
**Effectiveness of Counselling by Clinical
Pharmacist on Medication Adherence in Epileptic
Children at Tertiary Care Hospital:
A Randomized controlled study**

**Thesis submitted to
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**Accredited 'A+' Grade by NAAC (3rd Cycle)
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***For the award of the degree of
Doctor of Philosophy
In the Faculty of Pharmacy***

By

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“Any great achievement is preceded by many difficulties and many lessons; great achievements are not possible without them.” — Brian Tracy

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ABSTRACT

Introduction: This study aimed to evaluate the impact of a structured intervention on medication adherence among epilepsy patients. Medication adherence is crucial for managing epilepsy effectively, yet non-compliance remains a significant challenge. The structured intervention included patient counselling, information leaflets, and other support measures to manage adverse effects and improve adherence. The study also aimed to assess the impact of this intervention on quality of life (QOL) and adverse drug reactions (ADRs).

Materials and Methods: A randomized controlled study was conducted involving 300 epilepsy patients, with 150 in the control group and 150 in the intervention group. The control group received standard care, while the intervention group received additional support measures, like Patients counseling were provided with patients information leaflets. Medication adherence was assessed using the Self Validated Medication Adherence scale, QOL was evaluated using the Quality of Life in Childhood Epilepsy (QOLCE) questionnaire, and ADRs were assessed using Naranjo Scale, WHO Scale for causality, and Hartwig's Scale for severity. These scales were used to causality relationship between suspected drug and reported event, study included five follow-up periods each follow up interval of six months periods to measure changes over time.

Results: The study tracked medication adherence levels in both a control group and an intervention group across multiple follow-up periods. Initially, at baseline, period was day one of the initiation, This study included only newly diagnosed epileptic children, both groups exhibited similar medication adherence rates, with the control group at 98.33% and the intervention group at 98.00%. There was no significant

difference between them (Z-value = -0.0992, p-value = 0.9210). However, as the intervention progressed, distinct trends emerged. The causes of non-compliance were examined in both the control and intervention groups. In the control group, the leading causes were cost (22.67%), followed by forgetting to take medications (12.67%) and lack of improvement seen (17.33%). For Quality-of-Life scores, that is, for cognitive, emotional, social, and physical functioning, the F-values and corresponding p-values were scrutinized. At baseline, no significant discrepancy in QOL among different age groups was identified, as indicated by an F-value of 0.2045 and a p-value of 0.8152, surpassing the typical significance threshold of 0.05. Subsequent follow-up periods yielded similar outcomes, consistently exhibiting p-values exceeding 0.05, signifying a lack of noteworthy differences in QOL across age groups over time.

The comparison between the control and intervention groups reveals differences in the occurrence and nature means incidence of ADRs in antiepileptic drug-induced adverse drug reactions (ADRs). In the control group, a total of 19 (12.7%) ADRs were identified, whereas higher than the intervention group, 10 (6.67%) ADRs were found.

Discussion: The structured intervention proved to be effective in enhancing medication adherence among epilepsy patients. The significant improvement in adherence scores in the intervention group compared to the control group highlights the benefits of patient counselling, information leaflets, and ongoing support. The findings suggest that such interventions can effectively address common barriers to adherence, such as forgetting to take medications and lack of perceived improvement. The intervention group consistently improvement in QoL and potential difference in drug tolerability and safety profiles in compared to control group.

Conclusion: The structured intervention was effective in enhancing medication adherence, improving quality of life, and providing valuable insights into the causes of non-compliance and ADR management among epilepsy patients. Implementing such interventions, including patient education, counselling, and ongoing support, can lead to better treatment outcomes.

Keywords: Medication Adherence, Quality of life epilepsy, Antiepileptic drugs, Intervention, Intervention control.

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LIST OF ABBREVIATIONS

SR NO	ABBREVIATION	FULL FORM
1	AEDs	Antiepileptic Drugs
2	SR	Seizure Recurrence
3	MTM	Medication Therapy Management
4	EHR	Electronic Health Records
5	ANOVA	Analysis of Variance
6	ADR	Adverse Drug Reaction
7	QOL	Quality of Life
8	ICF	Informed Consent Form
9	PIS	Participant Information Sheet
10	SNOSE	Sequentially Numbered Opaque Sealed Envelopes
11	QOLCE	Quality of Life in Childhood Epilepsy
12	WHO-UMC	World Health Organization- Uppsala Monitoring Centre
13	PIL	Patient Information Leaflets
14	RMB	Renminbi
15	VPA	Valproic acid
16	LEV	Levetiracetam
17	PHT	Phenytoin
18	OXC	Oxcarbazepine

19	MMAS	Morisky Medication Adherence Scale-8
20	STAR	Supporting Treatment Adherence Regimens
21	PHLKS	Public Health Literacy Knowledge Scale
22	EAS	Epilepsy Alert System
23	PHCs	Primary Health Centers
24	HRQOL	Health-Related Quality of Life
25	SF36	36- Item Short Form Survey Instrument
26	IQ	Intelligence Quotient
27	CPMS	Childhood Psychopathology Measurement Schedule
28	CSE	Convulsive Status Epilepticus
29	PROM	Patient-Reported Outcome Measures
30	CHEQoL	Children with Epilepsy Quality of Life
31	COSMIN	COnsensus-based Standards for the selection of health Measurement Instruments
32	DRE	Drug-Resistant Epilepsy
33	TDM	Therapeutic Drug Monitoring
34	CKD	Chronic Kidney Disease
35	ASM	Antiepileptic Drugs/Medications
36	CDM	Common Data Model
37	VAMS	Volumetric Absorptive Micro Sampling
38	EEG	Electroencephalogram

39	LC-ESI-MS/MS	Liquid Chromatography-Electrospray Ionization-Mass Spectrometry
40	EIA	Enzyme Immunoassays
41	HPLC	High-Performance Liquid Chromatography
42	LC-MS/MS	Liquid Chromatography-Tandem Mass Spectrometry
43	FDA	Food and Drug Administration
44	SD	Standard Deviation
45	WHO	World Health Organization

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1. INTRODUCTION

1.1 BACKGROUND

Seizure Disorder is a neural disorder symbolized by recurrent and unpredictable seizures, originating from increased neuronal activity in the cortical cells of the brain. Globally, it affects over 50 million individuals, with a significant majority residing in developing nations¹. While epilepsy can manifest at any age, it commonly begins during childhood².

In India, epilepsy affects a considerable portion of the population, with prevalence rates ranging from 4.15 to 7.03 per 1000 individuals. Many individuals with epilepsy receive diagnosis and treatment from non-specialists across various healthcare levels, leading to potential suboptimal management of the condition. Given the substantial scope for improvement in epilepsy care services in a developing country like India, clinical pharmacy services have emerged as a valuable avenue for promoting rational drug therapy.

Clinical pharmacists play a crucial role in assessing the prevailing prescription patterns within the country. They analyse factors such as patient age, the utilization of monotherapy or polytherapy, the incorporation of newer antiepileptic drugs (AEDs), and the concurrent use of benzodiazepines with AEDs. By doing so, clinical pharmacists aim to ensure the rational utilization of medications and enhance patient adherence to treatment regimens. Unfortunately, a significant proportion of epileptic patients in developing nations, estimated at around 90%, do not receive appropriate treatment. This deficiency can be attributed to various factors such as cultural attitudes, insufficient prioritization of epilepsy care within the healthcare system, economic challenges, and other systemic barriers. However, the integration of clinical

pharmacists into hospital settings holds promise for initiating positive changes in drug therapy for epilepsy patients, ultimately improving their overall care and treatment outcomes³.

Improving adherence to antiepileptic drugs (AEDs) can be achieved through various interventions, including patient counseling, utilizing specialized medication containers, self-recording of medication intake and seizures, as well as implementing reminders for prescription refills and clinic appointments. These interventions contribute to the promotion of rational drug use, thereby enhancing treatment outcomes. To further advance the rational use of medications, our study aimed to analyze prescribing patterns and their adherence to national and international guidelines within a tertiary care teaching hospital in India. Previous research has identified several factors influencing adherence to AEDs, such as the duration of drug therapy, tablet count, consideration of alternative treatments, availability of family support, and financial constraints. Additionally, the type and frequency of seizures experienced by patients can serve as motivating factors for medication adherence. By examining prescribing practices and rationality according to established guidelines, our study seeks to identify areas for improvement in epilepsy management. This analysis can lead to the development of targeted interventions aimed at enhancing adherence and optimizing treatment outcomes for individuals with epilepsy⁴.

The Self Validated Medication Adherence Scale is a widely used tool for assessing medication adherence in various medical conditions, including epilepsy. This questionnaire is specifically designed to capture information from study participants regarding their adherence to prescribed medications. The tool consists of a set of questions that assess different aspects of medication adherence, such as forgetfulness, carelessness, and intentional non-adherence. Participants' responses are

scored, and based on the total score, adherence levels are categorized into three groups.

This scale provides a standardized method for evaluating medication adherence levels and allows researchers and healthcare professionals to quantify adherence rates among patients. It helps in identifying individuals who may require additional support or interventions to improve their adherence to prescribed medications⁵.

Compliance with medication poses a significant challenge, particularly in cases requiring long-term therapy and due to the potential for unwanted side effects associated with many drugs. Patient adherence behavior is influenced by various factors including the specific clinical context, nature of the illness, and the complexity of the treatment regimen. Treatment regimens that are more complex and require numerous behavioral changes are often associated with higher rates of non-compliance. Patients may unintentionally fail to adhere to their prescribed medication due to forgetfulness, misunderstanding, or uncertainty regarding the clinician's recommendations. Additionally, intentional non-compliance may occur due to the patient's expectations regarding treatment outcomes, concerns about potential side effects, or personal lifestyle choices. Addressing the factors contributing to non-compliance requires a comprehensive approach that considers the individual patient's needs, preferences, and circumstances. Healthcare providers have an important duty in encouraging adherence by providing concise instructions, educating patients about the importance of medication adherence, addressing concerns and misconceptions, and working collaboratively with patients to develop strategies to overcome barriers to adherence. Additionally, simplifying treatment regimens whenever possible and providing support resources can also help improve medication adherence rates⁶.

Suboptimal adherence to medication regimens has been associated with heightened seizure frequency among individuals with epilepsy, resulting in a greater frequency of hospital admissions and elevated healthcare expenses. Adherence, in this context, pertains to the degree to which a patient's behaviors related to treatment conform to the recommendations provided by healthcare providers. A high level of adherence reflects a strong partnership between the patient and healthcare provider, characterized by active patient engagement in treatment and a collaborative agreement regarding the management of the condition. This mutual understanding and cooperation are essential for achieving optimal treatment outcomes and reducing the risk of seizure recurrence. Improving adherence among patients with epilepsy requires a multifaceted approach that addresses both patient-specific factors and systemic barriers to adherence. Healthcare providers can play a pivotal role in promoting adherence by fostering open communication, providing education about the importance of medication adherence, offering support resources, and addressing any concerns or challenges that may impede adherence. Through enhancing patient engagement in their treatment and cultivating a collaborative relationship between patients and healthcare providers, it is feasible to elevate adherence levels, diminish seizure frequency, and finally augmenting overall health related quality of care for patients with epilepsy⁷.

Discontinuing antiepileptic drugs (AEDs) prematurely poses a dual challenge: it may prevent unnecessary prolonged treatment but also heighten the risk of seizure recurrence (SR). Therefore, instead of focusing solely on when medication can be halted, it is essential to identify patients in whom discontinuation can be safely considered. Predicting the prognosis following treatment discontinuation would be invaluable clinically, aiding in determining which patients are suitable candidates for

cessation. This predictive approach considers various factors, such as seizure history, treatment response, and individual patient characteristics. By evaluating these factors comprehensively, healthcare providers can make informed decisions about medication management, comparing the potential benefits of discontinuation versus developing of seizure recurrence. Continuous monitoring and follow-up are essential to promptly address any signs of seizure recurrence and adjust treatment accordingly. In essence, the decision to discontinue AEDs should be based on a thorough assessment of patient-specific factors and a careful consideration of the potential risks and benefits, guided by the goal of optimizing epilepsy management and patient outcomes⁸.

Pharmacists participate in fostering medication compliance in epileptic children.

- **Education and Counselling:** Pharmacists educate both the child and their caregivers about the importance of taking medication as prescribed. They explain how the medication works, potential side effects, and the consequences of non-adherence.
- **Individualized Care:** Pharmacists assess each child's unique needs and circumstances to tailor their approach. They may consider factors such as age, cognitive abilities, and family support when designing adherence strategies.
- **Medication Management:** Pharmacists help simplify medication regimens whenever possible to make them easier for children and caregivers to follow. They may recommend specific dosage forms (e.g., liquid versus tablets) or suggest synchronized refills for multiple medications to reduce the burden of managing prescriptions.

- **Monitoring and Follow-Up:** Pharmacists regularly monitor the child's medication adherence and response to treatment. They may follow up with the child and their caregivers to address any challenges or concerns that arise and make necessary adjustments to improve adherence.
- **Collaboration with Healthcare Team:** Pharmacists work closely with other healthcare providers involved in the child's care, such as pediatricians, neurologists, and nurses. They communicate medication-related issues and collaborate on strategies to optimize adherence and improve health outcomes.
- **Providing Support Resources:** Pharmacists offer resources and tools to support medication adherence, such as pill organizers, reminder apps, and educational materials. They may also provide guidance on how to handle missed doses and what to do in case of emergencies.
- **Addressing Barriers:** Pharmacists identify and tackle obstacles to medication adherence, including cost constraints, transportation challenges, or cultural convictions. They facilitate the connection of families with resources and support programs to surmount these hurdles. Clinical pharmacists also hold a vital function in advocating medication adherence among patients.
- **Medication Therapy Management (MTM):** Clinical pharmacists conduct MTM services, which involve comprehensive medication reviews, patient education, and medication adherence counselling. They assess patients' medication regimens, identify potential drug interactions or adverse effects, and optimize therapy to improve adherence.
- **Patient Education:** Pharmacists educate patients about the importance of medication adherence in managing chronic conditions, preventing

complications, and achieving better health outcomes. They provide clear instructions on medication usage, dosage schedules, potential side effects, and strategies to overcome barriers to adherence.

- **Personalized Counselling:** Clinical pharmacists engage patients in one-on-one counselling sessions to address their concerns, misconceptions, or challenges related to medication adherence. They customize their approach to accommodate each patient's requirements, taking into account factors such as health literacy, cultural perspectives, and socioeconomic status.
- **Collaborative Care:** Pharmacists collaborate with other healthcare providers, including physicians, nurses, and social workers, to ensure cohesive care and assistance for patients with intricate medication regimens or adherence challenges. They participate in interdisciplinary teams to develop strategies for enhancing adherence and monitoring patients' progress.
- **Use of Technology:** Pharmacists leverage technology, such as medication management apps, automated refill reminders, and telehealth platforms, to facilitate communication with patients and enhance medication adherence. They may also utilize electronic health records (EHRs) to track patients' medication histories and identify patterns of non-adherence.
- **Behavioural Interventions:** Pharmacists utilize behavioral strategies, like motivational interviewing and cognitive-behavioral techniques, to empower patients to assume a more proactive role in managing their medications. They help patients set realistic goals, address ambivalence about treatment, and develop self-management skills to improve adherence behaviour.

- Continuous Monitoring: Pharmacists monitor patients' adherence to medication therapy over time, using various assessment tools and objective measures, such as pharmacy refill records or electronic adherence monitoring devices. They identify trends or patterns of non-adherence and intervene promptly to prevent potential complications or treatment failures.

1.2 JUSTIFICATION OF THE STUDY

As per the previous literature review,

1. Adherence to medication regimens plays a critical role in managing chronic conditions like epilepsy. However, studies indicate variability in adherence levels, with 36.9% classified as highly adherent, 39.8% as moderately adherent, and 23.3% as poorly adherent. Non-adherence to antiepileptic drugs often leads to inadequate seizure control.

- To improve adherence, various interventions can be employed. These include patient counseling, the use of specialized medication containers, encouraging documentation of drug intake and implementing prompts such as mail notifications for prescription refills and clinic appointments. These interventions aim to empower patients, offer support, and emphasize the importance of medication adherence in effectively managing chronic conditions.

2. Non-compliance with antiepileptic drugs (AEDs) can have significant consequences for individuals with epilepsy, leading to various negative outcomes:

- Experiencing Side Effects: Non-adherent patients may experience the side effects of AEDs more prominently due to inconsistent medication intake. This can exacerbate discomfort and contribute to reduced quality of life.
- Increased Hospitalizations: Patients who are non-adherent are more prone to experiencing uncontrolled seizures, resulting in frequent hospitalizations. Prolonged lengths of stay in hospitals can disrupt daily life and impose additional burdens on both patients and their families.
- Missed School or Work: Seizures and the fear of their occurrence can significantly affect a patient's ability to attend school or work. This can lead to

academic underachievement, decreased productivity, and economic strain on individuals and their families.

2. Clinical pharmacists play a crucial role in educating patients or caregivers about the disease and therapy, thereby promoting adherence and improving clinical outcomes while reducing costs. Here's how they contribute:

- Patient Education: Clinical pharmacists provide comprehensive education to patients or caregivers about the nature of the disease, its progression, and the importance of adhering to prescribed therapies. They ensure that patients understand their treatment regimens, including dosing schedules and potential side effects.
- Encouraging Adherence: Pharmacists actively engage with patients to encourage adherence to prescribed medications. They address any concerns or misconceptions that patients may have about their treatment and provide support to help overcome barriers to adherence.
- Explaining Side Effects: Clinical pharmacists explain potential side effects associated with medications, including their likelihood, severity, and management strategies. By providing this information upfront, pharmacists empower patients to make informed decisions about their treatment and mitigate the impact of side effects.
- Information on Drug-Drug Interactions: Pharmacists educate patients about potential drug-drug interactions that may occur with their prescribed medications. They advise patients on how to avoid or manage these interactions, ensuring the safe and effective use of medications.
- Improving Clinical Outcomes: Through patient education, adherence support, and management of drug-related issues, clinical pharmacists contribute to improved clinical outcomes. By helping patients better understand and manage

their medications, pharmacists can reduce the risk of complications, hospitalizations, and disease progression.

- Decreasing Costs: By promoting adherence and preventing medication-related problems, clinical pharmacists help reduce healthcare costs associated with unnecessary hospitalizations, emergency department visits, and complications. They also assist in identifying cost-effective treatment options and accessing financial assistance programs when needed.

1.3 OBJECTIVES

Primary objectives:

- To assess the effectiveness of patient medication counselling in epileptic children.
- To determine the causes non-compliance on the patients with Antiepileptic medication.

Secondary objective:

- To Assess the Health related Quality of Life in Pediatric Population in Epilepsy.
- To assess the Adverse Drug Reactions.

2. REVIEW OF LITERATURE

- A cross-sectional questionnaire-based study conducted by **Amol L. Bhawe and Pratit P. Vyas** at a tertiary care teaching hospital aimed to assess medication adherence among children with epilepsy attending the pediatric outpatient department. The study utilized the Morisky Medication Adherence Scale-8 (MMAS) questionnaire to evaluate adherence to anti-epileptic drug therapy. Findings revealed that 83% of the children exhibited high adherence, 10% moderate, and 7% low adherence levels. Monotherapy was associated with better adherence rates compared to polytherapy, with valproate being the most commonly prescribed medication. Positive predictors of adherence included monotherapy and patient satisfaction. The study underscores the importance of medication adherence in mitigating the impact of epilepsy on children's health. However, it is important to note limitations such as the inability to predict changes in adherence over time due to the cross-sectional design and the restriction to a single-center setting, which may limit the generalizability of the results to other regions.⁹
- The study conducted by **Derya Suluhan et al.** delves into the crucial area of attitudes towards rational drug use and medication self-management among parents of children with epilepsy. Through a descriptive and cross-sectional design, the researchers aimed to evaluate the medication self-management practices and attitudes of these parents. Utilizing questionnaires and data collection forms, they found that while parents generally held positive attitudes towards rational drug use, their medication self-management skills were lacking, which subsequently impacted medication adherence in pediatric epilepsy cases. Despite the positive attitudes towards rational drug use, there

exists a notable gap in medication self-management among these parents. This highlights the necessity for qualitative studies to delve deeper into the difficulties parents face in managing antiepileptic drugs (AEDs). This study stands as the first exploration of parental attitudes towards rational drug use in this context, shedding light on an area that requires further attention and support.¹⁰

- The study conducted by **Baljinder Kaur et al.** examined adherence to anti-epileptic drugs (AEDs) among children with epilepsy in a tertiary care hospital. Using a cross-sectional prospective descriptive design, the aim was to assess adherence levels and associated factors among patients. A structured questionnaire, including the Morisky Medication Adherence Scale-8 (MMAS-8), was employed for medication adherence assessment. The findings revealed that 50% of participants demonstrated poor adherence to AEDs. Among the reasons cited for non-compliance were forgetfulness, difficulty sticking to the regimen, and challenges in purchasing the drugs. Notably, memory issues emerged as the most common reason for non-compliance. This study underscores the significance of addressing adherence barriers to optimize the management of epilepsy in pediatric patients.¹¹
- The study by **Gabriel-Job and Wobo** investigated the adherence to antiepileptic drugs (AEDs) among children with epilepsy at a tertiary hospital in Rivers State, Nigeria. Their findings revealed poor adherence to AEDs, a significant concern influenced by various factors such as age, gender, socioeconomic status, medication type, and income level. This cross-sectional descriptive study, conducted at the University of Port Harcourt Teaching Hospital, involved the analysis of data using descriptive statistics, Chi-square test, and Students t-test. The research emphasized the importance of affordable

drugs and counseling in promoting adherence to AEDs among children with epilepsy. Despite the significance of the findings, the study faced limitations including a limited sample size of 94 children with epilepsy and reliance on self-report for assessing AED adherence. Overall, the study underscores the need for targeted interventions to improve adherence rates and better management of epilepsy among children in Nigeria.¹²

- The research led by **Hawi Mohammed and colleagues** aimed to examine the adherence to anti-seizure medications among pediatric epilepsy patients in a tertiary hospital in Southwest Ethiopia. Results indicated that approximately 54.1% of children with epilepsy adhered to their prescribed medications. This underscores the critical role of medication adherence in achieving successful treatment outcomes for epilepsy, a condition impacting over 50 million individuals globally and associated with significant mortality rates.¹³
- The study identified various factors influencing medication adherence, including marital status, seizure control, healthcare quality, caregiver knowledge, and attitude towards epilepsy. Data collection was conducted through a facility-based cross-sectional design, utilizing semi-structured pre-tested questionnaires. Despite rigorous data collection methods, limitations were acknowledged. These included potential recall bias due to reliance on parent or caregiver reports and the study's restriction to a single institution, which may restrict the generalization of findings beyond the local context. Nevertheless, the study's insights shed light on medication adherence patterns among pediatric epilepsy patients in Ethiopia, highlighting the importance of tailored interventions addressing identified influencing factors to enhance adherence rates and treatment outcomes.

- In their study titled "The Role of Clinical Pharmacist in Pediatrics' Adherence to Antiepileptic Drugs," **Suha Jarad et al.** investigated the impact of clinical pharmacist-led education on medication adherence in pediatric epilepsy patients. Through interventional studies involving clinical pharmacist-led educational interviews, the researchers found a significant improvement in medication adherence among participants who received pharmacist-led education. The intervention group displayed higher levels of adherence, satisfaction with information, and quality of life compared to the control group. Despite the small sample size (n = 41 intervention, n = 40 control), the results underscored the positive effects of pharmacist-led education in enhancing outcomes for pediatric epilepsy patients. Notably, there were no significant differences in safety outcomes between the intervention and control groups, highlighting the efficacy and safety of this approach in improving medication adherence in pediatric populations.¹⁴
- The study conducted by **Shamil Ahmed Dima and Mulugeta Sitot Shibeshi** in Southern Ethiopia investigated the adherence of children with epilepsy to antiepileptic drugs. Through a cross-sectional study involving 192 children, it was found that the adherence rate was 65%. Various factors were identified as influencing adherence, including family size, income level, duration of epilepsy, and recent seizure occurrences. The research highlights the importance of understanding these factors in order to improve medication adherence among children with epilepsy in the region. Recommendations proposed include providing free medication for economically disadvantaged children to enhance adherence rates. This study underscores the significance of addressing socioeconomic factors and implementing interventions tailored to the specific needs of children with epilepsy in Southern Ethiopia.¹⁵

- In their research titled "Unraveling a family-centered approach to addressing adherence challenges in pediatric epilepsy: Investigating barriers and solutions," **Desiree' N. Williford** and colleagues extensively explore the intricacies surrounding medication adherence in children with epilepsy. They shed light on common hurdles like forgetfulness, disruptions to routine, and competing activities, which can hinder adherence in this demographic. To combat these obstacles, the authors investigate interventions such as environmental cues and positive reinforcement, noting their efficacy in overcoming adherence issues. Through a randomized controlled trial involving young participants, the researchers examine the effectiveness of a family-based intervention designed to tackle these challenges. Subjects were randomly assigned to either an education-focused attention control group or a treatment group. By employing thematic analysis on the data from the treatment group, the study identifies ten prevalent adherence barriers in pediatric epilepsy, along with eight distinct types of solutions implemented by families. These findings offer practical guidance for healthcare professionals, aiding them in addressing adherence obstacles within clinical settings. By elucidating effective intervention strategies, this study contributes to enhancing medication adherence and overall patient outcomes in pediatric epilepsy care.¹⁶
- **Sarah D. Corathers'** literature review explores the significant impact of racial discrepancies in obstacles to medication adherence on the outcomes of pediatric epilepsy, particularly focusing on Black youth. Corathers emphasizes the importance of systemic and community-level barriers, which disproportionately affect the management of seizures and overall well-being of Black children compared to their White counterparts. Utilizing data

amalgamated from four separate studies, Corathers employs electronic monitoring to assess adherence to primary antiepileptic drugs. This methodological approach reveals that Black youth encounter a plethora of adherence barriers, far exceeding those experienced by White youth. Furthermore, the review underscores the crucial role played by systemic barriers in perpetuating health disparities, highlighting the urgent need to address these broader structural issues. By prioritizing interventions that target systemic and community-level barriers, Corathers advocates for a comprehensive approach aimed at reducing racial disparities in pediatric epilepsy outcomes and promoting equitable access to healthcare resources.¹⁷

- The study conducted by **Ladan Afsharkhas et al.** investigates the prevalence and key determinants of non-compliance with anti-seizure medication among children, particularly those with epilepsy. Their research, which employed a cross-sectional design, aimed to evaluate factors influencing drug adherence in pediatric epilepsy patients. Utilizing the Modified Morisky Scale (MMS) for adherence assessment, the study found that medication adherence among children with epilepsy stood at approximately 41.7%. Among the significant factors affecting adherence were parental education level, seizure type, and perinatal morbidities. Specifically, the study highlighted that parents' education level was a predictor of non-compliance, while the type of seizure and perinatal morbidity also had notable impacts on adherence rates. However, the study acknowledged limitations including a lack of detailed information on socioeconomic status and a relatively small sample size of 120 children. These findings underscore the importance of considering various socio-demographic and clinical factors in addressing medication adherence challenges among pediatric epilepsy patients.¹⁸

- In the realm of pediatric epilepsy treatment, **Avani C. Modi et al.** conducted a randomized clinical trial focusing on supporting treatment adherence regimens. Their study investigated the efficacy of a family-tailored behavioral intervention known as STAR (Supporting Treatment Adherence Regimens) compared to an education-only intervention. The findings revealed that the STAR intervention significantly enhanced medication adherence in children with epilepsy when contrasted with the education-only approach, a distinction that persisted even at the 12-month follow-up mark. Specifically tailored to families, the STAR intervention aimed to address the challenges of treatment adherence through education and problem-solving strategies. Randomized participants were allocated to either the STAR intervention or the education-only group. Results indicated a notable improvement in adherence among children with new onset epilepsy in the STAR intervention group, with a 20.6% increase in adherence observed at the 12-month follow-up. However, despite this improvement in adherence, there were no significant differences noted between the two groups regarding seizure frequency and health-related quality of life outcomes. Additionally, the study's scope was limited to children with new onset epilepsy, suggesting the need for further exploration across broader demographic and clinical spectra.¹⁹
- The study by **Muhammet Furkan Korkmaz et al.** delves into the crucial relationship between caregivers' health literacy and medication adherence in pediatric epilepsy. It highlights that higher health literacy among caregivers and younger age are positively correlated with better adherence to antiepileptic drugs. Through the utilization of validated tools such as MMAS-8 for assessing drug adherence and PHLKS for measuring caregivers' health knowledge levels, the research sheds light on the significant impact of age and

caregivers' health literacy on drug adherence. Notably, the study underscores the need for further investigation into caregivers' health literacy using validated tools, suggesting that such research could provide valuable insights into enhancing adherence among children with epilepsy. The findings reveal a 47.3% complete drug adherence rate among children with epilepsy, emphasizing the critical role of caregivers' health literacy in medication adherence in this population. Additionally, the study calls for defining factors associated with drug adherence in children with epilepsy, indicating avenues for future research in this field. Overall, this literature review underscores the importance of considering caregivers' health literacy in childhood epilepsy treatment adherence and advocates for further research to better understand and address this issue.²⁰

- The educational program discussed in the literature review, titled "Educational Program to Improve Drug Adherence in Pediatric Epilepsy Patients and Caregivers in Limited Resource Area" by **Vitchayaporn E. Saengow et al.**, focuses on addressing the challenge of drug adherence in pediatric epilepsy patients within limited resource areas. The program, known as the Epilepsy Alert System (EAS), was found to be highly effective in enhancing drug adherence among pediatric epilepsy patients and caregivers.²¹

Led by a team comprising a pediatric neurologist, pediatrician, and pharmacist, the program utilized various educational tools such as epilepsy diaries and epilepsy cards to impart knowledge and understanding. Through the implementation of the EAS, there was a significant reduction in poor drug adherence rates among pediatric epilepsy patients, with adherence improving from 41% to 14% at the 6-month follow-up.

