Asian countries. This study will have the potential to benefit the population in Pakistan and also contribute to the global body of knowledge on deprescribing interventions.

1.8 Problem Statement

Proton pump inhibitors are among the most frequently prescribed medications worldwide, with growing evidence of their inappropriate long-term use in the absence of valid clinical indications. In Pakistan, irrational PPIs prescribing remains prevalent across healthcare settings, increasing the risk of adverse outcomes such as nutrient deficiencies, fractures, kidney disease, and infections. The absence of structured deprescribing models, coupled with limited collaboration between physicians and pharmacists, further worse this issue. There is an urgent need to develop and evaluate evidence-based interventions, particularly randomized controlled approaches, to promote the rational use of PPIs.

1.9 Aim and Objectives

1.9.1 Aim

The primary aimed of the study to evaluated the effectiveness of collaborative deprescribing in reducing the in appropriate prolonged use of proton pump inhibitors in Pakistan and to promote rational drug use.

1.9.2 Objectives of the Study

These following were the main objectives of the study

i. To assess the impact of collaborative pharmacist intervention in the management of PPIs for deprescribing.

ii. To assess the changes in the rebound symptoms, health-related quality of life, medication adherence, and patient satisfaction.

iii. To evaluate the efficacy of lifestyle modifications and alternative therapies.

Chapter 2

Literature Review

2.1 Proton Pump Inhibitors

Proton pump inhibitors reduce gastric acid secretion and are widely used due to their efficacy, safety, and tolerability [18]. Their use has increased dramatically over the past two decades, making them one of the most prescribed drug classes globally, with 15-20% of adults in some Western countries reported as PPI users [19]. Their use has increased dramatically over the past two decades, making them one of the most prescribed drug classes globally, with 15-20% of adults in some Western countries reported as PPI users [20].

2.2 Mechanism of Action

The mechanism of action of proton pump inhibitors is based on the reduction of gastric acid secretion by inhibiting the H^+/K^+ ATPase proton pump in the gastric parietal cell membranes, blocking the final step in acid secretion. After being absorbed in the proximal part of the small intestine, the drug is distributed into the circulation and concentrated in the acidic canaliculi of the parietal cell membranes, where it is activated as a prodrug and irreversibly inhibits the proton

pump. The drug is metabolized in the liver by the cytochrome P450 enzyme family, in particular CYP2C19 [21, 22].

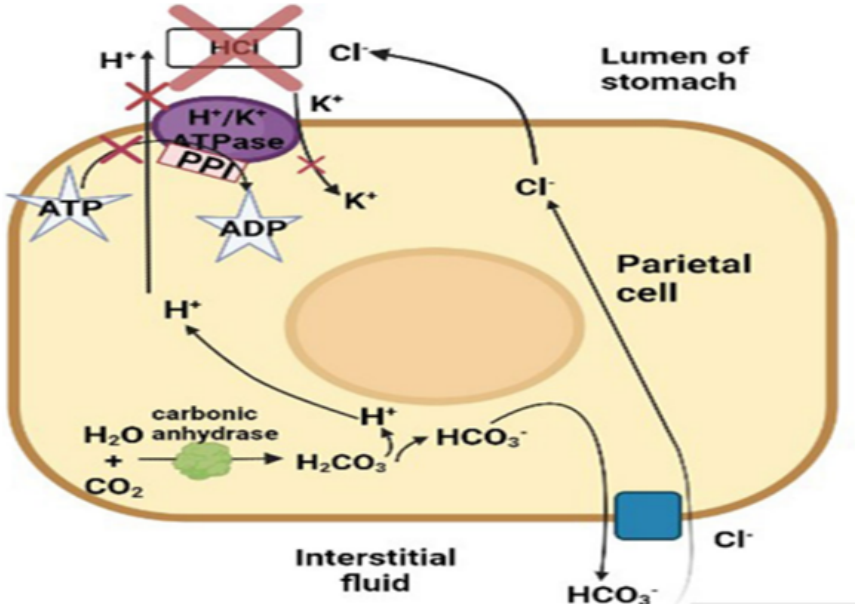

FIGURE 2.1: Mechanism of action of proton pump inhibitors in a parietal cell [21].

2.3 Risk Associated with Long Term Use of PPIs

The use of PPIs is usually regarded as effective and well-tolerated. However, they are frequently used beyond FDA approved indications is known as indication creep. It encompasses use of PPIs to treat circumstances with incomplete evidence, like non-ulcer dyspepsia and prophylaxis of stress ulcers in low-risk individuals and continuing therapy beyond suggested guideline durations [23]. Long-term or inappropriate use of PPIs has been associated with gut microbiome changes, infections, micronutrient deficiencies, fundic gland polyps, gastrointestinal disorders, chronic kidney disease, cognitive impairment, cardiovascular events, bacterial overgrowth, pneumonia, bone fractures, drug interactions, and increased mortality. The FDA has issued warnings regarding risks such as fractures, hypomagnesemia, enteric infections, and interactions with clopidogrel. Habitual use may increase fracture risk and contribute to chronic kidney disease, possibly via repeated episodes of acute kidney injury [24, 25]. Some studies have investigated high-dose, long-term

PPI use and its potential link to gastric cancer, though results are inconsistent [26].

Clostridioides difficile, a common healthcare-associated pathogen, can cause mild diarrhea to life-threatening colitis. Evidence supporting dose reduction, individualized prescribing, and regular therapy review is limited. Over 50% of PPI users are treated inappropriately regarding indication or dose, and meta-analyses have summarized these risks [27].

2.4 Burden of PPI Overuse across the Globe

The following section outlines the global burden of PPI overuse.

2.4.1 Global Patterns for Overuse of PPIs

Proton pump inhibitors are the highly effective pharmacological agents used for the management of acid related disorders. Nevertheless, the prevalence of their over use leading to the possible risks of patient's health and significant financial issue. A study among pharmacies in all Lebanese governorates represented a cross-sectional study, indicating the overuse of PPI and an estimated economic cost per year of about USD 25 million [28].

A large systematic review across 23 countries reported that nearly one-quarter of adults use PPIs, with 63% of users aged under 65 years and 56% being female. A substantial proportion exceeded the recommended daily dose, while approximately one-quarter continued therapy beyond one year and 28% used PPIs for more than three years [10].

Additionally, a systematic review and meta-analysis found that nearly two-thirds of PPI prescriptions globally were inappropriate, with the highest prevalence observed among older adults 63% [29]. Intravenous PPIs have also been found to be used alarmingly in hospital settings and particularly in surgical wards [30].

2.4.2 Influence of Cultural Prescribing Norms on Overuse of PPIs

The prescribing norms of cultural influence on the long term and high dose PPIs use are strong. A retrospective cohort of 472,146 patients in Germany showed that PPIs were widely prescribed in general and gastroenterology care usually outside guideline recommendations.

Reflux, gastritis, duodenitis, heartburn are common gastrointestinal symptoms that were habitually treated with PPIs and the chained over prescription patterns. The co-prescription, NSAIDs is another example of the anticipation of PPIs as default gastroprotection.

Although Canadian and American deprescribing guidelines advice dose reduction or discontinuation when symptoms are controlled, German practice indicates that PPI must be continued with little use of other agents such as alginates 0.2- 1.4 %of patients. This brings the cultural norms that promote the use of PPIs as opposed to the evidence-based alternatives available [31].

2.4.3 Influence Limited regulatory control on Overuse of PPIs

The consumption of PPIs has been increasing worldwide, driven by limited regulation and extensive marketing. They are not recommended for low-risk patients for gastro-duodenal ulcer prevention, non-ICU stress-ulcer prophylaxis, steroid use alone, or gastro protection in patients without gastrointestinal risk factors such as those on antiplatelet or anticoagulant therapy.

PPIs are also frequently misused to treat functional dyspepsia. These practices are major contributors to PPI overuse and associated patient harm [32].

2.5 Importance of Deprescribing in Clinical Practice

The following section outlines the importance of deprescribing in clinical practice.

2.5.1 Deprescribing

Deprescribing is typically described as a methodical approach for stopping, reducing, or replacing unsuitable medications which are overseen by a healthcare provider [33].

Deprescribing can enhance patient safety by promptly decreasing the medication burden, which may subsequently lead to a reduction in adverse drug events, illness and death [34].

2.5.2 Core Principle for Deprescribing

The goal of Deprescribing is a program to address polypharmacy and enhance patient outcomes by reducing unnecessary medication, adverse effects and medication-related hospitalizations [35].

2.5.3 Need for Deprescribing for Minimizing Overuse of PPIs

The use of PPIs in the long term is linked to infections, chronic kidney disease, fracture, micronutrient deficiency, and cardiovascular danger.

Inappropriate prescription of PPIs on indicators leads to undesirable drug reactions to patients. Despite the existence of effective deprescribing strategies, they are not introduced to clinical practice in the routine [36].

2.5.4 Barriers to Deprescribing

The deprescribing process is intricate and shaped by various factors, such as clinician perceptions, patient hesitance, and systemic obstacles.

Lack of time, lack of training, fear of relapse of symptoms, lack of understanding of protocols and legal issues are often reported by physicians. Patients will not be willing to stop long-term drugs especially those started by other clinicians. [37].

The shortage of clinician availability to deprescribe, competing responsibilities, inadequate staffing, the absence of a standardized deprescribing process, insufficient financial resources, limitations in physical space for deprescribing conversations, collaborating with numerous prescribers and a lack of regular medicine reviews have also contributed to limit the deprescribing phenomena.

These well-recognized obstacles also persisted alongside a strong culture for prescribing [38, 39].

2.5.5 Facilitators of deprescribing

Patient-centered care, shared decision-making, enhanced collaboration between healthcare professionals and evidence-based guidance are among the facilitators.

Once well informed, a number of patients would choose fewer drugs. Consistent communication between medical workers and pharmacist participation has a great impact on the success of deprescribing [39, 40].

2.6 Role of Health Policy and Guidelines

The following sections highlight the role of health policy and guidelines.

2.6.1 Global Health Policy Frameworks Supporting Deprescribing

The WHO's Medication Without Harm program emphasizes reducing inappropriate non-acute medication use through routine medication review, multidisciplinary care, and patient-centered deprescribing. International guidelines recommend reassessing PPI therapy after 4-8 weeks for uncomplicated conditions and considering deprescribing in patients with clear long-term indications. Effective implementation can be supported by system-level interventions, such as education, electronic tools, or pharmacist-led programs [41, 42].

2.6.2 National and Institutional Guidelines for PPIs Prescribing

National and institutional guidelines for PPIs prescribing emphasize appropriate indication, short-term use for most conditions and regular review for potential deprescribing. Overuse is a common concern due to potential long-term risks [14]. Electronic alerts, requiring indicators to be documented, pharmacist-led leadership and patient education are increasingly utilized in institutions to help reduce inappropriate long-term use and enhance patient safety [13, 17]. Through these national and local frameworks, health systems aim to improve therapeutic appropriateness, reduce polypharmacy and enhance patient safety by ensuring that PPIs are used only when clinically justified and for their minimum effective duration [43].

2.7 Influence of Pharmacovigilance systems on Minimizing overuse of PPIs

Pharmacovigilance systems minimize the overuse of PPIs by using data mining to detect adverse event signals, implementing clinical decision support tools in

electronic health records EHR, and facilitating "PPIs stewardship" programs led by pharmacists and clinicians [44]. National and international databases such as the FDA, Adverse Event Reporting System FAERS, and the European Medicines Agency's EMA and the WHO's Play a central role in pharmacovigilance. These systems aggregate spontaneous reports from healthcare professionals and patients, allowing researchers to detect safety signals and inform regulatory actions [45].

2.8 Evidence-Based Deprescribing Recommendations for PPIs

Evidence-based deprescribing encompasses routine medication review, education of the patient, tapering the dose gradually, on-demand or step-down use and treatment of the rebound symptoms with the help of adjunctive therapies and the change of lifestyle [46]. Effective deprescribing also requires patient education about expected temporary symptom flare-ups and clear follow-up plans to reassess symptoms burden and treatment necessity. Studies consistently show that structured deprescribing algorithms, pharmacist-led interventions and routine medication reviews improve deprescribing success rates and reduce unnecessary chronic PPIs use without compromising patients outcomes [47].

2.9 Randomized Controlled Trials on PPI Deprescribing

The following section highlights randomized controlled trials on PPI deprescribing.

2.9.1 Deprescribing Strategies Tested

Randomized controlled trials have been performed to study strategies to reduce long-term unnecessary use of PPIs with ongoing symptom management such as

dose tapering, step-down therapy e.g. twice daily to once daily dosing and on demand use [48, 49].

Some studies also compares these gradual strategies with abrupt discontinuation, although this is less frequently recommended due to the risk of rebound acid hyper-secretion and temporary symptoms flare-ups [5].

Adjunctive measures such as the use of H2-receptor antagonists or antacids during the deprescribing process are often incorporated to manage breakthrough symptoms. These trials consistently show that structured, individualized deprescribing approaches are effective for most patients, with step-down and on-demand strategies generally preferred for better tolerance and adherence. Overall, the evidence supports the use of tailored deprescribing algorithms to minimize unnecessary PPIs exposure while maintaining patients comfort and safety [50].

2.9.2 Outcomes and Effectiveness of Randomized Controlled Trials

PPI discontinuation or dose reduction, maintenance of symptom control, less adverse effects and patient adherence and satisfaction are positive results achieved by RCTs. Returning acid hypersecretion is temporary in nature and can be successfully treated using H2-receptor antagonists. Interventions by pharmacists and clinicians are more effective, as they recognize the specific case, provide guidance and follow-ups, which promotes safe deprescribing and effective utilization of healthcare resources [51].

2.10 Collaborative Approaches to Deprescribing of PPIs

The following section outlines collaborative approaches to PPI deprescribing.

2.10.1 Role of Pharmacist in Deprescribing

Pharmacist and clinician-led interventions are pivotal in optimizing proton pump inhibitors use and implementing evidence-based deprescribing strategies [52]. These interventions generally involve comprehensive medication reviews, identification of patients without ongoing indications for long-term PPIs therapy and collaborative planning for dose reduction or discontinuation [53].

Pharmacists play a key role by flagging inappropriate prescriptions providing step-down or on-demand dosing recommendations, and counseling patients on lifestyle modifications and symptoms management [54]. Clinicians incorporate these recommendations into individualized care plans, carefully considering patients history, comorbidities and risk factors for gastrointestinal complications [55].

Randomized controlled trials have shown that such interventions improve the success of deprescribing, reduce unnecessary medication exposure and maintain an adequate symptoms control [56].

2.10.2 Physician-pharmacist Teamwork

General Practitioners and clinical pharmacists working in collaboration increase the feasibility of deprescribing by determining and identifying inappropriate prescriptions of PPIs, engaging in the deprescribing and monitoring process and relying on the best-practice recommendations [39].

Physicians provide diagnostic expertise and determine valid clinical indications, while pharmacists contribute medication review, patients counseling, structured follow-up to support safe and effective deprescribing. This teamwork ensures continuity of care, minimizes inappropriate discontinuation and empowers patients with informed choices. Implementing deprescribing best practice advice BPA through coordinated physician-pharmacist efforts can help optimize PPIs therapy and improve patients outcomes [13].

2.10.3 Shared decision-making with patients

Pharmacist called eligible patients to discuss the benefits and risks of PPIs therapy and established shared decision making of PPIs deprescribing if the patient is agreed. Shared decision-making is a collaborative process between the patients and pharmacist to reach a joint decision about the medication plan. Shared decision making allowed for variations in the deprescribing plan, such as individualized deprescribing timeline, implementation of varying medication administration frequencies.

If patients declined the PPIs deprescribing intervention it was documented in the chart, and no further action was needed Pharmacists also counseled patients on non-pharmacological therapies [57].

2.11 Education-based Strategies

Pharmacists conduct oral education and written education with patient information booklets. The materials clarify the indications of rational PPI use [59]. The dangers of chronic therapy, the advantages of deprescribing, withdrawal symptoms and the methods of addressing the effects of rebound.

The educational content was created based on an validated deprescribing resource, https://deprescribing.org/ [7], as shown in figure 2.2.

2.12 Drug-Drug Interactions and PPIs

Interacting medications [58]. The use of anticancer therapies is associated with the use of PPIs, but concomitant palbociclib absorption is pH-dependent and the concomitant use of rabeprazole with metastatic breast cancer has been demonstrated to reduce progression-free survival [59]. Pantoprazole is also known to interact with Breast Cancer Resistance Protein BCRP and P-glycoprotein, which can also alter tyrosine kinase inhibitor pharmacokinetics, potentially altering efficacy [60].

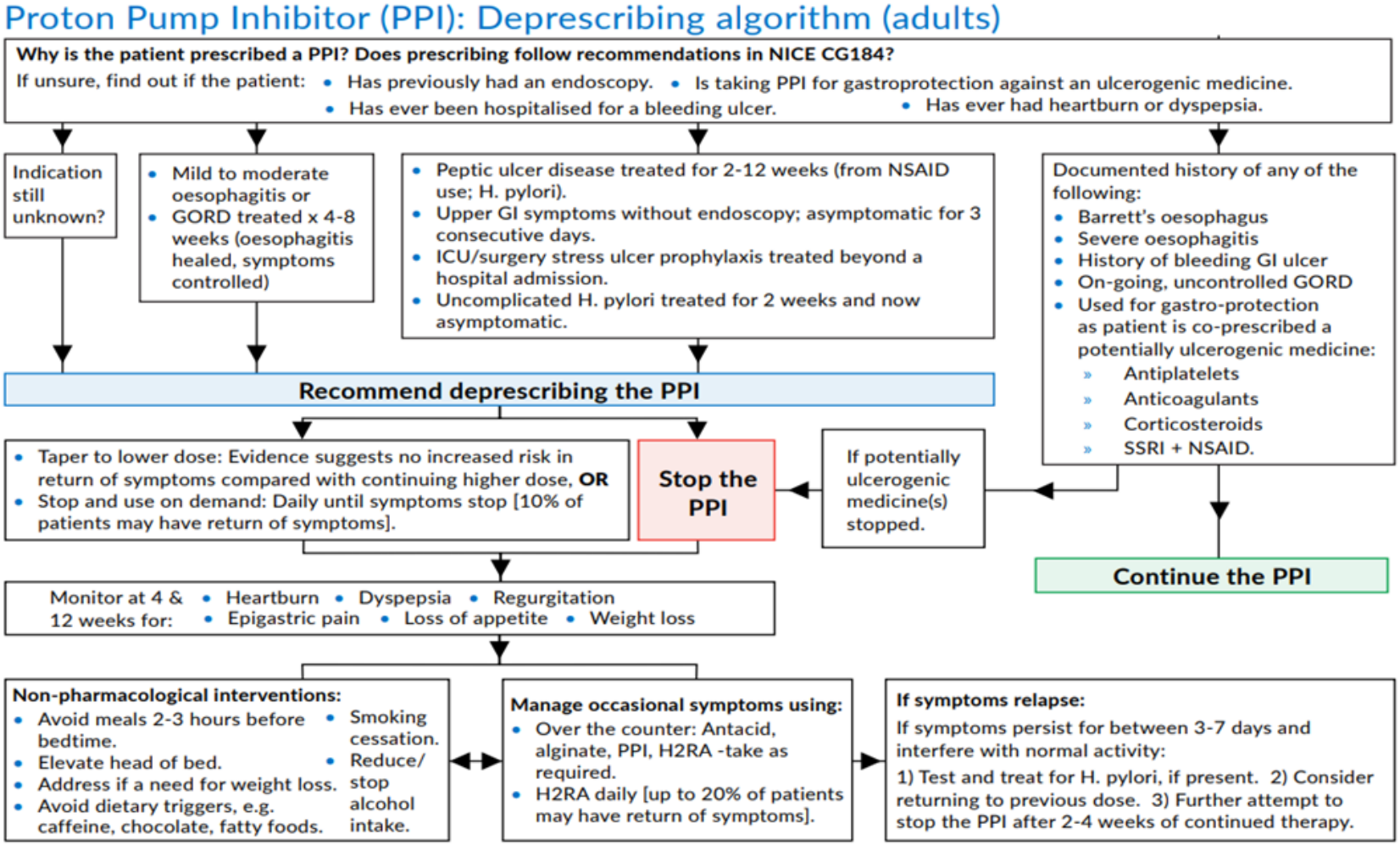

FIGURE 2.2: Proton Pump Inhibitors Deprescribing Algorithm

Retrospective studies and meta-analyses have shown that the use of PPIs in patients receiving TKIs, including pazopanib, sunitinib, gefitinib, and erlotinib, is associated with reduced survival and lower treatment adherence [58, 61–63].

Chapter 3

Research Design and Methodology

3.1 Methodology Overview

Clinical trials include human participants and are carried out in order to test interventions in the diagnosis, prevention or treatment of diseases. Study designs are generally divided into interventional clinical trials and observational studies with the strength of evidence largely defined by the quality of design. Bias can be a result of misclassification, missing data, participant selection, differences in prognostic factors, which can affect the validity of results [64]. Randomized controlled trials are considered to be of the highest standard, as they are able to establish causality. These include assigning study subjects randomly to either a control group or an experimental group. These are often compared with a placebo, standard care, or an active control group. In addition, active-controlled trials can include non-inferiority, superiority, and equivalence, depending on their scientific and ethical justification 65. Though traditional RCTs are static designs, adaptive and platform trials are dynamic in the sense that certain changes are possible in the design based on the data collected, in such a way that ineffective treatments are removed and new treatments are added. These designs are advantageous in terms

of efficiency and ethical considerations in that more participants are on effective treatments [66]. Advantages of RCT are randomization, controlled delivery of interventions, blinding etc. that reduce bias and support causal inference [67]. Adaptive and platform trials can also include changes to study design based on various data obtained. These are often able to eliminate ineffective treatments and include new ones that are promising. Even though RCTs are able to reduce bias, as shown by randomization, control, and blinding, these are often limited in their generalizability due to their complexity and cost [68].