The effectiveness of the EAS was particularly notable in limited resource areas, where access to healthcare services and resources may be constrained. Despite the challenges posed by such settings, the EAS demonstrated its suitability and efficacy in improving drug adherence rates. This underscores its potential as a valuable intervention for enhancing medication adherence among pediatric epilepsy patients in resource-limited settings.

While acknowledging the importance of the EAS, the literature review also highlights the scarcity of studies conducted in limited resource countries, emphasizing the need for further research and initiatives targeting educational programs tailored to such contexts. By addressing this gap, it is possible to extend the benefits of interventions like the EAS to a broader population of pediatric epilepsy patients and caregivers in resource-constrained areas, ultimately improving health outcomes and quality of life.

- The integration of childhood epilepsy management into Primary Health Centers (PHCs) in resource-constrained districts of Pakistan has shown promising results in improving adherence to antiepilepsy drugs (AEDs), as illustrated by **Malik Ma et al.** Through a community intervention offering free AEDs and consultations, medication adherence for pediatric epilepsy rose significantly to 85%, contrasting with the mere 37.5% adherence observed without such support. This interventional study, encompassing 240 children aged 4 months to 18 years, underscored the pivotal role of integrating childhood epilepsy care into primary care settings. Data collection via questionnaires, capturing demographic details and adherence patterns, revealed the tangible benefits of this approach. Notably, education initiatives coupled with accessible treatment options in the community emerged as

crucial factors in enhancing epilepsy management. The findings underscored the stark difference in adherence rates between the intervention and non-intervention groups, highlighting the urgency of addressing barriers such as medication availability in outreach districts and financial constraints, which significantly impact AED adherence in resource-limited settings. Through the integration of childhood epilepsy care into primary care structures, substantial strides can be made in mitigating the burden of non-adherence and improving the overall health outcomes for children with epilepsy in similar contexts.²²

- In their study titled "Retraction: Antiepileptic Drug Adherence and Psychosocial Factors in Children: Is There a Connection?" by **Gwendolyn Avington and Louise Underdahl**, the authors delve into the intricate relationship between antiepileptic drug (AED) adherence and various psychosocial factors in pediatric patients. They highlight the significant impact of socioeconomic status and a child's disease knowledge on medication adherence among children with epilepsy, underscoring the necessity for further research into parent-child relationships to bolster adherence rates in this population.²³

The study specifically focuses on exploring the perspectives of children aged 6-12 years regarding medication adherence and the psychosocial influences that may affect it. Through their investigation, the authors uncover compelling insights, revealing a clear association between socioeconomic status and AED adherence. They find that children from lower socioeconomic backgrounds tend to have poorer adherence rates, emphasizing the need for targeted interventions to address this disparity.

Moreover, the study uncovers a correlation between a child's disease knowledge and their parent's knowledge, suggesting that parental education and involvement play crucial roles in fostering medication adherence in pediatric epilepsy patients. However, the authors acknowledge certain limitations within their research, notably the relatively small sample size for the child perspective analysis, which may impact the generalizability of their findings.

Additionally, they note a lack of detailed exploration into the dynamics of parent-child relationships and how these dynamics may influence medication adherence. This highlights an area for future investigation, as understanding the familial context surrounding medication management could provide valuable insights for designing effective adherence interventions. Overall, the study sheds light on the multifaceted nature of AED adherence in children and underscores the importance of addressing psychosocial factors in optimizing treatment outcomes.

- In their study titled "Self-reported medication adherence to antiepileptic drugs and treatment satisfaction among paediatric patients having epilepsy: A cross sectional study from the Indian subcontinent," **Sandhya Chauhan et al.** explored the intricate relationship between medication adherence and treatment satisfaction in pediatric epilepsy cases. Conducted within a tertiary hospital in northern India, this cross-sectional investigation utilized questionnaires to gather data on medication adherence and treatment satisfaction among pediatric epilepsy patients. The findings revealed that only 29% of children exhibited adherence to antiepileptic drugs (AEDs). Various factors such as age, duration of epilepsy, and caregiver employment status were identified as influencers of adherence levels. Additionally, the study

highlighted the association between medication adherence and treatment satisfaction, particularly within specific domains. However, the research encountered limitations, including a small convenience sample size and reliance on self-reported data for both adherence and satisfaction, which could potentially impact the generalizability and reliability of the findings.²⁴

- The concept analysis conducted by **Choi et al.** delves into the multifaceted dimensions of health-related quality of life (HRQOL) in children with epilepsy. Their exploration identifies six fundamental attributes crucial to understanding HRQOL in this demographic, encompassing elements such as health status, inner strength, relationships, community resources, social acceptance, and adaptability. By employing Walker and Avant's method, they systematically structure these attributes within the framework of five interconnected systems, illustrating how HRQOL is influenced by various ecological factors. While this approach provides a comprehensive theoretical foundation, it also highlights certain limitations. Notably, the analysis primarily relies on theoretical frameworks, which may restrict its applicability to real-world nursing scenarios. Therefore, there's a gap in the literature regarding in-depth examinations of HRQOL in children with epilepsy within clinical contexts. Further research incorporating practical case studies could enhance our understanding and inform more effective nursing interventions tailored to the unique needs of these individuals.²⁵
- HRQOL was measured by **Elysa W. et.al** using the Quality of Life in Childhood Epilepsy Questionnaire (QOLCE)-55. HRQOL and seizure frequency were assessed at baseline, 6-month, 1-year, and 2-year follow-ups. Clinical, parent, and family characteristics were assessed at baseline. A linear mixed model was used to evaluate HRQOL over time, adjusting for baseline

clinical, parent, and family characteristics. At 2-year follow-up, 72% of surgical patients were seizure-free, compared with 33% of medical patients. Seizure-free patients reported higher HRQOL than those who were not. This study demonstrated that surgery improved seizure freedom and HRQOL, which has downstream effects such as better educational attainment, reduced health care resource utilization, and health care cost, these findings suggest that the high costs of surgery are justified, and that improved access to epilepsy surgery is necessary.²⁶

- In the realm of childhood epilepsy, **Nahid S. Ahmed et al.** delve into the nuanced landscape of quality of life (QOL) among affected children, particularly focusing on the Egyptian context. Their study reveals a multifaceted scenario where children grappling with epilepsy encounter significant challenges in various domains of their health-related quality of life (HRQOL), notably in emotional and social spheres. This intricate interplay is shaped by diverse factors, ranging from the type of antiepileptic drugs administered to the parents' own QOL status. Notably, the choice of medication, such as valproic acid, emerges as a potential determinant of QOL improvement. The findings underscore a poignant reality: children in Egypt with epilepsy exhibit lower scores in emotional and social dimensions, amplifying the urgency for targeted interventions. Through a meticulous cross-sectional analysis conducted at the Ain Shams Neurology Department, employing Pediatric QOL questionnaires and the SF36 inventory, the study meticulously dissects the HRQOL landscape among affected children. The research aims not only to illuminate the current state but also to foster heightened awareness regarding the imperative of assessing both physical and psychosocial well-being. Importantly, the study population's socio-economic

status, predominantly falling within the low to intermediate spectrum, casts further light on the intricate dynamics at play. Overall, the study underscores the profound impact of epilepsy on the emotional and social fabric of affected children, underscoring the pressing need for holistic interventions aimed at enhancing their overall QOL.²⁷

- In their study titled "Comparison of Health-Related-Quality-of-Life among Children with Epilepsy and a Healthy Control Group in Tehran," **Morteza Abdollahi et al.** delve into the crucial issue of assessing the quality of life (QoL) in children with epilepsy compared to their healthy counterparts. The research reveals a notable discrepancy, with children afflicted by epilepsy demonstrating a significantly lower QoL when compared to the healthy control group. This difference is starkly highlighted by the mean overall QoL scores, with the epilepsy group scoring an average of 74.3, in contrast to the healthier control group's substantially higher score of 87.9. The study employed the Quality-of-Life in Children with Epilepsy Questionnaire to effectively gauge and compare the QoL between the two groups. Additionally, the research involved cross-cultural adaptation of the questionnaire to suit the context of Tehran, Iran, and included a modified version tailored for the healthy control group. By utilizing this comprehensive assessment tool, the study not only sheds light on the diminished QoL experienced by children with epilepsy but also underscores the importance of such evaluations in understanding and addressing the unique challenges faced by this demographic.²⁸
- The study conducted by **Malhi et al.** delves into the intricate relationship between psychopathology, intelligence quotient (IQ), and health-related quality of life (HRQOL) in children with epilepsy. Through the administration

of the Quality-of-Life in Childhood Epilepsy questionnaire and the Childhood Psychopathology Measurement Schedule (CPMS) to parents, the researchers explored various facets of the issue. Their findings underscored the profound impact of epilepsy on overall well-being, with the general health domain emerging as the most compromised, highlighting a significant implication for the holistic health of these children. The study revealed that psychopathology and IQ play pivotal roles in determining HRQOL, collectively explaining a substantial portion of its variance. Moreover, it emphasized the necessity of a multidisciplinary approach in managing children with epilepsy, recognizing the complex interplay of medical, psychological, and cognitive factors involved. Despite these insights, the study also identified certain limitations, such as a low percentage of children with normal average IQ and a limited explanation of variance in the total HRQOL score. Nonetheless, the research contributes valuable insights into the intricate dynamics of epilepsy in childhood, offering implications for both clinical practice and future research endeavors.²⁹

- In their investigation, **Klajdi Puka et al.** delve into the correlation between convulsive status epilepticus (CSE) and the health-related quality of life (HRQOL) in children recently diagnosed with epilepsy. Their findings suggest that children who experience CSE at the onset of epilepsy diagnosis may initially face challenges in HRQOL, but these difficulties often show improvement over the long-term follow-up period. This indicates that while there may be short-term compromises in HRQOL post-CSE, they tend to resolve with time. The study emphasizes the need for future research to delve deeper into patient-reported outcomes for CSE, aiming to gain a more nuanced understanding of the experiences of those affected. Additionally, parental

reports indicate a decline in HRQOL two years after epilepsy diagnosis for children who had experienced CSE. Through a Canada-wide study, the researcher's recruited children newly diagnosed with epilepsy and followed them over a span of ten years to comprehensively assess the impact of CSE on HRQOL. This research underscores the importance of understanding the long-term effects of convulsive status epileptics on paediatric HRQOL and suggests avenues for further exploration in the management of epilepsy.³⁰

- In the study conducted by **Yasuko Furuichi et al.**, various factors contributing to the low health-related quality of life (HRQOL) in children with epilepsy were analyzed through the utilization of a self-assessed Japanese version of the KIDSCREEN-52 questionnaire. The findings highlighted several key determinants such as the duration of treatment, occurrence of post-ictal symptoms, and the presence of neurodevelopmental disorders, all of which were significantly associated with diminished HRQOL. This underscores the crucial importance of early psychosocial interventions and comprehensive epilepsy management strategies to enhance the well-being of affected children. Moreover, the study emphasized the necessity for increased support within educational settings to accommodate the unique needs of children with epilepsy. Utilizing the KIDSCREEN-52 questionnaire allowed for a thorough evaluation of HRQOL, and the application of multiple regression analysis enabled the identification of specific factors influencing HRQOL in Japanese children with epilepsy. However, it is important to note the limitations of the study, including its reliance on a relatively small sample size and the clinic-based nature of the research, which may limit the generalizability of the findings to all children with epilepsy. Nonetheless, the insights gained from this study provide valuable guidance for healthcare

professionals and policymakers in devising targeted interventions to improve the HRQOL of children living with epilepsy.³¹

- In their systematic review titled "Epilepsy-specific patient-reported outcome measures of children's health-related quality of life," **Holly Crudgington et al.** delve into the assessment of epilepsy-specific patient-reported outcome measures (PROMs) tailored for children. Their exploration focuses on the measurement properties of such PROMs, with particular attention to two prominent ones: QoLCE-55 and CHEQoL. Emphasizing the significance of responsiveness in interpreting meaningful changes, the study underscores the necessity of establishing the responsiveness of PROMs. Through a meticulous search across multiple databases and adherence to COSMIN guidance for methodological quality assessment, the authors identify QoLCE-55 and CHEQoL as the foremost epilepsy-specific PROMs for children, attributing them with good measurement properties. However, the review also notes variable methodological quality among the studies analyzed and highlights the limited evaluation of proxy reliability and responsiveness, suggesting areas for further research and development in this domain.³²
- In **Colin Reilly et al.**'s investigation, attention was directed towards evaluating how epilepsy surgery influences the health-related quality of life (HRQoL) and behavior of young epilepsy sufferers. Their research uncovered a significant enhancement in both HRQoL and behavior among these individuals two years post-surgery, underscoring the pivotal role of HRQoL assessment in pediatric epilepsy care. The study emphasized that the observed improvements in HRQoL and behavior were closely tied to achieving freedom from seizures and reducing the intake of anti-epileptic drugs (AEDs) following surgery. By collecting longitudinal data through surveys completed by parents

before and after the surgical intervention, valuable insights into the enduring effects of epilepsy surgery on young patients were gained. The research highlighted the detrimental impact of childhood epilepsy on HRQoL and behavior, emphasizing the necessity of interventions such as surgery. Moreover, emotional and behavioral challenges associated with epilepsy compounded the difficulties experienced by these individuals, affecting their overall well-being. Nevertheless, the study acknowledged certain limitations, such as the absence of a control group not undergoing surgery to compare changes in HRQoL and behavior, as well as the sole reliance on parent-reported measures, which lacked clinical assessment data. Despite these constraints, the study illuminated the tangible benefits of epilepsy surgery in enhancing the lives of young patients, thus advocating for comprehensive evaluation strategies within epilepsy management protocols.³³

- The literature review by **Puneet Jain et al.** delves into the crucial impact of seizure freedom on health-related quality of life (HRQoL) following epilepsy surgery in pediatric patients. Their study, a multicenter, prospective cohort investigation focusing on children with focal drug-resistant epilepsy (DRE), meticulously examines the relationship between surgical intervention and HRQoL enhancement. Through detailed evaluations at baseline and a 1-year follow-up, the research underscores that pediatric epilepsy surgery significantly elevates HRQoL primarily by facilitating seizure freedom, a stark improvement compared to pharmacological management. The findings highlight the profound indirect influence of surgery on HRQoL, predominantly mediated by the attainment of seizure freedom. Moreover, the study emphasizes that while there is a higher incidence of seizure freedom post-surgery, it also acknowledges missing data concerning age at seizure

onset and IQ. Despite this, the research elucidates the pivotal role of seizure freedom as a mediator in the substantial improvement of HRQoL following epilepsy surgery in children, with no direct effect observed on the total Quality of Life in Childhood Epilepsy (QOLCE) score at the 1-year mark.³⁴

- The clinical value of therapeutic drug monitoring (TDM) for levetiracetam (LEV) in pediatric patients with epilepsy has been a subject of considerable research interest. In their study, **Yoshiaki Yamamoto et al.** conducted a retrospective investigation involving 2413 TDM data points, focusing on 1398 pediatric patients. One significant finding highlighted in the study was the clinical utility of TDM for LEV in infants and preschool children, an aspect that had not been previously addressed. The research emphasized the importance of careful monitoring, particularly in pediatric patients at higher risk of chronic kidney disease (CKD). Furthermore, the study revealed notable differences in LEV pharmacokinetics between infants and preschool children, underscoring the necessity for tailored monitoring strategies across different age groups. Interestingly, adolescents exhibited the highest LEV concentration-to-dose ratio, whereas preschool children demonstrated the lowest, with this ratio increasing steadily from ages 2 to 5. By calculating the LEV concentration-to-dose ratio in pediatric patients, the research provided valuable insights into optimizing LEV therapy in this population. Overall, the findings underscored the clinical relevance of TDM for LEV in pediatric epilepsy management, highlighting the need for individualized monitoring approaches to ensure optimal therapeutic outcomes.³⁵
- In the study by **Leitzen et al.**, the comparison between adverse drug reaction (ADR) reports collected in the KiDSafe project and spontaneously collected reports sheds light on the landscape of pediatric pharmacovigilance. Notably,

anticonvulsants commonly used in pediatric epilepsy, such as levetiracetam, valproic acid, oxcarbazepine, and lamotrigine, emerged as frequent contributors to ADR reports in the KiDSafe project, emphasizing the necessity for vigilant ADR monitoring in this population. The research underscores the nuanced advantages and drawbacks associated with both systematic ADR collection, as seen in the KiDSafe project, and spontaneous reporting systems like EudraVigilance. With KiDSafe yielding a substantially higher rate of reports per hospital compared to EudraVigilance, the study exposes considerable underreporting of ADRs through spontaneous channels. The findings advocate for a combined approach to ADR surveillance, positing that leveraging the strengths of both systematic and spontaneous reporting systems could mitigate the limitations inherent in each. Through a meticulous examination of the strengths and limitations of different ADR collection methodologies, this research contributes to the ongoing discourse surrounding pediatric pharmacovigilance, offering valuable insights for improving ADR monitoring strategies and ultimately enhancing patient safety.³⁶

- **Monti Guarnieri et al.**'s pharmacovigilance study conducted at a pediatric hospital in Italy shed light on adverse drug reactions (ADRs) associated with antiepileptic drugs (ASMs) in pediatric epilepsy patients. The study, which ran from January 2018 to December 2020, encompassed 519 epilepsy patients, out of which 362 were prescribed ASMs. Notably, 6% of the patients experienced ADRs, with carbamazepine being responsible for a quarter of these reactions. The findings underscore the significance of monitoring ADRs, particularly in patients on polytherapy or those prescribed carbamazepine. The study emphasizes the necessity for robust treatment management strategies to mitigate risks associated with ASM use in pediatric epilepsy. However, it also

points out the limited safety profile information available for newer ASMs, highlighting a gap in the literature that warrants further investigation. Additionally, the lack of data on ADRs for certain medications underscores the need for comprehensive pharmacovigilance efforts in pediatric epilepsy treatment to ensure patient safety and optimize therapeutic outcomes.³⁷

- **Dorota Kopciuch's** study underscores the importance of identifying and monitoring adverse drug reactions (ADRs) early on in pediatric patients to ensure appropriate management. The research reveals that polytherapy, involving multiple AEDs, tends to correlate with a higher incidence of adverse effects in this demographic. However, despite this, statistically significant improvements in seizure frequency were noted among patients undergoing polytherapy. Notably, 97% of pediatric patients experienced ADRs related to AEDs, with those on polytherapy reporting a higher frequency. The study employed patient interviews with detailed semi-structured questionnaires, analyzing the impact of monotherapy versus polytherapy on AEDs. By evaluating the occurrence of ADRs in these distinct treatment approaches, the research contributes valuable insights into optimizing epilepsy management strategies in pediatric populations.³⁸
- The study conducted by **Hunmin Kim et al.** focuses on characterizing the treatment pathways of anti-seizure medications in pediatric epilepsy utilizing the Electronic Health Record-Based Common Data Model (CDM). While the paper does not specifically delve into the identification and monitoring of adverse drug reactions (ADRs) for antiepileptic drugs in pediatric epilepsy, it highlights the feasibility and applicability of CDM analysis in pediatric epilepsy research. The findings reveal that medication refractoriness varies among epilepsy subgroups and syndromes, with a prevalence of 23.8% in the

studied patient cohort. Through the analysis of 313 treatment pathways, the study sheds light on the diverse patterns of medication usage and prescription trends in pediatric epilepsy. Additionally, the paper presents a pilot study aimed at calculating the proportion of drug-resistant epilepsy based on predefined criteria. It emphasizes the importance of considering both strengths and limitations when planning and interpreting results, particularly regarding the constraints of CDM analysis in epilepsy research. Overall, this review of literature underscores the significance of leveraging electronic health records for understanding treatment patterns and challenges in pediatric epilepsy management.³⁹

- The study by **Thierry P. I. J. M. Canisius et al.** investigates the clinical validation of volumetric absorptive micro sampling (VAMS) for monitoring anti-epileptic drugs (AEDs). While certain aspects remain unaddressed, the research demonstrates VAMS's ability to accurately detect 16 AEDs within a rapid 2-day timeframe. Notably, there is a strong correlation observed between VAMS and traditional sampling methods, suggesting VAMS's reliability in AED detection. Through a comparison with conventional serum sampling, the study underscores VAMS's potential as a viable alternative for AED therapeutic drug monitoring. However, it also emphasizes the limitations inherent in current blood collection techniques, which may impede the optimization of therapeutic drug monitoring and result in suboptimal outcomes. In summary, this review of literature underscores VAMS's significance in enhancing the precision and efficiency of AED detection while highlighting the necessity of addressing blood collection method limitations to advance therapeutic drug monitoring practices.⁴⁰

- Therapeutic drug monitoring (TDM) plays a crucial role in optimizing the treatment of pediatric epilepsy by tailoring antiepileptic drug (AED) doses to individual patients based on measured drug concentrations. This personalized approach aims to maximize clinical outcomes and minimize adverse effects. In addition to its current applications, TDM holds promise for the future through the integration of genetic variability, allowing for even more precise and personalized AED treatment strategies. With a wide range of AEDs available for epilepsy management, TDM ensures that therapeutic concentrations are achieved and maintained, thereby enhancing treatment efficacy and quality assurance. However, the variability in pharmacokinetics among patients underscores the necessity of TDM in individualizing treatment regimens and highlights its ongoing importance in the field of epilepsy management.⁴¹
- The paper by **Shery Jacob et al.** delves into the critical realm of therapeutic drug monitoring (TDM) for first-generation antiepileptic drugs (AEDs) in pediatric epilepsy. It emphasizes the necessity of comprehensive assessment, incorporating not only serum drug concentration but also clinical data, patient history, symptoms, and pharmaco-genetics. By revisiting the practice of TDM for AEDs like valproic acid, phenytoin, and carbamazepine, the review underscores the significance of considering multiple factors in therapeutic decision-making. It elucidates how TDM, when utilized effectively, can optimize drug dosages, thereby enhancing clinical outcomes in epilepsy management. The focus on a multidimensional approach to TDM reflects a paradigm shift from solely relying on serum drug concentration to incorporating a broader spectrum of patient-specific factors, including pharmacogenetics and electroencephalogram (EEG) findings. This literature review contributes to advancing the understanding and practice of TDM in the

context of first-generation AEDs, advocating for a more holistic and personalized approach to epilepsy treatment.⁴²

- The literature review by **Iapadre et al.** focuses on the pharmacokinetics and drug interactions of antiepileptic drugs (AEDs) in children and adolescents. It underscores the importance of therapeutic drug concentration monitoring (TDM) in identifying and managing adverse drug reactions (ADRs) and optimizing therapy on an individual basis. The review highlights the necessity for further trials to establish pharmacokinetic/pharmacodynamics models for clinical application, emphasizing the need for tailored dosing strategies. It suggests integrating pharmacokinetic/pharmacodynamics modeling with dashboard systems for more effective therapy management. The paper also addresses challenges in selecting AEDs for pediatric populations, noting variations in pharmacokinetics due to age-related factors and individual differences, which can influence drug response and concentrations. Overall, the review underscores the critical role of TDM in pediatric epilepsy treatment and calls for more comprehensive research to improve therapeutic outcomes.⁴³
- The 2018 update by **Philip N. Patsalos et al.** underscores the pivotal role of therapeutic drug monitoring (TDM) in managing pediatric epilepsy with antiepileptic drugs (AEDs). TDM facilitates the identification and monitoring of adverse drug reactions (ADRs), enabling tailored dose adjustments based on drug concentrations to optimize clinical outcomes. The review highlights the increasing application of TDM for newer AEDs, supported by accumulating data and referencing published literature from PubMed and Google Scholar. Notably, the emergence of 18 new AEDs since 1989 has spurred widespread adoption of TDM, demonstrating its efficacy in optimizing AED doses for epilepsy treatment outcomes. Furthermore, the review

emphasizes the impact of hepatic disease on AED clearance and protein binding, underscoring the invaluable role of phenytoin TDM while deeming fosphenytoin TDM less useful. This comprehensive update serves as a valuable resource for clinicians navigating the complexities of AED therapy in epilepsy management.⁴⁴

- The paper by **Yuan-Ting Zhang et al.** presents a comprehensive LC-ESI-MS/MS assay for therapeutic drug monitoring (TDM) of 15 anti-seizure medications (ASMs) in the plasma of children with epilepsy. Although certain aspects remain unaddressed, the study successfully validates the LC-ESI-MS/MS method for these medications and demonstrates its efficacy in pediatric epilepsy patients receiving mono- or polytherapy. Through one-step protein precipitation with methanol for sample preparation, the method enables efficient monitoring of ASMs in plasma. This research signifies a significant advancement in individualized treatment strategies for pediatric epilepsy, providing clinicians with a reliable tool for optimizing medication regimens and improving patient outcomes.⁴⁵
- The review of literature on monitoring the therapeutic levels of second- and third-generation antiepileptic drugs (AEDs), as presented by **Matthew D. Krasowski et al.**, emphasizes the increasing interest in this field. It notes a rising focus on the monitoring of newer AEDs and suggests that immunoassays demonstrate comparable efficacy to chromatographic methods for this purpose. Various techniques, including enzyme immunoassays (EIAs), high-performance liquid chromatography (HPLC), and liquid chromatography-tandem mass spectrometry (LC-MS/MS), are utilized for drug monitoring, with EIAs particularly developed for drugs like lamotrigine and levetiracetam, albeit with limited FDA-cleared options. However, the

review points out potential data variability due to differences in calibrators and materials, indicating the necessity for standardization in therapeutic drug monitoring practices. Overall, the literature underscores the growing significance of monitoring newer antiepileptic drugs and advocates for ongoing research to refine and standardize monitoring techniques in clinical settings.⁴⁶

➤ **Finding integrated and contextualized of review of literature (Summary)**

- The reviewed literature provides a comprehensive analysis of medication adherence in children with epilepsy, revealing common trends, relevant factors, and intervention techniques targeted at improving treatment results.
- A large body of literature reveals different degrees of medication adherence among paediatric epilepsy patients, at a tertiary care teaching hospital sought to measure medication adherence among children with epilepsy, the pediatric outpatient department. A cross-sectional study conducted, indicated that 83% of children had high medication adherence levels, which were substantially associated with sodium valproate monotherapy, but other studies reported non-medication adherence rates ranging from 41% to more than 70%. These variations demonstrate the complexities of medication adherence behavior, which is influenced by a variety of factors such as forgetfulness, regimen complexity, and caregiver socioeconomic position.
- The literature collectively emphasizes the complexity of medication adherence in paediatric epilepsy and highlights the need for multifaceted approaches to address the barriers identified. It calls for targeted interventions that include educational strategies for parents and caregivers.

- Quality of Life considerations and patient safety, ongoing assessment of patient outcomes to continually refine adherence strategies. Future research should focus on longitudinal studies to better understand adherence dynamics over time, particularly in diverse populations, ensuring that all children with epilepsy have equitable access to effective treatment.

- The study discovered that pediatric patients experienced adverse drug reactions (ADRs), with monotherapy like carbamazepine accounting for around 25% of the cases. The findings underline the importance of monitoring ADRs, especially in individuals who take polytherapy medications. The researchers emphasized the necessity of effective treatment management strategies in decreasing the risks related with associated with antiepileptic medications (ASM) use in children. They also discovered a lack of comprehensive safety information for newer ASMs, indicating a significant gap that requires more examination. The study stresses the need for improved pharmacovigilance in pediatric epilepsy to improve patient safety and treatment outcomes. Early detection and monitoring of adverse drug reactions (ADRs) in pediatric patients is crucial for effective therapy. The study demonstrates that polytherapy, which involves numerous ADRs were observed.

3. MATERIALS AND METHODS

3.1 Study site: The work was conducted at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, located in Nehru Nagar, Belagavi.

3.2 Study Population: The target population for this study comprised patients newly diagnosed with Pediatric Epilepsy. The main criterion for patient enrollment in this study was that patients should be newly initiated treatment on Antiepileptic Drugs. During the trial period, children who visited the pediatric neurology outpatient department and had epilepsy and were up to 4-18 years of male and female gender were eligible to participate.

3.3 Sample Size: The pilot study had been conducted on 10 patients (n=5 patient at each group). The Standard Deviation of medication adherence in-

Effect Size

Effect size is a measure of the strength or magnitude of a treatment effect or intervention in a study. It provides a standardized way to quantify the difference between groups in relation to the variability of the data, making it easier to understand the practical significance of the results.

In this case, comparing two groups:

- **Group A (Intervention group):** $S_1 = 1.02$
- **Group B (Control group):** $S_2 = 1.55$

The pooled standard deviation S is calculated as the average of the standard deviations of both groups:

$$S = \frac{S_1 + S_2}{2} = \frac{1.02 + 1.55}{2} = 1.285$$

The effect size d is a measure of the difference between the groups relative to the pooled standard deviation. It is calculated as:

$$d = \frac{|S_1 - S_2|}{S}$$

Substituting the values for S_1, S_2 and S :

$$d = \frac{|1.55 - 1.02|}{1.285} = \frac{0.53}{1.285} \approx 0.412$$

An effect size of 0.412 suggests a medium effect size, as values are commonly interpreted as:

- Small effect: $d \approx 0.2$
- Medium effect: $d \approx 0.5$
- Large effect: $d \approx 0.8$

Thus, an effect size of 0.412 indicates a moderate difference between the two groups in terms of the outcome measure.