3.2 Study Design

The following section outlines the study design of the research.

3.2.1 Study Setting

This study is pragmatic, multi-center, RCT having a parallel-group design. It's done to evaluate pharmacist-GP collaborative deprescribing intervention in adult patients with dyspepsia on long-term PPI therapy, this is being conducted at PIMS Hospital, Life Care Hospital. The viability of patient's recruitment, intervention delivery, follow-ups and safety of the deprescribing process. Figure 3.1 illustrates the overall study design.

3.2.2 Sample Size and Recruitment

A non-probability selective sampling approach was used to recruit patients during routine visits, eligible patients were identified through their medical records and were invited to participate at the beginning or at the end of their appointment to minimize disruption. Out of the estimated population of 446 eligible outpatients, adult patients with dyspepsia receiving proton pump inhibitors therapy, a targeting 400 patients successfully recruited at baseline. Similar to the previous study

[69], which enrolled 400 participants to ensure adequate power while accounting for potential drop-outs, this study also initially planned to enroll 400 participants.

The sample size was calculated to provide 80% statistical power at a 5% significance level to detect meaningful differences in study outcomes. Over the course of follow-up, an overall attrition of 28.5% was observed, which is acceptable within the context of real-world outpatient research.

Attrition rates in deprescribing and PPI management studies are widely reported, typically ranging from 8% to 15% due to refusal, loss to follow-up, or non - completion. Similarly, previous ambulatory deprescribing and PPI discontinuation trials have documented exclusion and non-completion rates between 10% and 19%, supporting the methodological appropriateness of the retention achieved in the present study [70].

3.2.3 Sampling Technique

A non-probability purposive sampling approach was adopted for participant selection, after which eligible participants were randomly allocated using a lottery method to the intervention and control groups in a 1:1 ratio.

This method was appropriate given the targeted nature of the study to reduce contamination both the intervention and control participants are recruited and followed at separate centers, including PIMS Hospital, Life Care Hospital. All the data baseline characteristics, dyspepsia symptoms, medication use and follow-up results are collected at their corresponding sites.

3.2.4 Study Population

Adults $\geq$18 years having long-term PPIs therapy for non-complicated conditions, receiving primary care, excluding severe GERD, active ulcers, chronic NSAIDs users at high GI risk, severe co-morbidity, pregnancy, or cognitive impairment.

3.2.5 Inclusion Criteria

Eligible participants would include adult 18 years or older who are prescribed proton pump inhibitors for acid-related disorders. Patients who must have been receiving PPIs for at least three months prior to enrollment. Only those who express willingness to participate, provide informed consent and have access to the primary healthcare settings involved in the study would be involved.

3.2.6 Exclusion Criteria

Those patients would not be included if they have conditions requiring long-term PPIs therapy e.g., Barrett's esophagus, a history of severe gastrointestinal bleeding, peptic ulcer perforation, or malignancy. Pregnant or breastfeeding women, patients suffer chronic illness like hypertension, diabetes or other issue like cognitive impairment or psychiatric disorders that may affect compliance with the study protocol, will also be excluded.

3.2.7 Intervention Description: Collaborative Deprescribing Pathway

In the following interventional study, pharmacist and general practitioners work collaboratively to safely minimize inappropriate PPIs use. GPs will identify and refer eligible patients, while pharmacists will provide follow-up care and counseling. This coordinated approach ensures effective communication and integrated patient care. However, this randomized controlled trial evaluates the effectiveness of a collaborative deprescribing intervention for PPIs in primary care.

3.2.8 Deprescribing Strategy: The DROP-IT Approach

A total of 400 participants are randomly assigned to an intervention group or a control group. The intervention group followed the DROPIT approach Document,

Review, Optimize, Plan, Implement, Track, designed to guide healthcare providers in safely reducing or efficiently stopping unnecessary PPIs use. These are the following steps:

Step 1: Document

The pharmacist reviews the patient's medication record from patient reports and clinical information. A therapeutic profile of the patient is documented, including the type of PPIs taken, indication for prescribing, duration of consumption and potential drug-drug interactions.

Step 2: Review

In this collaborative intervention trial, pharmacists in Pakistan assess the inappropriate consumption of proton pump inhibitors using a deprescribing algorithm developed by the research team, based on patients' self-reported indications. Pharmacists deliver a structured patient education as a core component of intervention. The educational strategy involves both Oral counseling and written materials

Oral education is provided in-person by the pharmacist, focusing on patient engagement, clarification of the clinical need for on-going PPIs use and preparation for possible withdrawal effects.

Written education is provided through brochures by Gp.

The brochures included:

i. Rational use of PPIs and appropriate clinical indications.

ii. Risks of chronic PPI consumption, such as fractures, nutrient deficiencies, and infections.

iii. Benefits of deprescribing, particularly in case of inappropriate or prolonged use.

iv. Common withdrawal symptoms (e.g., rebound acid hyper- secretion)

v. Non-pharmacological and lifestyle strategies (e.g., dietary modifications, weight management) to support symptom control during and after deprescribing.

vi. The booklet was introduced for using best practices in patient's education, drawing from existing evidence-based deprescribing tools (e.g., deprescribing.org).

Following education, a therapeutic profile including PPIs history and drug-drug interaction.

This information was summarized in a "patient report", a paper-based document shared with the patient's GP to support continuity of care.

Step 3: Optimize

The GPs and pharmacist both review the clinical records (medical history, diagnosis and lab results) to check if the PPIs are still needed and if there is any safety concern. The GPs or pharmacist then inform the patient (or meets with person if needed) to talk about whether stopping the PPIs, based on national guidelines.

After discussing with the patient thoroughly, the GP:

i. Decides whether the PPIs should be stopped.

ii. Makes step-by-step plan to reduce the dose safely (if needed).

iii. Recommended lifestyle tips (like diet changes) help to manage symptoms.

iv. The GP then sends this plan and key information back to pharmacist using the clinical records.

Step 4: Plan

i. After the clinic visit, the GP and pharmacist agree on a PPIs tapering or stopping plan using deprescribing guidelines.

ii. Patients receive written instructions on expected symptoms, when to seek help and OTC options like antacids.

iii. Pharmacist will follow up by phone at 3 and 6 months (only for those reducing/stopping PPIs) to check symptoms, answer questions and suggest management strategies like dietary changes.

iv. At the end, pharmacist will share patient's progress with GPs using the Patient's Past report. Patients can contact the GP or pharmacist anytime; chronic symptoms must be managed by the GP.

Step 5: Implement and Track

The pharmacist will provide follow-up support to patients 3-6 months after their GP appointment to assess symptom relapse and guide pharmacological and non-pharmacological management strategies, including dietary modifications, in line with the intervention protocol. Telephone calls will be used solely to contact patients for appointment scheduling. Patients instructed to reduce or discontinue PPI therapy will receive follow-up guidance and monitoring at 3 months to support safe dose reduction or withdrawal. Patient reports will be shared with GPs to assist clinical monitoring at the end of the withdrawal period. Patients may consult the pharmacist at any time during the study, and GP support will be available if severe symptoms occur. Healthcare professionals in the intervention arm will receive printed materials, including the intervention flowchart and deprescribing guidelines. The control group will receive usual care. A baseline paper-based questionnaire will be completed at recruitment, with follow-up data collected within the first week after enrolment in both study arms.

3.2.9 Control Group Usual Care

In the control group, participants continue to go through their usual treatment as prescribed by their general practitioners, without any structured deprescribing intervention. Throughout the study period, no additional guidance or protocol

driven support is provided to modify or reduce their current medication regimen. Data collection for these participants is conducted at the same predefined intervals as the intervention group to ensure methodological consistency and enable a fair comparison of outcomes between both groups.

3.3 Data Collection Procedure

The following section describes the data collection procedure.

3.3.1 Baseline Data Collection

A total of 400 participants with dyspepsia were assessed at baseline. Baseline data was collected prior to the intervention to establish a reference point and evaluate the stability of study outcomes. Demographic characteristics were recorded and dyspepsia symptoms were assessed using the RDQ questionnaire for both, symptoms frequency days and symptoms intensity. Medication adherence was being evaluated with the help of GMAS scale, while quality of life was measured with a standardized QoL questionnaire. Patient satisfaction was also assessed at this stage for both the control and intervention groups. In addition, participants in the intervention group completed an intervention specific questionnaire at baseline, first follow-up and second follow-up to capture changes associated with the pharmacist-led intervention. After collecting baseline information, the pharmacist provided structured counselling that covered the nature of dyspepsia, common symptoms, dietary modifications, lifestyle practices, medication use and techniques for monitoring symptom progression and treatment responses.

3.3.2 Study Intervention

All participants allocated to intervention group received a structured, pharmacist-led deprescribing intervention carried out in the OPD setting. During routine OPD visits trained pharmacists conducted face-to-face sessions in which they reviewed

each participant's medication history, assessed the ongoing need for proton pump inhibitors therapy and identified potential cases of inappropriate long-term use.

Pharmacist's educated patients about the risks associated with prolonged PPIs therapy, the clinical advantages of deprescribing and the expected course of symptoms during dose reduction or discontinuation. Based on established deprescribing criteria, the pharmacist prepared individualized recommendations and documented them using a standardized checklist. These recommendations were communicated to the collaborating general practitioners in Islamabad clinics, who confirmed the suitability of the deprescribing plan and discussed it with the patient during follow-up consultations. Follow-up visits in the OPD and GP clinics were used to monitor symptoms, support adherence to the deprescribing plan, and adjust the tapering approach where necessary.

3.4 Follow-Up Structure

The following section outlines the follow-up structure used in this study.

3.4.1 First Follow-Up Month 3

The pharmacist scheduled monthly follow-ups assessment for all enrolled participants. First Follow-up was conducted at the end of the third month at this stage, a total of 150 participants from the control group remained in the study. In the control arm, 50 participants were lost to follow-up, 15 reported overall symptom improvements, 10 did not responded despite being contacted repeatedly, 14 cited medication cost as a barrier to continuing treatment and 16 expressed a lack of interest in further participation despite reminders. In the intervention group, 33 participants were lost at the first follow-up. Among these, 20 reported complete resolution of mild symptoms, 10 did not responded to repeated after being contacted multiple times, and 5 had migrated to another city and 3 had migrated to another city.

For all among those participants who remained, data was collected with full cooperation. During each follow-up visit, the pharmacist conducted a detailed clinical interview to assess patients' ongoing need for proton pump inhibitors therapy and to monitor progress with the deprescribing plan. The pharmacist identified factors contributing to continued or inappropriate PPIs use, evaluated barriers to adherence with the step-down or discontinuation regimen and provided individualized counselling. This counselling included education on appropriate PPIs consumption, recognition of rebound symptoms, lifestyle and dietary modifications for managing gastrointestinal discomfort and guidance on safe tapering practices to support successful deprescribing.

3.4.2 Second Follow-Up Month 6

The second follow-up was conducted during the sixth month of the study. At this stage, additional attrition was observed in both study arms. In the control group, 14 further participants were lost: 9 were not reachable despite repeated contact attempts, 2 had died, and 3 withdrew for personal or unspecified reasons.

In the intervention group, 17 additional participants were lost to follow-up, including 8 who were out of the city during the follow-up period, 7 who remained unresponsive to multiple reminders and 2 who withdrew for other reasons. Data collection procedures remained consistent with earlier phases of the study.

3.5 Data Collection Tools

The questionnaire had five sections. Demographic data and patient medical history were collected first. Next, the symptoms of gastroesophageal reflux disease were collected using the Reflux Disease Questionnaire RDQ, which measures the frequency and severity of symptoms [6]. Health-related quality of life was collected by using the EQ-5D-3L, which measures five health domains, such as mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, with three levels of severity ranging from no problems to extreme problems [71].

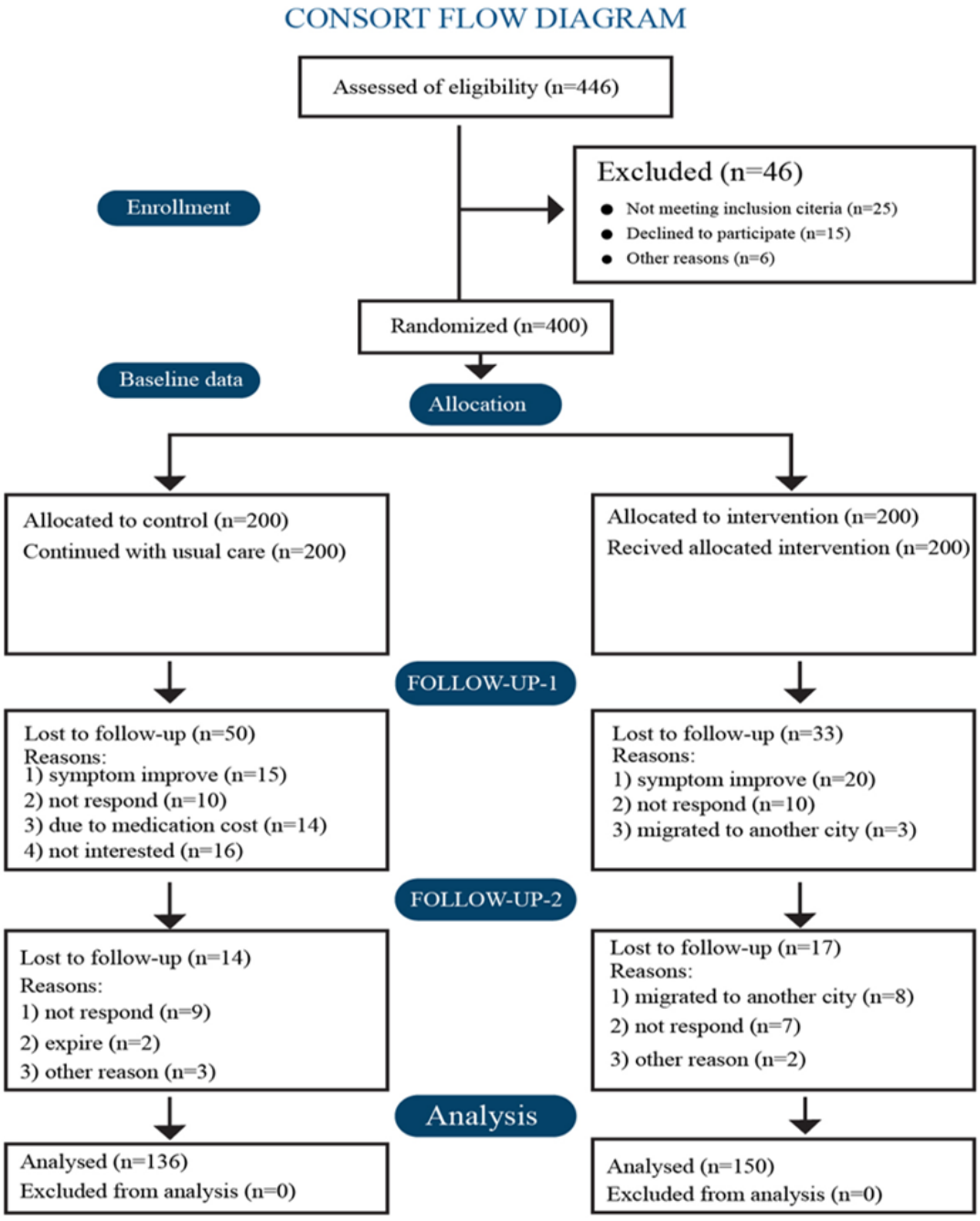

FIGURE 3.1: Methodology Flow Chart

Medication adherence was collected by using the General Medication Adherence Scale GMAS, which is available in English and Urdu. It has 11 questions and measures patient-related factors, such as the presence of co-morbid conditions and the number of medications, and financial constraints [72, 73]. Patient satisfaction was collected by using a new questionnaire, which is bilingual and specifically for Pakistani patients to assess their satisfaction after being counseled by the pharmacist, which is a pilot study [74].

Additionally, a structured tool to assess PPI dose, duration, drug interactions, and symptom severity was administered at the beginning, 3 months F1, and 6 months F2 to assess the patients' adherence, changes in symptoms, and the effect of de-prescribing [7].

3.6 Primary and Secondary Outcomes

i. The primary outcome of the study was changes in patient medication adherence and reduction in PPI therapy, evaluated by documenting dose adjustments, discontinuation, and frequency of use. Upper gastrointestinal symptoms, including heartburn, regurgitation, and dyspepsia, were assessed using the Reflux Disease Questionnaire to measure symptom frequency and severity at baseline and during follow-up.

ii. Secondary outcome measures further include changing in quality of life assessed using EQ-5D-3L patients satisfaction following patient centered care approach, rates of PPIs discontinuation, dose reduction or by switching to alternative acid reducing therapies, use of treatments such as H2 blockers or antacids, assessing PPIs related adverse effects over 6-month study period.

3.7 Trial Registration and Ethical Consideration

This study was registered in the Thai Clinical Trials Registry TCTR, a WHO-recognized primary clinical trial registry (Registration No: TCTR20260213005). Ethical approval was obtained from the Pharmacy Research Ethics Committee, Capital University of Science and Technology, Islamabad (Ref. No. REC/ FoP/ S2025/ 03), and from the Ethics Review Committee of PIMS (Ref. No. F-5-2/2024 (ERRC)/ PIMS), Islamabad Hospital, Life Care Hospital.

3.8 Statistical Analysis

For statistical analysis, SPSS software version 27 was used. Descriptive statistics, including frequencies, percentages, and standard deviations, were used to describe the baseline demographic information. Normality of the data was checked by the Kolmogorov-Smirnov test. The Mann-Whitney U-test and Chi-square tests were used for comparing the differences between the two groups. In addition, the Wilcoxon signed rank test was used for analyzing the differences before and after the intervention. A p-value of ¡0.05 was considered statistically significant. In the intervention group, structured questionnaires regarding the details of PPI therapy, including dose, duration, and drug interactions, were administered at baseline, after 3 months F1, and after 6 months F2. Changes in symptoms and patient perception were recorded using ordered categorical choices ranging from much better to much worse, expressed as frequency and percentage.

Chapter 4

Results

4.1 Respondents Demographic Characteristics

As shown in Table 4.1 the baseline demographic information about the participants. In the control group as well as the intervention group, there are no statistically significant differences in terms of age (p = 0.772), gender (p = 0.346), marital status (p = 0.636), living arrangements (p = 0.650), education (p = 0.177), occupation (p = 0.593), and area of residence (p = 0.765). This shows that the allocation of the group has been successful in minimizing biasness.

TABLE 4.1: Demographic Characteristics of Patients (n = 400)

Variable	**Category**	**Control**	**Intervention**	**Chi-square test**
		n = 200 (%)	**n = 200 (%)**	**P value**
Age (groups)				0.772
	18-29	64 (32.0)	58 (29.0)	
	30-49	78 (39.0)	84 (42.0)	
	50 Above	58 (29.0)	58 (29.0)	
Gender				0.346
	Male	75 (37.5)	66 (33.0)	
	Female	125 (62.5)	134 (67.0)	
Marital Status				0.636

Table 4.1 continued from previous page

Variable	Category	Control	Intervention	Chi-square test
		n = 200 (%)	**n = 200 (%)**	**P value**
	Single	43 (21.5)	36 (18.0)	
	Married	150 (75.0)	158 (79.0)	
	Widowed/Divorced	7 (3.5)	6 (3.0)	
Living arrangement				0.650
	Alone	43 (21.5)	37 (18.5)	
	With Spouse	156 (78.0)	161 (80.5)	
	With children	1 (0.5)	2 (1.0)	
Highest level of education				0.177
	No formal education	80 (40.0)	78 (39.0)	
	Secondary education	91 (45.5)	104 (52.0)	
	Higher education	29 (14.5)	18 (9.0)	
Occupation				0.593
	Employed	48 (24.0)	57 (28.5)	
	Unemployed	135 (67.5)	127 (63.5)	
	Student/Home marker	17 (8.5)	16 (8.0)	
Residence				0.765
	Islamabad	102 (51.0)	95 (47.5)	
	Rawalpindi	75 (37.5)	79 (39.5)	
	Other	23 (11.5)	26 (13.0)	

4.2 Assessment of Patients Health History

Baseline assessment of patients' health history showed no statistically significant differences between the both control and intervention groups between all evaluated variables Table 4.2. The time period for PPIs usage was comparable between groups, PPIs for 3-12 months and those using PPIs for more than one year (p = 0.108). Similarly in case of smoking status (never, former, and current smokers) differ significantly between the two groups (p = 0.185). The number regularly used medications, are categorized as 1-3, 4-6, and 7-10 medicines, was similarly distributed across groups (p = 0.223). Awareness regarding side effects of long-term use of PPI showed no significant variation between control and intervention

group (p = 0.761). Additionally, prior attempts to reduce or stop of PPIs therapy were also comparable between both groups (p = 0.217).

TABLE 4.2: Key points from Patients Health History

Variable	**Category**	**Control n = 200 (%)**	**Intervention n = 200 (%)**	**Chi square test P value**
Taking a PPIs				0.108
	3-12 months	83 (41.5)	99 (49.5)	
	More than 1 year	117 (58.5)	101 (50.5)	
Currently smoker				0.185
	Never	178 (89.0)	188 (94.0)	
	Former smoker	17 (8.5)	10 (5.0)	
	Current smoker	5(2.5)	2 (1.0)	
Medication do you take regularly				0.223
	1-3	116 (58.0)	100 (50.0)	
	4-6	81 (40.5)	98 (49.0)	
	7-10	3 (1.5)	2 (1.0)	
Aware of any side effect of long-term use of PPIs				0.761
	Yes	3 (1.5)	5 (2.5)	
	No	174 (87.0)	171 (85.5)	
	Not sure	23 (11.5)	24 (12.0)	
Tried to stop or reduced PPIs in the past				0.217
	Yes	6 (3.0)	13 (6.5)	
	No	169 (84.5)	159 (79.5)	
	Not at all	25 (12.5)	28 (14.0)	

4.3 Assessment of Baseline Reflux Disease Questionnaire across Follow-ups in both Groups

4.3.1 RDQ Baseline Assessment of Groups in Terms of Days

Participants in the both groups had reported changes in frequencies of reflux-related symptoms across all RDQ domains at the baseline. Feedback was shared,

those categories that did not had 1 day, 2 days, 3-4 days, 5 days and daily. At the baseline RDQ responses with in the both control and intervention group, revealed no statistically remarkable differences ($p > 0.05$). Table 4.3 presents baseline comparison of frequency of reflux symptoms in days per week.