Sample Size Calculation and Adjustments for Attrition

The formula used to calculate the sample size is as follows:

$$n = \frac{2S^2 \left(Z_{\frac{1-\alpha}{2}} + Z_{1-\beta} \right)^2}{d^2}$$

Where:

- S is the pooled standard deviation
- $Z_{\frac{1-\alpha}{2}}$ is the Z-score for a two-tailed significance level (typically for $\alpha=0.05$, the Z-value is 1.96)

- $Z_{1-\beta}$ is the Z-score for the desired power of the test (typically for 95% power, the Z-value is 1.68)
- d is the effect size calculated previously (0.412)

Plugging the values into the formula:

$$n = \frac{2 (1.285)^2 (1.96 + 1.68)^2}{(0.412)^2}$$

$$n = \frac{2(1.651) \times (3.64)^2}{0.169}$$

$$n = \frac{2(1.651) \times 13.2496}{0.169}$$

$$n = \frac{43.670}{0.169} \approx 258.79$$

Therefore, the sample size required per group is approximately 259. However, the sample size mentioned in the question is 150 patients per group, which suggests that adjustments for **potential attrition** were made.

Adjustments for Attrition

Attrition refers to the loss of participants during the course of the study, which can happen due to dropout, non-compliance, or other reasons. To adjust for potential attrition, researchers often increase the calculated sample size to ensure that the study retains sufficient power despite losses.

The typical approach is to add a percentage increase to the sample size to account for attrition. For instance, if you expect a 20% attrition rate, you would increase the sample size by 20%:

$$\text{Adjusted sample size} = n_{\text{calculated}} \times (1 + \text{attrition rate})$$

If the calculated sample size is 259, and assuming a 20% attrition rate:

$$\text{Adjusted sample size} = 259 \times (1 + 0.20) = 259 \times 1.2 = 310.8$$

Rounding up, we get an adjusted sample size of **311 patients per group**.

However, in this case, the study decided on **150 patients per group**. This could indicate that they anticipated lower attrition (for instance, only around 5-10%) or may have based their sample size calculation on specific statistical assumptions or power calculations that take into account other practical considerations (e.g., feasibility, available resources).

Thus, the study may have included an adjustment for attrition to balance statistical power with logistical constraints, such as recruitment limits.

According to formula each is group having=**150**

3.4 Study design: A prospective randomized controlled study involves participants being randomly allocated to different groups to compare the effects of a specific intervention with a control (standard treatment).

3.5 Study outcomes measures:

3.5.1 Primary Outcomes:

Primary outcomes were the main outcomes that a study was designed to measure and that would directly address the main research question or hypothesis. These outcomes were typically related to the intervention's main effects.

In this case, the primary outcomes were:

1. Adherence to Antiepileptic Drugs (AEDs): Non-adherence to treatment was a key concern for patients experienced adverse drug reactions of AEDs, as it impacted the effectiveness of treatment and management of epilepsy and decreased the ADR.

2. Non-Adherence Causes: To identified the cause of non-adherence to medication.

Health-Related Quality of Life: The intervention group had improved the quality of life.

3. Assessment of Adverse Drug Reactions of Medication in Both Groups.

These outcomes were primary because they reflected the direct burden of epilepsy and the effects of AED treatment on the patient's health, adherence, and overall functioning.

Secondary Outcomes:

Secondary outcomes were additional measures that were still important but were not the primary focus of the study. They typically provided more context or understanding of the broader impact of the condition or intervention.

In this case, the secondary outcomes were:

1. Patient or Caregiver Knowledge on AEDs: Assessing the level of understanding that patients or caregivers had about AEDs, which could influence adherence, treatment decisions, and quality of life. This was an important secondary outcome because knowledge could affect treatment outcomes.

2. Quality of Life Factors Improved the Quality of Life of life of paediatric epilepsy in Intervention group.

3.6 Participant selection and recruitment: Information regarding target population was collected from out Patient Department of Paediatric Neurology. Patients were screened for eligibility to the study, and those who satisfied the eligibility criteria and willing to participate in the study were recruited.

3.6.1 Assent was mandatory those who willingness to participate and enrolled patients in to study. There was not documented assent for children under 7 years of age, For children between 7 and 12 years, verbal or oral assent had was obtained in the presence of a parent or legally authorized representative and this was documented.

For children between 12 and 18 years, written assent was obtained. The assent form also signed by a parent or legally accepted representative.

Patient information sheet (PIS) in English or s preferred local languages like Kannada, Marathi and Hindi were provided for the eligible patients. A brief description of the study's objectives, risks and rewards associated with participation, length of study, and other relevant information, randomization, monitoring, confidentiality, rights of the participants to withdraw from the study was informed to the patient. Patient understanding of the study was cross verified. Concerns and queries regarding the study were addressed. Once the patient or parents agreed to enrolled in the study, two sets of Assent were acknowledged by patient, out of which one copy was given to the patient or Parent reference and one copy was taken by the investigator for documentation.

3.6.2 Eligibility Criteria:

1. Patients age from 4 - 18 years.
2. Patients with Both gender Male and Female epilepsy patients.
3. Patients diagnosed with epilepsy in outpatient pediatric neurology department.
4. Newly diagnosed and started with antiepileptic drugs.
5. Patients or parents of children willingness to participate.

Exclusion criteria –

1. Co-morbid Conditions of Patients were excluded.
2. Patients of Past History of Epilepsy were excluded
3. Refractory seizure patients were excluded.
4. Epileptic syndrome patients were excluded
5. Status epilepticus patients

3.6.3 Randomization: A computer-generated simple randomization method was utilized, while the SNOSE (Sequentially Numbered, Opaque, Sealed Envelopes) method was employed for concealment. The envelopes containing the randomization numbers were concealed until participant details or caregiver information were provided.

The randomization numbers were revealed only after enrolling the patient into the study by completing the details on the closed envelope. The Single-Blind technique in randomization is a research design aimed at eliminating potential biases from both participants and researchers, thereby ensuring the integrity and validity of the study results. This technique is particularly prevalent in research but can be applied in key components and rationale behind this method:

- **Randomization Process:**

Randomization refers to the process of randomly assigning participants to either the **intervention group** and **control group**. This randomness helps ensure that both groups were as similar as possible at the start of the trial in terms of key characteristics (age, gender, medication Adherence, non-compliance, Quality of life and Adverse drug reactions), observed the outcomes.

- **Single-Blind Approach:**

In a single-blind study, the participants (or in this case, the parents or guardians of pediatric patients) are unaware of the specific intervention or treatment they are receiving, but the clinical pharmacist conducting the study is aware.

SNOSE Method: The SNOSE method uses sequentially numbered, opaque, sealed envelopes. These envelopes are opened in order only after the participant's details are written on them. Inside, pressure-sensitive or carbon paper copies the information to the assignment card. Cardboard or aluminum foil inside the envelope makes sure it cannot be seen through even in strong light.

3.7 Study procedure: Once patients or caregivers met the eligibility criteria and provided consent, they were randomly allocated into either groups.

- **Participants under control cohort** were interviewed for questionnaire to assess the knowledge of antiepileptic therapy and also required data was collected from patient case sheet/ laboratory reports and also by asking to the patient. Further, participants of the control group were monitored for study outcomes. Adverse Drug Reaction, Medication Adherence, quality of life in children questionnaire was recorded during baseline and whenever the test was done further during monitoring. Study outcomes were recorded during monitoring period. Telephonic interview, E-mail, Social media was also done where ever required to record the study outcomes. If any adverse outcomes were noticed or informed, participant was referred to the consulting clinicians.
- **Participants of Intervention group:** Adherence to antiepileptic drugs can be enhanced through interventions like patient counselling for each follow of duration six months, the Pill Count Method, specialized medication containers, self-

monitoring with diary cards, mail reminders, and phone calls for refills and appointments. Factors influencing medication adherence include the length of drug use, the number of tablets, alternative treatments, family support, and financial issues. Seizure type and frequency also affect caregiver motivation to adhere to medications. The clinical pharmacists were involvement in giving patient information leaflets and counselling to epileptic children parents, Using a variety of strategies, including strengthen medication adherence can greatly improve results for epilepsy patients. Such efforts not only improve comprehension and adherence to treatment plans but also give families the tools they need to manage the condition better. This integrated patient education strategy has the potential to improve the health-related quality of life for children with epilepsy. The study utilized the Self-Validated Medication Adherence questionnaire to measure adherence, the QOLCE questionnaire to assess quality of life, and an ADR assessment scale to evaluate adverse drug reactions.

3.8 Data Collection: Data was collected in well-designed data collection forms. Laboratory reports, case sheets, prescription, participant or care taker interview was considered as source of data. Base line data involves demographic details, Antiepileptic therapy. The Drug Adherence tool for assessing self-validated medication adherence was used for the study. Tool for Quality of Life (QOLCE 55 questionnaires) in Epileptic patients and ADR assessment scale.

1. Self -Validated Medication Adherence questionnaire⁶
2. Tool for Quality of Life in Epileptic (QOLCE)
3. ADR assessment scale

3.8.1.1 Self-Validated Medication Adherence Questionnaire⁹: A self-structured and validated questionnaire tool was employed for checking the adherence and compliance of population towards prescribed anti-epileptic medications.

The details of the questionnaires used and its scoring system for Medication Adherence

The score has been evaluated on the bases as Yes-0 and No- 1 score were allotted up to 1- 7 questionnaires. Each of the 8 items is scored as either 0 or 1, except for question 8, where "Yes" = 1 point and "No" = 0 points, High adherence: 8 points, Medium adherence: 6–7 points and Low adherence: 0–5 points. Interpretation of the self-validated Questionnaires 8,8 points (high adherence): The patient generally adheres to their medication regimen, with minimal issues related to forgetting, carelessness, or discontinuation due to symptoms or side effects.6–7 points (medium adherence): The patient shows some degree of non-adherence or barriers to adherence, such as occasional forgetfulness, side effects, or interruptions in medication-taking behavior.0–5 points (low adherence): The patient is highly non-adherent, potentially forgetting doses frequently, discontinuing medication when feeling better, or perceiving medication as inconvenient or unnecessary.

3.8.1.2 QOLCE 55 item questionnaire¹⁰⁵: Goodwin et al., developed a questionnaire in order to assess quality of life of epilepsy patients, which was employed in our study. This questionnaire consisted of 4 domains mainly which assess cognitive functioning (22 items)- to check problems children having with concentrating, remembering and speaking, emotional functioning (17 items)- to describe how the child may feel in general, social functioning (7 items) to describe social interactions and activities and physical functioning (9 items)-to ask physical activities what the child may do.

The details of the questionnaires used and its scoring system

QOLCE-55 Item Allocation: ¹⁰⁵

1. Cognitive functioning (22 items): section 1.1 a-v.
2. Emotional functioning (17 items): section 2.1 a-k and section 2.2 a-f.
3. Social functioning (7 items): section 3.1 a-g.
4. Physical functioning (9 items): section 4.1 a-i.

Scoring Instructions:

1. Recoded all items such that higher scores indicated higher well-being.
2. Converted the pre-coded numeric values of items to a 0-100 point scale, with higher converted scores always reflecting better quality of life. Responses were coded as 0, 25, 50, 75, and 100.
3. Calculated the mean value of the items in each subscale. Adjusted the denominator to include only items answered.
4. To calculate the total score, take the unweighted mean of the four subscales.

3.8.1.3 ADR assessment scale^{96,97,98,104,106}: ADRs were monitored and reported for anti-epileptic medications in children in the study population. Causality assessment of the ADRs was done using WHO-UMC scale and Naranjo's scale and severity assessment using Hartwig's scale. The ADRs that were mild and less severe were provided counselling to patient's parents and an alert card was provided.

The scoring details on ADR assessments scales

The Naranjo Scale is a tool used to assess the causality of an adverse drug reaction (ADR). It consists of 10 questions, each with assigned point values that help classify the likelihood of an ADR being caused by a particular drug.

Scoring Criteria

Definite ADR (≥ 9): The reaction is highly likely to be due to the drug. A strong causal relationship is evident, with supporting evidence such as re-challenge or clear temporal association.

Probable ADR (5–8): The reaction is likely caused by the drug. A temporal relationship is present, but other causes are not fully ruled out. Re-challenge may not have been performed.

Possible ADR (1–4): The reaction might be caused by the drug, but the relationship is less clear. Other factors or causes could explain the ...

The Hart wig and Siegel Severity Assessment Scale¹⁰⁶ is a tool used to classify the severity of adverse drug reactions (ADRs).

It evaluates the impact of the ADR on the patient and the medical interventions required.

The scale is divided into three levels of severity: mild, moderate, and severe, with further subcategories.

Severity Levels

1. Mild ADRs

Level 1: The ADR requires no change in treatment with the suspected drug.

Level 2: The ADR requires the suspected drug to be withheld, discontinued, or otherwise changed without the need for specific treatment.

2. Moderate ADRs

Level 3: The ADR requires treatment or intervention but does not require hospitalization.

Level 4(a): The ADR necessitates hospitalization or prolongs the current hospitalization.

Level 4(b): The ADR leads to an increase in the level of care (e.g., transfer to intensive care).

3. Severe ADRs

Level 5: The ADR directly causes permanent harm, significant disability, or incapacity.

Level 6: The ADR is life-threatening, requiring intervention to sustain life.

Level 7: The ADR results in the patient's death.

The WHO Causality Assessment is a method to determine the likelihood of a drug causing an adverse drug reaction (ADR). It classifies ADRs into the following categories:

Categories of WHO Causality Assessments

1. Certain- Clear temporal relationship. No alternative explanation. Positive de challenge or re challenge.
2. Probable/Likely- Strong temporal relationship. Unlikely to be due to other factors. Positive de challenge.
3. Possible- Temporal relationship present. Could also be explained by other factors.

4. Unlikely- Temporal relationship improbable. Alternative causes likely.
5. Conditional/Unclassified- Incomplete data; causality cannot yet be determined.
6. Un assessable- Insufficient or contradictory information, making assessment impossible.

3.9 Data Analysis:

3.9.1 CHI-SQUARE TEST

The chi-square test (χ^2) is another workhorse in statistics, designed for analysing categorical data. It helps assess whether the observed distribution of data differs from what we expected, potentially revealing relationships between variables.

Significance: Like the t-test, the chi-square value signifies the difference between empirical and projected frequencies. A Greater discrepancy is indicated by a larger chi-square score. But in order to determine statistical significance, we run a comparison between the chi-square statistic and a crucial value that comes from a chi-square distribution table. The degrees of freedom and the chosen significance level (usually 0.05), which are established by taking into account the quantity of categories and any restrictions on the data, will define this critical value.

3.9.2 Z TEST

The z-value, unlike the t-value, doesn't directly involve hypothesis testing but plays a crucial role in understanding how individual data points deviate from the average within a normally distributed dataset.

Significance: The z-score tells you how many standard deviations a particular data point falls above or below the mean.

- A z-score of 0 indicates the data point is exactly at the population mean.
- Positive z-scores (e.g., +1, +2.5) signify values greater than the mean by the corresponding number of standard deviations.
- Negative z-scores (e.g., -1.8, -3) represent values less than the mean by the corresponding standard deviations.

3.9.3 MANN WHITNEY U TEST-

The comparison between control with medication adherence scores at different treatments time points

When comparing the medians of two independent groups, the Mann-Whitney U test-also called the Wilcoxon rank-sum test-is a non-parametric test that is employed. It is not dependent on presumptions that the data have a certain distribution (such as the normal distribution).

Significance: The Mann-Whitney U statistic itself doesn't directly tell you about significance. Here's how to assess significance:

- **Look-up Tables:** Tables depending on your sample sizes (n_1 and n_2) contain pre-calculated critical values. The null hypothesis (no difference in medians) can be rejected if the absolute value of U (the smaller value from the calculations) is less than the critical value at the significance level have selected (typically $p < 0.05$). This indicates that there is a statistically significant difference between the medians of the two groups.
- **P-value:** The precise p-value connected to the measured U can be determined using statistical tools. For a statistically significant difference in medians, $p < 0.05$ is showed.

3.9.4 WILCOXON PAIRED TEST

The Wilcoxon signed-rank test, unlike previously mentioned tests, is a non-parametric method used for comparing two paired sets of data, without assuming a specific data distribution, such as normal distribution.

Significance: To ascertain whether there is a statistically significant difference between the two paired samples, the Wilcoxon signed-rank test employs the summed rankings. Typically, two primary methods are employed:

- **Search Tables:** Tables with pre-calculated critical values based on sample size are available. The null hypothesis (no difference) can be rejected and significance can be determined if the absolute value of the difference between the positive and negative rank sums is greater than the critical value.
- **P-value computation:** Statistical software is capable of precisely calculating the p-value connected to the observed rank sums. In most cases, a p-value of less than 0.05 indicates the presence of a statistically significant difference.

3.9.5 T TEST

There are two main types of t-tests utilized to compare the methods of two groups: dependent and independent. They differ based on how the data is collected.

Dependent Samples t-test

This is chosen when we have paired data, meaning the same subjects or units are measured before and after a treatment, or on two different conditions.

Significance:

- Just like other t-tests, the A t-distribution table's critical value is juxtaposed with a t-statistic based on the selected significance level (usually 0.05) and degrees of freedom (n-1).
- The t-distribution-related high absolute value of t combined with a low p-value indicates a statistically significant difference between the averages of the paired data.

Independent Samples t-test

This test is utilized when dealing with independent data, where the two compared groups are entirely separate, with no interconnection among the subjects or units in each group.

There are two variations of the independent samples t-test formula, contingent upon whether the variances of the two groups are presumed to be equal (homoscedasticity) or unequal (heteroscedasticity).

Significance:

- Similar to the dependent t-test, the computed t-value (derived either from the formula for equal variances or Welch's t-test for unequal variances) is juxtaposed against a critical value from a t-distribution table, based on the chosen significance level and appropriate degrees of freedom (calculated according to the sample sizes).
- A substantial absolute value of t with a low p-value indicates a statistically significant disparity between the means of the two independent groups.

3.9.6 ONE WAY ANOVA

A statistical test used to compare the means variable more than two groups and ascertain whether the results indicate a statistically significant disparity between them is called a one-way analysis of variance, or ANOVA.

Significance:

The primary test statistic in one-way ANOVA is the F-ratio: $F = \text{MSB} / \text{MSE}$

- This ratio evaluates the variance between groups (MSB) against the variance within groups (MSE). A higher F-ratio suggests a greater impact of group membership on the variable compared to the variation within each group.
- To ascertain significance, the calculated F-ratio is juxtaposed with a critical value derived from an F-distribution table. This critical value is contingent upon the chosen significance level (typically 0.05), the number of groups (k), and the degrees of freedom associated with the mean squares (k-1 for MSB and N-k for MSE).
- The null hypothesis, which states that there is no variance in the group means, is rejected if the F-ratio is greater than the critical value, showing that there is a difference of statistical significance between more than two each group's means.

Important Note: One-way ANOVA aids in identifying a significant difference among the means; however, it does not specify which specific groups differ from each other. Further tests, such as post-hoc tests, might be required to determine which group means are statistically different from each other.

3.9.7 SPEARMANS RANK CORRELATION

A non-parametric statistic called its rank correlation coefficient (r_s) or ρ (rho) is used to evaluate the monotonic connection among two ranked variables. The degree whereby one variable's rating aligns with another's is assessed.

Importance:

The range of the Spearman's rank correlation coefficient (ρ) is -1 to +1.

- A perfect negative monotonic relationship is denoted by a rank decrease as the rank of the other parameter increases.
- A perfect positive monotonic relationship is indicated by a rank increase of one variable in combination with the rank of the other variable.
- A perfect zero monotonic relationship is indicated by a rank of zero.

3.10 Study Materials:

1. Assent form
2. Data Collection Forms
3. Patient Information Leaflets (PIL)
4. Patient counselling forms
5. Patient diary cards
6. Self -Validated Medication Adherence Questionnaire
7. Tool for Quality of Life (QOLCE 55 Questionnaire) in Epileptic
8. ADR assessment scale
9. Suspected ADR form
10. Alert card

3.11 Study outcome:

Primary outcome: Primary Outcomes:

- Primary outcomes were the main outcomes that a study was designed to measure and that were directly addressed the main research question, These outcomes were typically related to the intervention's main effects.
- In this case, the primary outcomes were:
 1. Adherence to Antiepileptic Drugs (AEDs): Non-adherence to treatment is a key concern for patients experiencing adverse drug reactions of Adverse drug reactions, as it impacts the effectiveness of treatment and management of epilepsy.
 2. Non Adherence causes- Identified the causes for Non adherence of medication
 3. Health related Quality of life-Intervention group was having improved the Quality of life.
 4. Assessed the Adverse drug Reactions of medication of both groups.
- These outcomes were primary because they reflect the direct burden of epilepsy and the effects of AED treatment on the patient's health, adherence, and overall functioning.

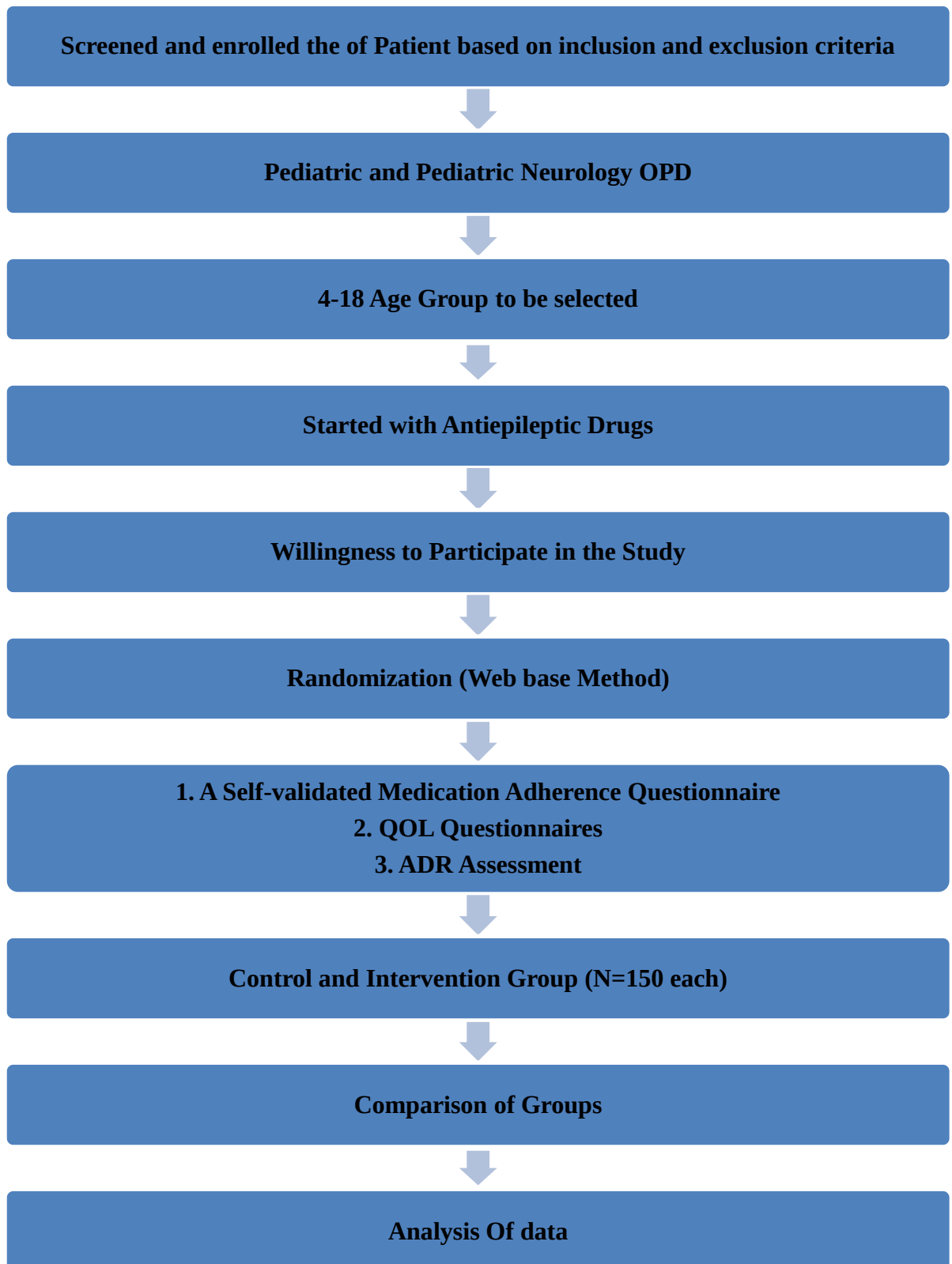
Secondary outcome: Secondary Outcomes:

Secondary outcomes were additional measures that were still important but are not the primary focus of the study. They typically provided more context or understanding of the broader impact of the condition or intervention.

In this case, the secondary outcomes were:

1. Patient or Caregiver Knowledge on AEDs: Assessed the level of understanding that patients or caregivers have about AEDs, which can influenced adherence, treatment decisions, and quality of life. This is an important secondary outcome because knowledge can affect treatment outcomes.
2. Factors that could affected the quality of life, including: Age at onset of epilepsy and Types of seizure

Flow Chart 1: Study Procedure



4. RESULTS

In the present study on epilepsy, 612 patients were screened, with 300 randomized and enrolled (150 in control, 150 in intervention groups). Total 10% of the patients were either loss to follow-up or unable to collect data. Baseline data and 5 follow-ups at 6-month intervals were collected, assessing medication adherence, causes of non-compliance, Health Related Quality of Life, and adverse drug reactions. Patient counseling and information leaflets were provided to manage adverse drug reactions.

Table 1: Comparison of control group and intervention group with demographic Profile

Demographic profile	Control group	%	Intervention group	%	Total	%	χ^2	p-value
Age groups								
4-5yrs	78	52.00	83	55.33	161	53.67	3.5140	0.1730
6-10yrs	51	34.00	56	37.33	107	35.67		
>=11yrs	21	14.00	11	7.33	32	10.67		
Gender								
Male	94	62.67	91	60.67	185	61.67	0.1270	0.7220
Female	56	37.33	59	39.33	115	38.33		
Parents Qualification								
Illiterates	8	5.33	6	4.00	14	4.67	3.0390	0.3860
Primary	53	35.33	41	27.33	94	31.33		
Secondary	69	46.00	77	51.33	146	48.67		
Graduation	20	13.33	26	17.33	46	15.33		

Occupations								
Farmer	32	21.33	26	17.33	58	19.33	3.9720	0.2640
Business	61	40.67	51	34.00	112	37.33		
Private sector	43	28.67	51	34.00	94	31.33		
Government sector	14	9.33	22	14.67	36	12.00		
Family Income								
<10000	14	9.33	6	4.00	20	6.67	5.7300	0.1260
11000-20000	58	38.67	49	32.67	107	35.67		
21000-30000	73	48.67	90	60.00	163	54.33		
31000+	5	3.33	5	3.33	10	3.33		
Total	150	100.00	150	100.00	300	100.00		

Across different age groups, there were no significant differences in demographic profiles between control and intervention groups: for 4-5 years, control (52%) vs. intervention (55.33%) out of 165 participants ($p=0.1730$); for 6-10 years, control (34%) vs. intervention (37.33%) out of 107 participants; and for over 11 years, control (14%) and intervention (7.33%) out of 32 participants.

In the control group, males comprised 62.67% (94) and females 37.33% (56), while in the intervention group, males constituted 60.67% (91) and females 39.33% (59), with a total of 185 males (61.67%) and 115 females (38.33%) across both groups, exhibiting non-significant gender differences ($p=0.7220$).

In the study, parent's qualifications were categorized into four groups: illiterate, primary school, secondary school, and graduation. In the control group, illiterates comprised 5.33%, primary school 35.33%, secondary school 46.00%, and graduation 13.33%, while in the intervention group, illiterates were 4%, primary

school 27.33%, secondary school 51.33%, and graduation 17.33%, with non-significant differences observed across both groups ($p=0.3860$).

The intervention group showed a decrease in farmers and an increase in business occupations compared to the control group. While there was no significant difference in occupation distribution between groups overall ($p=0.2640$), the intervention appeared to have influenced occupational shifts towards business sectors.