TABLE 4.3: Baseline Comparison of Reflux Symptoms Frequency Days/Week

Symptoms (baseline)	**No of days**	**Control n = 136 (%)**	**Intervention n = 150 (%)**	**Chi square test P value**
A burning feeling behind your breastbone				0.937
	Have not had	19 (14.0)	21 (14.0)	
	1 day	5 (3.7)	5 (3.3)	
	2 days	11 (8.1)	18 (12.0)	
	3-4 days	8 (5.9)	9 (6.0)	
	5 days	42 (30.9)	45 (30.0)	
	Daily	51 (37.5)	52 (34.7)	
Pain behind your Breast bone				0.973
	Have not had	30 (22.1)	34 (22.7)	
	1 day	10 (7.4)	10 (6.7)	
	2 days	15 (11.0)	18 (12.0)	
	3-4 days	11 (8.1)	12 (8.0)	
	5 days	22 (16.2)	29 (19.3)	
	Daily	48 (35.3)	47 (31.3)	
Pain in the center of the upper stomach				0.516
	Have not had	40 (29.4)	40 (26.7)	
	1 day	5 (3.7)	6 (4.0)	
	2 days	7 (5.1)	9 (6.0)	
	3-4 days	17 (12.5)	25 (16.7)	
	5 days	21 (15.4)	32 (21.3)	
	Daily	46 (33.8)	38 (25.3)	
An acid taste in your mouth				0.548
	Have not had	13 (9.6)	19 (12.7)	
	1 day	6 (4.4)	6 (4.0)	
	2 days	12 (8.8)	10 (6.7)	
	3-4 days	17 (12.5	24 (16.0)	
	5 days	23 (16.9)	33 (22.0)	
	Daily	65 (47.8)	58 (38.7)	
Unpleasant movement of material upward from the stomach				0.531
	Have not had	19 (14.0)	22 (14.7)	

Table 4.3 continued from previous page

Symptoms (baseline)	**No of days**	**Control n = 136 (%)**	**Intervention n = 150 (%)**	**Chi square test P value**
	1 day	4 (2.9)	2 (1.3)	
	2 days	7 (5.1)	11 (7.3)	
	3-4 days	19 (14.0)	31 (20.7)	
	5 days	32 (23.5)	29 (19.3)	
	Daily	58 (42.6)	55 (36.7)	
Burping (gas coming from the stomach through the mouth				0.642
	Have not had	25 (18.4)	29 (19.3)	
	1 day	6 (4.4)	5 (3.3)	
	2 days	12 (8.8)	9 (6.0)	
	3-4 days	15 (11.0)	26 (17.3)	
	5 days	27 (19.9)	31 (20.7)	
	Daily	51 (37.5)	50 (33.3)	
A bitter taste in your mouth				0.599
	Have not had	36 (26.5)	34 (22.7)	
	1 day	3 (2.2)	7 (4.7)	
	2 days	13 (9.6)	18 (12.0)	
	3-4 days	25 (18.4)	30 (20.0)	
	5 days	19 (14.0)	26 (17.3)	
	Daily	40 (29.4)	35 (23.3)	
Heart burn				0.214
	Have not had	29 (21.3)	26 (17.3)	
	1 day	12 (8.8)	6 (4.0)	
	2 days	10 (7.4)	11 (7.3)	
	3-4 days	21 (15.4)	39 (26.0)	
	5 days	31 (22.8)	34 (22.7)	
	Daily	33 (24.3)	34 (22.7)	

4.3.2 RDQ Baseline Assessment of Groups in Terms of Intensity

Participants in the both groups had reported changes in intensity of reflux-related symptoms across all RDQ domains at the baseline. Feedback was shared, those categories that did not had, very mild, Mild, Moderate, Moderately and Severe.

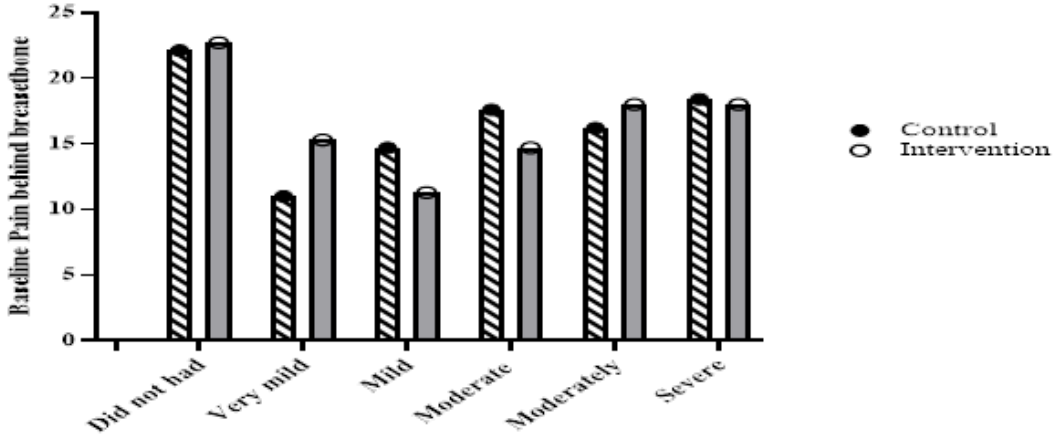

FIGURE 4.1: Comparison of intensity of Baseline Pain behind Breast Bone

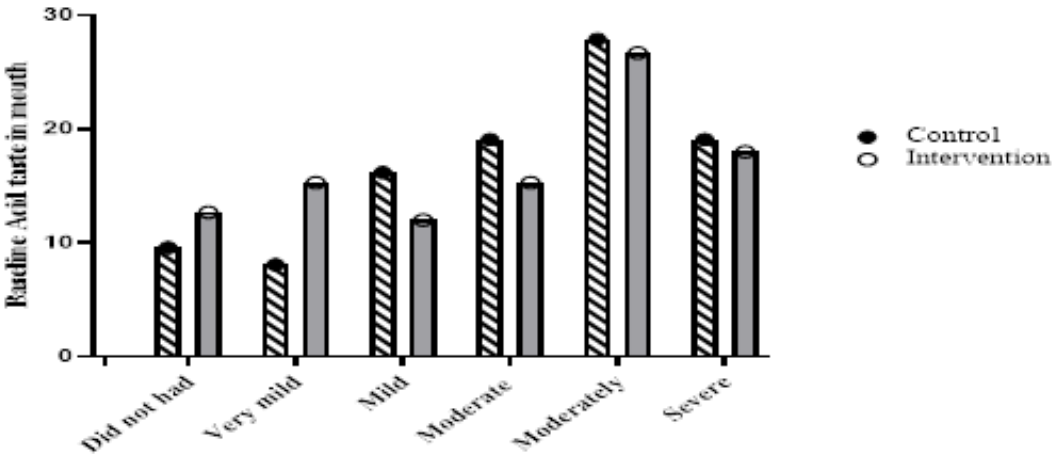

FIGURE 4.2: Comparison of Intensity of Baseline Acid Taste in Mouth

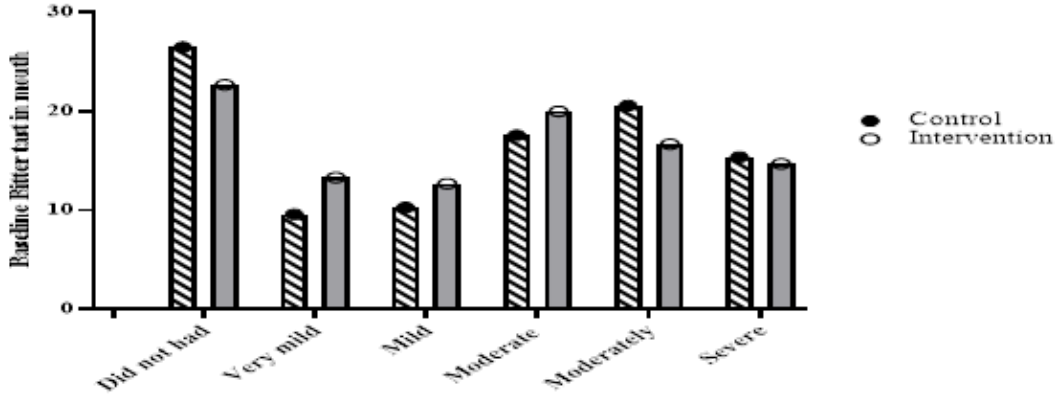

FIGURE 4.3: Comparison of Intensity of Baseline Bitter Taste in Mouth

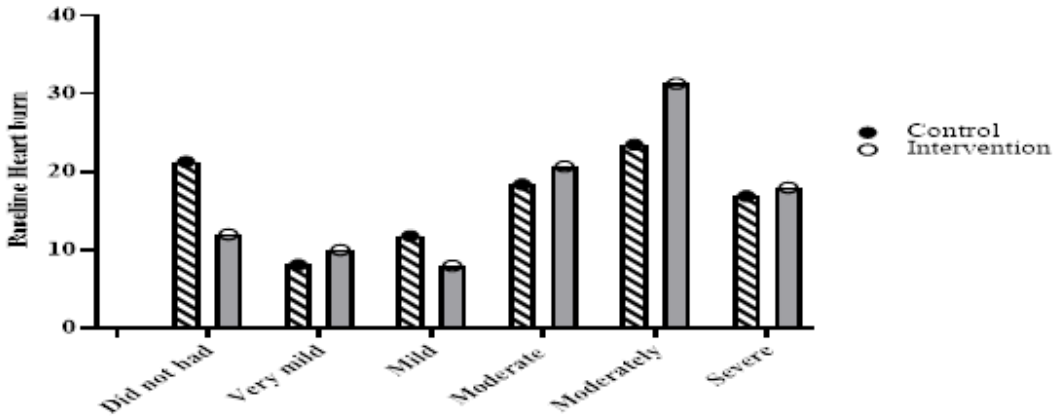

FIGURE 4.4: Comparison of Intensity of Baseline Heart Burn

At the baseline RDQ responses with in the both control and intervention group revealed no statistically remarkable differences ($p > 0.05$). Statistical analysis showed that there were no notable changes in the symptoms and severity. Table 4.4 presents the baseline comparison of intensity of reflux symptoms.

TABLE 4.4: Baseline Comparison of Reflux Symptom Intensity

Symptoms (Baseline)	**Intensity**	**Control n =136 (%)**	**Intervention n = 150 (%)**	**Chi-square test P value**
A burning feeling behind your breastbone				0.712
	Did not had	19 (14.0)	21 (14.0)	
	Very mild	15 (11.0)	15 (10.0)	
	Mild	22 (16.2)	18 (12.0)	
	Moderate	19 (14.0)	27 (18.0)	
	Moderately	34 (25.0)	45 (30.0)	
	Severe	27 (19.9)	24 (16.0)	
Pain behind your Breast bone				0.825
	Did not had	30 (22.1)	34 (22.7)	
	Very mild	15 (11.0)	23 (15.3)	
	Mild	20 (14.7)	17 (11.3)	
	Moderate	24 (17.6)	22 (14.7)	
	Moderately	29 (16.2)	27 (18.0)	
	Severe	25 (18.4)	27 (18.0)	
Pain in the center of the upper stomach				0.943
	Did not had	40 (29.41)	40 (26.7)	
	Very mild	18 (13.2)	19 (12.7)	

Table 4.4 continued from previous page

Symptoms (Baseline)	**Intensity**	**Control n =136 (%)**	**Intervention n = 150 (%)**	**Chi-square test P value**
	Mild	18 (13.2)	19 (12.7)	
	Moderate	20 (14.7)	27 (18.0)	
	Moderately	20 (14.7)	26 (17.3)	
	Severe	20 (14.7)	19 (12.7)	
An acid taste in your mouth				0.376
	Did not had	13 (9.6)	19 (12.7)	
	Very mild	11 (8.1)	23 (15.3)	
	Mild	22 (16.2)	18 (12.0)	
	Moderate	26 (19.1)	23 (15.3)	
	Moderately	38 (27.9)	40 (26.7)	
	Severe	26 (19.1)	27 (18.0)	
Unpleasant movement of material upward from the stomach				0.933
	Did not had	19 (14.0)	22 (14.7)	
	Very mild	21 (15.4)	29 (19.3)	
	Mild	12 (8.8)	14 (9.3)	
	Moderate	28 (20.6)	32 (21.3)	
	Moderately	35 (25.7)	33 (22.0)	
	Severe	21 (15.4)	20 (13.3)	
Burping (gas coming from the stomach through the mouth				0.759
	Did not had	25 (18.4)	29 (19.3)	
	Very mild	15 (11.0)	19 (12.7)	
	Mild	15 (11.0)	12 (8.0)	
	Moderate	24 (17.6)	32 (21.3)	
	Moderately	29 (21.3)	35 (23.3)	
	Severe	28 (20.6)	23 (15.3)	
A bitter taste in your mouth				0.780
	Did not had	36 (26.5)	34 (22.7)	
	Very mild	13 (9.6)	20 (13.3)	
	Mild	14 (10.3)	19 (12.7)	
	Moderate	24 (17.6)	30 (20.0)	
	Moderately	28 (20.6)	25 (16.7)	
	Severe	21 (15.4)	22 (14.7)	
Heart burn				0.228
	Did not had	29 (21.3)	18 (12.0)	
	Very mild	11 (8.1)	15 (10.0)	

Table 4.4 continued from previous page

Symptoms (Baseline)	Intensity	Control n =136 (%)	Intervention n = 150 (%)	Chi-square test P value
	Mild	16 (11.8)	12 (8.0)	
	Moderate	25 (18.4)	31 (20.7)	
	Moderately	32 (23.5)	47 (31.3)	
	Severe	23 (16.9)	27 (18.0)	

4.3.3 Follow-up 1 Assessment between Groups in Terms of Days

Table 4.5 shows the difference of reflux symptoms frequency between the control and intervention groups at follow-up 1 using the chi-square test, this analysis however reveals statistically notable differences between both the groups for all evaluated symptoms. A burning sensation behind the breastbone (p = 0.043), pain behind the breastbone (p = 0.045), pain in the center of the upper stomach (p = 0.023), acid taste in the mouth (p = 0.047) unpleasant upward movement of gastric contents (p = 0.017), burping (p = 0.044) bitter taste in the mouth (p = 0.008), and heartburn (p = 0.045) all showed notable group-wise variation at the follow-up.

TABLE 4.5: Follow-up1 Comparison of Reflux Symptoms Frequency Days/Week

Symptoms Follow-up 1	No. of days	Control n = 136 (%)	Intervention n = 150 (%)	Chi-square test P value
A burning feeling behind your breastbone				0.043
	Have not had	30 (22.1)	42 (28.0)	
	1 day	10 (7.4)	17 (11.3)	
	2 days	26 (19.1)	12 (8.0)	
	3-4 days	11 (8.1)	17 (11.3)	
	5 days	30 (22.1)	24 (16.0)	
	Daily	29 (21.3)	38 (25.3)	
Pain behind your Breast bone				0.045
	Have not had	43 (31.6)	39 (26.0)	
	1 day	6 (4.4)	13 (8.7)	

Table 4.5 continued from previous page

Symptoms	**No. of days**	**Control**	**Intervention**	**Chi-square test**
Follow-up 1		**n = 136 (%)**	**n = 150 (%)**	**P value**
	2 days	10 (7.4)	25 (16.7)	
	3-4 days	11 (8.1)	18 (12.0)	
	5 days	21 (15.4)	16 (10.7)	
	Daily	45 (33.1)	39 (26.0)	
Pain in the center of the upper stomach				0.023
	Have not had	44 (32.4)	52 (34.7)	
	1 day	3 (2.2)	10 (6.7)	
	2 days	6 (4.4)	10 (6.7)	
	3-4 days	8 (5.9)	21 (14.0)	
	5 days	15 (11.0)	12 (8.0)	
	Daily	60 (44.1)	45 (30.0)	
An acid taste in your mouth				0.047
	Have not had	31 (22.8)	47 (31.3)	
	1 day	5 (3.7)	7 (4.7)	
	2 days	7 (5.1)	20 (13.3)	
	3-4 days	16 (11.8)	16 (11.8)	
	5 days	19 (14.0)	15 (10.0)	
	Daily	58 (42.6)	50 (33.3)	
Unpleasant movement of material upward from the stomach				0.017
	Have not had	39 (28.7)	52 (34.7)	
	1 day	4 (2.9)	9 (6.0)	
	2 days	5 (3.7)	19 (12.7)	
	3-4 days	13 (9.6)	13 (8.7)	
	5 days	20 (14.7)	15 (10.0)	
	Daily	55 (40.4)	42 (28.0)	
Burping (gas coming from the stomach through the mouth				0.044
	Have not had	35 (25.7)	56 (37.3)	
	1 day	3 (2.2)	5 (3.3)	
	2 days	8 (5.9)	17 (11.3)	
	3-4 days	15 (11.0)	14 (9.3)	
	5 days	19 (14.0)	10 (16.7)	
	Daily	56 (41.2)	48 (32.0)	
A bitter taste in your mouth				0.008
	Have not had	49 (36.0)	54 (36.0)	
	1 day	3 (2.2)	15 (10.0)	

Table 4.5 continued from previous page

Symptoms	**No. of days**	**Control**	**Intervention**	**Chi-square test**
Follow-up 1		**n = 136 (%)**	**n = 150 (%)**	**P value**
	2 days	5 (3.7)	17 (11.3)	
	3-4 days	20 (14.7)	17 (11.3)	
	5 days	28 (20.6)	22 (14.7)	
	Daily	31 (22.8)	26 (16.7)	
Heart burn				0.045
	Have not had	32 (23.5)	42 (28.0)	
	1 day	5 (3.7)	11 (7.3)	
	2 days	7 (5.1)	20 (13.3)	
	3-4 days	26 (19.1)	26 (17.3)	
	5 days	23 (16.9)	20 (13.3)	
	Daily	43 (31.6)	31 (20.7)	

4.3.4 Follow-up 1 Assessment between Groups in Terms of Intensity

As shown in Table 4.6 shows the difference of reflux symptoms intensity between the control and intervention groups at follow-up 1. Data interpretation is done by using the chi-square test tells significant differences between the groups for all analyzed symptoms.

Participants in the intervention group had described a higher proportion of "did not have" or "very mild" symptoms compared with the control group, showed substantial symptoms improvement.

Particularly the significant differences were noticed for burning sensation behind the breastbone (p = 0.037), pain behind the breastbone (p = 0.021), pain in the center of the upper stomach (p = 0.033), acid taste in the mouth (p = 0.023), unpleasant upward movement of stomach contents (p = 0.003), burping (p = 0.024), bitter taste in the mouth (p = 0.026) and heartburn (p = 0.046).

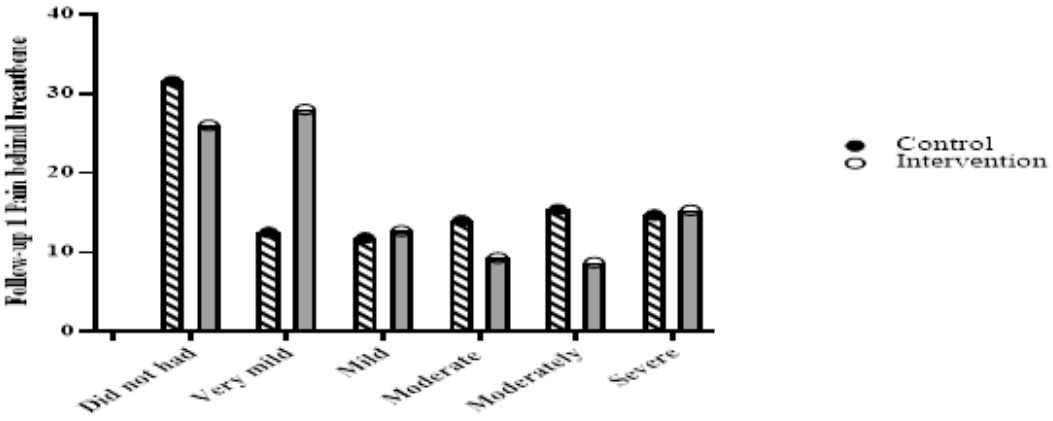

FIGURE 4.5: Comparison of Intensity of Follow-up 1 Pain behind breast bond

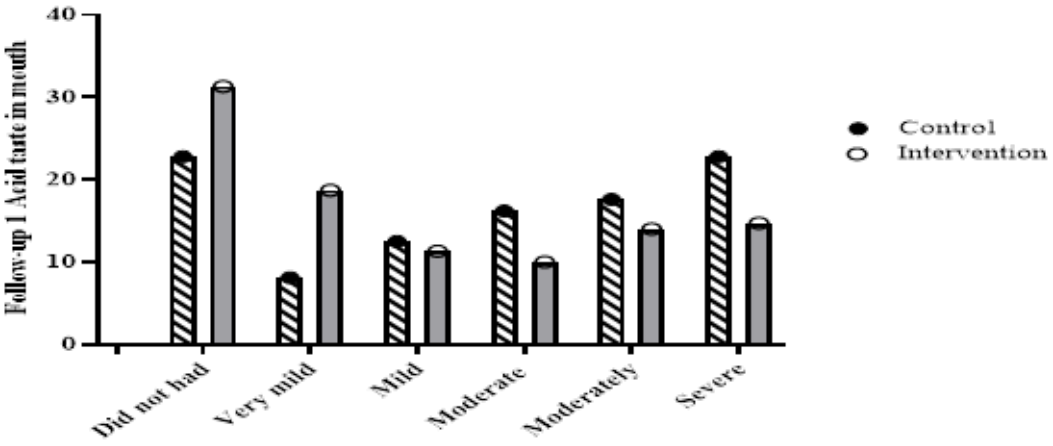

FIGURE 4.6: Comparison of Intensity of Follow-up 1 Acidic Taste in Mouth

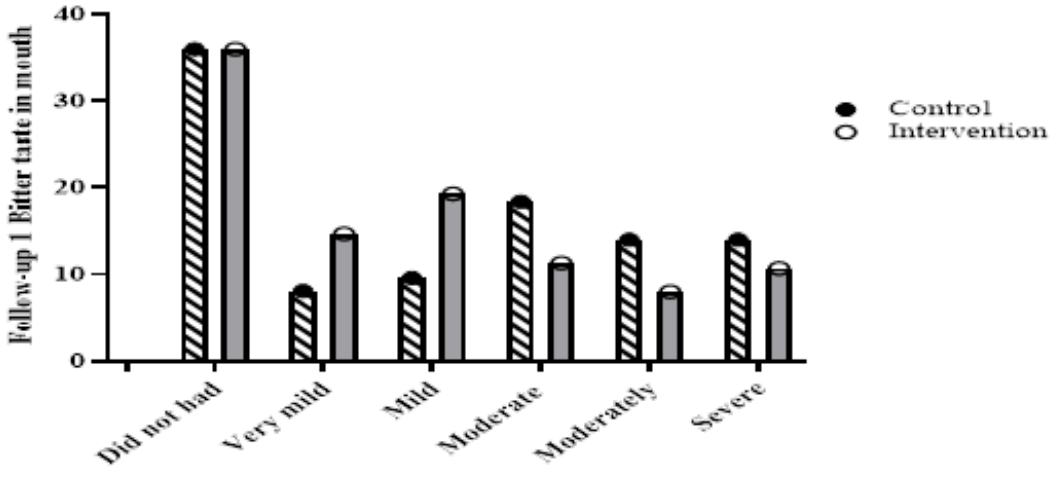

FIGURE 4.7: Comparison of Intensity of Follow-up 1 Bitter Taste in Mouth

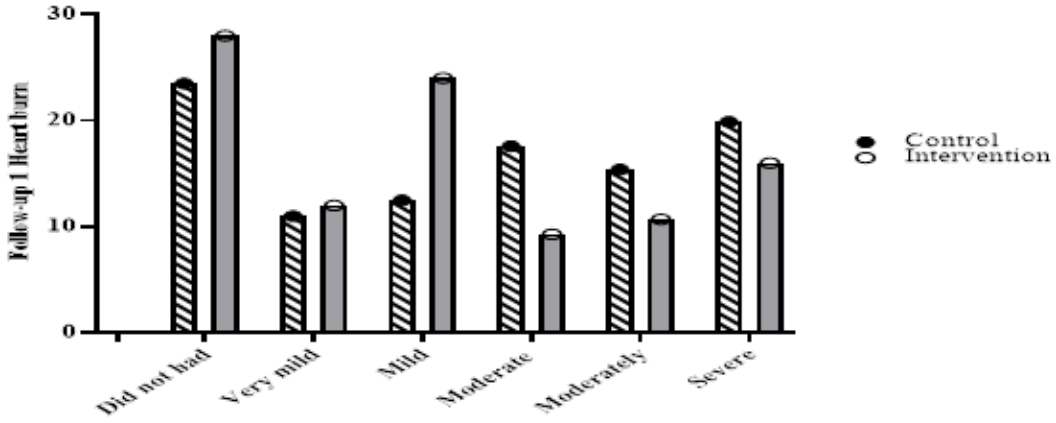

FIGURE 4.8: Comparison of Intensity of Follow-up 1 Heart Burn

TABLE 4.6: Follow-up1 Comparison of Reflux Symptoms Intensity

Symptoms (F1)	**Intensity**	**Control n = 136 (%)**	**Intervention n = 150 (%)**	**Chi-square test P value**
A burning feeling behind your breastbone				0.037
	Did not had	30 (22.1)	42 (28.0)	
	Very mild	11 (8.1)	14 (9.3)	
	Mild	13 (9.6)	31 (20.7)	
	Moderate	21 (15.4)	14 (9.3)	
	Moderately	31 (22.8)	24 (16.0)	
	Severe	30 (22.1)	25 (16.7)	
Pain behind your Breast bone				0.021
	Did not had	43 (31.6)	39 (26.0)	
	Very mild	17 (12.5)	42 (28.0)	
	Mild	16 (11.8)	19 (12.7)	
	Moderate	19 (14.0)	14 (9.3)	
	Moderately	21 (15.4)	13 (8.7)	
	Severe	20 (14.7)	23 (15.3)	
Pain in the center of the upper stomach				0.033
	Did not had	44 (32.4)	52 (34.7)	
	Very mild	13 (9.6)	29 (19.3)	
	Mild	12 (8.8)	15 (10.0)	
	Moderate	17 (12.5)	23 (15.3)	
	Moderately	24 (17.6)	17 (11.3)	
	Severe	26 (19.1)	14 (9.3)	
An acid taste in your mouth				0.023
	Did not had	31 (22.8)	47 (31.3)	

Table 4.6 continued from previous page

Symptoms (F1)	**Intensity**	**Control n = 136 (%)**	**Intervention n = 150 (%)**	**Chi-square test P value**
	Very mild	11 (8.1)	28 (18.7)	
	Mild	17 (12.5)	17 (11.3)	
	Moderate	22 (16.2)	15 (10.0)	
	Moderately	24 (17.6)	21 (14.0)	
	Severe	31 (22.8)	22 (14.7)	
Unpleasant movement of material upward from the stomach				0.003
	Did not had	29 (28.7)	52 (34.7)	
	Very mild	11 (8.1)	26 (17.3)	
	Mild	6 (4.4)	15 (10.0)	
	Moderate	18 (13.2)	18 (12.0)	
	Moderately	27 (19.9)	22 (14.7)	
	Severe	35 (25.7)	17 (11.3)	
Burping (gas coming from the stomach through the mouth)				0.024
	Did not had	35 (25.7)	40 (29.4)	
	Very mild	15 (11.0)	18 (13.2)	
	Mild	16 (11.8)	14 (10.3)	
	Moderate	14 (10.3)	14 (10.3)	
	Moderately	25 (18.4)	15 (11.0)	
	Severe	31 (22.8)	35 (25.7)	
A bitter taste in your mouth				0.026
	Did not had	49 (36.0)	54 (36.0)	
	Very mild	11 (8.1)	22 (14.7)	
	Mild	13 (9.6)	29 (19.3)	
	Moderate	25 (18.4)	17 (11.3)	
	Moderately	19 (14.0)	12 (8.0)	
	Severe	19 (14.0)	16 (10.7)	
Heart burn				0.046
	Did not had	32 (23.5)	42 (28.0)	
	Very mild	15 (11.0)	18 (12.0)	
	Mild	17 (12.5)	36 (24.0)	
	Moderate	24 (17.6)	14 (9.3)	
	Moderately	21 (15.4)	16 (10.7)	
	Severe	27 (19.9)	24 (16.0)	

4.3.5 Follow-up 2 Assessment between Groups in Terms of Days

As shown in Table 4.7 shows the difference of reflux symptom frequency between the control and intervention groups at second follow up. Statistical analysis using chi-square test shows highly notable comparison between both groups for all assessed symptoms ($p < 0.001$) for most symptoms; pain in the center of the upper stomach, ($p < 0.002$); unpleasant movement of stomach contents, ($p = 0.001$). Covering all symptoms, participants in the intervention group had described a considerable proportion of "did not have" or less symptomatic days compared with the control group, indicating considerable improvement

TABLE 4.7: Follow-up 2 Comparison of Reflux Symptoms Frequency Days/Week

Symptoms F-2	**No. of days**	**Control n =136 (%)**	**Intervention n = 150 (%)**	**Chi-square test P value**
A burning feeling behind your breastbone				<0.001
	Have not had	35 (25.7)	55 (36.7)	
	1 day	7 (5.1)	16 (10.7)	
	2 days	5 (3.7)	19 (12.7)	
	3-4 days	12 (8.8)	17 (11.3)	
	5 days	7 (5.1)	12 (8.0)	
	Daily	57 (41.9)	31 (20.7)	
Pain behind your Breast bone				<0.001
	Have not had	38 (29.7)	49 (32.7)	
	1 day	4 (2.9)	14 (9.3)	
	2 days	12 (8.8)	18 (12.0)	
	3-4 days	8 (5.9)	25 (16.7)	
	5 days	24 (17.6)	14 (9.3)	
	Daily	50 (36.8)	30 (20.0)	
Pain in the center of the upper stomach				<0.002
	Have not had	45 (33.3)	56 (37.3)	
	1 day	4 (3.0)	12 (8.0)	
	2 days	6 (4.4)	17 (11.3)	
	3-4 days	11 (8.1)	18 (12.0)	
	5 days	24 (17.8)	9 (6.0)	

Table 4.7 continued from previous page

Symptoms F-2	**No. of days**	**Control n =136 (%)**	**Intervention n = 150 (%)**	**Chi-square test P value**
	Daily	45 (33.3)	38 (25.3)	
An acid taste in your mouth				<0.001
	Have not had	30 (22.1)	53 (35.3)	
	1 day	3 (2.2)	7 (4.7)	
	2 days	7 (5.1)	18 (12.0)	
	3-4 days	16 (11.8)	23 (15.3)	
	5 days	15 (11.0)	9 (6.0)	
	Daily	65 (47.8)	40 (26.7)	
Unpleasant movement of material upward from the stomach				0.001
	Have not had	37 (27.2)	63 (42.0)	
	1 day	3 (2.2)	10 (6.7)	
	2 days	7 (5.1)	17 (11.3)	
	3-4 days	19 (14.0)	16 (10.7)	
	5 days	8 (5.9)	4 (2.7)	
	Daily	62 (45.6)	40 (26.7)	
Burping (gas coming from the stomach through the mouth)				<0.001
	Have not had	40 (29.4)	60 (40.0)	
	1 day	5 (3.7)	5 (3.3)	
	2 days	9 (6.6)	26 (17.3)	
	3-4 days	12 (8.8)	21 (14.0)	
	5 days	22 (16.2)	14 (9.3)	
	Daily	48 (35.3)	24 (16.0)	
A bitter taste in your mouth				<0.001
	Have not had	40 (29.4)	57 (38.0)	
	1 day	3 (2.2)	11 (7.3)	
	2 days	5 (3.7)	21 (14.0)	
	3-4 days	25 (18.4)	24 (16.0)	
	5 days	27 (18.4)	14 (9.3)	
	Daily	36 (26.5)	23 (15.3)	
Heart burn				<0.001
	Have not had	42 (30.9)	55 (36.7)	
	1 day	3 (2.2)	6 (4.0)	
	2 days	6 (4.4)	29 (19.3)	
	3-4 days	23 (16.9)	20 (13.3)	
	5 days	30 (22.1)	12 (8.0)	

Table 4.7 continued from previous page

Symptoms F-2	No. of days	Control n =136 (%)	Intervention n = 150 (%)	Chi-square test P value
	Daily	32 (23.5)	28 (18.7)	

4.3.6 Follow-up 2 Assessment between Groups in Terms of Intensity

As shown in Table 4.8 presents the difference of reflux symptoms intensity between the control and intervention groups at the follow-up 2. Chi-square analysis showed significant differences between both groups for all assessed symptoms ($p < 0.05$). Intervention group participants had consistently reported a higher proportion of "did not have" or "very mild" symptoms in contrast with the control group, indicating a relevant reduction in symptoms intensity. Particularly remarkable advances are being observed for a burning sensation behind the breastbone ($p = 0.039$), pain behind the breastbone ($p = 0.008$), pain in the center of the upper stomach ($p = 0.019$), acid taste in the mouth ($p = 0.011$), unpleasant upward movement of stomach contents ($p = 0.003$), burping ($p = 0.020$), bitter taste in the mouth ($p < 0.001$), and heartburn ($p = 0.026$).

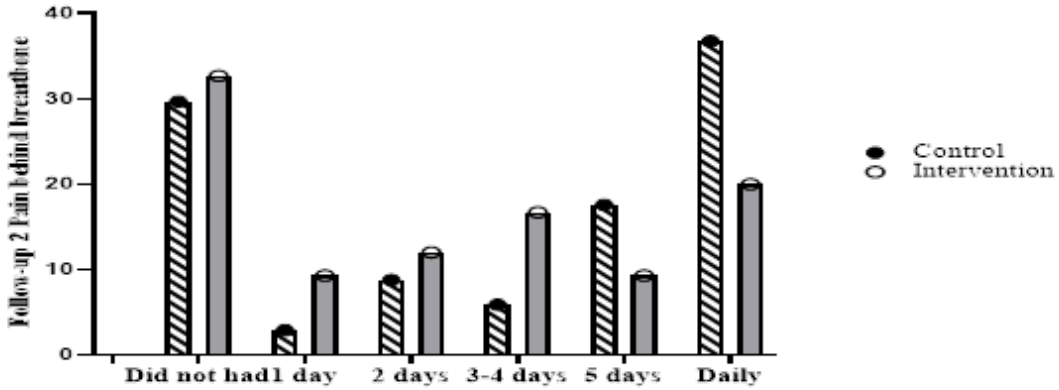

FIGURE 4.9: Comparison of Intensity of Follow-up 2 Pain behind breast bone

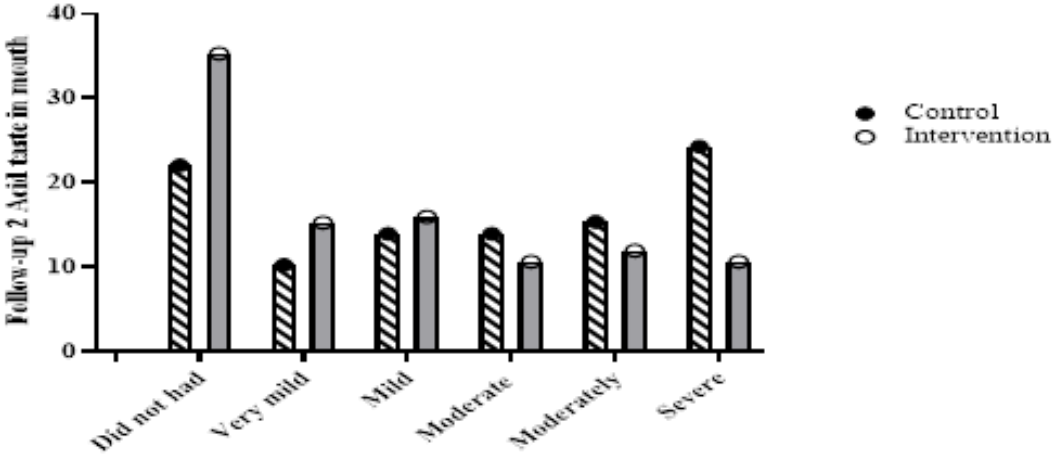

FIGURE 4.10: Comparison of Intensity of Follow-up 2 Acid Taste in Mouth

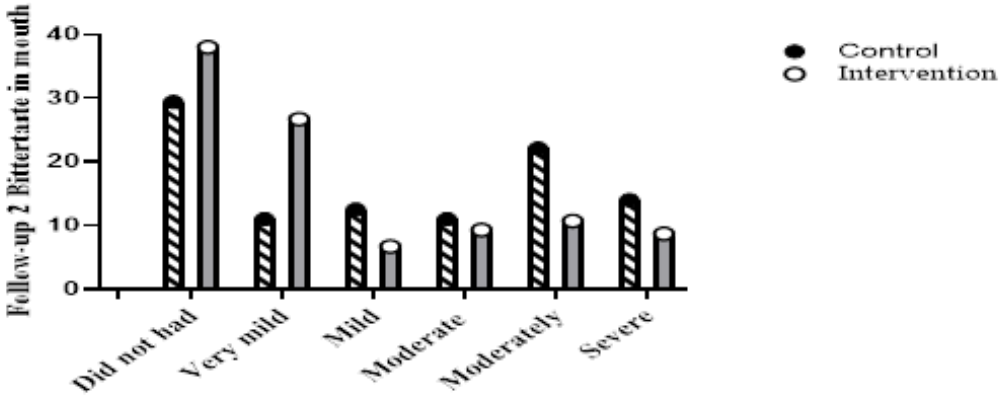

FIGURE 4.11: Comparison of Intensity of Follow-up 2 Bitter Taste in Mouth

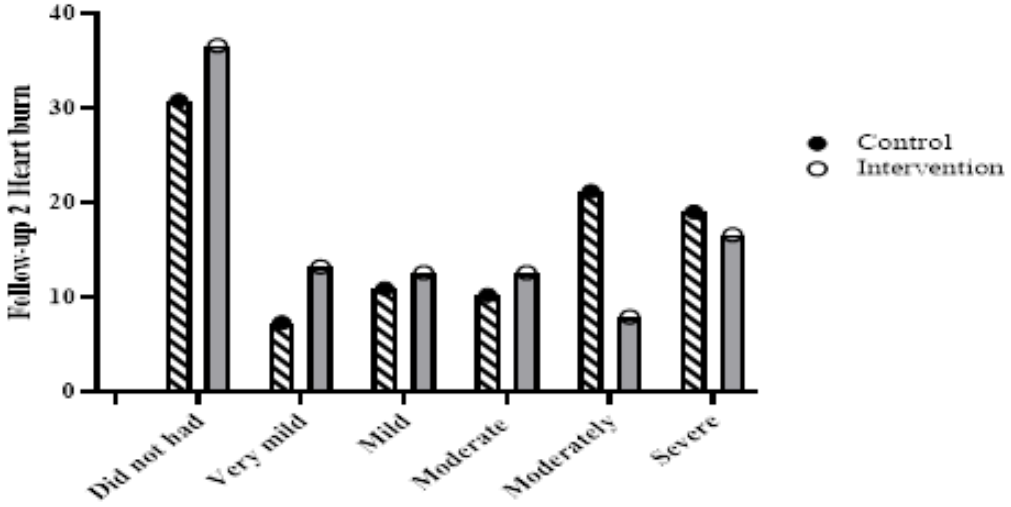

FIGURE 4.12: Comparison of Intensity of Follow-up 2 Heart Burn

TABLE 4.8: Follow-up 2 Comparison of Reflux Symptom Intensity

Symptoms (F-2)	**Intensity**	**Control n = 136 (%)**	**Intervention n = 150 (%)**	**Chi-square test P value**
A burning feeling behind your breastbone				0.039
	Did not had	35 (25.7)	55 (36.7)	
	Very mild	5 (3.7)	14 (9.3)	
	Mild	14 (10.3)	17 (11.3)	
	Moderate	14 (10.3)	10 (6.7)	
	Moderately	30 (22.1)	29 (19.3)	
	Severe	38 (27.9)	25 (16.7)	
Pain behind your Breast bone				0.008
	Did not had	38 (27.9)	49 (32.7)	
	Very mild	13 (9.6)	30 (20.0)	
	Mild	14 (10.3)	21 (14.0)	
	Moderate	19 (14.0)	21 (14.0)	
	Moderately	28 (20.6)	15 (10.0)	
	Severe	24 (17.6)	14 (9.3)	
Pain in the center of the upper stomach				0.019
	Did not had	45 (33.1)	56 (37.3)	
	Very mild	12 (8.8)	21 (14.0)	
	Mild	12 (8.8)	24 (16.0)	
	Moderate	14 (10.3)	18 (12.0)	
	Moderately	24 (17.6)	‘16 (10.7)	
	Severe	29 (21.3)	15 (10.0)	
An acid taste in your mouth				0.011
	Did not had	30 (22.1)	53 (35.3)	
	Very mild	14 (10.3)	23 (15.3)	
	Mild	19 (14.0)	24 (16.0)	
	Moderate	19 (14.0)	16 (10.7)	
	Moderately	21 (15.4)	18 (12.0)	
	Severe	33 (24.3)	16 (10.7)	
Unpleasant movement of material upward from the stomach				0.003
	Did not had	37 (27.2)	63 (42.0)	
	Very mild	16 (11.8)	20 (13.3)	
	Mild	9 (6.6)	14 (9.3)	
	Moderate	14 (10.3)	18 (12.0)	
	Moderately	22 (16.2)	20 (13.3)	
	Severe	38 (27.9)	15 (10.0)	

Table 4.8 continued from previous page

Symptoms (F-2)	Intensity	Control n = 136 (%)	Intervention n = 150 (%)	Chi-square test P value
Burping (gas coming from the stomach through the mouth				0.02
	Did not had	40 (29.4)	60 (40.0)	
	Very mild	18 (13.2)	15 (10.0)	
	Mild	14 (10.3)	21 (14.0)	
	Moderate	14 (10.3)	20 (13.3)	
	Moderately	15 (11.0)	18 (12.0)	
	Severe	35 (25.7)	16 (10.7)	
A bitter taste in your mouth				<0.001
	Did not had	40 (29.4)	57 (38.0)	
	Very mild	15 (11.0)	40 (26.7)	
	Mild	17 (12.5)	10 (6.7)	
	Moderate	15 (11.0)	14 (9.3)	
	Moderately	30 (22.1)	16 (10.7)	
	Severe	19 (14.0)	13 (8.7)	
Heart burn				0.026
	Did not had	42 (30.9)	55 (36.7)	
	Very mild	10 (7.4)	20 (13.3)	
	Mild	15 (11.0)	19 (12.7)	
	Moderate	14 (10.3)	19 (12.7)	
	Moderately	29 (21.3)	12 (8.0)	
	Severe	26 (19.1)	25 (16.7)	

4.4 Follow-up evaluation of PPIs Deprescribing Profile in Intervention Group

As shown in Table 4.9, the most frequently selected deprescribing strategies included rapid discontinuation of proton pump inhibitors and the use of rescue medications at the baseline each reported in (28.7%) of patients however this was followed by continuance of PPIs at a high dose (13.3%). Gradual dose- adjustment strategies were infrequently selected which included 4-week dose reduction (12.0%), 2-week dose reduction (11.3%) and 8-week dose reduction (6.0%).