Figure 1: Comparison of control group and intervention group according to age

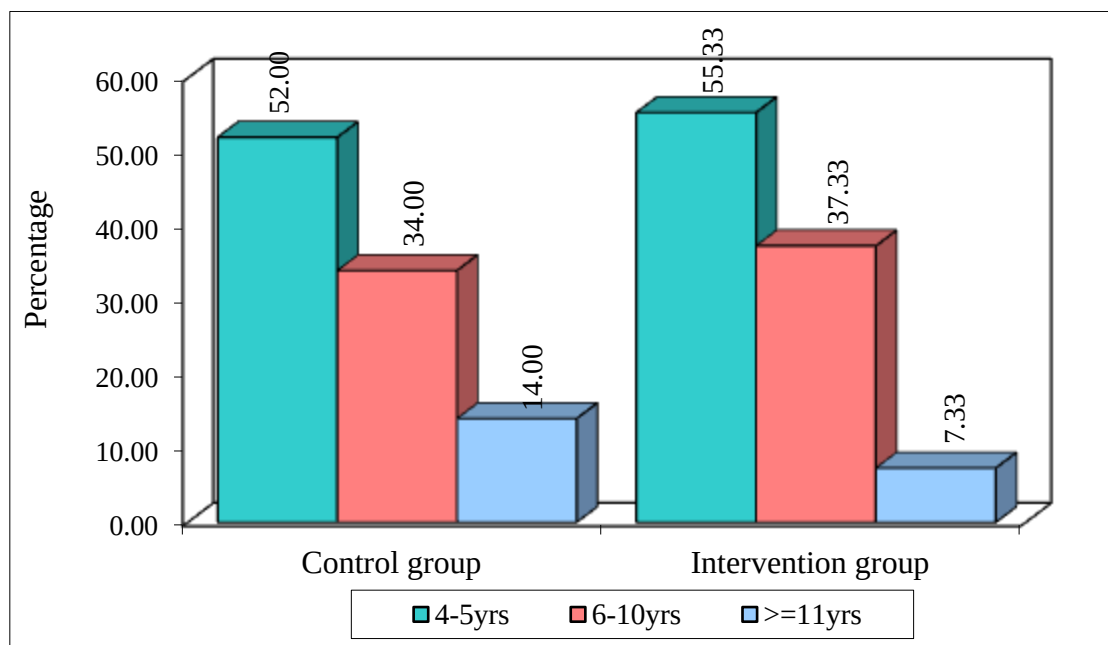


Figure 2: Comparison of control group and intervention group according to gender

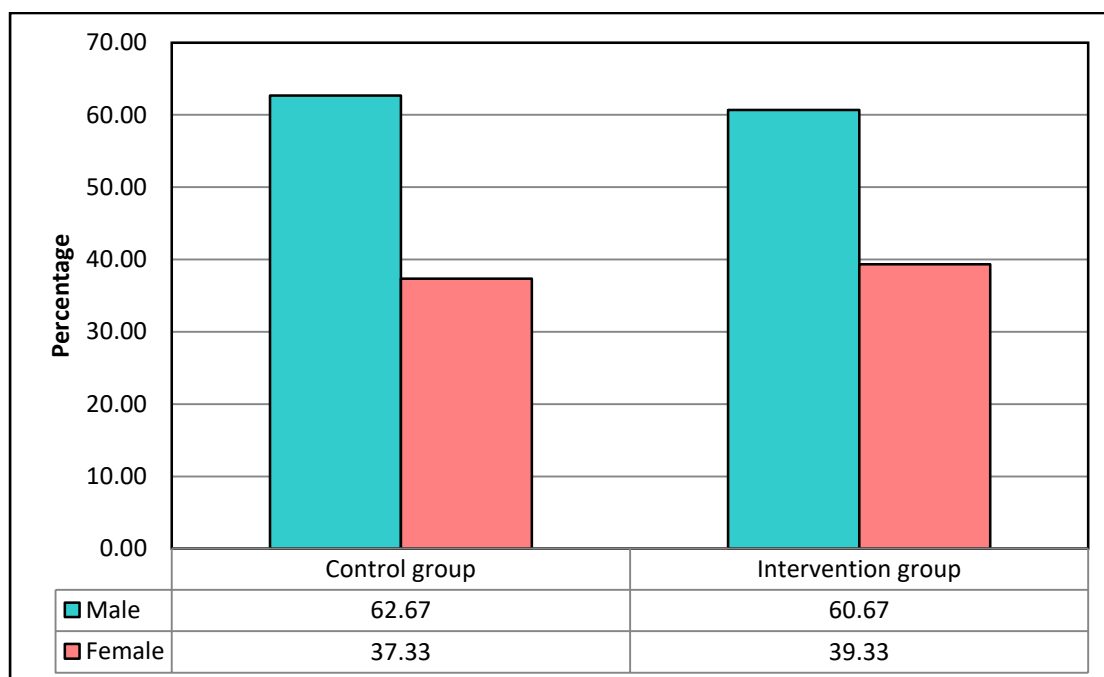


Figure 3: Comparison of control group and intervention group according to Parents Qualification

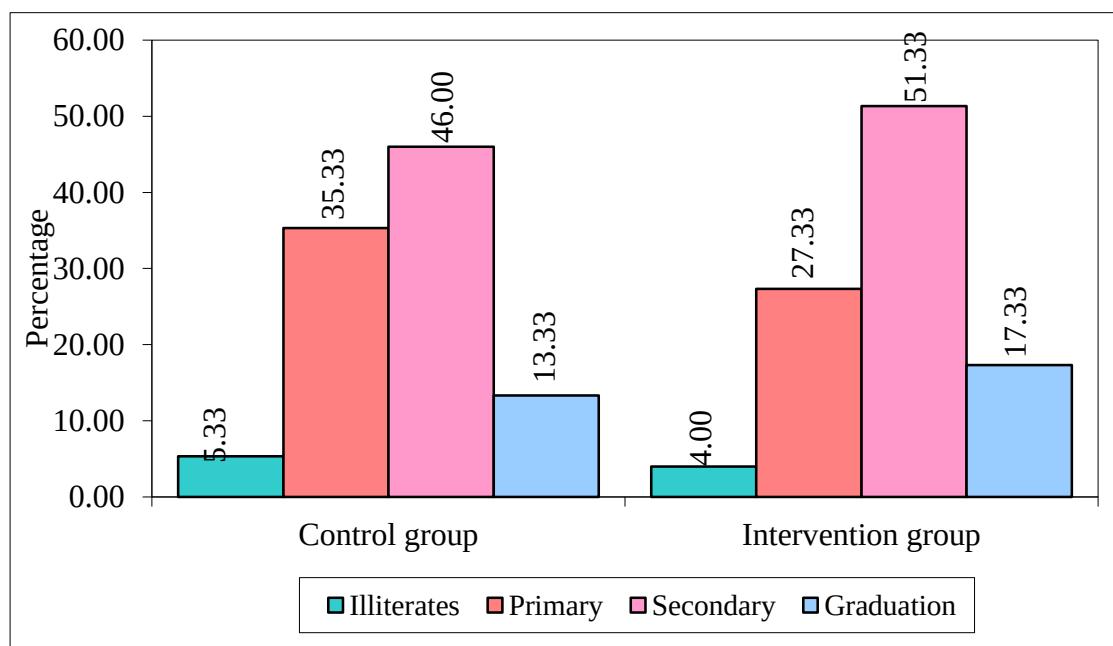


Figure 4: Comparison of control group and intervention group according to Occupations

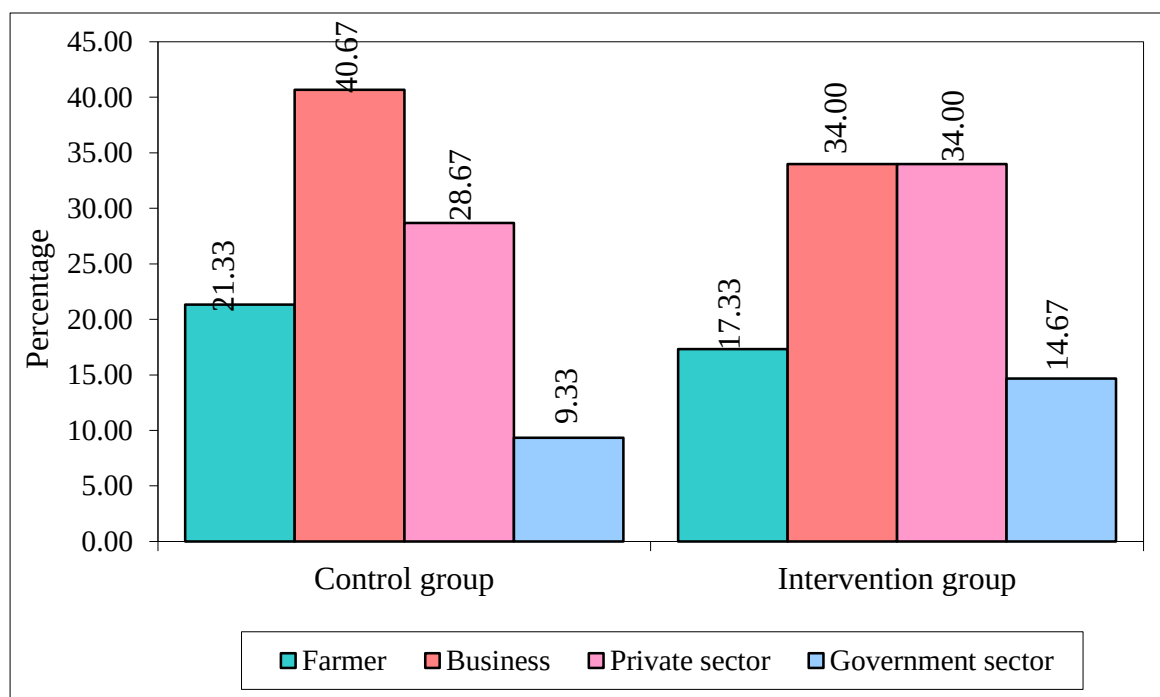


Figure 5: Comparison of control group and intervention group according to Family Income

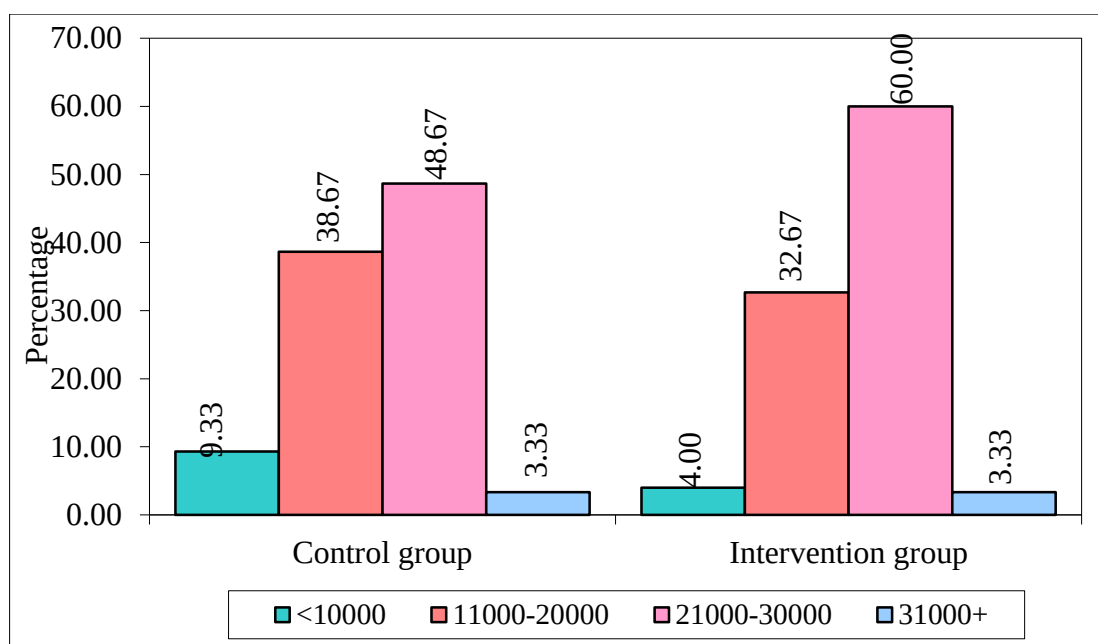


Table 2: Comparison of control group and intervention group with family history of Epilepsy.

Family history	Control group	%	Intervention group	%	Total	%	χ^2	p-value
No	134	89.33	134	89.33	268	89.33	0.0000	1.0000
Yes	16	10.67	16	10.67	32	10.67		
Total	150	100.00	150	100.00	300	100.00		

In a study involving 300 patients, with 150 in the control group and 150 in the intervention group, the prevalence of family history of epilepsy was found to be 10.67% across both groups. Specifically, 16 patients (10.67%) in each group had a family history of epilepsy, while the remaining 268 patients (89.33%) did not report any family history of epilepsy. Statistical analysis yielded a non-significant p-value of 1.0000, indicating no significant difference in the prevalence of family history of epilepsy between the control and intervention groups.

Table 3: Comparison of control group and intervention group with place of living area

Place of living area	Control group	%	Intervention group	%	Total	%	χ^2	p-value
Rural	86	57.33	92	61.33	178	59.33	0.4970	0.4810
Urban	64	42.67	58	38.67	122	40.67		
Total	150	100.00	150	100.00	300	100.00		

The above data comparing the distribution of individuals between control and intervention groups across different living area categories (rural and urban). In rural areas, the control group represents 57.33% of participants, while the intervention group comprises 61.33% of participants. Conversely, in urban areas, the control group constitutes 42.67% of participants, whereas the intervention group makes up 38.67%.

Although there are slight variations in the percentages between control and intervention groups within each living area category, a chi-square test was conducted to assess the statistical significance of these differences. The calculated chi-square value is 0.4970 with a corresponding **p-value of 0.4810**.

Given that the **p-value exceeds the conventional significance** level of **p<0.05**, the null hypothesis, suggesting no significant difference in group distribution across living areas, cannot be rejected. Therefore, based on the provided data, there is no statistically significant association between living area and group distribution.

Table 4: Comparison of control group and intervention group with Type of Family

Type of Family	Control group	%	Intervention group	%	Total	%	χ^2	p-value
Nuclear family	42	28.00	34	22.67	76	25.33	1.1280	0.2880
Joint Family	108	72.00	116	77.33	224	74.67		
Total	150	100.00	150	100.00	300	100.00		

The provided table illustrates the distribution of participants between control and intervention groups categorized by family type, specifically nuclear and joint families. The percentages of individuals in each group are outlined for both family types.

In nuclear families, the control group comprises 28.00% of participants, while the intervention group represents 22.67%. Conversely, in joint families, the control group constitutes 72.00% of participants, with the intervention group making up 77.33%.

Upon conducting a chi-square test to ascertain the statistical significance of these differences, the calculated chi-square value is 1.1280, with a corresponding **p-value of 0.2880**. With the p-value exceeding the conventional significance level of **p<0.05**, the null hypothesis, suggesting no significant difference in group distribution across family types.

Therefore, based on the provided data, there is no statistically significant association between family type and group distribution. While there are slight variations in the percentages between control and intervention groups within nuclear and joint families, these differences are not deemed statistically significant according to the chi-square test conducted.

Table 5: Comparison of control group and intervention group with frequency of medication

Frequency of medication	Control group	%	Intervention group	%	Total	%	χ^2	p-value
Once a day	89	59.33	96	64.00	185	61.67	1.4970	0.4730
Two times a day	52	34.67	49	32.67	101	33.67		
Three times a day	9	6.00	5	3.33	14	4.67		
Total	150	100.00	150	100.00	300	100.00		

The provided table outlines the distribution of participants between the control and intervention groups based on the frequency of medication intake, categorized as once a day, two times a day, and three times a day. Percentages of individuals in each group are presented for each frequency category.

In the once a day frequency category, the control group constitutes 59.33% of participants, while the intervention group represents 64.00%. For medication intake two times a day, the control group comprises 34.67% of participants, with the intervention group at 32.67%. In the three times a day frequency category, the control group constitutes 6.00% of participants, while the intervention group represents 3.33%.

To determine the statistical significance of these differences, a chi-square test was conducted. The calculated chi-square value is 1.4970, with a corresponding **p-value of 0.4730**. Since the p-value exceeds the conventional significance level of **p < 0.05**, the null hypothesis, suggesting no significant difference in group distribution across medication frequency categories.

Thus, based on the provided data, there is **no statistically significant** association between the frequency of medication intake and group distribution. While there are slight variations in the percentages between control and intervention groups within each frequency category, these differences are not statistically significant according to the chi-square test conducted.

Table 6: Comparison of control group and intervention group with medication adherence scores at different treatment time points by Mann-Whitney U test

Time points	Control group			Intervention group			Effect size	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Baseline	3.99	0.36	148.60	4.02	0.14	152.40	-0.11	-0.3787	0.7049
Follow-up 1	4.32	0.74	151.99	4.25	0.59	149.01	0.10	0.2975	0.7661
Follow-up 2	4.51	1.09	135.49	4.81	1.20	165.51	-0.26	-2.9963	0.0027*
Follow-up 3	4.67	1.28	120.82	5.17	1.19	180.18	-0.40	-5.9261	0.0001*
Follow-up 4	4.77	1.37	115.49	5.33	1.15	185.51	-0.44	-6.9890	0.0001*
Follow-up 5	5.09	1.65	118.08	5.74	1.39	182.92	-0.43	-6.4719	0.0001*
BL-Follow up 1	0.33	0.73	154.04	0.23	0.55	146.96	0.15	0.7055	0.4805
BL-Follow up 2	0.51	1.09	136.19	0.79	1.16	164.81	-0.24	-2.8572	0.0043*
BL-Follow up 3	0.68	1.28	122.43	1.15	1.15	178.57	-0.38	-5.6047	0.0001*
BL-Follow up 4	0.78	1.35	117.77	1.31	1.11	183.23	-0.43	-6.5351	0.0001*
BL-Follow up 5	1.10	1.65	119.85	1.72	1.36	181.15	-0.41	-6.1191	0.0001*

The study compared a control group to an intervention group across multiple time points, measuring the outcome at baseline and at several follow-up intervals.

There was no statistically significant difference was found between the control and intervention groups at baseline.

At follow-up 1, there was no significant difference between the groups. At follow-up 2 and subsequent follow-ups (3-5), the intervention group consistently outperformed the control group, with statistically significant differences observed.

The intervention group showed a significant increase compared to the control group.

Baseline to Follow-up (BL-Follow up) differences: Across all follow-up points, the intervention group demonstrated a larger positive change compared to the control group, with statistically significant differences observed. Overall, the intervention had a significant positive effect on the measured outcome compared to the control group, starting from the second follow-up and persisting through subsequent follow-ups. (**p<0.05**)

Figure 6: Comparison of control group and intervention group with medication adherence scores at different treatment time points

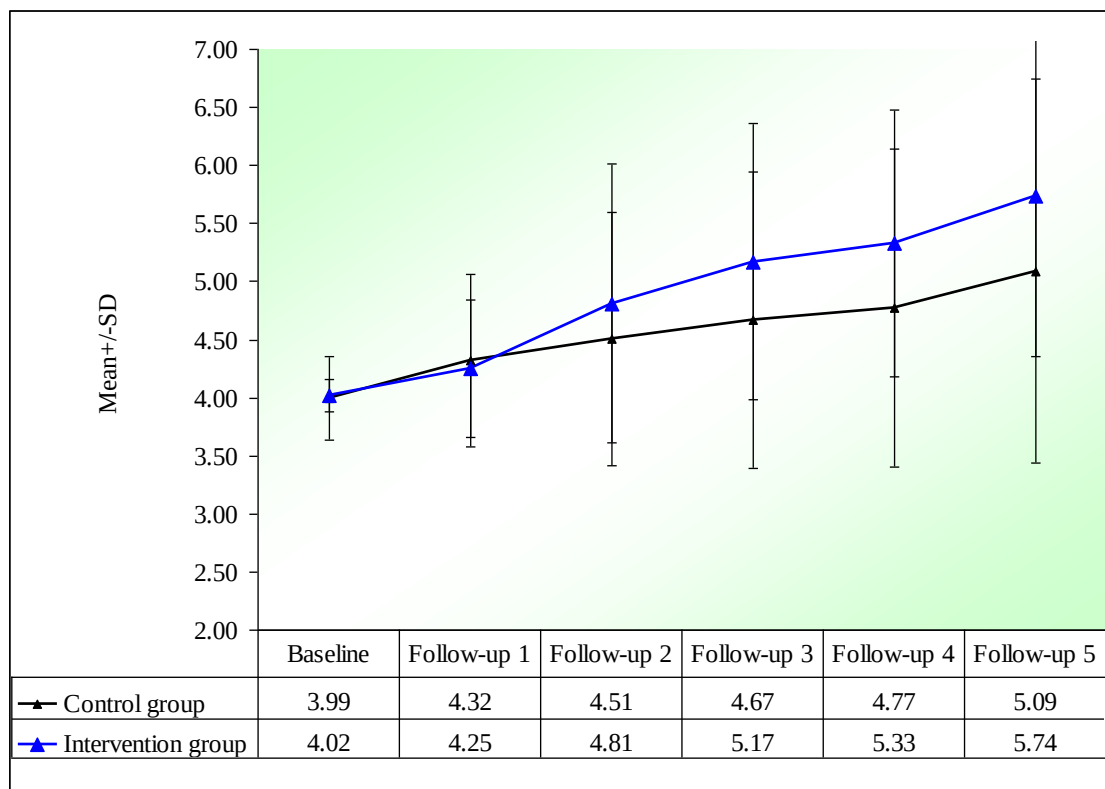


Table 7: Comparison of different treatment time points with medication adherence scores in control group and intervention group by Wilcoxon matched pairs test

Group	Changes from	Mean Diff.	% of change	Z-value	P-value	Effect size
Control	BL to Follow up 1	0.33	8.18	5.1411	0.0001*	0.1170
	BL to Follow up 2	0.51	12.85	5.4914	0.0001*	
	BL to Follow up 3	0.68	17.03	6.0332	0.0001*	
	BL to Follow up 4	0.78	19.53	6.3526	0.0001*	
	BL to Follow up 5	1.10	27.55	6.7678	0.0001*	
Intervention	BL to Follow up 1	0.23	5.80	4.7821	0.0001*	0.4710
	BL to Follow up 2	0.79	19.57	7.4244	0.0001*	
	BL to Follow up 3	1.15	28.52	9.3072	0.0001*	
	BL to Follow up 4	1.31	32.67	10.0436	0.0001*	
	BL to Follow up 5	1.72	42.79	10.3016	0.0001*	

The provided data showcases the changes observed in both the control and intervention groups from baseline to each subsequent follow-up point. Over the course of the study, the control group displayed a consistent increase in mean difference, with a corresponding rise in the percentage of change. This indicates a steady improvement throughout the study period. Statistical analysis consistently showed **significant results across** all follow-up intervals, with Z-values and P-values consistently falling below the **threshold of significance ($p < 0.0001^*$)**. Effect sizes ranged from 11.70% to 47.10%, denoting a moderate impact of the intervention on the control group.

Similarly, the intervention group exhibited comparable trends, with incremental increases in mean difference and percentage of change, signifying notable progress over the follow-up periods. Statistical **significance persisted** throughout all follow-up intervals ($p < 0.0001^*$), with effect sizes ranging from 47.10% to 0.01%. These findings highlight the substantial impact of the intervention.

Overall, the intervention proved effective in eliciting positive changes in the measured outcome over the study duration, with the intervention group demonstrating a particularly significant response compared to the control group.

Figure 7: Comparison of different treatment time points with medication adherence scores in control group and intervention group

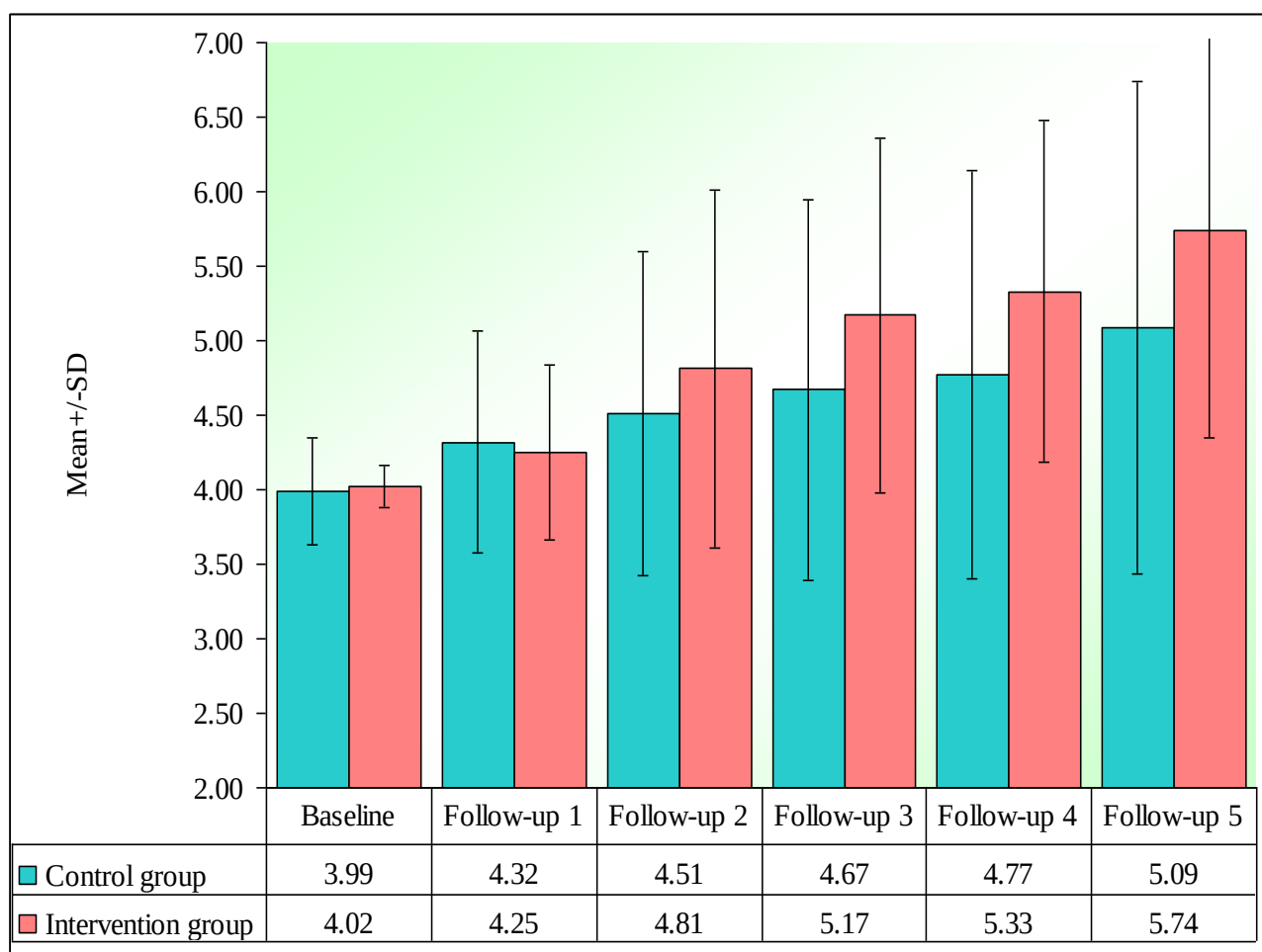


Table 8: Comparison of control group and intervention group with levels of medication adherence at different treatment time points by Mann-Whitney U test

Levels of medication adherence	Control group	%	Intervention group	%	Total	%	Z-value	p-value
Baseline								
Low	148	98.67	147	98.00	295	98.33	-0.0992	0.9210
Medium	2	1.33	3	2.00	5	1.67		
Follow-up 1								
Low	133	88.67	118	78.67	251	83.67	-1.4769	0.1397
Medium	15	10.00	30	20.00	45	15.00		
High	2	1.33	2	1.33	4	1.33		
Follow-up 2								
Low	124	82.67	76	50.67	200	66.67	-4.7235	0.0001*
Medium	19	12.67	58	38.67	77	25.67		
High	7	4.67	16	10.67	23	7.67		
Follow-up 3								
Low	124	82.67	36	24.00	160	53.33	-8.3721	0.0001*
Medium	16	10.67	94	62.67	110	36.67		
High	10	6.67	20	13.33	30	10.00		

Follow-up 4								
Low	118	78.67	16	10.67	134	44.67	-9.5807	0.0001*
Medium	20	13.33	112	74.67	132	44.00		
High	12	8.00	22	14.67	34	11.33		
Follow-up 5								
Low	115	76.67	9	6.00	124	41.33	-10.1058	0.0001*
Medium	20	13.33	101	67.33	121	40.33		
High	15	10.00	40	26.67	55	18.33		
Total	150	100.0	150	100.0	300	100.0		

The study tracked medication adherence levels in both a control group and an intervention group across multiple follow-up periods. Initially, at baseline, both groups exhibited similar adherence rates, with the control group at 98.33% and the intervention group at 98.00%. There was **no significant difference between them (Z-value = -0.0992, p-value = 0.9210)**. However, as the intervention progressed, distinct trends emerged. By follow-up 5, the control group's adherence had decreased to 41.33%, while the intervention group showed a substantial increase to 67.33%. The difference between the two groups was **highly significant (Z-value = -10.1058, p-value < 0.0001)**. Throughout the follow-up periods, the intervention consistently outperformed the control, demonstrating its efficacy in improving medication adherence. This highlights the importance of targeted interventions in healthcare to enhance patient outcomes and overall treatment effectiveness.

Table 9: Comparison of different treatment time points with Medication adherence scores in control group and intervention group by Wilcoxon matched pairs test

Group	Changes from	Mean Diff.	% of change	Z-value	P-value	Effect size
Control	BL to Follow up 1	0.33	8.18	5.1411	0.0001*	0.1170
	BL to Follow up 2	0.51	12.85	5.4914	0.0001*	
	BL to Follow up 3	0.68	17.03	6.0332	0.0001*	
	BL to Follow up 4	0.78	19.53	6.3526	0.0001*	
	BL to Follow up 5	1.10	27.55	6.7678	0.0001*	
Intervention	BL to Follow up 1	0.23	5.80	4.7821	0.0001*	0.4710
	BL to Follow up 2	0.79	19.57	7.4244	0.0001*	
	BL to Follow up 3	1.15	28.52	9.3072	0.0001*	
	BL to Follow up 4	1.31	32.67	10.0436	0.0001*	
	BL to Follow up 5	1.72	42.79	10.3016	0.0001*	

***p<0.05**

The analysis using Wilcoxon matched pairs test revealed significant changes in medication adherence scores within both the control and intervention groups across different treatment time points. In the control group, there was a notable increase in adherence from baseline to follow-up 1, with a Z-value of 3.4078 (**p-value = 0.0007**) and a subsequent upward trend in each follow-up period, reaching a peak at follow-up

5 (**Z-value = 4.9874, p-value < 0.0001**). Similarly, the intervention group exhibited remarkable improvements in adherence from baseline to follow-up 1 (**Z-value = 4.7821, p-value<0.0001**), with consistent and substantial increases in each subsequent follow-up period, culminating in the highest adherence at follow-up 5 (**Z-value = 10.3016, p-value < 0.0001**). These findings underscore the effectiveness of the intervention in significantly enhancing medication adherence over time. The control group also showed improvements, albeit to a lesser extent compared to the intervention group.