At follow-ups, a clear shift towards more decisive deprescribing was being observed, the number of patients who discontinued PPIs had rapidly increased, gradually from 28.7% at baseline to 34.7% at the first follow-up and 40.0% at second follow-up.

Comparison with baseline continuance with a high dose declined from 13.3% to 9.3% at second follow-up, all the stepwise dose-reduction strategies showed a slow decrease across follow-ups. Counseling on lifestyle modifications increased over time regarding non-pharmacological strategies. Advice to avoid large or fatty meals late at night increased from 28.0% at baseline to 30.7% at the first follow-up and 32.7% at the second follow-up.

Similarly, guidance to elevate the head during sleep rose slightly from 15.3% at baseline to 16.7% at the first follow-up and 17.3% at the second follow-up. In contrast, counseling to avoid caffeine, alcohol, and smoking decreased over time, from 31.3% at baseline to 30.0% at the first follow-up and 32.0% at the second follow-up. Recommendations for weight reduction among overweight patients declined from 25.3% at baseline to 22.7% at the first follow-up and 18.0% at the second follow-up.

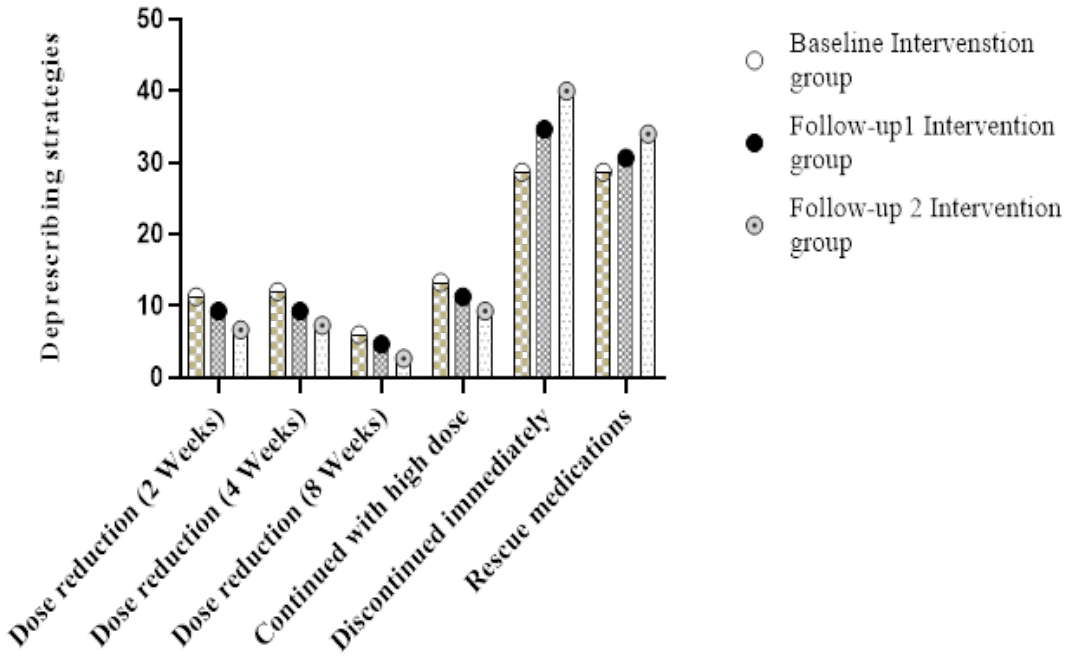

FIGURE 4.13: Selected Deprescribing strategies

TABLE 4.9: Presents the summary of follow-ups evaluation along with their responses for intervention groups.

Question	**Response**	**Baseline n%**	**Followup-1 n%**	**Followup-2 n%**
Deprescribing strategies selected	Dose reduction (2 Weeks)	17 (11.3)	14 (9.3)	10 (6.7)
	Dose reduction (4 Weeks)	18 (12.0)	14 (9.3)	11 (7.3)
	Dose reduction (8 Weeks)	9 (6.0)	7 (4.7)	4 (2.7)
	Continued with high dose	20 (13.3)	17 (11.3)	14 (9.3)
	Discontinued immediately	43 (28.7)	52 (34.7)	60 (40.0)
	Rescue medications	43 (28.7)	46 (30.7)	51 (34.0)
Non- Pharmacological strategies were discussed	Avoid large/fatty meals late at night	42 (28.0)	46 (30.7)	49 (32.7)
	Elevate head while sleeping	23 (15.3)	25 (16.7)	26 (17.3)
	Avoid caffeine, alcohol, smoking	47 (31.3)	45 (30.0)	48 (32.0)
	Reduce weight if overweight	38 (25.3)	34 (22.7)	27 (18.0)
Identified drug-drug interactions		53 (35.3)	36 (24.0)	29 (19.3)

4.5 Assessment of EQ-5D-3L Utility Scores Between Control and Intervention Groups

The utility assessment technique developed from 1st section of EQ-5D-3L scale, reveals patients observed quality of life rooted in 5 key health aspects. In the control group a mean EQ-5D-3L score is 0.659 $\pm$ 0.316 at baseline, intervention

group also had a similar score of 0.606 ± 0.276, indicating that the groups' baseline quality of life levels almost similar. In the control group's mean score decreased slightly 0.655 ± 0.275 at the first follow-up to 0.628 ± 0.269 at the second follow-up showed a modest decreased in quality of the life with passage of time. On the other hand, the intervention group had a mean score from baseline to first follow-up were 0.606 ± 0.276 to 0.655 ± 0.367 illustrated that slightly increased quality of life of patients initially after the intervention and continued to increase at second follow-up 0.683 ± 0.390. These results have been summarized in Table 4.10.

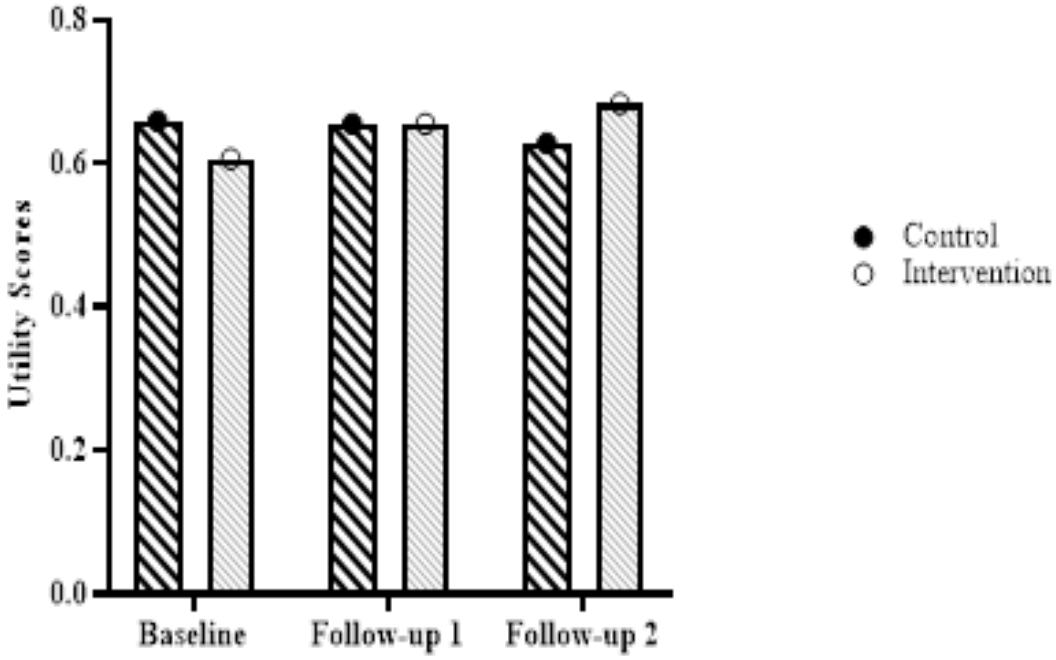

FIGURE 4.14: Calculation of Mean and SD for EQ-5D-3L among both groups

TABLE 4.10: Mean and SD of EQ-5D-3L Utility score among Control and Intervention groups from Baseline to Follow-up 2

EQ-5D-3L Utility Score	**Control Group (Mean ± SD)**	**Intervention Group (Mean ± SD)**
Baseline	0.659 ± 0.316	0.606 ± 0.276
Follow-up 1	0.655 ± 0.275	0.655 ± 0.367
Follow-up 2	0.628 ± 0.269	0.683 ± 0.390

EQ-5D-3L; EuroQol Five-Dimension Three-Level

4.6 Statistical Comparison of EQ - 5D - 3L Utility Scores between Control and Intervention Groups

The statistical comparison between the control and intervention group obtained at each follow-up stage by Wilcoxon Signed Rank Test. The table 4.11 suggested mean difference from Baseline to follow-up 2.

Baseline to first follow-up score detected in control group were (0.004 ± 0.273; p = 0.066) showed insignificant change in utility scores showing no marked development showed in the quality of life, while in the intervention group statistically small significant change were (-0.048 ± 0.411; p = 0.031). These changes reflect patient-level adapting to medication reduction and clinical monitoring during the starting phase of deprescribing.

From follow-up 1 to follow-up 2, the mean difference was (0.027 ± 0.333; p = 0.157) in the control group indicate no improvement in quality of life while the intervention group with mean score (-0.027 ± 0.313; p = 0.055) indicated minimal changes in patient quality of life and continued with intervention.

The mean score from baseline to follow-up 2 suggested in control group showed non-significant improvement (0.031 ± 0.380; p = 0.241), while the intervention group were (-0.076 ± 0.446; p = 0.002) illustrated significant improvement comparison with the control group at the end of second follow-up.

TABLE 4.11: Comparison of Health Utility Scores EQ-5D-3L Between Control and Intervention Groups

EQ-5D-3L Utility score Mean Difference	**Control group (Mean ± SD)**	**P value**	**Intervention group (Mean ± SD)**	**P value**
Baseline-Follow-up 1	0.004 ± 0.273	0.066	-0.048 ± 0.411	0.031
Follow-up 1-Follow-up 2	0.027 ± 0.333	0.157	-0.027 ± 0.313	0.055
Baseline-Follow-up 2	0.031 ± 0.380	0.241	-0.076 ± 0.446	0.002

4.7 Statistical Comparison of Utility Scores Follow - Up 2 Between Control and Intervention Groups

The Table 4.12 shows the statistical comparison of utility scores between the control and intervention group by Mann- Whitney at follow-up 2. The test showed significant value (p = < 0.001) in control and intervention group and mean rank of intervention group had high value that is 162.03 as compared to control group which is 123.06.

TABLE 4.12: Mean Rank for Utility Scores between Control and Intervention groups

Variable	**Control Group Mean Rank**	**Intervention Group Mean Rank**	**P Value**
Utility scores	123.06	162.03	<0.001

US; Utility Scores

4.8 Descriptive Analysis of Visual Analogue Scale between Control and Intervention Groups

As shown in Table 4.13 presents the descriptive analysis of mean and standard deviation of the control and intervention groups across three follow-ups. The VAS suggested patient's personal point of view about their overall health. Before intervention mean of both the control group 53.58 ± 9.78 and intervention group 54.36 ± 10.22 were similar. In follow up 1 mean decrease slightly in the control group 52.75 ± 11.38 while in intervention group mean increases from baseline 58.08 ± 12.11 revealed that according to patient's perception the quality of life was improved after pharmacist-led intervention. No improvement seen in the control group, mean continued decreased 52.02 ± 12.00 at the end of second follow-up, whereas in intervention group the mean 56.84 ± 13.76 at the end of second follow-up respectively.

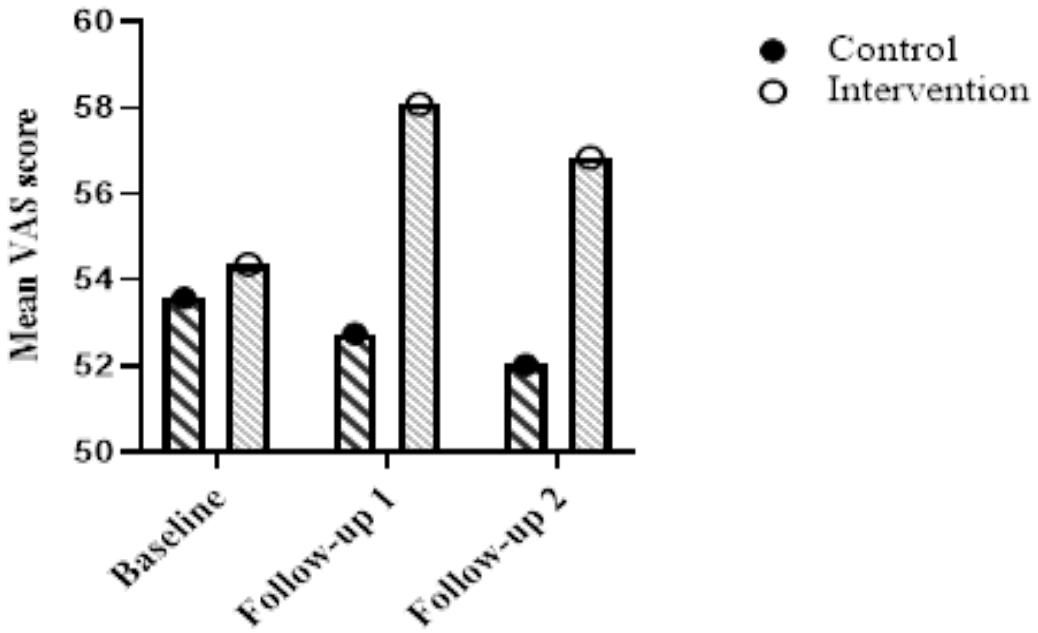

FIGURE 4.15: Trend in mean VAS score across Follow-ups

TABLE 4.13: Mean and SD of VAS score among Control and Intervention groups from Baseline to Follow-up 2

EQ-5D-3L VAS	**Control group (Mean ± SD)**	**Intervention group (Mean ± SD)**
Baseline	53.58 ± 9.78	54.36 ± 10.22
Follow-up 1	52.75 ± 11.38	58.08 ± 12.11
Follow-up 2	52.02 ± 12.00	56.84 ± 13.76

VAS; Visual Analogue Scale

4.9 Comparison of Mean VAS Score Changes between Control and Intervention

As shown in Table 4.14 the statistically significant results of the control and the intervention groups by Wilcoxon signed rank test. In VAS score, from baseline to follow-up 1 the mean difference was 0.830 ± 6.223 in the control group with non-significant p = 0.115, while follow-up 1 to follow-2 the mean score decreased

to 0.720 ± 8.566 with non-significant results p = 0.156. Similarly, from baseline to follow-up 2 there was modest improvement with mean score 1.551 ± 9.467 and significant results (p = 0.046). However, intervention group showed significant improvement with mean difference -3.720 ± 11.329; p = 0.001 from baseline to first follow up and from follow-up 1 to follow-up 2 a non-significant improvement with mean difference 1.240 ± 9.036; p = 0.356 has been calculated. A short follow-up period for about three months may be insufficient to fully capture the influence of the deprescribing intervention on quality of life. Results might account for the lack of a statistically significant improvement at this point. However, from baseline to follow-up 2, the significant improvement with p = 0.041 and the mean difference -2.480 ± 12.817 showed there is better improvement in the intervention group.

TABLE 4.14: Comparison of VAS Scores Between Control and Intervention Groups

VAS Scores Mean Difference	**Control group (DM)**	**P value**	**Intervention group (DM)**	**P value**
Baseline-Follow-up 1	0.830 ± 6.223	0.115	-3.720 ± 11.32	0.001
Follow-up 1-Follow-up 2	0.720 ± 8.566	0.156	1.240 ± 9.036	0.356
Baseline-Follow-up 2	1.551 ± 9.467	0.046	-2.480 ± 12.817	0.041

B; Baseline, F1; Follow-up 1, F2; Follow-up 2 and QoL; Quality of life, DM; Difference in Means

4.10 Statistical Comparison of Visual Analogue Scale Follow-Up 2 Between Control and Intervention Groups

The statistical comparison of VAS in the control and intervention group by Mann-Whitney test. This test presented the statistically significance results between

both the control and intervention groups having p value of 0.002 which is significant ($p < 0.05$) and the mean rank value of the intervention group is 157.63 which is also increased from the control group 127.92, as showed in Table 4.15.

TABLE 4.15: Mean Rank for Utility Scores between Control and Intervention groups

Variable	**Control Group Mean Rank**	**Intervention Group Mean Rank**	**P Value**
VAS score	127.92	157.63	0.002

VAS; Visual Analogue Scale

4.11 Simple Mean and Standard Deviation of GMAS Domains between Control and Intervention Group

As mentioned in Table 4.16, the mean score for Domain 1 non-adherence due to patient behavior in the control group suggested that in the baseline the mean score was (1.485 ± 1.424) this score was slight decrease in follow-up 1 (1.470 ± 1.392) and further decline to 1.404 ± 1.426. Follow-up 2 showed no improvement of adherence seen in the control group, whereas in intervention group, the baseline mean score detected was (1.480 ± 1.299) which increased in follow-ups. In short, the follow-up 1 showed the mean score of (1.906 ± 1.485) that was further improved to (2.113± 1.504) in follow-up 2 confirming the adherence.

In Domain 2 non- adherence due to additional disease and pill burden, the control group showed mean score baseline of (1.661 ± 1.446) which declined at follow-up 1 (1.360 ± 1.386).

Follow up 2 showed mean score of (1.161 ± 1.254) that revealed that there was no improvement of adherence, in the control group, while in intervention group the baseline score was (1.660 ± 1.389). Initially after intervention the score of

adherences improved in follow-up 1 and 2 respectively by (1.846 ± 1.445) and (2.206 ± 1.410).

The Domain 3 non-adherence due to financial constraints had a baseline mean score (1.882 ± 1.419) in the control group which decreased in follow-up 1 to (1.500 ± 1.377). The score showed slight improvement in follow up 2 (1.580 ± 1.347) correspondingly while in the intervention group mean score baseline was (1.760 ± 1.383) which after the intervention improved to (2.020 ± 1.439) and (2.153±1.468) in follow-up 1 and 2.

TABLE 4.16: Mean and SD of GMAS across Domains

Follow-ups	**Control group (Mean ± SD)**	**Intervention group (Mean ± SD)**
Domain 1: Non-Adherence due to patient behavior (unintentional and intentional)		
Baseline	1.485 ± 1.424	1.480 ± 1.299
Follow-up 1	1.470 ± 1.392	1.906 ± 1.485
Follow-up 2	1.404 ± 1.426	2.113 ± 1.504
Domain 2: Non-adherence due to additional disease and pill burden		
Baseline	1.661 ± 1.446	1.660 ± 1.389
Follow-up 1	1.360 ± 1.386	1.846 ± 1.445
Follow-up 2	1.161 ± 1.254	2.206 ± 1.410
Domain 3: Non-adherence due to financial constraints		
Baseline	1.882 ± 1.419	1.760 ± 1.383
Follow-up 1	1.500 ± 1.377	2.020 ± 1.439
Follow-up 2	1.580 ± 1.347	2.153 ± 1.468

B; Baseline, F1; Follow-up 1, F2; Follow-up

4.12 Non - Adherence Due to Patient Behavior between Control and Intervention Groups

The adherence level in terms of frequency and percentage between the control and intervention group across follow-ups. Initially from baseline, both groups

showed the less percentage of high adherence such as in the control group 18 (13.2) and 17 (11.3) in intervention group, while the good adherence was reported in both groups i.e. 20 (14.7) and 13 (8.7) respectively. In contrast, number of participants showed partial adherence in the control group that was 18 (13.2%) and 38 (25.3%) in intervention group and remaining were low and poor adherence with a percentage of 34 (25.0), 39 (26.0) with low adherence, 46 (33.8) and 43 (28.7) with poor adherence, as shown in Table 4.17.

By First follow-up, the control group showed decreased adherence, while the marked increase of percentage of all domains in the intervention groups, the high adherence was 16 (11.8) and 31 (20.7) in the control and intervention group, while the good adherence 19 (14.0) and 28 (18.7) that were stable in the control group and increase in intervention group. Partial adherence showed in the control group is 25 (18.4) participants and in intervention group were 24 (16.0) participants respectively. The low unchanged in the control group with 29 (21.3) and 30 (20.0) in intervention group and poor adherence also same in the control group 47 (34.6) but decreased in intervention group 37 (24.7).

At follow-up 2 adherence levels showed further parting between both the two groups. High adherence increased to 16 (11.8%) and 38 (25.3) while good adherence to 19 (14.0) and 31 (20.7) in the control group same and in intervention group improved similarly. Meanwhile, Partial adherence relatively stable in both the control group is 23 (16.9) and in intervention group to 24 (16.0) participants. Similarly low adherence declined slightly in both the groups, 24 (17.6) in the control group and 24 (16.0) in intervention group. Similarly poor adherence increased 54 (39.7) in the control group and significantly decreased 33 (22.0) in intervention group.

TABLE 4.17: Non-Adherence due to patient behavior (un-intentional and intentional)

Adherence Level	**Control Group n (%)**	**Intervention Group n (%)**
Grading 1 (Baseline)		
High Adherence	18 (13.2)	17 (11.3)
Good Adherence	20 (14.7)	13 (8.7)

Table 4.17 continued from previous page

Adherence Level	Control Group n (%)	Intervention Group n (%)
Partial Adherence	18 (13.2)	38 (25.3)
Low Adherence	34 (25.0)	39 (26.0)
Poor Adherence	46 (33.8)	43 (28.7)
Grading 1 (Follow-up 1)		
High Adherence	16 (11.8)	31 (20.7)
Good Adherence	19 (14.0)	28 (18.7)
Partial Adherence	25 (18.4)	24 (16.0)
Low Adherence	29 (21.3)	30 (20.0)
Poor Adherence	47(34.6)	37(24.7)
Grading 1 (Follow-up 2)		
High Adherence	16 (11.8)	38 (25.3)
Good Adherence	19 (14.0)	31 (20.7)
Partial Adherence	23 (16.9)	24 (16.0)
Low Adherence	24 (17.6)	24 (16.0)
Poor Adherence	54 (39.7)	33 (22.0)

4.13 Non - Adherence Due to Disease Burden and Polypharmacy

In the baseline the non-adherence due to polypharmacy and comorbid conditions had let out sub-optimal adherence in both the groups. Only 20 (14.7) and 19 (12.7) showed high adherent, with 23 (16.9) and 27 (18.0) showing good adherence in both groups. The remaining were mostly having partial adherence that were 27 (19.9) and 31 (20.7) in both groups followed by low and poor adherence that were 23 (16.9) and 30 (20.0) whereas, 43 (31.6) and 43 (28.7) in the control and intervention groups.

At follow-up 1 in control group showed decreased adherence, while the marked increase of percentage of all domains in intervention groups, the high adherence that were 14 (10.3) and 26 (17.3) in the control and intervention group, while the good adherence 16 (11.8) and 30 (20.0) slightly decrease in the control group and slightly increase in intervention group. Partial adherence relatively high with 31

(22.8) in the control group participants and in intervention group were 27 (18.0) respectively. The low slightly decrease in the control group with 19 (14.0) and 29 (19.3) in intervention group while poor adherence increase in the control group 56 (41.2) but slightly decreased in intervention group 38 (25.3).

At follow-up 2 adherence showed varying trends between both the groups High adherence reached 10 (7.4) and 34 (22.7), good adherence decreased with 8 (5.9) in the control and increased in 39 (26.0) in intervention group. Meanwhile, Partial adherence relatively stable in both the control group at 35 (25.7) and intervention group to 27 (18.0) participants, Low adherence increased slightly 24 (17.6) in the control group and decreased 24 (16.0) in intervention group, similarly poor adherence increased 59 (43.4) in the control group and significantly decreased 26 (17.3) in intervention group. These domains have been summarized below in Table 4.18.

TABLE 4.18: Non-adherence due to additional disease and pill burden

Adherence Level	**Control Group n (%)**	**Intervention Group n (%)**
Grading 2 (Baseline)		
High Adherence	20 (14.7)	19 (12.7)
Good Adherence	23 (16.9)	27 (18.0)
Partial Adherence	27 (19.9)	31 (20.7)
Low Adherence	23 (16.9)	30 (20.0)
Poor Adherence	43 (31.6)	43 (28.7)
Grading 2 (Follow-up 1)		
High Adherence	14 (10.3)	26 (17.3)
Good Adherence	16 (11.8)	30 (20.0)
Partial Adherence	31 (22.8)	27 (18.0)
Low Adherence	19 (14.0)	29 (19.3)
Poor Adherence	56 (41.2)	38 (25.3)
Grading 2 (Follow-up 2)		
High Adherence	10 (7.4)	34 (22.7)
Good Adherence	8 (5.9)	39 (26.0)
Partial Adherence	35 (25.7)	27 (18.0)
Low Adherence	24 (17.6)	24 (16.0)
Poor Adherence	59 (43.4)	26 (17.3)

4.14 Non - Adherence Due to Financial Constraints

Baseline adherence indicated sub-optimal adherence of domain 3 in the both control and intervention group. These groups that were 24 (17.6), 25 (18.4) and 23 (15.3), 24 (16.0) in high and good adherence. However, the partial, low and poor responses were 30 (22.1%), 25 (18.4%), 32 (22.0), 34 (22.7), 32 (23.5) and 36 (24.0) accordingly. At the baseline these results suggests that most of the participants exhibited partial, low, or poor adherence.

At follow-up 1 the high adherence moved decreased 16 (11.8) in the control group while increased 31 (20.7) in intervention groups similarly, good adherence decreased 19 (14.0) in the control group and increased 32 (21.3%) in intervention group. The partial, adherence was somehow reducing to 26 (19.1%), 27 (18.0%) in both. similarly, low and poor adherence increased 31 (22.8), 44 (32.4) in control group and decreased 29 (19.3), 31 (20.7) in intervention group.

By follow-up 2, the interventions group adherence trends showed further improvements. The high adherence slightly decreased 15 (11.0) in the control group while increased 35 (23.3) in intervention groups however, good adherence slightly increased 23 (16.9) in the control group and markedly increased 38 (25.3%) in intervention group. The partial, adherence was somehow same in to 26 (19.1%) control group and slightly decreased 23 (15.3%) in intervention group. Similarly, low adherence increased 34 (25.0) in control group and decreased 23 (15.3) in intervention group. However poor adherence decreased 38 (27.9) in control group same in intervention group 31 (20.7). These results have been summarized below in Table 4.19.

Table 4.19: Non-adherence due to financial constraints

Adherence Level	**Control Group n (%)**	**Intervention Group n (%)**
Grading 3 (Baseline)		
High Adherence	24 (17.6)	23 (15.3)
Good Adherence	25 (18.4)	24 (16.0)
Partial Adherence	30 (22.1)	33 (22.0)

Table 4.19 continued from previous page

Adherence Level	Control Group n (%)	Intervention Group n (%)
Low Adherence	25 (18.4)	34 (22.7)
Poor Adherence	32 (23.5)	36 (24.0)
Grading 3 (Follow-up 1)		
High Adherence	16 (11.8)	31 (20.7)
Good Adherence	19 (14.0)	32 (21.3)
Partial Adherence	26 (19.1)	27 (18.0)
Low Adherence	31 (22.8)	29 (19.3)
Poor Adherence	44 (32.4)	31 (20.7)
Grading 3 (Follow-up 2)		
High Adherence	15 (11.0)	35 (23.3)
Good Adherence	23 (16.9)	38 (25.3)
Partial Adherence	26 (19.1)	23 (15.3)
Low Adherence	34 (25.0)	23 (15.3)
Poor Adherence	38 (27.9)	31 (20.7)

4.15 Assessment of Overall GMAS Score between Control and Intervention Groups

The mean and standard deviation of overall medication adherence scale between the control and intervention group are shown in Table 4.20 from baseline to follow-up 2. At baseline the mean score indicates comparable adherence in both control and intervention group 1.397 ± 1.076 and 1.393 ± 1.048 accordingly, and afterwards the baseline mean decreased to 1.183 ± 0.982 in the control group and increased markedly to 1.720 ± 1.165 in intervention group at first follow-up. However, at second follow up, the mean score of control group slightly increased to 1.102 ± 1.027 while the intervention group showed a marked improvement, with mean score of 1.986 ± 1.215.

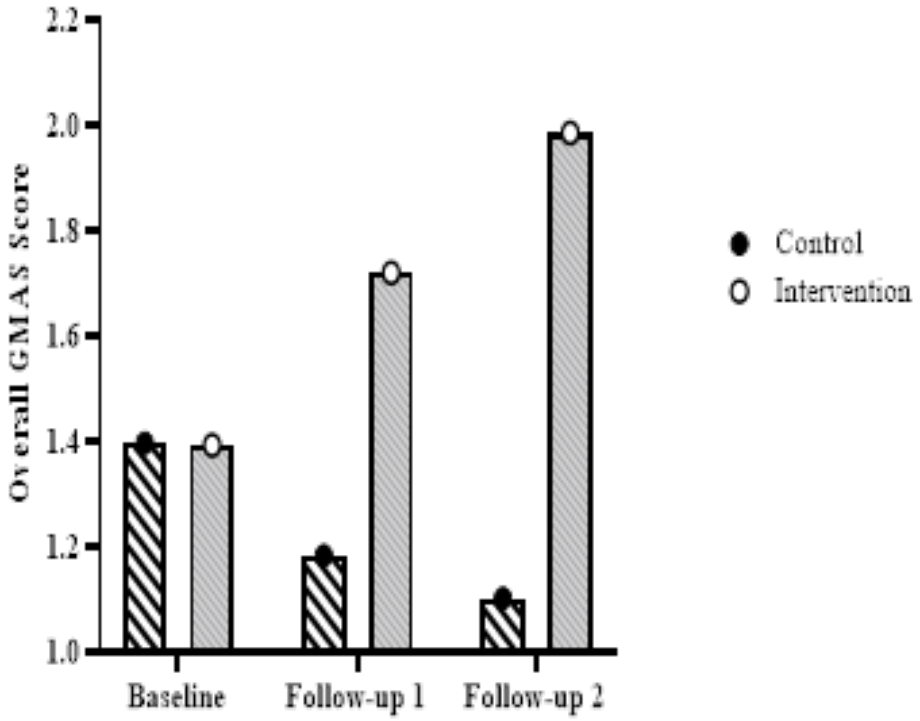

FIGURE 4.16: Trends in overall medication adherence

TABLE 4.20: Mean and SD of overall medication adherence among the Control and Intervention groups

Follow-ups	**Control Group (Mean ± SD)**	**Intervention Group (Mean ± SD)**
Baseline	1.397 ± 1.076	1.393 ± 1.048
Follow up 1	1.183 ± 0.982	1.720 ± 1.165
Follow up 2	1.102 ± 1.027	1.986 ± 1.215

4.16 Statistical Comparison of Overall GMAS Scale between Control and Intervention Groups

As shown in Table 4.21, the mean difference and p value of the control and intervention group. From baseline to follow-ups the statistically significant difference

was recorded in intervention group as from baseline to first follow-up, the mean difference was (-0.326 ± 1.206; p = 0.001) whereas in the control group the mean score was (0.213 ± 1.416; p = 0.064) which showed non-significant difference. From follow-up 1 towards follow-up 2 in the intervention group, the mean score was increased to (-0.266 ± 1.468; p = 0.057). The intervention group had showed modest development throughout this period but this change had not reached statistical importance as compared to control group having mean score of (-0.080 ± 1.319; p = 0.418), showed no significant improvement. From baseline to follow-up 2 the control group showed a non-significant change in adherence (mean difference = 0.294 ± 1.626 p = 0.059), while in the intervention group achieved statistically significant improvement, with a mean difference of (-0.593 ± 1.502 p = < 0.001).

TABLE 4.21: Comparison of GMAS Scores Between Control and Intervention Groups

GMAS Mean Difference	**Control Group (DM)**	**P Value**	**Intervention Group (DM)**	**P value**
Baseline - Follow-up 1	0.213 ± 1.416	0.064	-0.326 ± 1.206	0.001
Follow-up 1 - Follow-up 2	0.080 ± 1.319	0.418	-0.266 ± 1.468	0.057
Baseline - Follow-up 2	0.294 ± 1.626	0.059	-0.593 ± 1.502	¡0.001

GMAS; General Medication Adherence Scale, DM; Difference in Means

4.17 Statistical Comparison of GMAS Follow-Up 2 Between Control and Intervention Groups

The Table 4.22 shows the statistical comparison of GMAS in the control and intervention group by Mann-Whitney test. This test presented the statistically significance results between both the control and intervention groups having p

value of < 0.001 which is significant ($p < 0.05$) and the mean rank value of the intervention group is 171.81 which is also increased from the control group 112.1.

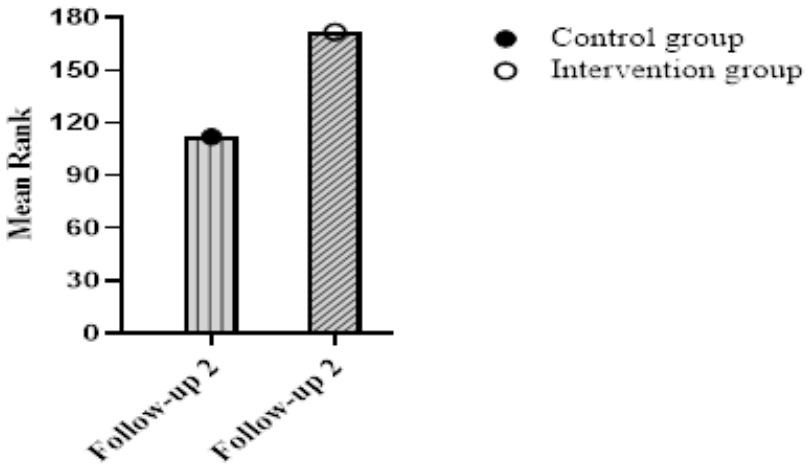

FIGURE 4.17: Mann-Whitney test for GMAS score at Follow-up 2

TABLE 4.22: Mean Rank for GMAS score between Control and Intervention group

Variable	**Control Group**	**Intervention Group**	**P Value**
Mean Rank	112.1	171.81	< 0.001

4.18 Patient Satisfaction Feedback on Pharmacist Counseling

At baseline, between both the control and intervention group's patient satisfaction results were largely comparable. A higher number of patients in the intervention group described receiving counseling without difficulty 67.3% compared with the control group 61.8%. Complete addition of required knowledge and perception of the pharmacist was very helpful and were also more frequent in the intervention group 47.3% and 45.3% respectively, than in the control group 40.4% and 40.4%. In both groups, 47.3% & 46.3% of patients view the counseling time was appropriate. However, 24.7% in the intervention group and 25.0% in control group

considered it as a waste of time 28.0% and 28.7% both in the intervention and control group observed more time should be given. Willingness to suggested pharmacist counseling and to pay for the service was similar in both 69.3% intervention and 68.4% control group. However, support for providing counseling services in local pharmacies was notably higher in the intervention group 86.0% compared with the control group 71.3%. Overall satisfaction was being average at baseline, with higher satisfaction scores (8–10) reported more often in the intervention group 53.3% than in the control group 47.8%. These results have been summarized in Table 4.23.

TABLE 4.23: Effect of pharmacist-led counseling on patient satisfaction at Baseline

Patient satisfaction feedback Baseline	**Control n (%)**	**Intervention n (%)**
1) Were you able to get counseling without any difficulty?		
Yes	84 (61.8)	101 (67.3)
No	52 (38.2)	49 (32.7)
2) Were you able to get knowledge which you required?		
Yes Completely	55 (40.4)	71 (47.3)
Yes, to some extent	50 (36.8)	55 (36.7)
No, I did not get what I was seeking to know	31 (22.8)	24 (16.0)
3) Did you find pharmacist helpful in resolving your queries?		
Very helpful	55 (40.4)	68 (45.3)
Somewhat helpful	51 (37.5)	54 (36.0)
Not helpful	30 (22.1)	28 (18.7)
4) What is your opinion about the time duration of pharmacist counseling?		
More time should be given	39 (28.7)	42 (28.0)
Appropriate time was given	63 (46.3)	71 (47.3)
My time was wasted	34 (25.0)	37 (24.7)
5) Will you recommend getting counseling from pharmacists to others?		
Yes	93 (68.4)	104 (69.3)
No	43 (31.6)	46 (30.7)
6) Would you like the pharmacies in your locale to provide this service?		
Yes	97 (71.3)	129 (86.0)
No	39 (28.7)	21 (14.0)
7) Are you willing to pay for this counseling service?		
Yes	93 (68.4)	104 (69.3)
No	43 (31.6)	46 (30.7)

Table 4.23 continued from previous page

Patient satisfaction feedback (Baseline)	Control n (%)	Intervention n (%)
8) What grade would you give on pharmacist counseling?		
Very satisfied	35 (25.7)	42 (28.0)
Satisfied	32 (23.5)	36 (24.0)
Uncertain	34 (25.0)	34 (22.7)
Not satisfied	35 (25.7)	35 (23.3)
9) Indicate you satisfaction rate with pharmacist counseling on a scale of 1 – 10?		
1-3 Worst	35 (25.7)	36 (24.0)
4-7 (in between)	36 (26.5)	34 (22.7)
8-10 (best)	65 (47.8)	80 (53.3)

4.19 Effect of Pharmacist-led Counseling on Patient Satisfaction at Follow-up 1

As shown in Table 4.24, after the initial intervention, patient satisfaction showed noticeable improvement when compared with baseline in both the control and intervention groups. A larger number of patients in the intervention group reported having received counseling without difficulty 78.0% compared with the control group 71.3%. Complete addition of required knowledge and perception of the pharmacist was very helpful and also more frequent in the intervention group 60.0% and 58.0% respectively, than in the control group 43.4% and 50.7%. In both groups, 52.0-49.3% of patients considered the counseling time appropriate. While, 22.7% in intervention group and 23.5% in control group which had recognized it as a waste of time 25.3% and 27.2% in both the intervention and control group consider more time should be given. Willingness to suggest for the pharmacist guidance and to pay for the service was alike in both 80.7% intervention and 77.2% control group. However, there is support for providing counseling services in local pharmacies was remarkably higher in the intervention group 88.7% compared with the control group 74.3%. Overall satisfaction at follow-up 1 was form moderate to high, with a greater number of patients in the intervention group reporting high satisfaction scores (8-10) is 70.0% than in the control group 64.7%.

TABLE 4.24: Effect of pharmacist-led counseling on patient satisfaction at Follow-up 1

Patient Satisfaction Feedback Baseline	**Control n (%)**	**Intervention n (%)**
1) Were you able to get counseling without any difficulty?		
Yes	97 (71.3)	117 (78.0)
No	39 (28.7)	33 (22.0)
2) Were you able to get knowledge which you required?		
Yes Completely	59 (43.4)	90 (60.0)
Yes, to some extent	52 (38.2)	44 (29.3)
No, I did not get what I was seeking to know	25 (18.4)	16 (10.7)
3) Did you find pharmacist helpful in resolving your queries?		
Very helpful	69 (50.7)	87 (58.0)
Somewhat helpful	45 (33.1)	45 (30.0)
Not helpful	22 (16.2)	18 (12.0)
4) What is your opinion about the time duration of pharmacist counseling?		
More time should be given	37 (27.2)	38 (25.3)
Appropriate time was given	67 (49.3)	78 (52.0)
My time was wasted	32 (23.5)	34 (22.7)
5) Will you recommend getting counseling from pharmacists to others?		
Yes	105 (77.2)	121 (80.7)
No	31 (22.8)	29 (19.3)
6) Would you like the pharmacies in your locale to provide this service?		
Yes	101 (74.3)	133 (88.7)
No	35 (25.7)	34 (22.7)
7) Are you willing to pay for this counseling service?		
Yes	105 (77.2)	121 (80.7)
No	31 (22.8)	29 (19.3)
8) What grade would you give on pharmacist counseling?		
Very satisfied	50 (36.8)	58 (38.7)
Satisfied	43 (31.6)	49 (32.7)
Uncertain	21 (15.4)	19 (12.7)
Not satisfied	22 (16.2)	24 (16.0)
9) Indicate you satisfaction rate with pharmacist counseling on a scale of 1 – 10		
1-3 Worst	27 (19.9)	24 (16.0)
4-7 (in between)	21 (15.4)	21 (14.0)
8-10 (best)	88 (64.7)	105 (70.0)

4.20 Effect of Pharmacist-led Counseling on Patient Satisfaction at Follow-up 2

In the final follow-up, fundamental improvement in patient satisfaction showed further changes in both groups was observed. The number of patients in the intervention group reported receiving counseling without difficulty 86.7% compared with the control group 77.2%. Complete addition of required knowledge and perception of the pharmacist was very helpful were also more common in the intervention group 71.3% and 67.3% respectively, than in the control group 58.1% and 58.1%. In both groups, 64.0-59.6% of patients had viewed the counseling time appropriate, while 13.3% in the intervention group and 16.2% in control group perceived it as a waste of time, 24.3% and 22.7% in both intervention and control group consider more time should be given. Willingness to suggest pharmacist counseling and to pay for the service was alike in both 87.3% in the intervention and 83.1% control group. However, in order to support for providing counseling services in local pharmacies was remarkably higher in the intervention group 90.0% compared with the control group 90.4%. At follow-up 2, the distribution of satisfaction scores (8-10) indicated higher general satisfaction in the intervention group 80.0% than in the control group 75.0%. These results have been summarized in Table 4.25.