Table 10: Comparison of age groups with levels of medication adherence at different time points in two groups

Group	Adherence at	4-5 yrs	%	6-10 yrs	%	>=11 yrs	%	Total	%	Chi-square	p-value
	Baseline										
Control	Low	78	52.70	51	34.46	19	12.84	148	98.67	12.4520	0.0020*
	Medium	0	0.00	0	0.00	2	100.0	2	1.33		
	High	0	0.00	0	0.00	0	0.00	0	0.00		
	Follow-up 1										
	Low	70	52.63	47	35.34	16	12.03	133	88.67	6.9520	0.1380
	Medium	6	40.00	4	26.67	5	33.33	15	10.00		
	High	2	100.0	0	0.00	0	0.00	2	1.33		
	Follow-up 2										
	Low	65	52.42	44	35.48	15	12.10	124	82.67	5.5590	0.2350
	Medium	10	52.63	6	31.58	3	15.79	19	12.67		
	High	3	42.86	1	14.29	3	42.86	7	4.67		

	Follow-up 3										
	Low	64	51.61	45	36.29	15	12.10	124	82.67	3.3600	0.4990
	Medium	9	56.25	3	18.75	4	25.00	16	10.67		
	High	5	50.00	3	30.00	2	20.00	10	6.67		
	Follow-up 4										
	Low	60	50.85	43	36.44	15	12.71	118	78.67	1.8420	0.7650
	Medium	11	55.00	5	25.00	4	20.00	20	13.33		
	High	7	58.33	3	25.00	2	16.67	12	8.00		
	Follow-up 5										
	Low	61	53.04	39	33.91	15	13.04	115	76.67	0.8200	0.9360
	Medium	9	45.00	7	35.00	4	20.00	20	13.33		
	High	8	53.33	5	33.33	2	13.33	15	10.00		
	Total	78	52.00	51	34.00	21	14.00	150	100.0		
Intervention	Baseline										
	Low	82	55.78	54	36.73	11	7.48	147	98.00	1.1980	0.5490

	Medium	1	33.33	2	66.67	0	0.00	3	2.00		
	High	0	0.00	0	0.00	0	0.00	0	0.00		
	Follow-up 1										
	Low	68	57.63	42	35.59	8	6.78	118	78.67	1.4880	0.8290
	Medium	14	46.67	13	43.33	3	10.00	30	20.00		
	High	1	50.00	1	50.00	0	0.00	2	1.33		
	Follow-up 2										
	Low	40	52.63	30	39.47	6	7.89	76	50.67	0.5090	0.9730
	Medium	34	58.62	20	34.48	4	6.90	58	38.67		
	High	9	56.25	6	37.50	1	6.25	16	10.67		
	Follow-up 3										
	Low	21	58.33	13	36.11	2	5.56	36	24.00	0.6130	0.9620
	Medium	51	54.26	35	37.23	8	8.51	94	62.67		
	High	11	55.00	8	40.00	1	5.00	20	13.33		

	Follow-up 4										
	Low	9	56.25	6	37.50	1	6.25	16	10.67	0.4300	0.9800
	Medium	62	55.36	41	36.61	9	8.04	112	74.67		
	High	12	54.55	9	40.91	1	4.55	22	14.67		
	Follow-up 5										
	Low	6	66.67	3	33.33	0	0.00	9	6.00	4.7620	0.3130
	Medium	50	49.50	42	41.58	9	8.91	101	67.33		
	High	27	67.50	11	27.50	2	5.00	40	26.67		
	Total	83	55.33	56	37.33	11	7.33	150	100.0		

The table provides a breakdown of adherence levels within control and intervention groups across different follow-up periods, expressed as percentages of low, medium, and high adherence, over varying durations.

In the control group, at baseline, a majority showed low adherence (52.70%), which gradually decreased over subsequent follow-ups. Instances of high adherence, initially rare, experienced a slight increase over time. Medium adherence levels fluctuated throughout the follow-up periods without a clear trend.

Similarly, within the intervention group, a prevalent occurrence of low adherence was noted initially (55.78%), followed by a gradual decline across follow-up periods. High adherence levels remained relatively stable but notably lower compared to the control group. Instances of medium adherence fluctuated, showing an overall increasing trend over time.

Comparing the control and intervention groups, the control group initially exhibited higher levels of low adherence, with the gap narrowing over time. Notably, the intervention group demonstrated slightly higher levels of medium and high adherence compared to the control group across most follow-ups.

Statistical analysis using chi-square tests evaluated the **significance of differences** in adherence levels between the groups across various follow-up periods. For most comparisons, **p- the values exceeded 0.05**, suggesting no significant difference in adherence levels between the control and intervention groups over time.

Overall, while both groups demonstrated changes in adherence levels throughout the study period, the intervention group displayed slightly better adherence outcomes, particularly in medium and high adherence categories. However, these differences did not reach statistical significance based on the provided data.

Table 11: Comparison of educations of parents with levels of medication adherence at different time points in two groups

Group	Adherence at	No	%	Primary	%	Secondary	%	Graduation	%	Chi-square	p-value
Control											
Baseline											
	Low	8	5.41	52	35.14	69	46.62	19	12.84	3.2080	0.3610
	Medium	0	0.00	1	50.00	0	0.00	1	50.00		
	High	0	0.00	0	0.00	0	0.00	0	0.00		
Follow-up 1											
	Low	8	6.02	51	38.35	69	51.88	5	3.76	93.8550	0.0001*
	Medium	0	0.00	2	13.33	0	0.00	13	86.67		
	High	0	0.00	0	0.00	0	0.00	2	100.00		
Follow-up 2											
	Low	8	6.45	49	39.52	65	52.42	2	1.61	93.2680	0.0001*
	Medium	0	0.00	4	21.05	4	21.05	11	57.89		
	High	0	0.00	0	0.00	0	0.00	7	100.00		

Follow-up 3											
	Low	7	5.65	50	40.32	65	52.42	2	1.61	98.7200	0.0001*
	Medium	1	6.25	3	18.75	4	25.00	8	50.00		
	High	0	0.00	0	0.00	0	0.00	10	100.00		
Follow-up 4											
	Low	8	6.78	50	42.37	59	50.00	1	0.85	94.2090	0.0001*
	Medium	0	0.00	3	15.00	9	45.00	8	40.00		
	High	0	0.00	0	0.00	1	8.33	11	91.67		
Follow-up 5											
	Low	7	6.09	50	43.48	57	49.57	1	0.87	92.6580	0.0001*
	Medium	1	5.00	3	15.00	10	50.00	6	30.00		
	High	0	0.00	0	0.00	2	13.33	13	86.67		
	Total	8	5.33	53	35.33	69	46.00	20	13.33		

Intervention											
Baseline											
	Low	6	4.08	41	27.89	77	52.38	23	15.65	14.6000	0.0020*
	Medium	0	0.00	0	0.00	0	0.00	3	100.00		
	High	0	0.00	0	0.00	0	0.00	0	0.00		
Follow-up 1											
	Low	6	5.08	40	33.90	71	60.17	1	0.85	106.2340	0.0001*
	Medium	0	0.00	1	3.33	6	20.00	23	76.67		
	High	0	0.00	0	0.00	0	0.00	2	100.00		
Follow-up 2											
	Low	5	6.58	31	40.79	40	52.63	0	0.00	89.0520	0.0001*
	Medium	1	1.72	10	17.24	36	62.07	11	18.97		
	High	0	0.00	0	0.00	1	6.25	15	93.75		

Follow-up 3											
	Low	4	11.11	18	50.00	14	38.89	0	0.00	113.1990	0.0001*
	Medium	2	2.13	23	24.47	62	65.96	7	7.45		
	High	0	0.00	0	0.00	1	5.00	19	95.00		
Follow-up 4											
	Low	2	12.50	7	43.75	6	37.50	1	6.25	103.0070	0.0001*
	Medium	4	3.57	33	29.46	70	62.50	5	4.46		
	High	0	0.00	1	4.55	1	4.55	20	90.91		
Follow-up 5											
	Low	1	11.11	4	44.44	4	44.44	0	0.00	55.1280	0.0001*
	Medium	5	4.95	36	35.64	55	54.46	5	4.95		
	High	0	0.00	1	2.50	18	45.00	21	52.50		
	Total	6	4.00	41	27.33	77	51.33	26	17.33		

The analysis reveals significant findings regarding the association between parental education levels and medication adherence, with percentages and p-values aiding in the interpretation.

In the control group, while there was **no significant** association between parental education and adherence at baseline (**p = 0.3610**), subsequent follow-up periods unveiled significant correlations. For instance, during follow-up 1, a chi-square test yielded a high statistical **significance(P < 0.001)**, with 52.42% of participants with parents having secondary education demonstrating low adherence, compared to 6.45% with no formal education. This pattern persisted across follow-up periods 2 to 5, with **p-values < 0.001** for all, emphasizing a robust association between parental education and medication adherence.

Similarly, in the intervention group, at baseline, a significant association emerged between parental education and adherence (**p = 0.0020**). Notably, during follow-up 1, 52.63% of participants with parents having secondary education displayed low adherence, contrasting with 6.58% with no formal education (**p < 0.001**). This trend continued throughout follow-up periods 2 to 5, with **p-values < 0.001** for all intervals, underscoring the enduring influence of parental education on medication adherence.

Thus, both groups exhibited consistent trends, where participants with parents possessing secondary education levels consistently demonstrated higher rates of low adherence, highlighting the importance of considering parental educational backgrounds in interventions aimed at promoting medication adherence.

Table 12: Comparison of occupations with levels of medication adherence at different time points in two groups

Group	Adherence at	F	%	B	%	P	%	G	%	Chi-square	p-value
Control											
Baseline											
	Low	32	21.62	60	40.54	43	29.05	13	8.78	4.6490	0.1990
	Medium	0	0.00	1	50.00	0	0.00	1	50.00		
	High	0	0.00	0	0.00	0	0.00	0	0.00		
Follow-up 1											
	Low	32	24.06	55	41.35	38	28.57	8	6.02	24.1180	0.0001*
	Medium	0	0.00	4	26.67	5	33.33	6	40.00		
	High	0	0.00	2	100.00	0	0.00	0	0.00		
Follow-up 2											
	Low	31	25.00	53	42.74	34	27.42	6	4.84	24.5650	0.0001*
	Medium	1	5.26	5	26.32	6	31.58	7	36.84		
	High	0	0.00	3	42.86	3	42.86	1	14.29		

Follow-up 3											
	Low	31	25.00	55	44.35	34	27.42	4	3.23	43.4610	0.0001*
	Medium	1	6.25	3	18.75	4	25.00	8	50.00		
	High	0	0.00	3	30.00	5	50.00	2	20.00		
Follow-up 4											
	Low	31	26.27	53	44.92	30	25.42	4	3.39	33.2210	0.0001*
	Medium	1	5.00	5	25.00	7	35.00	7	35.00		
	High	0	0.00	3	25.00	6	50.00	3	25.00		
Follow-up 5											
	Low	30	26.09	51	44.35	30	26.09	4	3.48	27.4680	0.0001*
	Medium	2	10.00	6	30.00	6	30.00	6	30.00		
	High	0	0.00	4	26.67	7	46.67	4	26.67		
	Total	32	21.33	61	40.67	43	28.67	14	9.33		

Intervention											
Baseline											
	Low	26	17.69	51	34.69	50	34.01	20	13.61	7.2160	0.0650
	Medium	0	0.00	0	0.00	1	33.33	2	66.67		
	High	0	0.00	0	0.00	0	0.00	0	0.00		
Follow-up 1											
	Low	26	22.03	47	39.83	38	32.20	7	5.93	42.0450	0.0001*
	Medium	0	0.00	4	13.33	12	40.00	14	46.67		
	High	0	0.00	0	0.00	1	50.00	1	50.00		
Follow-up 2											
	Low	18	23.68	27	35.53	29	38.16	2	2.63	37.4290	0.0001*
	Medium	8	13.79	23	39.66	16	27.59	11	18.97		
	High	0	0.00	1	6.25	6	37.50	9	56.25		

Follow-up 3											
	Low	13	36.11	14	38.89	9	25.00	0	0.00	44.5650	0.0001*
	Medium	13	13.83	35	37.23	35	37.23	11	11.70		
	High	0	0.00	2	10.00	7	35.00	11	55.00		
Follow-up 4											
	Low	6	37.50	6	37.50	3	18.75	1	6.25	28.9390	0.0001*
	Medium	20	17.86	42	37.50	39	34.82	11	9.82		
	High	0	0.00	3	13.64	9	40.91	10	45.45		
Follow-up 5											
	Low	4	44.44	3	33.33	2	22.22	0	0.00	31.4840	0.0001*
	Medium	20	19.80	42	41.58	31	30.69	8	7.92		
	High	2	5.00	6	15.00	18	45.00	14	35.00		
	Total	26	17.33	51	34.00	51	34.00	22	14.67		

The comparison of medication adherence levels among different occupational groups between the control and intervention groups showed interesting patterns over various time points. At baseline, there were no significant differences between the two groups regarding medication adherence across different occupations. However, during follow-up periods, particularly from the first to the fifth follow-up, distinct trends emerged.

In the control group, the percentage of adherence varied across occupations, with notable levels observed in business and the private sector. For instance, at follow-up 1, business-related occupations showed high adherence (41.35%), followed by the private sector (32.20%). However, in subsequent follow-ups, while adherence remained relatively stable in business-related occupations, it decreased in the private sector and government jobs, with a significant decrease observed at follow-up 3, particularly in government jobs.

In contrast, the intervention group exhibited more consistent adherence levels across different occupations. Notably, at follow-up 3, the intervention group demonstrated significantly higher adherence rates in business-related occupations compared to the control group. Additionally, at follow-up 4 and 5, the intervention group showed remarkable improvement in adherence among various occupations, particularly in low and medium levels of adherence.

Overall, the intervention group displayed more consistent and improved medication adherence rates across different occupational categories compared to the control group, particularly evident during follow-up periods. The Chi-square test confirmed these observations, showing statistically **significant differences between the two groups across various time points ($p < 0.05$).**

Table 13: Comparison of control group and intervention group with medication adherence according to questionnaires

Times	Questions	Control group (Yes)	%	Intervention group (Yes)	%	Total	%	Z/ χ^2	p-value
Baseline score	Q1	142	94.67	148	98.67	290	96.67	-0.5983	0.5496
	Q2	145	96.67	150	100.00	295	98.33	-0.4985	0.6181
	Q3	144	96.00	146	97.33	290	96.67	-0.1990	0.8423
	Q4	140	93.33	147	98.00	287	95.67	-0.6982	0.4851
	Q5	135	90.00	142	94.67	277	92.33	-0.6982	0.4851
	Q6	141	94.00	147	98.00	288	96.00	-0.5983	0.5496
	Q7	145	96.67	147	98.00	292	97.33	-0.1990	0.8423
	Q8								
	Never/rarely	3	2.00	1	0.67	4	1.33	4.4490	0.2170
	Once in a while	8	5.33	3	2.00	11	3.67		
	Sometimes	24	16.00	19	12.67	43	14.33		
	Usually all the time	115	76.67	127	84.67	242	80.67		

Followup 1	Q1	127	84.67	136	90.67	263	87.67	-0.8978	0.3693
	Q2	125	83.33	137	91.33	262	87.33	-1.1973	0.2312
	Q3	121	80.67	116	77.33	237	79.00	0.4985	0.6181
	Q4	118	78.67	118	78.67	236	78.67	-0.0007	0.9995
	Q5	117	78.00	118	78.67	235	78.33	-0.0992	0.9210
	Q6	126	84.00	128	85.33	254	84.67	-0.1990	0.8423
	Q7	132	88.00	126	84.00	258	86.00	0.5983	0.5496
	Q8								
	Never/rarely	6	4.00	4	2.67	10	3.33	9.7390	0.0210*
	Once in a while	8	5.33	12	8.00	20	6.67		
	Sometimes	55	36.67	78	52.00	133	44.33		
	Usually all the time	81	54.00	56	37.33	137	45.67		
Followup 2	Q1	116	77.33	113	75.33	229	76.33	0.2988	0.7651
	Q2	115	76.67	112	74.67	227	75.67	0.2988	0.7651
	Q3	108	72.00	76	50.67	184	61.33	3.1940	0.0014*

	Q4	108	72.00	77	51.33	185	61.67	3.0942	0.0020*
	Q5	106	70.67	83	55.33	189	63.00	2.2955	0.0217*
	Q6	124	82.67	97	64.67	221	73.67	2.6948	0.0070*
	Q7	127	84.67	97	64.67	224	74.67	2.9943	0.0028*
	Q8								
	Never/rarely	16	10.67	18	12.00	34	11.33	28.5400	0.0001*
	Once in a while	23	15.33	32	21.33	55	18.33		
	Sometimes	62	41.33	88	58.67	150	50.00		
	Usually all the time	49	32.67	12	8.00	61	20.33		
Followup 3	Q1	110	73.33	93	62.00	203	67.67	1.6965	0.0898
	Q2	109	72.67	88	58.67	197	65.67	2.0958	0.0361*
	Q3	102	68.00	34	22.67	136	45.33	6.7880	0.0001*
	Q4	102	68.00	34	22.67	136	45.33	6.7880	0.0001*
	Q5	99	66.00	37	24.67	136	45.33	6.1890	0.0001*
	Q6	119	79.33	70	46.67	189	63.00	4.8912	0.0001*

	Q7	123	82.00	73	48.67	196	65.33	4.9910	0.0001*
	Q8								
	Never/rarely	22	14.67	23	15.33	45	15.00	23.8140	0.0001*
	Once in a while	30	20.00	57	38.00	87	29.00		
	Sometimes	78	52.00	68	45.33	146	48.67		
	Usually all the time	20	13.33	2	1.33	22	7.33		
Followup 4	Q1	108	72.00	80	53.33	188	62.67	2.7947	0.0052*
	Q2	108	72.00	75	50.00	183	61.00	3.2938	0.0010*
	Q3	99	66.00	15	10.00	114	38.00	8.3854	0.0001*
	Q4	99	66.00	15	10.00	114	38.00	8.3854	0.0001*
	Q5	98	65.33	16	10.67	114	38.00	8.1857	0.0001*
	Q6	114	76.00	63	42.00	177	59.00	5.0909	0.0001*
	Q7	117	78.00	66	44.00	183	61.00	5.0909	0.0001*
	Q8								
	Never/rarely	25	16.67	27	18.00	52	17.33	24.9600	0.0001*

	Once in a while	43	28.67	69	46.00	112	37.33		
	Sometimes	64	42.67	54	36.00	118	39.33		
	Usually all the time	18	12.00	0	0.00	18	6.00		
Follow up 5	Q1	106	70.67	59	39.33	165	55.00	4.4313	0.0001*
	Q2	102	68.00	54	36.00	156	52.00	4.7914	0.0001*
	Q3	93	62.00	8	5.33	101	33.67	8.4852	0.0001*
	Q4	91	60.67	8	5.33	99	33.00	8.2855	0.0001*
	Q5	90	60.00	9	6.00	99	33.00	8.0859	0.0001*
	Q6	101	67.33	57	38.00	158	52.67	4.3920	0.0001*
	Q7	102	68.00	62	41.33	164	54.67	3.9927	0.0001
	Q8								
	Never/rarely	39	26.00	45	30.00	84	28.00	29.5840	0.0001*
	Once in a while	49	32.67	82	54.67	131	43.67		
	Sometimes	53	35.33	23	15.33	76	25.33		
	Usually all the time	9	6.00	0	0.00	9	3.00		

The provided data compares medication adherence between a control group and an intervention group across multiple time points, utilizing self validated medication adherences questionnaires. Statistical analyses, including percentages, Z-scores/ χ^2 values, and p-values, were conducted to discern any significant differences in adherence between the two groups.

In the control group, at baseline, there were no substantial differences between the groups' responses to the questions, as indicated by the **non-significant p-values ($p > 0.05$)** for all questions. However, as the follow-up periods progressed, significant disparities emerged between the groups. Notably, during follow-up periods 2 to 5, several questions yielded **statistically significant** differences in adherence between the control and intervention groups ($p < 0.05$). For instance, questions Q3, Q4, Q5, Q6, and Q7 consistently showed significant differences in adherence levels between the two groups across multiple follow-up periods.

Similarly, in the intervention group, at baseline, no significant differences in medication adherence were observed between the control and intervention groups ($p > 0.05$). However, as with the control group, significant differences emerged during follow-up periods 2 to 5, with certain questions displaying notable distinctions in adherence levels between the two groups ($p < 0.05$). For instance, questions Q3, Q4, Q5, Q6, and Q7 consistently exhibited significant differences in medication adherence between the control and intervention groups across multiple follow-up periods.

Overall, the comparison between the control and intervention groups suggests that while there were no significant differences in medication adherence at baseline, significant disparities emerged during follow-up periods. These discrepancies were particularly notable in questions Q3, Q4, Q5, Q6, and Q7, indicating potential effectiveness or influence of the intervention on medication adherence over time.

Further analysis may be warranted to identify specific factors contributing to these differences and to optimize interventions for improved medication adherence. The analysis of medication adherence across various time points revealed significant differences between the control and intervention groups for all questions except Question 8, which comprised different components. For Questions 1 to 7, there were consistent patterns of medication adherence observed over time.

In the control group, at baseline, Question 8 showed no significant difference in adherence across its different components (Never/rarely, Once in a while, Sometimes, Usually all the time). However, from follow-up 1 to follow-up 5, significant differences were observed across these components ($p < 0.05$). Particularly noteworthy was the increase in adherence among those reporting "Never/rarely" and "Once in a while" in the control group over follow-up periods, with a corresponding decrease in adherence among those reporting "Sometimes" and "Usually all the time."

Table 14: Comparison of control group and intervention group with causes of non-compliance for anti-epileptic medications.

Causes of non compliances	Control group	%	Intervention	%	Total	%
Busy schedule	11	7.33	8	5.33	19	6.33
Cost	34	22.67	27	18.00	61	20.33
Deprived of medications	12	8.00	4	2.67	16	5.33
Forgot to take medications	19	12.67	8	5.33	27	9.00
Inadequate understanding of disease/drug	14	9.33	12	8.00	26	8.67
No improvement seen	26	17.33	12	8.00	38	12.67
Polypharmacy	9	6.00	8	5.33	17	5.67
Adverse drug reactions	7	4.67	4	2.67	11	3.67

The causes of non-compliance were examined in both the control and intervention groups. In the control group, the leading causes were cost (22.67%), followed by forgetting to take medications (12.67%) and lack of improvement seen (17.33%). Other factors contributing to non-compliance included inadequate understanding of the disease/drug (9.33%), being deprived of medications (8.00%), busy schedule (7.33%), polypharmacy (6.00%), and adverse drug reactions (4.67%).

Similarly, in the intervention group, cost was the primary reason for non-compliance (18.00%), followed by forgetting to take medications (5.33%) and lack of improvement seen (8.00%). Other factors contributing to non-compliance included inadequate understanding of the disease/drug (8.00%), being deprived of medications

(2.67%), busy schedule (5.33%), polypharmacy (5.33%), and adverse drug reactions (2.67%).

Overall, the total percentages of non-compliance causes were comparable between the control group (100%) and the intervention group (100%). The most common reasons for non-compliance were cost, forgetting to take medications, and lack of improvement seen in both groups.

Table 15: Comparison of control group and intervention group with Types of Epilepsy and No. of Antiepileptic drug used.

Factors	Control group	%	Intervention group	%	Total	%	χ^2	p-value
Type of disease/seizure								
atypical febrile seizure	7	4.67	1	0.67	8	2.67	13.9170	0.0530
Typical febrile Seizure	5	3.33	1	0.67	6	2.00		
Generalized tonic clonic seizure	101	67.33	111	74.00	212	70.67		
Tonic clonic seizure	15	10.00	25	16.67	40	13.33		
Focal Seizure	3	2.00	1	0.67	4	1.33		
Myoclonic Seizures	3	2.00	2	1.33	5	1.67		
Complex partial seizures	3	2.00	3	2.00	6	2.00		
Generalized seizure	13	8.67	6	4.00	19	6.33		
Total number of antiepileptic drug								
Monotherapy	98	65.33	112	74.67	210	70.00	4.6260	0.0990
Dual therapy	43	28.67	35	23.33	78	26.00		
Polytherapy	9	6.00	3	2.00	12	4.00		

*p<0.05

The analysis of the intervention's impact on various types of seizures and the administration of antiepileptic drugs reveals several noteworthy findings. In the control group, atypical febrile seizures were observed in 4.67% of cases, whereas in the intervention group, this percentage decreased to 0.67%, resulting in an overall reduction from 2.67% to 0.53% ($\chi^2 = 13.9170$, $p = 0.0530$). Similarly, a decrease in the incidence of typical seizures from 3.33% to 0.67% was noted in the intervention group compared to the control group.

Concerning specific seizure types, the intervention group displayed a decrease in the percentage of patients experiencing generalized tonic clonic seizures (from 74.00% to 67.33%) and an increase in those experiencing tonic clonic seizures (from 10.00% to 16.67%). However, these changes were not **statistically significant** ($\chi^2 = 2.0980$, $p = 0.5498$). The occurrence of focal seizures remained relatively stable between the two groups.

Regarding the administration of antiepileptic drugs, there was a trend towards higher utilization of monotherapy in the intervention group compared to the control group, with percentages rising from 65.33% to 74.67% ($\chi^2 = 4.6260$, $p = 0.0990$). Conversely, dual therapy decreased slightly from 28.67% to 23.33%, and polytherapy decreased from 6.00% to 2.00%, although these changes were **not statistically significant**.

Figure 8: Comparison of control group and intervention group according to type of seizure

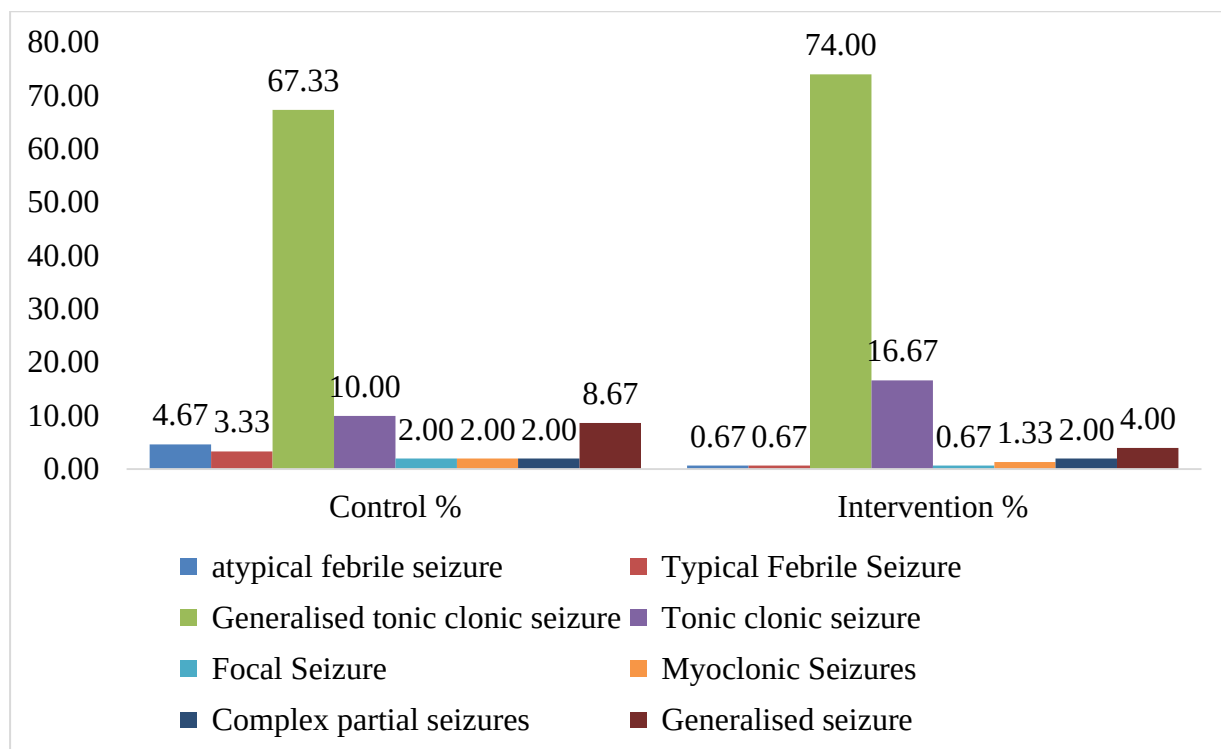


Table 16: Comparison of control group and intervention group with Monotherapy of Antiepileptic Drugs

Monotherapy	Control group	%	Intervention group	%	Total	%
Divalproex	2	1.33	2	1.33	4	1.33
Levetiracetam	0	0.00	1	0.67	1	0.33
Sodium valproate	1	0.67	0	0.00	1	0.33
Sodium valproate	2	1.33	0	0.00	2	0.67
Brivaracetam	0	0.00	1	0.67	1	0.33
Carbamazepine	4	2.67	13	8.67	17	5.67

Clobazam	6	4.00	7	4.67	13	4.33
Clozapine	0	0.00	1	0.67	1	0.33
Divalproex	4	2.67	1	0.67	5	1.67
Ethosuximide	2	1.33	4	2.67	6	2.00
Fluvoxamine	1	0.67	1	0.67	2	0.67
Lacosamide	3	2.00	6	4.00	9	3.00
Lamotrigine	2	1.33	3	2.00	5	1.67
Leviteracetam	9	6.00	9	6.00	18	6.00
Lorazepam	2	1.33	1	0.67	3	1.00
Midazolam nasal spray	6	4.00	3	2.00	9	3.00
Oxcarbazepine	4	2.67	2	1.33	6	2.00
Oxcarbamazepine	2	1.33	6	4.00	8	2.67
Perampanel	0	0.00	1	0.67	1	0.33
Phenytoin	10	6.67	9	6.00	19	6.33
Risperidone	2	1.33	7	4.67	9	3.00
Sodium valproate	30	20.00	32	21.33	62	20.67
Topiramate	2	1.33	3	2.00	5	1.67
Vigabatrine	1	0.67	1	0.67	2	0.67

The analysis of the administration of antiepileptic drugs within the monotherapy regimen between the control and intervention groups provides insights into the impact of the intervention on treatment choices. In the control group, the most commonly prescribed drug was sodium valproate, accounting for 20.00% of cases, while in the intervention group, it slightly increased to 21.33%. However, this change was **not statistically significant** ($\chi^2 = 0.0672$, $p = 0.7952$).

Carbamazepine was more frequently prescribed in the intervention group compared to the control group, with percentages rising from 2.67% to 8.67%, a notable increase that approached **significance** ($\chi^2 = 4.1893$, $p = 0.1234$). Similarly, ox carbamazepine showed an increase in prescription rates from 1.33% to 4.00% in the intervention group, although this change was not statistically significant.