TABLE 4.25: Effect of pharmacist-led counseling on patient satisfaction at Follow-up 2

Patient SatisfactionFeedback F2	**Control n (%)**	**Intervention n (%)**
1) Were you able to get counseling without any difficulty?		
Yes	105 (77.2)	130 (86.7)
No	31 (22.8)	20 (13.3)
2) Were you able to get knowledge which you required?		
Yes Completely	79 (58.1)	107 (71.3)
Yes, to some extent	41 (30.1)	32 (21.3)
No, I did not get what I was seeking to know	16 (11.8)	11 (7.3)
3) Did you find pharmacist helpful in resolving your queries?		
Very helpful	79 (58.1)	101 (67.3)
Somewhat helpful	42 (30.9)	38 (25.3)

Table 4.25 continued from previous page

Patient SatisfactionFeedback (F2)	**Control n (%)**	**Intervention n (%)**
Not helpful	15 (11.0)	11 (7.3)
4) What is your opinion about the time duration of pharmacist counseling?		
More time should be given	33 (24.3)	34 (22.7)
Appropriate time was given	81 (59.6)	96 (64.0)
My time was wasted	22 (16.2)	20 (13.3)
5) Will you recommend getting counseling from pharmacists to others?		
Yes	115 (84.6)	131 (87.3)
No	21 (15.4)	19 (12.7)
6) Would you like the pharmacies in your locale to provide this service?		
Yes	123 (90.4)	135 (90.0)
No	13 (9.6)	15 (10.0)
7) Are you willing to pay for this counseling service?		
Yes	113 (83.1)	131 (87.3)
No	23 (16.9)	19 (12.7)
8) What grade would you give on pharmacist counseling?		
Very satisfied	55 (40.4)	65 (43.3)
Satisfied	47 (34.6)	56 (37.3)
Uncertain	15 (11.0)	14 (9.3)
Not satisfied	19 (14.0)	15 (10.0)
9) Indicate you satisfaction rate with pharmacist counseling on a scale of 1 – 10		
1-3 Worst	19 (14.0)	15 (10.0)
4-7 (in between)	15 (11.0)	15 (10.0)
8-10 (best)	102 (75.0)	120 (80.0)

4.21 Comparison of counselling Scale Across Follow - ups

As shown in Table 4.26 at baseline, the mean PSF9 score was 17.98 ± 3.224 in control group and 18.59 ± 4.107 in the intervention group, showing an average level of satisfaction in both groups. Following the first follow-up, the mean score increased to 19.19 ± 3.345 and 20.00 ± 3.513 in the control and intervention group, showing an improvement in satisfaction, particularly in the intervention

group following the pharmacist-led intervention. In second follow-up, the mean score further improved to 19.80 ± 2.990 in the control group and 21.10 ± 2.789 in the intervention group, demonstrating a remarkable and support enhancement in satisfaction levels over time, with the intervention group consistently resulting in greater satisfaction.

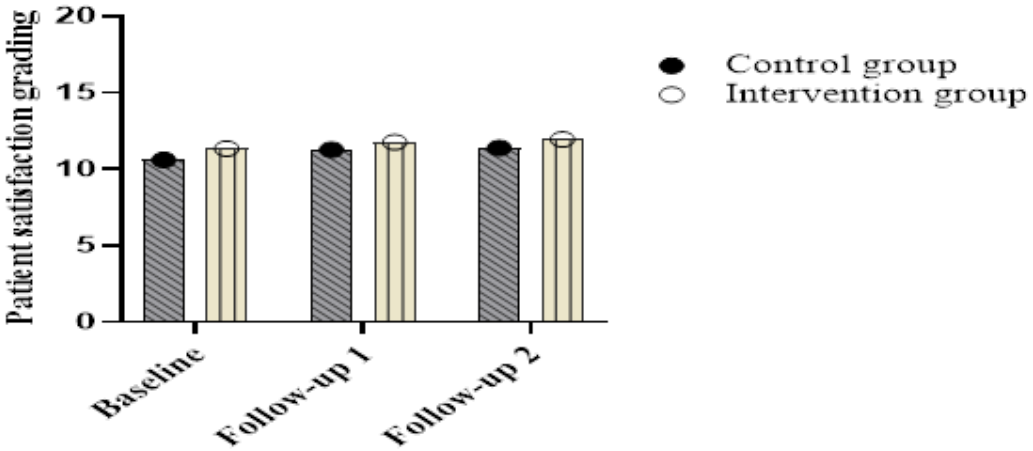

FIGURE 4.18: Differences in mean PSF values across Follow-ups

TABLE 4.26: Comparative analysis of mean PSF score

Follow-ups	**Control Group (Mean ± SD)**	**Intervention Group (Mean ± SD)**
Baseline PSF9	17.98 ± 3.224	18.59 ± 4.107
Follow-up 1 PSF9	19.19 ± 3.345	20.00 ± 3.513
Follow-up 2 PSF9	19.80 ± 2.990	21.10 ± 2.789

PSF; Patient satisfaction feedback

4.22 Statistical Comparison of Patient Satisfaction Feedback Follow-Up 2 Between Control and Intervention Groups

The Table 4.27 demonstrated the statistical comparison of PSF in the control and intervention group by Mann-Whitney test. This test presented the statistically

significance results between both the control and intervention groups having p value of < 0.001 which is significant ($p < 0.05$) and the mean rank value of the intervention group is 164.70 which is also increased from control group 120.12.

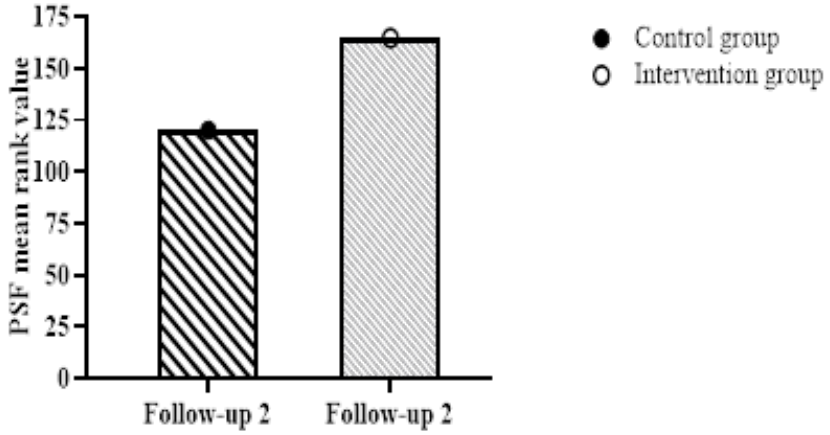

FIGURE 4.19: Mann-Whitney test for PSF between the Control and Intervention groups

TABLE 4.27: Mean Rank for PSF between Control and Intervention groups

Variable	**Control Group Mean Rank**	**Intervention Group Mean Rank**	**P Value**
PSF	120.12	164.70	< 0.001

PSF; Patient satisfaction feedback

Chapter 5

Discussions of Studies

5.1 Discussion

The present study demonstrated that a pharmacist-facilitated deprescribing intervention improved patient compliance, satisfaction, and quality of life, as well as reducing the inappropriate use of PPIs. This deprescribing intervention was achieved through a collaborative approach between a pharmacist and a physician, whereby a 15-to-20-minute education program for the physician and the patient facilitated the discussion on deprescribing and resulted in a predetermined outcome of 40% successful PPI deprescribing at six months. This study is in line with the previous studies on PPI deprescribing interventions facilitated by a pharmacist, which proves the efficacy and integration of the education-facilitated approach in routine practice without compromising the outcome [9, 36, 53, 75–77]. Significant improvements in the intensity of the symptoms of heartburn and burping were recorded. The intensity of heartburn and burping from baseline to follow-up 1 was significantly reduced (heartburn $p = 0.046$; burping $p = 0.024$). This shows the immediate effect of the pharmacist led intervention. The intensity of heartburn and burping continued to improve at follow-up 2. The frequency of the symptoms of heartburn also reduced significantly from baseline to follow-ups. The

results have a p-value of less than 0.05. These results are supported by a collaborative study by Puig-Molto et al. [80], Similarly, the importance of the pharmacist role in the management of reflux symptoms was emphasized by Bridgeman [81], in "Empowering Pharmacists in Heartburn Management: Practical Insights for OTC Treatment and Self-Care" (2023), emphasized that offering pharmacists a framework for clinical assessment and counseling allows for the management of self-care and OTC treatment, which can lead to improved public health outcomes. This study has shown that pharmacist interventions are effective, which lead to improved outcomes for patients through reduced severity and occurrence of reflux symptoms. Pharmacists are integral members of the multidisciplinary team and play an important role in the healthcare service, offering structured assessment, education, and counseling for the optimization of treatment and self-management of patients.

The study was based on the DROPIT approach, where there was a stepwise approach to PPI dose reduction, which was monitored for the prevention of the return of reflux symptoms. This approach was based on the DROPIT cluster-RCT study, where structured deprescribing was implemented using educational resources and decision aids, monitored using the RDQ, for the optimization of PPI treatment and improved patient outcomes, which was deemed safe and effective for patients within the Swiss primary care setting [6].

In the intervention group, 29.3% of the patients experienced a dose reduction of PPIs, thus showing the efficacy of the pharmacist intervention approach. This reduction is similar to the reductions seen in the quality improvement study conducted by Naren Nallapeta [82], where there was a 30% reduction of inappropriate PPI use in an academic primary care clinic without the direct involvement of a pharmacist. This shows that pharmacist intervention is effective in reducing inappropriate exposure to PPIs.

Dose reduction of PPIs to reduce the adverse outcomes of long-term therapy with higher doses, such as nutrient deficiencies, infections, and bone or kidney problems.[83], Proton Pump Inhibitors -An Evidence-Based Review of Indications, Efficacy, Harms, and Deprescribing, 2025. The most dominant percentage

of PPIs discontinuation was observed as 40.0%, and patients who discontinued PPIs also showed improvement in their symptoms. Schey et al. [84] reported that out of 205 patients, 92 patients (∼45%) rated their symptoms as "same or better" after discontinuing PPIs, showing that their symptoms do not recur or improve. [85, 86]. On the other hand, following dose reduction and discontinuation using the DROPIT approach, it was found that 34.0% of patients required re-commencement of medication following the recurrence of symptoms. In another study, Sustained Proton Pump Inhibitor Deprescribing among Dyspeptic Patients in General Practice: A Return to Self-Management through a Program of Education and Alginate Rescue Therapy, it was found that there was a 2.7-fold increase in the prescription of alginate therapy over a period of 12 months, despite a 49% reduction in PPI prescription, thus showing that deprescribing can be safely done [87, 88].

Meanwhile, high-dose PPIs decreased to 9.3% at the second follow-up. Thus, it was observed that the number of patients requiring high-dose PPIs was reduced over time; patients were maintained on low-dose PPIs, or they were withdrawn from PPIs following an improvement in their symptoms without worsening. These have also been demonstrated in step-down studies and deprescribing studies, wherein patients requiring high-dose PPIs were maintained on low-dose PPIs or withdrawn from PPIs following an improvement in their symptoms [89].

In addition to pharmacological deprescribing interventions such as dose reduction and discontinuation, non-pharmacological interventions were also used in this study to help manage symptoms. For instance, advice on avoiding large and fatty meals in the late hours of the night increased from 28.0% at baseline to 32.7% at the second follow-up, while advice on sleeping with the head elevated increased slightly from 15.3% to 17.3%.

However, compliance with advice on limiting caffeine, alcohol, and smoking intake remained relatively unchanged. This suggests that lifestyle changes can be used in conjunction with pharmacological deprescribing interventions in the management of symptoms, as some behaviors may be improved with repeated advice, such as avoiding large and fatty meals in the late hours of the night and sleeping with the

head elevated, while others may require more specific advice and reinforcement, such as limiting caffeine, alcohol, and smoking intake and losing weight.

This is in agreement with the systematic review: "Lifestyle Intervention in Gastroesophageal Reflux Disease" [90], which found that increasing the position of the head of the bed reduces acid exposure in supine position from 21% to 15%, avoidance of late-evening meals reduces supine reflux by 5.2 points, and stopping smoking reduces symptoms by 5.67 points. These results emphasize the effectiveness of lifestyle changes, along with deprescribing, in symptom control and reducing long-term PPI use. Although, in the case of adherence to weight reduction advice, the percentage of overweight patients who adhered to advice was lower at the second follow-up compared to the first, from 25.3% to 18.0%, respectively. These results are consistent with the study findings of "Patient Perspective on Adherence to Reflux Lifestyle Modifications: A Qualitative Study" [91], which indicated that patients face difficulties in adhering to lifestyle changes, thus requiring structured advice, positive dietary advice, and even referring them to a dietician to better understand their diet and lifestyle changes.

Pharmacists and physicians play a crucial role in minimizing drug–drug interactions by conducting structured medication review and deprescribing. In this study, the percentage of patients with DDIs was lower at follow-up compared to baseline, from 35.3% to 19.3%, respectively. These results are consistent with the randomized, double-blind study "Clinical-pharmacist intervention reduces clinically relevant drug–drug interactions in patients with heart failure," which indicated that pharmacist intervention significantly reduces both the number of patients with clinically relevant DDIs, from 18 in control patients compared with 8 in intervention patients, and the number of DDIs, from 31 to 10, respectively; $p < 0.01$.

These results emphasize that active involvement of healthcare professionals in medication management enhances patient safety, adherence, and confidence in their medication regimen [60, 92–94]. All of the above strategies, such as deprescribing, lifestyle counselling, and follow-up, have been shown to improve health-related quality of life, and this forms the rationale for the subsequent assessment

of HRQoL. HRQoL is a multidimensional construct that assesses the impact of health status on physical, psychological, and social functioning. It is widely used to assess changes in the health status of patients over time using standardized assessment tools [95–100].

In the control group of the current study, the results showed that the usual care did not have a significant effect on health-related quality of life utility scores, which remained statistically insignificant from the baseline to the follow-ups (baseline to first follow-up: 0.004 ± 0.273, $p = 0.066$; from the first to the second follow-up: 0.027 ± 0.333, $p = 0.157$; baseline to second follow-up: 0.031 ± 0.380, $p = 0.241$), while VAS scores also revealed insignificant changes (from baseline to the first follow-up: $p = 0.115$; from the first to the second follow-up: $p = 0.156$).

The results of the current study revealed a significant effect of the intervention on the HRQoL of patients. The utility scores of the EQ-5D-3L tool significantly improved from the baseline to the first follow-up (-0.048 ± 0.411; $p = 0.031$) and then to the second follow-up (-0.076 ± 0.446; $p = 0.002$). Similarly, the VAS tool revealed a significant improvement from the baseline to the first follow-up ($p = 0.001$), while the cumulative effect of the intervention on the HRQoL of patients from the baseline to the second follow-up revealed a significant effect ($p = 0.041$).

These results are parallel to the results of the previous studies conducted in different countries, including Pakistan, where patients with chronic diseases showed a significant improvement in the EQ-5D-3L domains in the intervention groups, while the control groups showed minimal changes [101, 102].

Adherence, in particular, plays a crucial role in deprescribing studies, as patients who do not adhere to deprescribing regimens are more prone to adverse effects of drug withdrawal, such as rebound phenomena, as well as premature resumption of withdrawn medications.

Moreover, existing evidence shows that deprescribing and adherence are subject to multidimensional influences, including beliefs, health literacy, and clinician–patient communication, which affect patients' ability to adhere to deprescribing regimens.

Although the systematic review, titled "Deprescribing Interventions and Their Impact on Medication Adherence in Community-Dwelling Older Adults with Polypharmacy," revealed conflicting results regarding the impact of deprescribing on medication adherence, it stressed that adherence is a critical factor that can affect deprescribing regimens, especially in a collaborative model of care [103].

In addition, baseline equivalence in terms of overall adherence mean values was found in the control and intervention groups, which were 1.397 ± 1.076 and 1.393 ± 1.048, respectively. The mean values were found to decrease in the control group, i.e., 1.183 ± 0.982, and increased significantly in the intervention group, i.e., 1.720 ± 1.165, during the first follow-up assessment.

At the second follow-up assessment, the control group showed a slight improvement in the overall adherence values, i.e., 1.102 ± 1.027, whereas the intervention group showed better improvement in the overall adherence values, i.e., 1.986 ± 1.215.

This study also found similar results to an observational study in which the overall adherence values in patients co-prescribed PPIs and NSAIDs were reported to be 73% to 81% fully adherent, while approximately 26% had adherence values ≤ 80%. These findings highlight that suboptimal adherence is common in routine practice without structured support. Both studies emphasize the importance of patient education and structured interventions in improving adherence and ensuring effective medication use, supporting the rationale for pharmacist-led interventions in this study [104].

A study based in the United States, titled "Patients' perceptions of proton pump inhibitor risks and attempts at discontinuation: a national survey," found that about 70% of patients who took PPIs over a long period of time had concerns about side effects, and over 50% of them tried to stop PPIs without any medical advice, showing inconsistent use based on perceptions [105].

This finding supports the observed non-adherence in the control group. On the contrary, the study's intervention group showed enhanced adherence with support from pharmacists. This finding supports previous observations locally and internationally.

In Pakistan, a randomized controlled study titled "Pharmacist-led counselling intervention to improve adherence in Pakistan" found that patients who received counseling from pharmacists in the intervention group were 7.74 times more likely to report fewer missed doses after being counselled by pharmacists compared to those who did not receive counseling, with p-value < 0.0001 [106]. On an international level, an Indian randomized controlled study found that medication adherence was enhanced from 49% to 80% after 24 months with pharmacist education, with a statistically significant difference of $p < 0.001$ [107]. These studies confirm that pharmacist-led patient education and follow-up can improve medication adherence. Internationally, structured pharmacist intervention, as evidenced by a non-randomized study from Malaysia, which demonstrated a reduction of PPI pill count by 66.1% and monthly medication expenditure by 72.0% following pharmacist review, supports the effectiveness of such targeted intervention in addressing medication cost and adherence issues [78, 108].

The financial constraints were also evident, as the control group scored 1.882 ± 1.419 and the intervention group scored 1.760 ± 1.383, indicating high levels of non-adherence related to medication costs. Over time, the control group showed minimal change at the first follow-up (1.500 ± 1.377) and the second follow-up (1.580 ± 1.347), whereas the intervention group demonstrated notable improvement at both the first (2.020 ± 1.439) and second (2.153 ± 1.468) follow-ups, suggesting that the intervention had a positive impact on reducing cost-related non-adherence. These results are supported by evidence from Pakistan, where 92.7% of patients reported high medication costs as a major factor contributing to non-adherence, highlighting the influence of financial barriers in resource-limited settings [109]. Internationally, findings from a Malaysian non-randomized study also support this observation, where pharmacist-led medication review reduced PPI pill count by 66.1% and monthly medication expenditure by 72.0% [78, 108].

Together, these findings indicate that structured pharmacist-led interventions including patient education, medication review, and deprescribing can effectively improve adherence while reducing cost- and pill-burden–related barriers among long-term PPI users. This highlights the importance of integrating pharmacists

into routine patient care to optimize medication use and enhance treatment outcomes.

Similarly, patient satisfaction, an important measure of the humanistic dimension, reflects the quality, acceptability, and value of the healthcare services provided. In the current research, the PSF-9 scale was used to measure changes in patient satisfaction over time in the control and intervention groups at baseline, first, and second follow-up visits. [110].

The mean PSF-9 values showed a gradual increase in patient satisfaction over time for both groups. At baseline, the scores for the control (17.98 ± 3.315) and intervention (18.59 ± 4.107) groups indicated moderate patient satisfaction. Overall satisfaction improved over time in both groups; however, the increase was more pronounced in the intervention group. This improvement may be attributed to structured pharmacist-led counselling, regular follow-up, improved access to information, and enhanced patient understanding of therapy, which positively influenced patients' perceptions of care.

Regional evidence also demonstrates improved patient satisfaction with pharmacist involvement. A recent study in Pakistan using a PSF-type questionnaire reported that 57.3% of participants expressed high satisfaction with pharmacist counselling services, and many were willing to pay for these services, indicating strong acceptability of pharmacist-led interventions in local healthcare practice [111, 112]. The results of the current study indicate that the level of patient satisfaction improves significantly through structured counselling by the pharmacist. This is also supported by international evidence. For instance, a study conducted in Swedish community pharmacies revealed that the majority of customers were satisfied with the counselling received from the pharmacist, followed the advice given, and experienced relief from the symptoms [**?**]. Overall, the above findings suggest that pharmacist intervention is important for enhancing patient satisfaction, knowledge, and confidence in disease management [**?**]. The study indicates that pharmacists should work collaboratively within the healthcare system and actively engage with physicians and other healthcare professionals to support effective deprescribing practices. Such collaboration not only ensures appropriate

medication management but also promotes patient adherence, improves health-related quality of life, increases patient satisfaction, and enhances the overall effectiveness and responsiveness of pharmaceutical care services.

5.2 Limitation of the study

This study's results might not be representative of the wider population since the study was conducted in a small number of hospitals. The study's three-month follow-up period might not be enough to evaluate the long-term PPI medication adherence, persistence of deprescribing, and possible side effects. The results of the study might be affected by social desirability bias since the study used patient-reported results. The results of the study might be affected by social desirability bias since the study used patient-reported results. The study did not utilize digital monitoring of medication adherence, which might have given a more accurate result. The study did not consider socio-economic factors, literacy levels, and health beliefs, which might have affected the results.

Chapter 6

Conclusion and Future Recommendation

6.1 Conclusion

This study proves that collaborative PPI deprescribing is not just about stopping a drug, but also about carefully assessing and optimizing patient therapy. Deprescribing, therefore, is an evidence-based approach that promotes rational use of medications, minimizes medication overuse, and enhances patient safety. Most importantly, this process enhances the professional relationship between physicians and pharmacists by mutual decision-making, thus leading to better health outcomes. The results of this study proved that a well-structured collaborative deprescribing intervention, assisted by pharmacists, can improve medication adherence, patient satisfaction, and quality of life. Moreover, the intervention was also successful in reducing the number of patients who are inappropriately using PPIs over long periods of time. These results, therefore, show that pharmacists can play a crucial role in multidisciplinary healthcare teams, especially in primary care settings with limited resources. Deprescribing, assisted by pharmacists, not only enhances patient outcomes, but also promotes the efficient use of healthcare resources. By reducing the use of medications like PPIs over long periods of time,

healthcare professionals can prevent adverse outcomes that may arise from long-term medication use, as well as empower patients to actively participate in their care.

6.2 Future Recommendation

Proton pump inhibitors are widely prescribed, yet inappropriate long-term use is common, leading to adverse effects, polypharmacy, and increased healthcare costs. In Pakistan, irrational PPI prescribing is prevalent, structured deprescribing programs are lacking, and physician–pharmacist collaboration is limited. Evidence-based interventions, particularly collaborative approaches involving pharmacists, are needed to optimize PPI use, improve patient safety, and reduce healthcare burden. This study evaluates a pharmacist-physician collaborative deprescribing intervention to address these gaps and enhance patient outcomes.