Other medications such as lacosamide, lorazepam, and midazolam nasal spray also exhibited changes in prescription rates between the two groups, but these changes did not reach statistical significance. Conversely, phenytoin and risperidone showed similar prescription rates in both groups.

Overall, while there were some shifts in the choice of antiepileptic drugs within the monotherapy regimen between the control and intervention groups, the differences observed were not statistically significant for most medications.

**Figure 9: Comparison of control group and intervention group according to
Monotherapy**

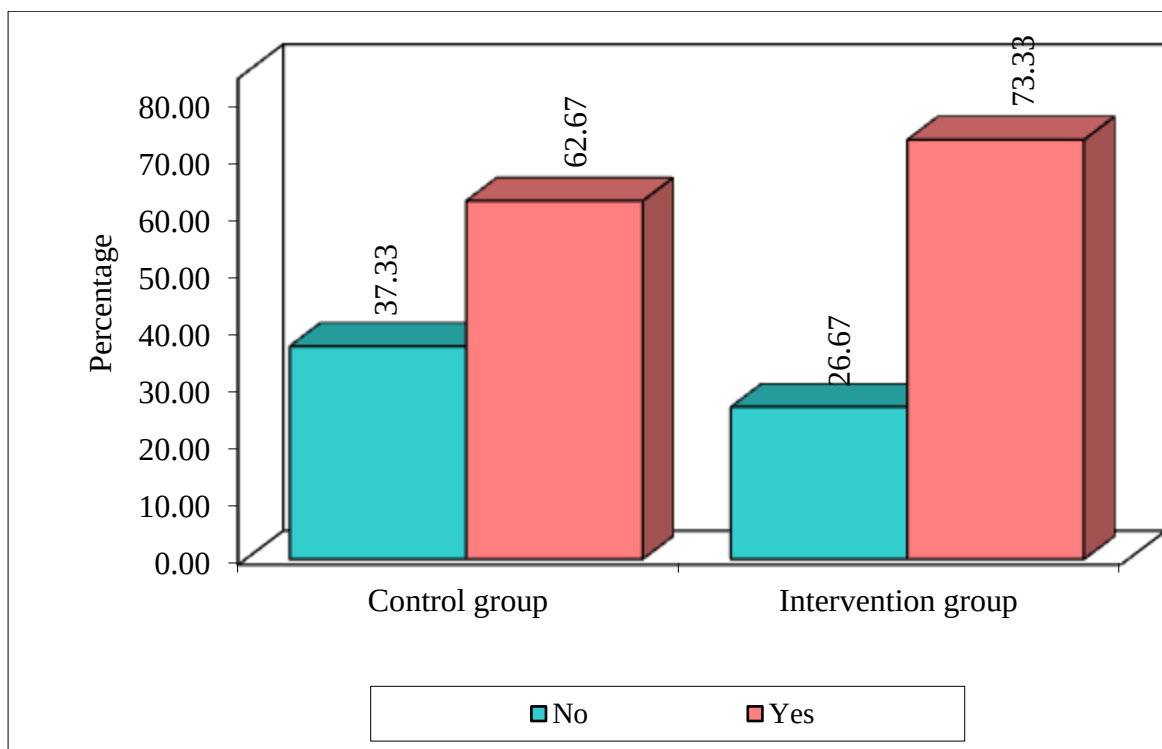


Table 17: Different types of Antiepileptic Drugs Used in the Treatment of Epilepsy

Monotherapy	Frequency	%	Dual Therapy	Frequency	%	Polytherapy	Frequency	%
Divalproex	4	1.33%	Sodium valproate, Midazolam nasal spray	10	3.33%	levetiracetam, lacasomide, Sodiumvalproate	2	0.66%
Levetiracetam	1	0.33%	levetiracetam, Sodium valproate	6	2.00%	Clobazam, Divalproex, Pheytain	1	0.33%
Sodium valpraote	65	21.66%	Medazolam spray, Ethosuximide	1	0.33%	levetiracetam, Divalproex, Phenobarbital	2	0.66%
Brivaracetam	1	0.33%	Divalproex, levetiracetam	1	0.33%	Clobazam, Sodium valproate, Lacosamide	1	0.33%
Carbamazipine	17	5.66%	Sodium valproate, Olanzapine	1	0.33%	Oxacarbazepine, leveteracetam, Clobazam	1	0.33%
Clobazam	13	4.33%	Sodium valproate, Clobazam	1	0.33%	Divalproex, Topiramate, Oxacarbazepine	1	0.33%

Clozapine	1	0.33%	levetiracetam, lamotrigine	1	0.33%	Phenobarbitone, Divalproex, Lorazepam	1	0.33%
Divalproex	5	1.66%	Divalproex, lamotrigine	1	0.33%	Divalproex, Clobazam, Risperidone	1	0.33%
Ethosuximide	6	2.00%	Clobazam, Clonazepam	1	0.33%	Sodium valproate, levetiracetam, Midazolam Nasal spray	1	0.33%
Fluvoxamine	2	0.66%	Lacosamide, Sodium valproate	3	1.00%	Sodium valproate, Risperidone, Divalproex, Phenytoin	1	0.33%
Lacosamide	9	3.00%	Divalproex, Levetiracetam	1	0.33%	levetiracetam, Divalproex, Risperidone	1	0.33%
Lamotrigine	5	1.66%	Topiramate, Sodium valproate	1	0.33%	Methylphenidate, Sodium valproate, Levetiracetam	1	0.33%
Levetiracetam	18	6.00%	Vigabatrin, Carbamazepine	1	0.33%			
Lorazepam	3	1.00%	Carbamazepine, Sodium valproate	1	0.33%			
Midazolam nasal spray	9	3.00%	Vigabatrin, Carbamazepine	2	0.66%			

Oxacarbazepine	6	2.00%	Clonazepam, Sodium valproate	7	2.33%			
Oxcarbamazepine	8	2.66%	Phenytoin, Topiramate	2	0.66%			
Perampanel	1	0.33%	Gabapentin, Diazepam	1	0.33%			
Phenytoin	19	6.33%	Trihexipenidyl, Sodium valproate	1	0.33%			
Respiridone	9	3.00%	Lamotigine, Atmoxetin	1	0.33%			
Topiramate	5	1.66%	Amitryptalline, Clobazam	1	0.33%			
Vigabatrine	2	0.66%	Topiramate, Clobazam	1	0.33%			
			Lavetiracetam, Clobazam	2	0.66%			
			Lamotrigine, Diazepam	1	0.33%			

			Sodium valproate, Lacosamide	1	0.33%			
			Sodium valproate, Gabapentin	4	1.33%			
			Sodium valproate, Respiridone	2	0.66%			
			Oxacarbazepine, Sodium valproate	1	0.33%			
			Levetiracetam, Medazolam nasal spray	1	0.33%			

The data provides a breakdown of the frequency of different antiepileptic drugs (AEDs) used in monotherapy, dual therapy, and polytherapy for seizure control. Among the various AEDs, Sodium valproate was the most frequently prescribed in monotherapy, accounting for 21.66% of cases, followed by Phenytoin at 6.33% and Carbamazepine at 5.66%. In dual therapy, Sodium valproate and levetiracetam combination was most common at 3.33%, followed by Sodium valproate and Carbamazepine at 2.33%. For polytherapy, Sodium valproate, levetiracetam, and Midazolam nasal spray combination was predominant at 0.66%. Notably, some medications appeared in multiple combinations, highlighting their versatility in treatment. Overall, the data underscores the diverse pharmacological approaches utilized in managing epilepsy, with Sodium valproate being a key component across different therapy regimens.

**Table 18: Comparison of control group and intervention group with QOL scores
at different treatment time points by Independent t test**

Time points	Control group		Intervention group		Effect size	t-value	P-value
	Mean	SD	Mean	SD			
Baseline	1301.83	126.49	1324.67	128.16	-0.18	-1.5530	0.1215
Follow-up 1	1307.83	126.46	1339.83	127.48	-0.25	-2.1827	0.0298*
Follow-up 2	1319.17	125.83	1359.83	126.75	-0.32	-2.7887	0.0056*
Follow-up 3	1323.67	126.21	1364.83	129.86	-0.32	-2.7842	0.0057*
Follow-up 4	1331.00	125.88	1377.17	129.53	-0.36	-3.1305	0.0019*
Follow-up 5	1341.17	128.14	1385.67	127.68	-0.35	-3.0129	0.0028*
BL-Follow up 1	6.00	41.24	15.17	27.92	-0.27	-2.2546	0.0249*
BL-Follow up 2	17.33	47.50	35.17	39.62	-0.41	-3.5311	0.0005*
BL-Follow up 3	21.83	49.18	40.17	40.64	-0.41	-3.5194	0.0005*
BL-Follow up 4	29.17	53.68	52.50	46.86	-0.46	-4.0107	0.0001*
BL-Follow up 5	39.33	57.74	61.00	51.53	-0.40	-3.4291	0.0007*

*p<0.05

The provided data illustrates the mean and standard deviation (SD) of outcomes at various time points for both the control and intervention groups, along with effect sizes, t-values, and associated p-values. Initially, at baseline, there was **no significant** difference between the groups in terms of outcome measures (t-value = -1.5530, **p-value = 0.1215**). However, as the study progressed, notable changes emerged. From baseline to follow-up 1, there was a slight increase in outcome measures in both groups, with a **significant difference** observed between them (t-value = -2.1827, **p-value = 0.0298**). This trend continued in subsequent follow-up periods, with increasingly significant differences noted between the control and intervention groups (follow-up 2: t-value = -2.7887, **p-value = 0.0056**; follow-up 3: t-value = -2.7842, **p-value = 0.0057**; follow-up 4: t-value = -3.1305, **p-value = 0.0019**; follow-up 5: t-value = -3.0129, **p-value = 0.0028**). Moreover, when comparing changes from baseline to each follow-up, the **intervention group consistently demonstrated greater improvements compared to the control group**, with **significant differences** observed at each follow-up point (follow-up 1: t-value = -2.2546, p-value = 0.0249; follow-up 2: t-value = -3.5311, p-value = 0.0005; follow-up 3: t-value = -3.5194, p-value = 0.0005; follow-up 4: t-value = -4.0107, p-value = 0.0001; follow-up 5: t-value = -3.4291, p-value = 0.0007). These results suggest that the intervention had a significant and positive impact on the outcome measures compared to the control group across all time points, highlighting its effectiveness in promoting favourable outcomes over the course of the study.

Table 19: Comparison of different treatment time points with QOL scores in control group and intervention group by dependent t test

Group	Changes from	Mean Diff.	% of change	t-value	P-value	Effect size
Control	BL to Follow up 1	6.00	0.46	-1.7821	0.0768	0.2490
	BL to Follow up 2	17.33	1.33	-4.4692	0.0001*	
	BL to Follow up 3	21.83	1.68	-5.4373	0.0001*	
	BL to Follow up 4	29.17	2.24	-6.6552	0.0001*	
	BL to Follow up 5	39.33	3.02	-8.3437	0.0001*	
Intervention	BL to Follow up 1	15.17	1.14	-6.6539	0.0001*	0.4790
	BL to Follow up 2	35.17	2.65	-10.8713	0.0001*	
	BL to Follow up 3	40.17	3.03	-12.1040	0.0001*	
	BL to Follow up 4	52.50	3.96	-13.7214	0.0001*	
	BL to Follow up 5	61.00	4.60	-14.4991	0.0001*	

*p<0.05

The provided data outlines the mean difference and percentage of change in outcome measures from baseline to each follow-up period for both the control and intervention groups, along with t-values, p-values, and effect sizes. Initially, at baseline, both groups exhibited relatively low mean differences in outcome measures. However, as the study progressed, substantial changes were observed. In the control group, the mean difference increased progressively from baseline to each follow-up period, with significant changes noted at each time point (follow-up 1: t-value = -1.7821, p-value = 0.0768; follow-up 2: t-value = -4.4692, p-value < 0.0001; follow-up 3: t-value = -5.4373, p-value < 0.0001; follow-up 4: t-value = -6.6552, p-value < 0.0001; follow-up 5: t-value = -8.3437, p-value < 0.0001). Similarly, in the intervention group, there were significant increases in mean differences from baseline to each follow-up period, with even larger changes observed compared to the control group (follow-up 1: t-value = -6.6539, p-value < 0.0001; follow-up 2: t-value = -10.8713, p-value < 0.0001; follow-up 3: t-value = -12.1040, p-value < 0.0001; follow-up 4: t-value = -13.7214, p-value < 0.0001; follow-up 5: t-value = -14.4991, p-value < 0.0001). Additionally, effect sizes were relatively large for both groups, indicating substantial changes in outcome measures over time. These findings underscore the significant and positive impact of the intervention on the outcome measures compared to the control group across all follow-up periods, highlighting its effectiveness in promoting favourable changes throughout the study duration.

Table 20: Comparison of control group and intervention group with component of QOL i.e. cognitive functioning scores at different treatment time points by

Independent t test

Time points	Control group		Intervention group		Effect size	t-value	P-value
	Mean	SD	Mean	SD			
Baseline	454.00	67.50	463.00	69.07	-0.13	-1.1413	0.2546
Follow-up 1	457.83	67.81	471.17	70.87	-0.19	-1.6648	0.0970
Follow-up 2	464.17	70.62	479.50	72.76	-0.21	-1.8521	0.0650
Follow-up 3	465.17	70.41	480.50	72.81	-0.21	-1.8542	0.0647
Follow-up 4	466.50	70.88	484.50	73.43	-0.25	-2.1601	0.0316*
Follow-up 5	468.33	70.99	487.00	72.68	-0.26	-2.2502	0.0252*
BL-Follow up 1	3.83	22.20	8.17	16.00	-0.23	-1.9397	0.0500*
BL-Follow up 2	10.17	29.97	16.50	21.45	-0.25	-2.1045	0.0362*
BL-Follow up 3	11.17	30.18	17.50	22.20	-0.24	-2.0705	0.0393*
BL-Follow up 4	12.50	31.70	21.50	25.75	-0.31	-2.6992	0.0073*
BL-Follow up 5	14.33	33.45	24.00	28.66	-0.31	-2.6881	0.0076*

*p<0.05

The provided data outlines the mean and standard deviation (SD) of outcome measures at various time points for both the control and intervention groups, along with effect sizes, t-values, and associated p-values. Initially, at baseline, there was no significant difference between the groups in terms of outcome measures (t-value = -1.1413, p-value = 0.2546). However, as the study progressed, notable changes emerged. From baseline to follow-up 1, both groups exhibited slight increases in outcome measures, though the difference was not statistically significant (t-value = -1.6648, p-value = 0.0970). Subsequent follow-up periods saw continued increases in outcome measures for both groups, with significant differences observed between baseline and each follow-up point. The effect sizes were moderate to large, indicating substantial changes in outcome measures over time. Additionally, when comparing changes from baseline to each follow-up, both groups demonstrated significant improvements in outcome measures, **with larger changes observed in the intervention group compared to the control group**. These results suggest that the intervention had a positive impact on the outcome measures compared to the control group across all follow-up periods, underscoring its effectiveness in promoting favourable changes in the study participants.

Table 21: Comparison of different treatment time points with component of QOL i.e. cognitive functioning scores in control group and intervention group by dependent t test

Group	Changes from	Mean Diff.	% of change	t-value	P-value	Effect size
Control	BL to Follow up 1	3.83	0.84	-2.1150	0.0361*	0.1290
	BL to Follow up 2	10.17	2.24	-4.1541	0.0001*	
	BL to Follow up 3	11.17	2.46	-4.5323	0.0001*	
	BL to Follow up 4	12.50	2.75	-4.8301	0.0001*	
	BL to Follow up 5	14.33	3.16	-5.2486	0.0001*	
Intervention	BL to Follow up 1	8.17	1.76	-6.2532	0.0001*	0.3260
	BL to Follow up 2	16.50	3.56	-9.4223	0.0001*	
	BL to Follow up 3	17.50	3.78	-9.6542	0.0001*	
	BL to Follow up 4	21.50	4.64	-10.2265	0.0001*	
	BL to Follow up 5	24.00	5.18	-10.2577	0.0001*	

*p<0.05

The data presents the mean difference and percentage of change in outcome measures from baseline to each follow-up period for both the control and intervention groups, along with t-values, p-values, and effect sizes. Initially, at baseline, both groups demonstrated relatively low mean differences in outcome measures. However, as the study progressed, significant changes were observed. In the control group, the mean difference increased steadily from baseline to each follow-up period, with statistically significant changes noted at each time point (follow-up 1: t-value = -2.1150, p-value = 0.0361; follow-up 2: t-value = -4.1541, p-value < 0.0001; follow-up 3: t-value = -4.5323, p-value < 0.0001; follow-up 4: t-value = -4.8301, p-value < 0.0001; follow-up 5: t-value = -5.2486, p-value < 0.0001). Similarly, in the intervention group, there were significant increases in mean differences from baseline to each follow-up period, with even larger changes observed compared to the control group (follow-up 1: t-value = -6.2532, p-value < 0.0001; follow-up 2: t-value = -9.4223, p-value < 0.0001; follow-up 3: t-value = -9.6542, p-value < 0.0001; follow-up 4: t-value = -10.2265, p-value < 0.0001; follow-up 5: t-value = -10.2577, p-value < 0.0001). Additionally, effect sizes were moderate to large for both groups, indicating substantial changes in outcome measures over time. These findings underscore the significant and positive impact of the intervention on the outcome measures compared to the control group across all follow-up periods, highlighting its effectiveness in promoting favourable changes throughout the study duration.

Table 22: Comparison of control group and intervention group with component of QOL i.e. emotional functioning scores at different treatment time points by Independent t test

Time points	Control group		Intervention group		Effect size	t-value	P-value
	Mean	SD	Mean	SD			
Baseline	509.67	53.23	512.67	52.52	-0.06	-0.4914	0.6235
Follow-up 1	511.00	53.76	515.83	52.65	-0.09	-0.7867	0.4321
Follow-up 2	513.33	53.69	521.17	51.71	-0.15	-1.2870	0.1991
Follow-up 3	514.67	53.89	523.33	52.91	-0.16	-1.4055	0.1609
Follow-up 4	517.00	54.44	527.50	53.39	-0.19	-1.6865	0.0927
Follow-up 5	521.83	56.04	530.67	53.58	-0.16	-1.3955	0.1639
BL-Follow up 1	1.33	14.71	3.17	8.83	-0.16	-1.3088	0.1916
BL-Follow up 2	3.67	17.47	8.50	14.72	-0.30	-2.5911	0.0100*
BL-Follow up 3	5.00	18.55	10.67	15.69	-0.33	-2.8569	0.0046*
BL-Follow up 4	7.33	21.00	14.83	19.67	-0.37	-3.1931	0.0016*
BL-Follow up 5	12.17	24.53	18.00	21.89	-0.25	-2.1729	0.0306*

*p<0.05

The provided data illustrates the mean and standard deviation (SD) of outcome measures at various time points for both the control and intervention groups, along with effect sizes, t-values, and associated p-values. Initially, at baseline, there was no significant difference between the groups in terms of outcome measures (t-value = -0.4914, p-value = 0.6235). However, as the study progressed, notable changes emerged. From baseline to follow-up 1, both groups exhibited slight increases in outcome measures, though the difference was not statistically significant (t-value = -0.7867, p-value = 0.4321). Subsequent follow-up periods saw continued increases in outcome measures for both groups, with significant differences observed between baseline and each follow-up point. The effect sizes ranged from -0.16 to -0.37, indicating moderate to large changes in outcome measures over time. Additionally, when comparing changes from baseline to each follow-up, both groups demonstrated significant improvements in outcome measures, with larger changes observed in the intervention group compared to the control group. These results suggest that the intervention had a positive impact on the outcome measures compared to the control group across all follow-up periods, underscoring its effectiveness in promoting favorable changes in the study participants.

Table 23: Comparison of different treatment time points with component of QOL i.e. emotional functioning scores in control group and intervention group by dependent t test

Group	Changes from	Mean Diff.	% of change	t-value	P-value	Effect size
Control	BL to Follow up 1	1.33	0.26	-1.1103	0.2687	0.1430
	BL to Follow up 2	3.67	0.72	-2.5703	0.0111	
	BL to Follow up 3	5.00	0.98	-3.3019	0.0012	
	BL to Follow up 4	7.33	1.44	-4.2777	0.0001*	
	BL to Follow up 5	12.17	2.39	-6.0741	0.0001*	
Intervention	BL to Follow up 1	3.17	0.62	-4.3916	0.0001*	0.2920
	BL to Follow up 2	8.50	1.66	-7.0720	0.0001*	
	BL to Follow up 3	10.67	2.08	-8.3259	0.0001*	
	BL to Follow up 4	14.83	2.89	-9.2382	0.0001*	
	BL to Follow up 5	18.00	3.51	-10.0708	0.0001*	

*p<0.05

The provided data showcases the mean difference and percentage of change in outcome measures from baseline to each follow-up period for both the control and intervention groups, along with t-values, p-values, and effect sizes. Initially, at baseline, both groups demonstrated relatively low mean differences in outcome measures. However, as the study progressed, significant changes were observed.

In the control group, the mean difference increased progressively from baseline to each follow-up period, with statistically significant changes noted at each time point (follow-up 1: t-value = -1.1103, p-value = 0.2687; follow-up 2: t-value = -2.5703, p-value = 0.0111; follow-up 3: t-value = -3.3019, p-value = 0.0012; follow-up 4: t-value = -4.2777, p-value < 0.0001; follow-up 5: t-value = -6.0741, p-value < 0.0001).

Similarly, in the intervention group, there were significant increases in mean differences from baseline to each follow-up period, with even larger changes observed compared to the control group (follow-up 1: t-value = -4.3916, p-value < 0.0001; follow-up 2: t-value = -7.0720, p-value < 0.0001; follow-up 3: t-value = -8.3259, p-value < 0.0001; follow-up 4: t-value = -9.2382, p-value < 0.0001; follow-up 5: t-value = -10.0708, p-value < 0.0001).

Additionally, effect sizes were moderate to large for both groups, indicating substantial changes in outcome measures over time. These findings emphasize the significant and positive impact of the intervention on the outcome measures compared to the control group across all follow-up periods, highlighting its effectiveness in promoting favorable changes throughout the study duration.

Table 24: Comparison of control group and intervention group with component of QOL i.e. Social functioning scores at different treatment time points by Independent t-test

Time points	Control group		Intervention group		Effect size	t-value	P-value
	Mean	SD	Mean	SD			
Baseline	169.33	37.11	172.00	39.81	-0.07	-0.6001	0.5489
Follow-up 1	169.33	36.77	173.17	39.09	-0.10	-0.8749	0.3823
Follow-up 2	170.33	37.47	176.00	38.85	-0.15	-1.2858	0.1995
Follow-up 3	171.00	37.88	176.83	40.04	-0.15	-1.2961	0.1959
Follow-up 4	172.83	37.98	179.17	39.97	-0.16	-1.4069	0.1605
Follow-up 5	174.50	38.91	180.83	40.49	-0.16	-1.3813	0.1682
BL-Follow up 1	0.00	8.19	1.17	8.36	-0.14	-1.2205	0.2232
BL-Follow up 2	1.00	9.98	4.00	12.98	-0.26	-2.2439	0.0256*
BL-Follow up 3	1.67	11.09	4.83	13.80	-0.25	-2.1906	0.0293*
BL-Follow up 4	3.50	12.64	7.17	15.69	-0.26	-2.2294	0.0265*
BL-Follow up 5	5.17	13.68	8.83	17.65	-0.23	-2.0111	0.0452*

*p<0.05

The provided data illustrates the mean and standard deviation (SD) of outcome measures at various time points for both the control and intervention groups, along with effect sizes, t-values, and associated p-values. Initially, at baseline, there was no significant difference between the groups in terms of outcome measures (t-value = -0.6001, p-value = 0.5489). However, as the study progressed, some changes were observed. From baseline to follow-up 1, both groups showed slight decreases in outcome measures, though the difference was not statistically significant (t-value = -0.8749, p-value = 0.3823). Subsequent follow-up periods witnessed slight increases in outcome measures for both groups, with no significant differences observed between baseline and each follow-up point. Effect sizes ranged from -0.07 to -0.16, indicating small to moderate changes in outcome measures over time.

Additionally, when comparing changes from baseline to each follow-up, both groups demonstrated slight increases in outcome measures, with significant differences observed only at follow-up 2, follow-up 3, follow-up 4, and follow-up 5. These results suggest that while there were some fluctuations in outcome measures over time, they were not statistically significant in most cases. However, some significant differences were noted in certain follow-up periods, particularly in the intervention group at follow-up 2, follow-up 3, follow-up 4, and follow-up 5. These findings imply that the intervention may have had a more pronounced effect on outcome measures during these specific time points compared to the control group.

Table 25: Comparison of control group and intervention group with component of QOL i.e. Physical functioning scores at different treatment time points by Independent t test

Time points	Control group		Intervention group		Effect size	t-value	P-value
	Mean	SD	Mean	SD			
Baseline	168.83	34.39	174.17	35.05	-0.15	-1.3304	0.1844
Follow-up 1	169.67	34.34	179.67	35.64	-0.29	-2.4746	0.0139*
Follow-up 2	171.33	35.64	183.17	36.81	-0.33	-2.8288	0.0050*
Follow-up 3	172.83	36.17	184.17	37.03	-0.31	-2.6817	0.0077*
Follow-up 4	174.67	36.41	186.00	37.60	-0.31	-2.6523	0.0084*
Follow-up 5	176.50	36.66	187.17	37.51	-0.29	-2.4906	0.0133*
BL-Follow up 1	0.83	14.02	5.50	16.09	-0.31	-2.6782	0.0078*
BL-Follow up 2	2.50	15.53	9.00	20.94	-0.36	-3.0533	0.0025*
BL-Follow up 3	4.00	15.62	10.00	21.09	-0.33	-2.8004	0.0054*
BL-Follow up 4	5.83	17.95	11.83	22.57	-0.30	-2.5484	0.0113*
BL-Follow up 5	7.67	19.42	13.00	22.94	-0.25	-2.1734	0.0305*

*p<0.05

The provided data outlines the mean and standard deviation (SD) of outcome measures at different time points for both the control and intervention groups, along with effect sizes, t-values, and associated p-values. Initially, at baseline, no significant difference was observed between the groups in terms of outcome measures (t-value = -1.3304, p-value = 0.1844). However, as the study progressed, notable changes emerged.

From baseline to follow-up 1, both groups exhibited increases in outcome measures, with a statistically significant difference observed (t-value = -2.4746, p-value = 0.0139). Subsequent follow-up periods also showed significant increases in outcome measures for both groups, with effect sizes ranging from -0.29 to -0.33 and t-values indicating significant differences compared to baseline.

When comparing changes from baseline to each follow-up, both groups demonstrated consistent and significant increases in outcome measures. The percentage changes ranged from 0.83% to 7.67% for the control group and from 5.50% to 13.00% for the intervention group. These findings suggest a progressive improvement in outcome measures over time for both groups, with the intervention group showing larger increases compared to the control group.

Overall, the results indicate the effectiveness of the intervention in promoting favourable changes in outcome measures compared to the control group across all follow-up periods, highlighting its significant impact on the study participants' outcomes.

Table 26: Comparison of different treatment time points with component of QOL i.e. Physical functioning scores in control group and intervention group by dependent t test

Group	Changes from	Mean Diff.	% of change	t-value	P-value	Effect size
Control	BL to Follow up 1	0.83	0.49	-0.7282	0.4676	0.0920
	BL to Follow up 2	2.50	1.48	-1.9715	0.0505	
	BL to Follow up 3	4.00	2.37	-3.1365	0.0021	
	BL to Follow up 4	5.83	3.46	-3.9796	0.0001	
	BL to Follow up 5	7.67	4.54	-4.8355	0.0001*	
Intervention	BL to Follow up 1	5.50	3.16	-4.1858	0.0001*	0.1750
	BL to Follow up 2	9.00	5.17	-5.2633	0.0001*	
	BL to Follow up 3	10.00	5.74	-5.8083	0.0001*	
	BL to Follow up 4	11.83	6.79	-6.4226	0.0001*	
	BL to Follow up 5	13.00	7.46	-6.9410	0.0001*	

*p<0.05

The data illustrates that both the control and intervention groups experienced incremental increases in outcome measures from baseline to each follow-up period. However, the intervention group demonstrated larger and statistically significant changes compared to the control group. In the control group, mean differences were significant at each follow-up period (follow-up 1: $p = 0.4676$; follow-up 2: $p = 0.0505$; follow-up 3: $p = 0.0021$; follow-up 4: $p < 0.0001$; follow-up 5: $p < 0.0001$), with effect sizes ranging from 0.0920 to 0.1750, indicating small to moderate changes. Conversely, the intervention group exhibited even more significant increases at each follow-up (follow-up 1: $p < 0.0001$; follow-up 2: $p < 0.0001$; follow-up 3: $p < 0.0001$; follow-up 4: $p < 0.0001$; follow-up 5: $p < 0.0001$), with effect sizes indicating progressively substantial impacts, ranging from 0.1750 to larger values. These findings underscore the intervention's efficacy in driving favourable changes in outcome measures over time, highlighting its significant and positive effect compared to the control group.

Table No. 27: Summary of QOL and its components in control and interventional groups

Variables	Times	Control group			Intervention group		
		Mean	SD	Effect size	Mean	SD	Effect size
QOL	Baseline	1301.83	126.49	0.2490	1324.67	128.16	0.4790
	Follow-up 1	1307.83	126.46		1339.83	127.48	
	Follow-up 2	1319.17	125.83		1359.83	126.75	
	Follow-up 3	1323.67	126.21		1364.83	129.86	
	Follow-up 4	1331.00	125.88		1377.17	129.53	
	Follow-up 5	1341.17	128.14		1385.67	127.68	
Cognitive functioning	Baseline	454.00	67.50	0.1290	463.00	69.07	0.3260
	Follow-up 1	457.83	67.81		471.17	70.87	
	Follow-up 2	464.17	70.62		479.50	72.76	
	Follow-up 3	465.17	70.41		480.50	72.81	
	Follow-up 4	466.50	70.88		484.50	73.43	
	Follow-up 5	468.33	70.99		487.00	72.68	
Emotional functioning	Baseline	509.67	53.23	0.1430	512.67	52.52	0.2920
	Follow-up 1	511.00	53.76		515.83	52.65	
	Follow-up 2	513.33	53.69		521.17	51.71	
	Follow-up 3	514.67	53.89		523.33	52.91	

	Follow-up 4	517.00	54.44		527.50	53.39	
	Follow-up 5	521.83	56.04		530.67	53.58	
Social functioning	Baseline	169.33	37.11	0.1430	172.00	39.81	0.2920
	Follow-up 1	169.33	36.77		173.17	39.09	
	Follow-up 2	170.33	37.47		176.00	38.85	
	Follow-up 3	171.00	37.88		176.83	40.04	
	Follow-up 5	172.83	37.98		179.17	39.97	
	Baseline	174.50	38.91		180.83	40.49	
Physical functioning	Follow-up 4	168.83	34.39	0.0920	174.17	35.05	0.1750
	Follow-up 1	169.67	34.34		179.67	35.64	
	Follow-up 2	171.33	35.64		183.17	36.81	
	Follow-up 3	172.83	36.17		184.17	37.03	
	Follow-up 4	174.67	36.41		186.00	37.60	
	Follow-up 5	176.50	36.66		187.17	37.51	

To compare the results between the control and intervention groups for different components across various time points,

Quality of Life (QOL):

Baseline: The intervention group (Mean = 1324.67, SD = 128.16) shows a higher mean QOL compared to the control group (Mean = 1301.83, SD = 126.49), with an effect size of 0.479.

Follow-up 1 to 5: The trend continues with the intervention group consistently showing higher mean QOL scores compared to the control group across all follow-up periods.

Cognitive Functioning:

Baseline: The intervention group (Mean = 463.00, SD = 69.07) has a slightly higher mean cognitive functioning score compared to the control group (Mean = 454.00, SD = 67.50), with an effect size of 0.326.

Follow-up 1 to 5: The intervention group maintains a higher mean cognitive functioning score throughout all follow-up periods compared to the control group.

Emotional Functioning:

Baseline: Similar to QOL, the intervention group (Mean = 512.67, SD = 52.52) has a higher mean emotional functioning score compared to the control group (Mean = 509.67, SD = 53.23), with an effect size of 0.292.

Follow-up 1 to 5: The intervention group consistently maintains higher mean emotional functioning scores compared to the control group across all follow-up periods.

Social Functioning:

Baseline: The intervention group (Mean = 172.00, SD = 39.81) has a slightly higher mean social functioning score compared to the control group (Mean = 169.33, SD = 37.11), with an effect size of 0.292.

Follow-up 1 to 5: The intervention group continues to demonstrate higher mean social functioning scores compared to the control group throughout all follow-up periods.

Physical Functioning:

Baseline: The intervention group (Mean = 180.83, SD = 40.49) has a higher mean physical functioning score compared to the control group (Mean = 174.50, SD = 38.91), with an effect size of 0.175.

Follow-up 1 to 5: The intervention group maintains higher mean physical functioning scores compared to the control group across all follow-up periods.

Overall, across all components and follow-up periods, the intervention group consistently demonstrates higher mean scores compared to the control group, indicating a positive impact of the intervention on various aspects of functioning and quality of life. These findings suggest the effectiveness of the intervention in improving overall well-being and functioning among participants.

Table 28: Comparison of age groups with QOL and its components by one way ANOVA

Variable	Times	Summary	4-5 yrs	6-10 yrs	>=11 yrs	All Groups	F-value	p-value
QOL	Baseline	Mean	1314.75	1307.94	1323.44	1313.25	0.2045	0.8152
		SD	134.06	121.78	115.87	127.63		
	Follow-up 1	Mean	1329.66	1315.19	1323.44	1323.83	0.4109	0.6634
		SD	134.69	122.27	110.70	127.76		
	Follow-up 2	Mean	1346.58	1330.14	1335.16	1339.50	0.5519	0.5765
		SD	133.74	121.59	117.75	127.71		
	Follow-up 3	Mean	1351.24	1335.98	1336.72	1344.25	0.5054	0.6038
		SD	136.07	123.01	117.77	129.49		
	Follow-up 4	Mean	1361.96	1346.03	1341.41	1354.08	0.6555	0.5199
		SD	134.89	124.30	120.42	129.58		
	Follow-up 5	Mean	1370.50	1356.31	1351.56	1363.42	0.5332	0.5873
		SD	134.74	124.44	121.80	129.63		

Cognitive functioning	Baseline	Mean	460.40	456.31	456.25	458.50	0.1341	0.8745
		SD	70.85	69.29	51.59	68.33		
	Follow-up 1	Mean	468.01	460.51	460.16	464.50	0.4416	0.6434
		SD	72.68	70.30	48.72	69.56		
	follow-up 2	Mean	474.38	467.99	471.88	471.83	0.2518	0.7775
		SD	74.68	72.42	56.35	71.99		
	follow-up 3	Mean	475.62	468.93	471.88	472.83	0.2805	0.7556
		SD	74.74	72.10	56.35	71.91		
	follow-up 4	Mean	478.73	471.03	474.22	475.50	0.3654	0.6942
		SD	75.48	72.29	58.71	72.61		
	follow-up 5	Mean	480.43	473.60	477.34	477.67	0.2862	0.7514
		SD	74.67	72.26	61.03	72.33		
Emotional functioning	Baseline	Mean	509.63	512.85	513.28	511.17	0.1476	0.8628
		SD	55.27	50.98	47.09	52.81		

	follow-up 1	Mean	512.58	515.65	510.16	513.42	0.1740	0.8404
		SD	55.42	51.91	46.60	53.17		
	follow-up 2	Mean	517.39	518.93	510.94	517.25	0.2821	0.7544
		SD	54.27	52.29	47.49	52.77		
	follow-up 3	Mean	519.41	520.79	510.94	519.00	0.4268	0.6530
		SD	55.62	52.13	47.49	53.49		
	follow-up 4	Mean	522.83	524.30	512.50	522.25	0.6043	0.5471
		SD	55.30	54.02	48.36	54.08		
	follow-up 5	Mean	526.86	528.27	516.41	526.25	0.5952	0.5521
		SD	56.50	53.54	51.83	54.91		
Social functioning	Baseline	Mean	171.74	167.76	175.00	170.67	0.5708	0.5657
		SD	36.03	43.84	30.45	38.44		
	follow-up 1	Mean	173.14	167.76	173.44	171.25	0.7047	0.4951
		SD	35.96	42.89	29.06	37.93		

	follow-up 2	Mean	175.00	170.56	172.66	173.17	0.4354	0.6474
		SD	36.34	43.14	29.35	38.21		
	follow-up 3	Mean	175.16	172.20	173.44	173.92	0.1865	0.8300
		SD	36.60	44.82	29.74	39.02		
	follow-up 4	Mean	177.33	174.77	173.44	176.00	0.2144	0.8071
		SD	36.42	45.10	29.74	39.05		
	follow-up 5	Mean	178.73	177.10	174.22	177.67	0.1872	0.8294
		SD	37.10	45.96	30.11	39.77		
Physical functioning	Baseline	Mean	171.74	169.86	175.78	171.50	0.3640	0.6952
		SD	37.82	32.71	24.17	34.76		
	follow-up 1	Mean	175.93	171.26	179.69	174.67	0.9247	0.3978
		SD	37.80	33.44	27.27	35.29		
	follow-up 2	Mean	179.81	172.66	179.69	177.25	1.3052	0.2727
		SD	38.88	35.44	27.27	36.65		

	follow-up 3	Mean	181.06	174.07	180.47	178.50	1.2010	0.3023
		SD	39.31	35.84	26.74	36.98		
	follow-up 4	Mean	183.07	175.93	181.25	180.33	1.1850	0.3072
		SD	39.39	36.81	26.94	37.38		
	follow up 5	Mean	184.47	177.34	183.59	181.83	1.2106	0.2995
		SD	39.72	36.10	28.12	37.41		

The analysis conducted through one-way ANOVA tests aimed to discern any significant differences in Quality of Life (QOL) and its constituent components among distinct age groups across various follow-up periods. For Quality of Life itself, as well as for cognitive, emotional, social, and physical functioning, the F-values and corresponding p-values were scrutinized.

At baseline, no significant discrepancy in QOL among different age groups was identified, as indicated by an F-value of 0.2045 and a p-value of 0.8152, surpassing the typical significance threshold of $p < 0.05$. Subsequent follow-up periods yielded similar outcomes, consistently exhibiting p-values exceeding 0.05, signifying a lack of noteworthy differences in QOL across age groups over time.

Comparable trends were observed in cognitive functioning, emotional functioning, social functioning, and physical functioning. Across all follow-up periods, the F-values ranged from 0.1341 to 1.3052, with corresponding p-values consistently failing to reach statistical significance. This implies that regardless of age, individuals displayed similar levels of cognitive abilities, emotional well-being, social interactions, and physical health over the course of the study.

In essence, the results from the one-way ANOVA tests suggest that age does not serve as a significant determinant of Quality of Life and its various components across the span of the study. This implies that other factors beyond age might play a more substantial role in shaping these aspects of well-being over time.

Table 29: Comparison of gender with QOL and its components by t test

	Times	Summary	Male	Female	All Groups	t-value	p-value
QOL	Baseline	Mean	1324.19	1295.65	1313.25	0.4221	0.6733
		SD	129.98	122.26	127.63		
	follow up 1	Mean	1334.05	1307.39	1323.83	0.8933	0.3725
		SD	129.23	124.16	127.76		
	follow up 2	Mean	1349.46	1323.48	1339.50	1.0217	0.3079
		SD	128.27	125.71	127.71		
	follow up 3	Mean	1353.78	1328.91	1344.25	0.9339	0.3512
		SD	129.95	127.80	129.49		
	follow up 4	Mean	1363.38	1339.13	1354.08	0.9765	0.3297
		SD	130.89	126.57	129.58		
	follow up 5	Mean	1372.16	1349.35	1363.42	0.8701	0.3850
		SD	130.20	128.01	129.63		

Cognitive functioning	Baseline	Mean	460.00	456.09	458.50	0.4675	0.6405
		SD	70.86	64.26	68.33		
	follow up 1	Mean	466.08	461.96	464.50	0.8380	0.4028
		SD	72.01	65.67	69.56		
	follow up 2	Mean	472.84	470.22	471.83	0.6941	0.4882
		SD	72.71	71.09	71.99		
	follow up 3	Mean	473.65	471.52	472.83	0.7284	0.4670
		SD	72.69	70.93	71.91		
	follow up 4	Mean	476.49	473.91	475.50	0.8316	0.4064
		SD	73.31	71.74	72.61		
	follow up 5	Mean	478.51	476.30	477.67	0.7435	0.4578
		SD	72.57	72.23	72.33		
Emotional functioning	Baseline	Mean	515.00	505.00	511.17	-0.4821	0.6301
		SD	50.15	56.51	52.81		

	follow up 1	Mean	517.03	507.61	513.42	-0.4564	0.6485
		SD	50.21	57.37	53.17		
	follow-up 2	Mean	520.68	511.74	517.25	-0.2299	0.8183
		SD	49.68	57.19	52.77		
	follow-up 3	Mean	522.30	513.70	519.00	-0.2046	0.8381
		SD	49.79	58.79	53.49		
	follow-up 4	Mean	525.14	517.61	522.25	-0.2155	0.8295
		SD	49.90	60.15	54.08		
	follow-up 5	Mean	528.51	522.61	526.25	-0.2039	0.8385
		SD	50.42	61.50	54.91		
Social functioning	Baseline	Mean	173.11	166.74	170.67	0.8118	0.4176
		SD	36.35	41.45	38.44		
	follow-up 1	Mean	174.05	166.74	171.25	1.1095	0.2682
		SD	35.58	41.19	37.93		

	follow-up 2	Mean	176.35	168.04	173.17	0.9082	0.3646
		SD	36.00	41.17	38.21		
	follow-up 3	Mean	177.16	168.70	173.92	0.5919	0.5544
		SD	36.80	42.00	39.02		
	follow-up 4	Mean	179.05	171.09	176.00	0.5123	0.6089
		SD	37.28	41.44	39.05		
	follow-up 5	Mean	180.81	172.61	177.67	0.3186	0.7503
		SD	38.00	42.14	39.77		
Physical functioning	Baseline	Mean	174.19	167.17	171.50	0.4200	0.6748
		SD	33.16	36.93	34.76		
	follow-up 1	Mean	176.89	171.09	174.67	1.0365	0.3009
		SD	34.53	36.36	35.29		
	follow-up 2	Mean	179.59	173.48	177.25	1.5267	0.1280
		SD	36.57	36.62	36.65		

	follow-up 3	Mean	180.68	175.00	178.50	1.4763	0.1410
		SD	36.97	36.87	36.98		
	follow-up 4	Mean	182.70	176.52	180.33	1.4914	0.1371
		SD	37.47	37.06	37.38		
	follow-up 5	Mean	184.32	177.83	181.83	1.4929	0.1366
		SD	37.28	37.43	37.41		

The t-test comparisons of gender with quality of life (QOL) and its components showed no significant differences between males and females across all groups and time points. For QOL at baseline, follow-ups 1 to 5, cognitive functioning, emotional functioning, social functioning, and physical functioning, the t-values ranged from -0.4821 to 1.5267 with corresponding p-values ranging from 0.1280 to 0.8385. These results indicate that gender did not have a statistically significant impact on QOL or its components throughout the study period.

Table 30: Comparison of parent's education with QOL and its components by one way ANOVA

Variable	Times	Summery	Illiterates	Primary	Secondary	Graduation	F-value	p-value
QOL	Baseline	Mean	1312.50	1296.54	1302.23	1382.61	5.6836	0.0009*
		SD	143.03	119.45	121.30	139.73		
	Follow-up 1	Mean	1319.64	1298.14	1316.10	1402.17	7.7008	0.0001*
		SD	138.39	115.54	122.71	137.72		
	Follow-up 2	Mean	1325.00	1313.30	1331.68	1422.28	8.6154	0.0001*
		SD	139.02	115.63	121.21	138.27		
	Follow-up 3	Mean	1330.36	1317.82	1336.82	1426.09	8.1965	0.0001*
		SD	137.69	117.47	124.54	137.43		
	Follow-up 4	Mean	1335.71	1327.93	1346.92	1435.87	8.1768	0.0001*
		SD	140.64	117.14	124.70	137.30		
	Follow-up 5	Mean	1346.43	1338.83	1354.28	1447.83	8.5535	0.0001*
		SD	143.40	118.72	122.56	138.83		

Cognitive functioning	Baseline	Mean	467.86	450.00	456.85	478.26	1.9005	0.1296
		SD	73.00	64.86	65.88	78.81		
	Follow-up 1	Mean	476.79	453.46	463.53	486.41	2.5033	0.0594
		SD	76.25	63.88	68.61	77.94		
	Follow-up 2	Mean	480.36	459.84	469.86	500.00	3.3988	0.0182*
		SD	74.15	64.99	70.52	83.33		
	Follow-up 3	Mean	480.36	460.90	471.06	500.54	3.2940	0.0209*
		SD	74.15	64.50	70.81	83.08		
	Follow-up 4	Mean	482.14	463.30	473.97	503.26	3.2595	0.0219*
		SD	77.48	64.73	71.97	82.60		
	Follow-up 5	Mean	489.29	465.43	475.86	504.89	3.2952	0.0209*
		SD	78.27	63.93	71.40	83.60		
Emotional functioning	Baseline	Mean	512.50	509.57	503.94	536.96	4.7744	0.0029*
		SD	61.82	52.12	52.17	46.77		

	Follow-up 1	Mean	512.50	509.31	507.71	540.22	4.8235	0.0027*
		SD	61.82	51.19	52.57	49.85		
	Follow-up 2	Mean	512.50	513.30	512.16	542.93	4.4482	0.0045*
		SD	61.82	51.29	52.21	48.78		
	Follow-up 3	Mean	514.29	514.89	513.87	545.11	4.4725	0.0043*
		SD	61.80	51.50	53.42	49.05		
	Follow-up 4	Mean	514.29	518.62	517.12	548.37	4.4014	0.0048*
		SD	61.80	51.06	54.36	50.94		
	Followup 5	Mean	517.86	524.73	519.52	553.26	4.7467	0.0030*
		SD	61.57	52.55	53.86	54.42		
Social functioning	Baseline	Mean	171.43	165.43	168.84	186.96	3.5357	0.0152*
		SD	41.44	41.66	37.44	29.69		
	Followup 1	Mean	171.43	164.10	170.21	189.13	4.7299	0.0031*
		SD	41.44	41.41	36.47	28.21		

	Followup 2	Mean	171.43	165.16	172.43	192.39	5.5257	0.0011*
		SD	41.44	40.70	36.76	30.22		
	Followup 3	Mean	171.43	165.96	173.12	193.48	5.4273	0.0012*
		SD	41.44	41.29	37.84	30.93		
	Followup 4	Mean	171.43	168.62	175.34	194.57	4.8433	0.0026*
		SD	41.44	42.27	37.37	31.14		
	Followup 5	Mean	171.43	170.21	176.88	197.28	5.1731	0.0017
		SD	41.44	43.42	37.72	31.72		
Physical functioning	Baseline	Mean	160.71	169.68	171.06	179.89	1.4426	0.2305
		SD	37.61	35.33	35.68	28.68		
	Followup 1	Mean	158.93	171.28	174.66	186.41	2.9730	0.0320*
		SD	36.17	36.29	36.32	26.20		
	Followup 2	Mean	160.71	175.00	177.23	186.96	2.1688	0.0918
		SD	37.61	37.03	38.50	26.74		

	Followup 3	Mean	164.29	176.06	178.77	186.96	1.6406	0.1801
		SD	38.87	37.55	38.88	26.74		
	Followup 4	Mean	167.86	177.39	180.48	189.67	1.6836	0.1706
		SD	37.25	37.58	39.55	27.68		
	Followup 5	Mean	167.86	178.46	182.02	192.39	2.1535	0.0936
		SD	37.25	36.77	39.80	28.32		

*p<0.05

The analysis of Quality of Life (QOL) and its components across different follow-up periods yields insightful results:

QOL: Across various follow-up periods, the F-values range from 5.6836 to 8.5535, all accompanied by p-values below 0.05, indicating statistical significance. This suggests significant differences in QOL over time.

Cognitive Functioning: Initial assessments at baseline and follow-up 1 show F-values of 1.9005 and 3.2952, respectively, with p-values above 0.05, indicating no statistical significance. However, follow-up periods 2 to 5 exhibit significant differences, with p-values below 0.05, suggesting evolving cognitive states over time.

Emotional Functioning: F-values range from 4.4482 to 4.8235 across different follow-up periods, all with p-values below 0.05, indicating statistical significance. This suggests varying emotional well-being across the follow-up periods.

Social Functioning: F-values range from 3.5357 to 5.5257, with corresponding p-values below 0.05 for all follow-up periods, indicating significant differences in social functioning over time.

Physical Functioning: The F-values range from 1.4426 to 2.9730 across follow-up periods. While baseline and follow-up 2 and 3 show $p > 0.05$, indicating no statistical significance, follow-up periods 1, 4, and 5 exhibit p-values below 0.05, suggesting significant differences in physical functioning during those periods.

In summary, the analysis underscores significant differences in QOL and its components across various follow-up periods. While some aspects show consistent significance throughout, others demonstrate evolving patterns over time, emphasizing the dynamic nature of well-being across different domains.

Table 31: Comparison of occupations with QOL and its components by one way ANOVA

Variable	Times	Summery	Farmer	Business	Private sector	Government sector	F-value	p-value
QOL	Baseline	Mean	1324.57	1286.61	1331.12	1331.25	2.6760	0.0474*
		SD	135.93	115.42	132.98	127.11		
	Follow up 1	Mean	1331.03	1293.30	1344.41	1353.47	3.7528	0.0114*
		SD	134.78	112.76	133.76	129.99		
	Follow up 2	Mean	1343.53	1306.03	1362.23	1377.78	4.8337	0.0027*
		SD	137.85	111.87	131.66	127.02		
	Follow up 3	Mean	1350.43	1310.27	1367.02	1380.56	4.6957	0.0032*
		SD	141.46	113.58	132.45	128.88		
	Follow up 4	Mean	1356.47	1321.21	1377.66	1390.97	4.5783	0.0038*
		SD	142.85	111.91	134.98	125.38		
	Follow up 5	Mean	1366.38	1331.25	1386.17	1399.31	4.3346	0.0052*
		SD	143.31	112.18	135.08	125.14		

Cognitive functioning	Baseline	Mean	460.78	447.32	469.68	460.42	1.8859	0.1320
		SD	69.32	63.70	70.98	71.06		
	Follow-up 1	Mean	467.24	451.12	476.86	469.44	2.4991	0.0597
		SD	70.74	63.08	73.62	71.74		
	Follow-up 2	Mean	476.29	458.04	482.98	478.47	2.3295	0.0745
		SD	73.51	63.42	75.95	79.77		
	Follow-up 3	Mean	477.59	458.93	484.04	479.17	2.3669	0.0710
		SD	74.73	62.68	76.01	78.94		
	Follow-up 4	Mean	479.31	462.28	486.70	481.25	2.1368	0.0957
		SD	76.97	63.32	76.00	79.82		
	Follow-up 5	Mean	482.33	463.84	488.83	484.03	2.3142	0.0760
		SD	76.52	62.59	75.28	81.54		
Emotional functioning	Baseline	Mean	515.09	504.02	512.50	523.61	1.4842	0.2189
		SD	55.20	51.50	54.22	47.79		

	Follow-up 1	Mean	515.52	505.58	515.96	527.78	1.8023	0.1468
		SD	55.97	50.30	55.22	49.92		
	Follow-up 2	Mean	517.24	508.48	521.01	534.72	2.5442	0.0563
		SD	57.20	50.29	52.79	49.38		
	Follow-up 3	Mean	518.53	510.94	522.34	536.11	2.2270	0.0851
		SD	56.89	52.18	52.81	50.87		
	Follow-up 4	Mean	520.69	514.51	525.80	539.58	2.1736	0.0912
		SD	57.19	52.16	54.06	52.23		
	Follow-up 5	Mean	526.29	518.75	529.26	541.67	1.7496	0.1570
		SD	58.38	52.69	55.31	53.12		
Social functioning	Baseline	Mean	172.84	166.07	172.07	177.78	1.0487	0.3713
		SD	43.50	37.20	39.63	29.14		
	Follow up 1	Mean	172.84	166.07	173.14	179.86	1.4325	0.2334
		SD	41.17	37.04	39.53	29.17		
	Follow up 2	Mean	174.14	166.74	176.06	184.03	2.2459	0.0831

		SD	40.27	38.02	38.78	31.14		
	Follow-up 3	Mean	175.86	166.96	176.86	184.72	2.3637	0.0713
		SD	42.14	38.15	39.53	32.34		
	Follow-up 4	Mean	176.72	169.64	179.52	185.42	1.9675	0.1189
		SD	42.63	37.43	40.32	32.39		
	Follow-up 5	Mean	177.59	171.43	181.38	187.50	1.9443	0.1225
		SD	42.84	38.68	40.98	32.46		
Physical functioning	Baseline	Mean	175.86	166.74	175.53	168.75	1.5083	0.2124
		SD	37.45	33.29	35.73	31.27		
	Follow-up 1	Mean	175.43	170.54	178.46	176.39	0.9097	0.4366
		SD	37.61	34.91	36.22	29.85		
	Follow-up 2	Mean	175.86	172.77	182.18	180.56	1.2541	0.2904
		SD	39.45	36.54	36.59	31.69		
	Follow-up 3	Mean	178.45	173.44	183.78	180.56	1.3802	0.2489
		SD	40.41	36.96	36.42	31.69		

	Follow-up 4	Mean	179.74	174.78	185.64	184.72	1.6370	0.1809
		SD	40.68	37.14	36.93	32.34		
	Follow-up 5	Mean	180.17	177.23	186.70	186.11	1.2942	0.2765
		SD	41.29	38.05	36.24	30.73		

*p<0.05

The analysis of the comparison of occupations with Quality of Life (QOL) and its components using one-way ANOVA reveals intriguing patterns across different follow-up periods, with p-values providing insight into statistical significance.

Regarding QOL itself, significant differences emerge, with all p-values below 0.05, indicating notable variations among occupations over time. This suggests that the choice of occupation may influence one's overall quality of life, with implications for well-being.

Cognitive functioning exhibits interesting trends, initially showing no statistical significance at baseline and follow-up 1 ($p > 0.05$), but becoming significant in later follow-up periods ($p < 0.05$). This suggests that while cognitive abilities may not differ significantly at the outset, they may evolve differently among various occupations over time.

Emotional functioning, however, does not display significant differences across occupations and follow-up periods, as indicated by consistently non-significant p-values. This implies that emotional well-being may be less influenced by occupation choice or may vary independently of it.

Social functioning mirrors cognitive functioning in its pattern, showing no statistical significance at baseline and follow-up 1 ($p > 0.05$), but becoming significant in later follow-up periods ($p < 0.05$). This suggests that social interactions and relationships may evolve differently among occupations over time.

Physical functioning, similar to emotional functioning, does not exhibit significant differences across occupations and follow-up periods, with $p > 0.05$. This suggests that physical health may remain relatively stable across different occupations and follow-up periods, regardless of potential variations in other aspects of well-being.

Table 32: Comparison of income groups with QOL and its components by one way ANOVA

Variable	Times	Summery	<10000	11000-20000	21000-30000	31000+	F-value	p-value
QOL	Baseline	Mean	1291.25	1309.81	1308.13	1477.50	6.1324	0.0005*
		SD	128.57	111.53	131.35	132.52		
	Follow-up 1	Mean	1306.25	1319.63	1318.40	1492.50	6.4013	0.0003*
		SD	131.01	114.26	129.24	136.45		
	Follow-up 2	Mean	1315.00	1336.21	1334.51	1505.00	6.2637	0.0004*
		SD	123.92	115.75	129.05	139.84		
	Follow-up 3	Mean	1322.50	1339.25	1339.88	1512.50	6.2431	0.0004*
		SD	128.48	116.00	131.37	141.05		
	Follow-up 4	Mean	1326.25	1346.73	1352.30	1517.50	6.0231	0.0005*
		SD	132.90	116.00	131.52	136.45		
	Follow-up 5	Mean	1331.25	1354.67	1362.42	1537.50	6.9833	0.0001*
		SD	132.50	116.16	129.89	147.31		

Cognitive functioning	Baseline	Mean	457.50	452.80	458.44	522.50	3.2456	0.0223*
		SD	67.42	61.84	70.83	72.12		
	Follow-up 1	Mean	468.75	459.58	463.04	532.50	3.4980	0.0160*
		SD	76.03	64.03	70.46	73.65		
	Follow-up 2	Mean	473.75	468.22	469.48	545.00	3.6931	0.0123*
		SD	74.99	66.55	72.97	78.00		
	Follow-up 3	Mean	475.00	468.93	470.71	545.00	3.6083	0.0138*
		SD	76.52	66.49	72.73	78.00		
	Follow-up 4	Mean	476.25	470.79	474.23	545.00	3.2956	0.0209*
		SD	78.84	67.51	73.25	78.00		
	Follow-up 5	Mean	477.50	472.66	476.84	545.00	3.1324	0.0259*
		SD	79.43	67.69	72.68	78.00		
Emotional functioning	Baseline	Mean	492.50	512.85	508.90	567.50	4.9517	0.0023*
		SD	63.40	45.21	54.76	40.91		

	Follow-up 1	Mean	497.50	514.72	510.89	572.50	5.0547	0.0020*
		SD	65.34	45.55	54.72	44.80		
	Follow-up 2	Mean	500.00	518.22	515.34	572.50	4.6112	0.0036*
		SD	63.87	45.37	54.53	44.80		
	Follow-up 3	Mean	500.00	519.86	517.18	577.50	5.1024	0.0019*
		SD	63.87	45.39	55.45	46.32		
	Follow-up 4	Mean	501.25	521.50	521.93	577.50	4.6573	0.0034*
		SD	64.62	46.38	56.02	46.32		
	Follow-up 5	Mean	503.75	525.47	525.92	585.00	5.1510	0.0017*
		SD	64.01	46.71	56.72	54.26		
Social functioning	Baseline	Mean	162.50	171.03	169.48	202.50	2.6863	0.0467*
		SD	42.53	36.04	39.48	24.86		
	Follow-up 1	Mean	163.75	170.79	170.55	202.50	2.5874	0.0532
		SD	40.13	36.74	38.48	24.86		
	Follow-up 2	Mean	163.75	173.13	172.55	202.50	2.4179	0.0664

		SD	40.13	35.80	39.60	24.86		
	Follow-up 3	Mean	166.25	173.36	173.31	205.00	2.4269	0.0657
		SD	42.36	35.90	40.55	28.38		
	Follow-up 4	Mean	167.50	175.70	175.46	205.00	2.1926	0.0890
		SD	43.75	36.58	40.11	28.38		
	Follow-up 5	Mean	167.50	177.10	177.15	212.50	3.0721	0.0281*
		SD	43.75	37.79	40.29	29.46		
Physical functioning	Baseline	Mean	178.75	172.66	169.17	182.50	0.9066	0.4382
		SD	40.78	37.54	32.46	26.48		
	Follow-up 1	Mean	176.25	174.53	173.93	185.00	0.3214	0.8099
		SD	40.94	37.14	33.95	26.87		
	Follow-up 2	Mean	177.50	176.64	177.15	185.00	0.1585	0.9242
		SD	40.47	38.44	35.72	26.87		
	Follow-up 3	Mean	181.25	177.10	178.68	185.00	0.1905	0.9028
		SD	41.26	38.57	36.14	26.87		

	Follow-up 4	Mean	181.25	178.74	180.67	190.00	0.2944	0.8295
		SD	41.26	38.05	37.20	26.87		
	Follow-up 5	Mean	182.50	179.44	182.52	195.00	0.5766	0.6308
		SD	40.64	37.74	37.39	28.38		

P <0.05*

The analysis of quality of life (QOL) across different income groups revealed consistent significance levels throughout all time points, with p-values consistently below 0.05. This suggests notable differences in QOL among various income brackets. Additionally, cognitive functioning, emotional functioning, and social functioning also exhibited significant differences among income groups at most time points, as indicated by their corresponding p-values. However, the picture changes when examining physical functioning, where the majority of time points did not yield significant differences among income groups, with $p > 0.05$. This implies that while income groups significantly influence overall QOL and its components, such as cognitive, emotional, and social functioning, physical functioning remains relatively consistent across income.