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Appendix A: Ethical Approval Letter from Hospital

بسم اللہ الرحمن الرحیم

ISLAMABAD HOSPITAL
PAKISTAN INSTITUTE OF MEDICAL SCIENCES
G-8/3, ISLAMABAD

Your Ref. No. _____
Our Ref. No. F-5-2/2024(ERRC)/PIMS ***Date:*** 17/6/24

Subject: - APPROVAL LETTER ETHICAL RESEARCH REVIEW COMMITTEE

1. MISS IRMA UMAR
2. DR. FARMAN ULLAH KHAN
3. DR.MUHAMMAD ALI

Reference your application submitted for study titled. "EFFECTIVENESS OF A COLLABORATIVE DEPRESCRIBING INTERVENTION OF PROTON PUMP INHIBITORS: A RANDOMIZED CONTROLLED TRIAL IN PAKISTAN. "After close review of the proposal, the study is approved on behalf of ethical and research review board. In case of any change in topic, authors or research methodology new ERRC certificate will be required.

The Board Reserves Right to stop the research project if report is received regarding any violation of ethics/ deviation from the proposed study plan.

Prof.Mumtaz Ahmad Khan Niazi
Chairman
Ethics Research Review Committee (ERRC)
Professor of General Surgery

MISS IRMA UMAR
Student of M.Phil. (Pharmacy Practice)
CUST University, Islamabad.
03220801611, 03240150148

Copy to:

- PS to Dean, PIMS, Islamabad
- Relevant File

Appendix B: Ethical Approval Letter from Hospital

To
Dr. Imran Yousaf
Head of Department, Gastroenterology and Hepatology
Life Care Hospital

Subject: Request for Permission for Data Collection for Research Study

Respected Sir,

I respectfully request your kind permission to conduct a research study at Life Care Hospital entitled *"Effectiveness of a Collaborative Deprescribing Intervention of Proton Pump Inhibitors: A Randomized Controlled Trial in Pakistan"*, being undertaken by the Faculty of Pharmacy at Capital University of Science and Technology, Islamabad.

With your approval, I hope to:

1. Conduct interviews with relevant patients.
2. Obtain feedback pertinent to the study.
3. Access existing patient data pertinent to the research objectives.

I assure you that all collected data will be handled strictly in accordance with ethical protocols and maintained with utmost confidentiality throughout the research process.

Your support and cooperation in enabling this study would be deeply appreciated.

Thank you for your consideration.

Sincerely,

Irma Umar
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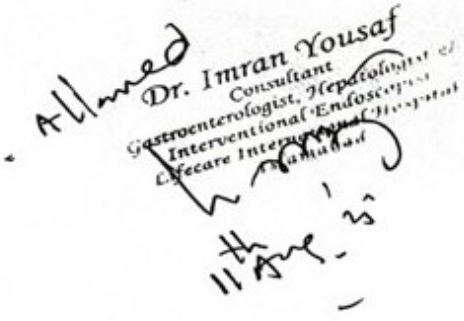


Appendix C: Patient Consent Form

Patient Informed Consent

You are invited to participate in a research study. **Effectiveness of a Collaborative Deprescribing Intervention of Proton Pump Inhibitors: A Randomized Controlled Trial in Pakistan.** The purpose of this study is to safely reduce or stop the use of stomach medicine (PPIs) with support from a pharmacist and a doctor. This may help improve your health and reduce unnecessary side effects. If you agree to take part, your medication will be reviewed, and changes may be made under professional guidance. You may withdraw from the study at any time without affecting your treatment. Your personal and medical information will be kept strictly confidential and used only for research purposes. You can ask any questions before or during the study. By signing below, you confirm that you have understood the purpose of this study and agree to take part in it voluntarily.

Participant's Signature: **Date:**

Researcher's Signature: **Date:**

Appendix D: Data Collection Tools

1: Participants Demographics

Demographics Questionnaire

1. What is your age?

(a)18-29 years **(b)** 30-49 years **(c)** 50 years and above

2. What is your gender?

(a) Male **(b)** Female **(c)** Other

3. What is your marital status?

(a) Single **(b)** Married **(c)** Widowed/Divorced

4. Living Arrangement:

(a) alone **(b)** with spouse **(c)** with children

5. What is your highest level of education?

(a) No formal education **(b)** Secondary education **(c)** Higher education

6. What is your occupation?

(a) Employed **(b)** Unemployed **(c)** Student/Homemaker

7. What type of residence do you live in? **(a)** Islamabad **(b)** Rawalpindi **(c)** other

2: Assessments of Patient Health History

Patient Health History Questionnaire

1. How long have you been taking a PPI?

(a) Less than 3 months **(b)** 3–12 months **(c)** More than 1 year

2. Do you currently smoke?

(a) Never **(b)** Former smoker **(c)** current smoker

3. How many medications do you take regularly (including prescribed and OTC)?

(a) 1-3 **(b)** 4-6 **(c)** 7-10

4. Are you aware of any side effects of long-term PPI use?

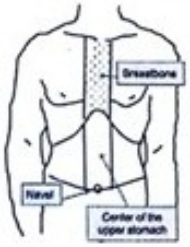
(a) Yes **(b)** No **(c)** Not sure

5. Have you ever tried stopping or reducing your PPI in the past?

(a) Yes **(b)** No **(c)** Not at all

Reflux Disease Questionnaire

Please answer the following questions to help us better understand the symptoms you have been experiencing over the past 7 days because of your reflux disease. For each question, please choose the answer that is most appropriate to you. Please answer each question by ticking one box per row.



RESQ-7

1. Thinking about your symptoms over the past 7 days, how often have you had the following?

	Have not had	1 day	2 days	3-4 days	5-6 days	Daily
a. A burning feeling behind your breastbone.	☐	☐	☐	☐	☐	☐
b. Pain behind your Breastbone	☐	☐	☐	☐	☐	☐
c. A burning feeling in the centre of the upper stomach	☐	☐	☐	☐	☐	☐
d. Pain in the centre of the upper stomach	☐	☐	☐	☐	☐	☐
e. An acid taste in your mouth	☐	☐	☐	☐	☐	☐
f. Unpleasant movement of material upward from the stomach	☐	☐	☐	☐	☐	☐
g. Burping (gas coming from the stomach through the mouth	☐	☐	☐	☐	☐	☐
h. Hoarseness	☐	☐	☐	☐	☐	☐
i. Coughing	☐	☐	☐	☐	☐	☐
j. Difficulty swallowing	☐	☐	☐	☐	☐	☐
k. A bitter taste in your mouth	☐	☐	☐	☐	☐	☐
l. Stomach contents (liquid or food) moving upwards to your throat or mouth	☐	☐	☐	☐	☐	☐
m. Heartburn	☐	☐	☐	☐	☐	☐

1. Thinking about your symptoms over the past 7 days, how would you rate the intensity of the following?

	Did not had	Very mild	Mild	Moderate	Moderately	Severe
a. A burning feeling behind your breastbone	☐	☐	☐	☐	☐	☐
b. Pain behind your breastbone	☐	☐	☐	☐	☐	☐
c. The burning feeling in the Centre of the upper stomach	☐	☐	☐	☐	☐	☐
d. Pain in the Centre of the upper stomach	☐	☐	☐	☐	☐	☐
e. An acid taste in your mouth	☐	☐	☐	☐	☐	☐
f. Unpleasant movement of materials upwards from the stomach	☐	☐	☐	☐	☐	☐
g. Burping (gas coming from the stomach through the mouth)	☐	☐	☐	☐	☐	☐
h. Hoarseness	☐	☐	☐	☐	☐	☐
i. Coughing	☐	☐	☐	☐	☐	☐
j. Difficulty swallowing	☐	☐	☐	☐	☐	☐
k. A bitter taste in your mouth	☐	☐	☐	☐	☐	☐
l. Stomach contents (liquid or food) moving upwards to your throat or mouth	☐	☐	☐	☐	☐	☐
m. Heartburn	☐	☐	☐	☐	☐	☐

4: Intervention Questions

Follow-up evaluation of PPIs Deprescribing Profile (Intervention Group)

Question	**Response**	**Baseline n %**	**Followup-1 n%**	**Followup-2 n%**
Deprescribing strategies selected	Dose reduction (2 Weeks)			
	Dose reduction (4 Weeks)			
	Dose reduction (8 Weeks)			
	Continued with high dose			
	Discontinued immediately			
	Rescue medications			
Pharmacological strategies were discussed	Avoid large/fatty meals late at night			
	Elevate head while sleeping			
	Avoid caffeine, alcohol, smoking			
	Reduce weight if overweight			
Identified drug-drug interactions				

5: General Medication Adherence Scale

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The General Medication Adherence Scale (GMAS)

CODING

No	Question	Categories	Grading	Grading within domain
Non-adherence due to patient behavior (un-intentional and intentional)				
1.	Do you have difficulty in remembering to take your medications?	Always Mostly Sometimes Never	0 1 2 3	• High adherence = 13 – 15 • Good adherence = 11 – 12 • Partial adherence = 8 – 10 • Low adherence = 5 – 7 • Poor adherence = 0 – 4
2.	Do you forget to take your medication due to your busy schedule, travelling, meeting, events at home, party, marriage, religious celebrations, etc.?	Always Mostly Sometimes Never	0 1 2 3	
3.	Do you discontinue your medication when you feel well?	Always Mostly Sometimes Never	0 1 2 3	
4.	Do you stop taking medications when you feel adverse effects such as gastric discomfort, etc.?	Always Mostly Sometimes Never	0 1 2 3	
5.	Do you stop taking medications without informing the doctor?	Always Mostly Sometimes Never	0 1 2 3	
Non-adherence due to additional disease and pill burden				
6.	Do you discontinue your medicines due to other medicines that you have to take for your additional disease?	Always Mostly Sometimes Never	0 1 2 3	• High adherence = 11 – 12 • Good adherence = 9 – 10 • Partial adherence = 6 – 8 • Low adherence = 4 – 5 • Poor adherence = 0 – 3
7.	Do you find it is a hassle to remember your medications due to medication regime complexity?	Always Mostly Sometimes Never	0 1 2 3	
8.	During the last month, had there been any occasion when you missed your medicines due to progression of disease and addition of new medicines?	Always Mostly Sometimes Never	0 1 2 3	
9.	Do you alter medication regimen, dose and frequency by yourself?	Always Mostly Sometimes Never	0 1 2 3	
Non-adherence due to financial constraints				
10.	Do you discontinue these medications because they are not worth of the money you spent on them?	Always Mostly Sometimes Never	0 1 2 3	• High adherence = 6 • Good adherence = 5 • Partial adherence = 3 – 4 • Low adherence = 2 • Poor adherence = 0 – 1
11.	Do you find it difficult to buy your medicines because they are expensive?	Always Mostly Sometimes Never	0 1 2 3	
Grading for overall medication adherence (cumulative) High Adherence = 30 – 33 Good adherence = 27 - 29 Partial Adherence = 17 – 26 Low Adherence = 11 – 16 Poor Adherence = 0 – 10				

6: Patient Satisfaction Feedback

Patient Serial Number _____ (For office use only)

PATIENT SATISFACTION FEEDBACK REGARDING PHARMACIST COUNSELLING مریض کا فارمسسٹ سے حاصل کردہ معلومات کے بارے میں اطمینان اوراظہارخیال	
1. Were you able to get counseling without any difficulty? ○ Yes ○ No	**۱. کیا آپ کو آسانی سے معلومات حاصل ہوگئیں؟** ○ ہاں ○ نہیں
2. Were you able to get knowledge which you required? ○ Yes completely ○ Yes to some extent ○ No, I did not get what I was seeking to know	**۲. کیا آپ کو وہ سب معلوم ہوگیا جو آپ جاننا چاہتے تھے؟** ○ ہاں، مکمل طور پر ○ ہاں، کسی حد تک ○ نہیں، مجھے وہ سب کچھ نہیں پتہ چلا جو میں جاننا چاہتا تھا
3. Did you find pharmacist helpful in resolving your queries? ○ Very helpful ○ Somewhat helpful ○ Not helpful	**۳. کیا فارمسسٹ نےآپ کے سب سوالات کے جوابات بہتر طور پردے دیئے؟** ○ بہت بہتر طور پر ○ کسی حد تک بہتر طور پر ○ بہتر طور پرنہیں دیئے
4. What is your opinion about the time duration of pharmacist counseling? ○ More time should be given ○ Appropriate time was given ○ My time was wasted	**۴. فارمسسٹ سے حاصل کردہ معلومات کے دورانیہ کے متعلق آپ کیا رائے رکھتے ہیں؟** ○ اس سے زیادہ وقت دینا چاہئے تھا ○ دورانیہ میری ضرورت کے مطابق تھا ○ میرا وقت برباد ہوگیا
5. Will you recommend getting counseling from pharmacists to others? ○ Yes ○ No	**۵. کیا آپ دوسروں کو فارمسسٹ سے مفید معلومات حاصل کرنے کی تجویز دیں گے؟** ○ ہاں ○ نہیں
6. In your opinion, should this service be offered by pharmacies in your locality? ○ Yes ○ No	**۶. کیا دوائیوں کی دوکان پراس قسم کی سہولت موجود ہونی چاہئے یا نہیں؟ آپ کی کیا رائے ہے؟** ○ ہاں ○ نہیں
7. Are you willing to pay for this counseling service? ○ Yes ○ No	**۷. کیا آپ فارمسسٹ سے مفید معلومات حاصل کرنے کے لئے پیسوں کی ادائگی کی ہمایت کریں گے؟** ○ ہاں ○ نہیں
8. If yes, how much counseling fee should be charged for this service?_____	**۸. اگر آپ ہاں کہتے ہیں تو کتنے پیسے تجویز کریں گے؟_____**
9. How would you rate your satisfaction with pharmacist counseling? ○ Very satisfied ○ Satisfied ○ Uncertain ○ Not satisfied	**۹. فارمسسٹ سے حاصل کردہ معلومات سے آپ کتنے مطمئن ہیں؟** ○ بہت مطمئن ○ مطمئن ○ کچھ کہ نہیں سکتا ○ مطمئن نہیں ہوں
10. Indicate you satisfaction rate with pharmacist counseling on a scale of 1 – 10. **Worst** 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10 **Best**	**۱۰. فارمسسٹ سے حاصل کردہ معلومات سے ہونے والے اطمینان کو ایک سے دس تک کے پیمانے پر ظاہر کیجیئے۔** بدترین 10 – 9 – 8 – 7 – 6 – 5 – 4 – 3 – 2 – 1 بہترین

7: EQ-5D-3L

سوال نامہ برائے صحت

اُردو ورژن برائے پاکستان

(Urdu version for Pakistan)

مندرجہ ذیل ہر گروپ کے کسی ایک خانے پر نشان ☑ لگائیے۔ برائے مہربانی ان جملوں کی نشاندہی کیجئے جو آپ کی آج کل کی صحت کی بہترین عکاسی کرتے ہیں۔

چلنا پھرنا

- ❑ مجھے چلنے پھرنے میں کوئی مشکل نہیں ہے
- ❑ مجھے چلنے پھرنے میں کچھ مشکل ہوتی ہے
- ❑ میں بالکل چل پھر نہیں سکتا/سکتی ہوں

اپنی دیکھ بھال کرنا

- ❑ مجھے اپنی دیکھ بھال کرنے میں کوئی مشکل نہیں ہے
- ❑ مجھے نہانے اور کپڑے پہننے میں کچھ مشکل ہوتی ہے
- ❑ میں خود نہا یا کپڑے نہیں پہن سکتا/سکتی ہوں

روزمرہ کے کام کاج *(مثلاً کام، پڑھائی، گھریلو کام کاج، خاندانی اور تفریحی مصروفیات)*

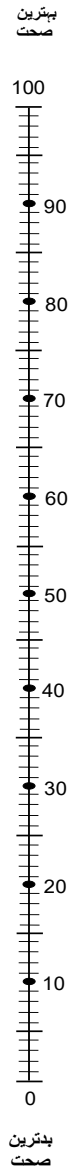
- ❑ مجھے اپنے روزمرہ کے کام کاج میں کوئی مشکل نہیں ہوتی ہے
- ❑ مجھے اپنے روزمرہ کے کام کاج میں کچھ مشکل ہوتی ہے
- ❑ میں اپنے روزمرہ کے کام کاج نہیں کر سکتا /سکتی ہوں

درد / بے آرامی

- ❑ مجھے کوئی درد یا بے آرامی نہیں ہے
- ❑ مجھے کچھ درد یا بے آرامی ہے
- ❑ مجھے شدید درد یا بے آرامی ہے

بے چینی/ ذہنی پریشانی (ٹینشن)

- ❑ مجھے کوئی بے چینی یا ذہنی پریشانی نہیں ہے
- ❑ مجھے کچھ بے چینی یا ذہنی پریشانی ہے
- ❑ مجھے شدید بے چینی یا ذہنی پریشانی ہے



اپنی آج کل کی صحت کی صحیح طور پر نشاندھی کرنے کے لیے ہم نے آپ کی آسانی کے لیے ایک (تھرمامیٹر کی طرح) پیمانہ بنایا ہے۔ اس پیمانے پر سو (100) آپ کی بہترین اور صفر (0) آپ کی بدترین صحت کی نشاندھی کرتا ہے۔

ہم چاہیں گے کہ آپ اس پیمانے پر نشاندھی کریں کہ آج کل آپ کے خیال میں آپ کی صحت کیسی ہے (بہترین یا بدترین) نیچے دئے گئے (آپ کی آج کل کی صحت) خانے سے ایک لائن لگائیں جو پیمانے پر موجوداس نشان تک ہو جو آپ کی آج کل کی صحت کی صحیح نشاندھی کرتی ہو۔

آپ کی آج کل کی صحت

Appendix E: Deprescribing card/ Patient Education Brochure


پروٹون پمپ انہیبیٹرز کیا ہوتے ہیں؟
PPIs ایک قسم کی دوا ہیں جو معدے سے تیزاب کی پیداوار کو کم کرنے کے لیے استعمال ہوتی ہیں۔ ان کا استعمال عام طور پر سینے کی جلن (ہارٹ برن)، معدے کے السر، اور معدے کی تیزابیت جیسے مسائل کے علاج کے لیے کیا جاتا ہے۔ پی پی آئیز کی کئی اقسام ہیں، جن میں
Lansoprazole (Prevacid)
Omeprazole (Risek)
Pantoprazole (Tecta, Pantoloc)
Rabeprazole (Pariet)
Esomeprazole (Nexium)
Dex lansoprazole (Dexilant)
پروٹون پمپ انہیبیٹرکو روکنا ہر کسی کے لیے موزوں نہیں ہوتا
PPI کچھ لوگوں کو طویل عرصے تک استعمال کرنے رہنا پڑتا ہے۔
کچھ لوگوں کو یہ دوا صرف ایک مختصر مدت کے لیے درکار ہوتی ہے
ضمنی اثرات کا خطرہ اس کے فائدے کے امکان سے زیادہ ہو سکتا ہے۔
کا استعمال PPIs
جاری رکھنا چاہیے،ان میں ہیں شامل
غیر اسٹیروئڈل سوزش کم کرنے والی دواؤں کا طویل مدتی استعمال(جیسے کہ ایڈویل
غذائی نالی کی شدید سوزش
معدے کے السر سے خون بہنے کی history تصدیق
(Barrett's esophagus)
پروٹون پمپ انہیبیٹرز کو محفوظ طریقے سے کم کرنے کا طریق
چار یا آٹھ ہفتے سے زائد استعمال کرنے والے بالغ افراد ڈاکٹر، یا فارماسسٹ سے مشورہ کریں۔
صحت کے ماہر فیصلہ کرنے میں مدد کریں گے کہ
دوا بند کی جائے
طرز زندگی بدلی جائے
خوراک کم کی جائے
پروٹون پمپ انہیبیٹرز کم کرنے کے طریقے
دن میں دو بار کے بجائے ایک بار لینا
خوراک کم کرنا (مثلاً 40 سے 20 mg)
ایک دن چھوڑ کر لینا، پھر مکمل بند کرنا
کیا پروٹون پمپ انہیبیٹر اب بھی ضروری ہے؟
پروٹون پمپ انہیبیٹرز یہ دوا سینے کی جلن اور معدے کے مسائل کے علاج کے لیے استعمال ہوتی ہے۔
خوراک کو کم کیا جا سکتا ہے یا ضرورت کے مطابق استعمال کیا جا سکتا ہے۔
ضمنی اثرات: سر درد، متلی، دست، خارش۔
یہ ضمنی اثرات کے خطرے کو بڑھا سکتے ہیں وٹامن بی12 اور میگنیشیم کی کمی ہڈیوں کی ٹوٹ پھوٹ نمونیا
C.difficile انتوں کی انفیکشن
پروٹون پمپ انہیبیٹر کو کم کرنے کے بعد کیا مانیٹر کریں
ڈاکٹر، نرس پریکٹیشنر یا فارماسسٹ کی مدد سے دوا کم کرنے یا بند کرنے کے بعد، درج ذیل علامات کو مانیٹر کرنا اور رپورٹ کرنا ضروری ہے
تیزاب کا ریفلوکس
معدے میں درد
اگر مریض بات نہیں کر سکتا، تو درج ذیل علامات کو مانیٹر کریں اور رپورٹ کریں
اگر معدے کے مسائل برقرار رہیں تو کیا کریں؟
اگر سینے کی جلن، واپسی، یا معدے میں درد 3-7 دن بعد بھی جاری رہے
ڈاکٹر یا فارماسسٹ سے بات کریں۔
وہ فیصلہ کریں گے کہ پچھلی خوراک پر واپس جانا چاہیے یا دوا کو صرف ضرورت کے مطابق استعمال کرنا چاہیے۔
ایسی حالت کے علاج کے لیے ایک ٹیسٹ تجویز کریں جسے ایچ۔ پائلوری کہا جاتا ہے۔