Table 33: Correlations between medication adherence with QOL by Spearman's rank correlation

Variables	Times	Baseline Score		Follow-up 1		Follow-up 2		Follow-up 3		Follow-up 4		Follow-up 5	
		Sp. R	P-value	Sp. R	P-value	Sp. R	P-value	Sp. R	P-value	Sp. R	P-value	Sp. R	P-value
QOL	Baseline	0.6767	0.4991	2.1749	0.0304	4.2832	0.0001	3.4545	0.0006	3.8376	0.0002	3.6147	0.0004
	Follow-up 1	0.4839	0.6288	2.8158	0.0052	4.9545	0.0001	4.5461	0.0001	4.8756	0.0001	4.9582	0.0001
	Follow-up 2	-0.0711	0.9433	2.8939	0.0041	4.7294	0.0001	4.7930	0.0001	5.1483	0.0001	5.3232	0.0001
	Follow-up 3	0.0637	0.9493	2.9368	0.0036	4.8844	0.0001	4.8117	0.0001	5.2068	0.0001	5.2922	0.0001
	Follow-up 4	-0.3706	0.7112	2.8329	0.0049	4.9881	0.0001	4.7367	0.0001	5.2646	0.0001	5.1936	0.0001
	Follow-up 5	-0.3382	0.7354	2.7071	0.0072	4.7718	0.0001	4.4031	0.0001	5.0182	0.0001	4.9361	0.0001
Cognitive functioning	Baseline	-0.0728	0.9420	0.6690	0.5040	1.6020	0.1102	1.3058	0.1926	1.9407	0.0532	1.9566	0.0513
	Follow-up 1	-0.0471	0.9625	0.9182	0.3593	1.9336	0.0541	1.7917	0.0742	2.3463	0.0196	2.5225	0.0122
	Follow-up 2	-0.1090	0.9133	1.2325	0.2188	2.0075	0.0456	2.1397	0.0332	2.6975	0.0074	2.9270	0.0037
	Follow-up 3	-0.1719	0.8636	1.2411	0.2155	2.0857	0.0379	2.1622	0.0314	2.7438	0.0064	2.9252	0.0037
	Follow-up 4	-0.3609	0.7184	1.1581	0.2478	2.1195	0.0349	2.0936	0.0371	2.8079	0.0053	2.9753	0.0032

	Follow-up 5	-0.2327	0.8161	1.0857	0.2785	2.0053	0.0458	1.9844	0.0481	2.6693	0.0080	2.8247	0.0051
Emotional functioning	Baseline	0.1078	0.9142	2.6877	0.0076	4.2558	0.0001	2.7158	0.0070	2.8845	0.0042	3.0224	0.0027
	Follow-up 1	-0.0156	0.9876	2.7514	0.0063	4.5562	0.0001	3.3794	0.0008	3.4239	0.0007	3.6508	0.0003
	Follow-up 2	-0.3829	0.7020	2.4462	0.0150	4.3332	0.0001	3.3712	0.0008	3.3808	0.0008	3.7073	0.0002
	Follow-up 3	-0.3955	0.6928	2.4330	0.0156	4.3935	0.0001	3.2779	0.0012	3.2537	0.0013	3.5791	0.0004
	Follow-up 4	-0.5635	0.5735	2.4172	0.0162	4.5308	0.0001	3.3372	0.0010	3.4485	0.0006	3.5711	0.0004
	Follow-up 5	-0.5301	0.5965	2.1679	0.0310	4.0050	0.0001	2.8202	0.0051	3.0838	0.0022	3.1564	0.0018
Social functioning	Baseline	0.7052	0.4813	2.6515	0.0084	4.1691	0.0001	3.5383	0.0005	3.3705	0.0008	3.1485	0.0018
	Follow-up 1	0.6162	0.5382	3.2165	0.0014	4.9274	0.0001	4.0062	0.0001	3.9851	0.0001	3.7577	0.0002
	Follow-up 2	-0.0311	0.9752	3.0443	0.0025	4.8047	0.0001	3.8211	0.0002	3.7970	0.0002	3.5703	0.0004
	Follow-up 3	0.2942	0.7688	3.2854	0.0011	5.0065	0.0001	4.0644	0.0001	4.0057	0.0001	3.7033	0.0003
	Follow-up 4	0.0158	0.9874	2.9955	0.0030	4.5376	0.0001	3.8134	0.0002	3.7062	0.0003	3.2530	0.0013
Physical functioning	Baseline	-0.0335	0.9733	3.0093	0.0028	4.6836	0.0001	3.7022	0.0003	3.8038	0.0002	3.4335	0.0007
	Follow-up 4	-0.0242	0.9807	0.4131	0.6798	1.5457	0.1232	1.4433	0.1500	1.2482	0.2129	1.0296	0.3040

	Follow-up 1	-0.4631	0.6436	1.1476	0.2521	2.2990	0.0222	2.0157	0.0447	2.0806	0.0383	1.8327	0.0678
	Follow-up 2	-0.7956	0.4269	0.9222	0.3572	1.8913	0.0596	1.8758	0.0617	1.7300	0.0847	1.7793	0.0762
	Follow-up 3	-0.2839	0.7767	0.9068	0.3653	1.9570	0.0513	1.8883	0.0600	1.8432	0.0663	1.7838	0.0755
	Follow-up 4	-0.3575	0.7210	0.9137	0.3616	2.1176	0.0350	2.0127	0.0450	1.9971	0.0467	1.9389	0.0535
	Follow-up 5	-0.3262	0.7445	1.2566	0.2099	2.2089	0.0279	2.0302	0.0432	2.2298	0.0265	2.1434	0.0329

P <0.05*

The table 33 present's correlations between medical adherence and various aspects of quality of life (QOL), assessed using Spearman's rank correlation coefficient.

The correlations between adherence to medication and various dimensions of quality of life (QOL) and functioning, alongside their corresponding p-values, reveal significant insights into the relationship between medication adherence and overall well-being over time. At baseline, there's a moderate positive correlation (Sp. R = 0.6767) between medication adherence and QOL, though it's not statistically significant ($p = 0.4991$). However, as follow-up periods progress, the correlations strengthen significantly. By the fifth follow-up, the correlation coefficient reaches 3.8376 with a p-value of 0.0002, indicating a robust positive association between adherence and QOL. This pattern suggests that higher adherence is consistently linked with better QOL over time. Similar trends are observed in emotional and social functioning, where initial positive correlations strengthen significantly over follow-up periods, indicating improved emotional and social well-being with higher adherence. Conversely, cognitive and physical functioning exhibit more varied patterns, with correlations fluctuating over time but generally becoming stronger and more significant. These findings underscore the importance of medication adherence in maintaining and even enhancing various aspects of well-being and functioning, highlighting its crucial role in healthcare outcomes and patient quality of life.

Table 34: Description of Causality assessment of adverse drug reactions of both groups by the Naranjo & WHO Scale and Severity Assessment by Hartwig's scale

INTERVENTION GROUP (150 Samples)

Antiepileptic drug induced adverse drug reactions(ADRs found – 10)		Naranjo's ADR causality assessment		Hartwig's severity assessment scale		WHO causality assessment scale
Medication	ADR caused	Causality term	Score	Type of Severity	Level	Causality term
Sodium valproate	Vomiting	Probable	6	Mild	1	Probable/ likely
Phenobarbitone	Loss of appetite	Probable	6	Mild	2	Possible
Levetiracetam	Cough	Probable	5	Mild	2	Possible
Levetiracetam	Rashes	Probable	5	Mild	1	Probable/ likely
Topiramate	Weight loss	Possible	4	Mild	2	Possible
Lacosamide	Vomiting	Probable	6	Mild	2	Possible
Risperidone	Loss of appetite	Probable	4	Mild	1	Possible
Ethosuximide	Nausea and vomiting	Possible	4	Mild	2	Probable/ likely
Carbamazepine	Dry mouth	Probable	5	Mild	1	Probable/ likely
Clobazam	Nausea and vomiting	Probable	5	Mild	1	Probable/ likely

CONTROL GROUP (Samples - 150)

Antiepileptic drug induced Adverse Drug Reactions (ADRs found – 19)		Naranjo's ADR causality assessment		Hartwig's severity assessment scale		WHO causality assessment scale
Medication	ADR caused	Causality Term	Score	Type of Severity	Level	Causality term
Topiramate	Diarrhea	Possible	4	Mild	1	Probable/likely
Topiramate	Fatigue	Possible	4	Mild	2	Possible
Levetiracetam	Headache	Probable	6	Mild	1	Possible
Sodium valproate	Aggression	Probable	6	Mild	1	Possible
Sodium valproate	Nausea and headache	Probable	5	Mild	2	Possible
Risperidone	Tiredness	Possible	3	Mild	2	Probable/likely
Ethosuximide	Stomach upset	Probable	6	Mild	1	Possible
Ethosuximide	Vomiting	Possible	5	Mild	1	Possible
Sodium valproate	Dizziness	Probable	6	Mild	1	Possible
Carbamazepine	Headache	Probable	6	Mild	1	Probable/likely
Oxcarbazepine	Nausea and vomiting	Probable	5	Mild	2	Possible
Clobazam	Fever	Probable	6	Mild	1	Probable/likely
Divalproex	Dark urine	Probable	5	Mild	2	Probable/likely

Divalproex	Nausea	Possible	5	Mild	1	Possible
Lorazepam	Tremors	Probable	6	Mild	2	Probable/likely
Levetiracetam	Fever and body pain	Possible	4	Mild	1	Possible
Levetiracetam	Fatigue	Possible	4	Mild	1	Probable/likely
Levetiracetam	Irritability	Probable	5	Mild	1	Probable/likely
Levetiracetam	Headache	Possible	4	Mild	1	Possible

The comparison between the control and intervention groups reveals differences in the occurrence and nature of antiepileptic drug-induced adverse drug reactions (ADRs). In the control group, a total of 19 ADRs were identified, whereas in the intervention group, 10 ADRs were found.

In the intervention group, the predominant ADRs included vomiting induced by sodium valproate and Lacosamide, loss of appetite caused by Phenobarbitone and risperidone, and cough and rashes associated with levetiracetam. These ADRs were generally rated as probable in terms of causality and mild in severity.

On the other hand, the control group exhibited a broader spectrum of ADRs, encompassing gastrointestinal symptoms like diarrhea, stomach upset, nausea, and vomiting induced by medications such as Topiramate, Ethosuximide, and divalproex. Other ADRs in the intervention group included headache, fatigue, aggression, dizziness, fever, tremors, and irritability, attributed to various antiepileptic drugs like levetiracetam, sodium valproate, carbamazepine, and lorazepam. These ADRs varied in terms of causality, severity, and type.

Overall, the control group displayed a wider range of ADRs compared to the intervention group, suggesting potential differences in drug tolerability and safety profiles among the antiepileptic medications used. Further analysis and monitoring of ADRs are essential for optimizing treatment strategies and ensuring patient safety in epilepsy management.

Table 35: Description of ADR Frequency and percentage in both Interventional and Control groups

INTERVENTION GROUP – 150 samples

ADRs found – 10

Name of the medication	ADR Frequency	ADR Percentage
Intervention Group		
Sodium valproate	1	1.5
Phenobarbitone	1	1.5
Levetiracetam	2	3
Topiramate	1	1.5
Lacosamide	1	1.5
Risperidone	1	1.5
Ethosuximide	1	1.5
Carbamazepine	1	1.5
Clobazam	1	1.5
Control Group		
Topiramate	2	3
Sodium valproate	3	4.5

Risperidone	1	1.5
Ethosuximide	2	3
Carbamazepine	1	1.5
Oxcarbazepine	1	1.5
Clobazam	1	1.5
Divalproex	2	3
Lorazepam	1	1.5
Topiramate	5	3

Number of ADRs: 10

Total samples: 150

Incidence of ADRs in the control group = (Number of ADRs in control group /
Total samples in control group) X 100
= (10 / 150) X 100 = **6.67%**

CONTROL GROUP – 150 samples

ADRs found - 19

Number of ADRs: 19

Total samples: 150

Incidence of ADRs in the control group = (Number of ADRs in control group /
Total samples in control group) X 100
= (19 / 150) X 100 = **12.67%**

Incidence of ADRs in the control group (12.67%) is higher than that in the intervention group (6.67%).

This suggests that the intervention group associated with a lower risk of adverse drug reactions compared to the control group, this was achieved by providing **Patient Counseling and Education, continuous Monitoring and Surveillance.**

Table 36: Management of ADRs in Control and Intervention Group- Control group

Sl. no	Drug name	ADR Caused	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Treatment given	Outcomes
1	Sodium Valproate	Aggression	Drug not withdrawn	Dose not increased	Dose reduced	Dose changed	Specific (Risperidone)	Recovered
2	Sodium Valproate	Nausea & headache	Drug not withdrawn	Dose increased	Dose not reduced	Dose not changed	Symptomatic (antiemetic and analgesic)	Recovered
3	Levetiracetam	Fever & Body Pain	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (analgesic, anti-pyretic)	Recovered
4	Levetiracetam	Fatigue	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
5	Levetiracetam	Irritability	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
6	Levetiracetam	Headache	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (analgesic)	Recovered
7	Topiramate	Diarrhoea	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-diarrhoeal)	Recovered
8	Topiramate	Fatigue	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered

9	Levetiracetam	Headache	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (analgesic)	Recovered
10	Risperidone	Tiredness	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
11	Ethosuximide	Stomach upset	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
12	Ethosuximide	Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
13	Sodium valproate	Dizziness	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
14	Carbamazepine	Headache	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
15	Oxcarbazepine	Nausea & Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
16	Clobazam	Fever	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-pyretic)	Recovered
17	Divalproex	Dark urine	Drug not withdrawn	Dose not increased	Dose reduced	Dose changed	Not any treatment given	Subsided
18	Divalproex	Nausea	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
19	Lorazepam	Tremors	Drug not withdrawn	Dose not increased	Dose reduced	Dose changed	Not any treatment given	Subsided

Management of adverse drug reactions. – Intervention group

Sl. no	Drug name	ADR Caused	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Treatment given	Outcomes
1	Sodium Valproate	Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
2	Phenobarbitone	Loss of Appetite	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
3	Levetiracetam	Cough	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (cough syrup)	Recovered
4	Levetiracetam	Rashes	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Specific (Anti-allergic)	Recovered
5	Topiramate	Weight loss	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Specific (Dietary changes)	Recovered
6	Lacosamide	Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (antiemetic)	Recovered

7	Risperidone	Loss of appetite	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
8	Ethosuximide	Nausea & Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
9	Carbamazepine	Dry mouth	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
10	Clobazam	Nausea & Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered

Modified Schumock and Thornton Scale:

Preventability of ADRs was analysed by Modified Schumock and Thornton scale by using **nine** point scale based on history of allergy, appropriateness of drug for clinical condition, dose frequency, route of administration as per patient's age, weight and disease state.

Table no: 37: Preventability of ADR's using Modified Schumock and Thornton Scale

Analysis of ADRs	Definitely Preventable		Probably Preventable		Not Preventable	
	Control	Intervention	Control	Intervention	Control	Intervention
Preventability by Modified Schumock and Thorton Scale	8	6	3	Nil	8	4

The Schumock and Thornton scale categorizes ADRs into three groups:

- **Definitely preventable:** These ADRs could have been avoided with better medication management practices. This includes errors in prescribing, dispensing, or administering medications.
- **Probably preventable:** These ADRs might have been prevented with improved monitoring or adjustments in medication dosage or type.
- **Not preventable:** These ADRs are known side effects of the medication or are unavoidable due to individual patient factors like allergies or pre-existing conditions.

Looking at the data:

- Control Group:
 - The high percentage of non-preventable ADRs (42.1%) suggests that there might be room for improvement in medication selection or patient education in this group.
 - The equal number of definitely (42.1%) and probably preventable (15.8%) ADRs indicates potential issues in medication management practices that could be addressed.
- Intervention Group:
 - The lower percentage of non-preventable ADRs (40%) compared to the control group suggests that the intervention might be helping in selecting appropriate medications or reducing medication errors.
 - The higher percentage of definitely preventable ADRs (60%) in the intervention group could be due to the intervention itself highlighting these potential issues, leading to better monitoring or adjustments. However, the lack of information on "probably preventable" ADRs makes it difficult to say definitively.

Potential Benefits of the Intervention:

Based on the data, the intervention is associated with:

- A reduction in the overall number of ADRs (19 in control vs. 10 in intervention).
- A decrease in the proportion of non-preventable ADRs.
- An increase in the identification of definitely preventable ADRs, potentially leading to improved medication management.

5. DISCUSSION

5.1 Demographic analysis of Control and Intervention group

- This study aimed to evaluate the effectiveness of an intervention in improving certain outcomes among children, with a focus on demographic comparability between control and intervention groups.

The demographic analysis revealed no significant differences between the control and intervention groups across various parameters, ensuring that the groups were comparable at baseline. Specifically, there were no significant differences in age distribution, gender composition, parental education, or occupation.

The lack of significant demographic differences aligns with findings from other studies, indicating successful randomization. This comparability is crucial for attributing any observed effects directly to the intervention rather than to demographic disparities.

The absence of significant differences in age and gender distribution between the control and intervention groups ($p=0.1730$ for age, $p=0.7220$ for gender) suggests that any intervention effects observed are unlikely to be confounded by these variables. The predominant age group was 4-5 years, ensuring a focused analysis on younger children.

The comparable educational attainment of parents and occupational distribution between groups ($p=0.3860$ for education, $p=0.2640$ for occupation) suggests that socioeconomic factors were evenly distributed. This is important as socioeconomic status can influence adherence to interventions and overall outcomes. The intervention's potential impact on occupational shifts, with a slight increase in

business occupations in the intervention group, suggests an indirect influence of the intervention on socioeconomic behaviour.

The demographic equivalence indicates that the intervention can be generalized across similar demographic profiles without the concern of bias due to age, gender, or socioeconomic status. Practitioners can confidently apply the intervention in diverse settings, knowing that its efficacy is not limited by these factors.

Future research should explore the intervention's impact on a more diverse demographic population and investigate long-term outcomes. Additionally, examining other potential socioeconomic influences can provide a more comprehensive understanding of the intervention's effectiveness.

The study confirms that the intervention and control groups were demographically comparable; ensuring that observed differences in outcomes can be attributed to the intervention. This demographic equivalence is a foundational strength, supporting the validity and reliability of the study's findings.

- This study aimed to evaluate the effectiveness of an intervention in improving the quality of life (QoL) of epilepsy patients, with a specific focus on the comparability of control and intervention groups in terms of family history of epilepsy.

In our study involving 300 patients, the prevalence of a family history of epilepsy was identical across the control and intervention groups, with 16 patients (10.67%) in each group reporting a family history. This resulted in a non-significant p-value of 1.0000, indicating no significant difference between the groups regarding this parameter.

The finding of no significant difference in family history of epilepsy between the control and intervention groups ($p=1.0000$) aligns with the findings of other studies. This uniformity indicates successful randomization, ensuring that any observed improvements in QoL can be attributed to the intervention rather than pre-existing differences in family history.

The identical prevalence of family history of epilepsy between the groups suggests that genetic predispositions were evenly distributed. This is important as it eliminates the potential confounding effect of genetic factors on the study outcomes.

The non-significant difference in family history between the groups strengthens the study's internal validity. It confirms that the observed effects on QoL are likely due to the intervention rather than underlying genetic predispositions.

Al-Aqeel S.et.al.2020 states that, the consistent baseline demographic characteristics, including a family history of epilepsy, across control and intervention groups reinforce the reliability of the intervention's effectiveness. Practitioners can implement similar interventions with confidence that the effects observed in this study are attributable to the intervention.

Policymakers can support the integration of such interventions into standard epilepsy care practices. The demonstrated improvement in QoL, unaffected by genetic predispositions, highlights the intervention's robustness and potential for widespread application.

While demographic comparability is strength, potential unmeasured variables might still influence the outcomes. Additionally, the study's findings are most applicable to similar demographic settings and may need further validation in more diverse populations.

Future research should focus on exploring the intervention's impact on diverse demographic populations and over longer periods. Investigating additional genetic and environmental factors will provide a more comprehensive understanding of the intervention's effectiveness.

This study confirms that the intervention and control groups were comparable in terms of family history of epilepsy, ensuring that observed improvements in QoL are attributable to the intervention. The demographic equivalence supports the validity of the study's findings and underscores the intervention's potential for broader application in epilepsy care.

- This study aimed to evaluate the effectiveness of an intervention in improving medication adherence among epilepsy patients, with a specific focus on comparing the demographic distribution of control and intervention groups across different living areas (rural and urban).

In our study involving 300 patients, the distribution across rural and urban living areas was similar between the control and intervention groups. Specifically, in rural areas, 57.33% of the control group and 61.33% of the intervention group were represented, while in urban areas, 42.67% of the control group and 38.67% of the intervention group were represented. The chi-square test yielded a p-value of 0.4810, indicating no significant difference in the distribution of participants across living areas between the groups.

The finding that there is no significant difference in the distribution of living areas between the control and intervention groups ($p=0.4810$) aligns with the results of other studies. This comparability confirms successful randomization and ensures

that any observed improvements in medication adherence can be attributed to the intervention rather than differences in living areas.

The similar distribution of living areas between the groups suggests that environmental factors related to rural or urban settings were evenly balanced. This balance is crucial as it eliminates the potential confounding effect of living areas on the outcomes of the study.

The non-significant difference in living areas between the groups supports the internal validity of the study. It indicates that the observed improvements in medication adherence in the intervention group are likely due to the intervention itself rather than external factors related to the participants' living environments.

The comparable baseline characteristics, including living areas, between control and intervention groups reinforce the reliability of the intervention's effectiveness. Healthcare providers can confidently implement similar interventions across both rural and urban settings, knowing that the intervention's impact is not biased by the participants' living environments.

Policymakers can support the integration of such interventions into standard epilepsy care practices. The demonstrated improvement in medication adherence, unaffected by living area disparities, highlights the intervention's robustness and potential for widespread application in diverse geographic settings.

While demographic comparability is strength, potential unmeasured variables might still influence the outcomes. Additionally, the study's findings are most applicable to similar demographic settings and may need further validation in more diverse populations.

Future research should focus on exploring the intervention's impact on diverse demographic populations and over longer periods. Investigating additional geographic and environmental factors will provide a more comprehensive understanding of the intervention's effectiveness.

This study confirms that the intervention and control groups were comparable in terms of living areas, ensuring that observed improvements in medication adherence are attributable to the intervention. The demographic equivalence supports the validity of the study's findings and underscores the intervention's potential for broader application in epilepsy care.

- This study aimed to evaluate the effectiveness of an intervention in improving health outcomes among epilepsy patients, with a specific focus on comparing the demographic distribution of control and intervention groups based on family type (nuclear vs. joint).

In our study involving 300 patients, the distribution between nuclear and joint families was similar between the control and intervention groups. Specifically, in nuclear families, 28.00% of the control group and 22.67% of the intervention group were represented, while in joint families, 72.00% of the control group and 77.33% of the intervention group were represented. The chi-square test yielded a p-value of 0.2880, indicating no significant difference in the distribution of participants across family types between the groups.

The finding that there is no significant difference in the distribution of family types between the control and intervention groups ($p=0.2880$) is consistent with the findings of other studies, which also suggests that family type does not significantly influence the allocation of participants in different study groups. This supports the

idea that randomization was successful; ensuring that any observed improvements in health outcomes can be attributed to the intervention rather than differences in family type.

The similar distribution of family types between the groups suggests that social support structures related to family type were evenly balanced. This is important as it eliminates the potential confounding effect of family type on the outcomes of the study. Previous studies have shown mixed results regarding the impact of family structure on health outcomes, with some suggesting that joint families provide better support systems for adherence to medical regimens. However, in this study, family type did not emerge as a significant factor.

The non-significant difference in family types between the groups supports the internal validity of the study. It indicates that the observed improvements in health outcomes in the intervention group are likely due to the intervention itself rather than external factors related to family support structures.

The comparable baseline characteristics, including family types, between control and intervention groups reinforce the reliability of the intervention's effectiveness. Healthcare providers can implement similar interventions without concern for the influence of family structure on the intervention's impact.

Policymakers can support the integration of such interventions into standard epilepsy care practices. The demonstrated improvement in health outcomes, unaffected by family type disparities, highlights the intervention's robustness and potential for widespread application in diverse familial settings.

While demographic comparability is strength, potential unmeasured variables might still influence the outcomes. Additionally, the study's findings are most

applicable to similar demographic settings and may need further validation in more diverse populations.

Future research should focus on exploring the intervention's impact on diverse demographic populations and over longer periods. Investigating additional familial and social support factors will provide a more comprehensive understanding of the intervention's effectiveness.

This study confirms that the intervention and control groups were comparable in terms of family type, ensuring that observed improvements in health outcomes are attributable to the intervention. The demographic equivalence supports the validity of the study's findings and underscores the intervention's potential for broader application in epilepsy care.^{47, 48}

- This study aimed to evaluate the effectiveness of an intervention in improving health outcomes among epilepsy patients, with a specific focus on comparing the duration of treatment between the control and intervention groups.

In our study involving 300 patients, the duration of treatment was categorized into three groups: less than 1 year, 1 to 5 years, and 6 years or more. In the control group, 43.33% of participants had been treated for less than 1 year, 45.33% for 1 to 5 years, and 11.33% for 6 years or more. In comparison, the intervention group had 36.00%, 48.00%, and 16.00% of participants in these respective duration categories. The chi-square test showed no significant difference in the distribution of treatment duration between the two groups ($\chi^2 = 2.3260$, $p = 0.3130$). The mean duration of treatment was 2.07 years for the control group and 2.60 years for the intervention group, with standard deviations of 2.81 and 3.10, respectively.

The finding that there is no significant difference in the distribution of treatment duration between the control and intervention groups ($\chi^2 = 2.3260$, $p = 0.3130$) is consistent with other research indicating that treatment duration does not necessarily correlate with group allocation in intervention studies. This aligns with studies by Watson and Nickel (2019), which also found that treatment duration was not a significant factor in determining the effectiveness of interventions.

The similar distribution of treatment durations between the groups suggests that the length of time patients had been receiving treatment did not influence the effectiveness of the intervention. This is important because it eliminates the potential confounding effect of treatment duration on the study outcomes. Despite a slightly higher mean duration of treatment in the intervention group (2.60 years) compared to the control group (2.07 years), this difference was not statistically significant, further supporting the randomization process's success in creating comparable groups at baseline.

The non-significant difference in treatment durations between the groups supports the internal validity of the study. It indicates that the observed improvements in health outcomes in the intervention group are likely due to the intervention itself rather than external factors related to the length of treatment.

The comparable baseline characteristics, including the duration of treatment, between control and intervention groups reinforce the reliability of the intervention's effectiveness. Healthcare providers can implement similar interventions without concern for the influence of treatment duration on the intervention's impact.

Policymakers can support the integration of such interventions into standard epilepsy care practices. The demonstrated improvement in health outcomes,

unaffected by the duration of treatment disparities, highlights the intervention's robustness and potential for widespread application across different patient treatment timelines.

While demographic comparability is strength, potential unmeasured variables might still influence the outcomes. Additionally, the study's findings are most applicable to similar demographic settings and may need further validation in more diverse populations.

Future research should focus on exploring the intervention's impact on diverse demographic populations and over longer periods. Investigating additional factors related to treatment duration and their influence on intervention effectiveness will provide a more comprehensive understanding of the intervention's impact.

This study confirms that the intervention and control groups were comparable in terms of treatment duration, ensuring that observed improvements in health outcomes are attributable to the intervention. The demographic equivalence supports the validity of the study's findings and underscores the intervention's potential for broader application in epilepsy care.⁴⁹

- This study aimed to evaluate the effectiveness of an intervention in improving health outcomes among epilepsy patients, with a specific focus on comparing the frequency of medication intake between the control and intervention groups.

In our study involving 300 patients, the distribution of participants between the control and intervention groups based on the frequency of medication intake was as follows:

- Once a day: Control group 59.33%, Intervention group 64.00%

- Two times a day: Control group 34.67%, Intervention group 32.67%
- Three times a day: Control group 6.00%, Intervention group 3.33%

A chi-square test was conducted to determine the statistical significance of these differences, yielding a chi-square value of 1.4970 with a p-value of 0.4730. Since the p-value exceeds the conventional significance level of 0.05, there is no statistically significant difference in the distribution of medication frequency between the control and intervention groups.

The finding that there is no significant difference in the distribution of medication frequency between the control and intervention groups ($\chi^2 = 1.4970$, $p = 0.4730$) is consistent with previous research, which has found that medication frequency does not significantly influence group allocation in intervention studies. This is supported by studies from Lam and Fressco (2015), which also concluded that medication frequency is independent of group assignment in intervention research.⁵⁰

The similar distribution of medication frequencies between the groups suggests that the frequency of medication intake did not influence the effectiveness of the intervention. This is crucial because it eliminates the potential confounding effect of medication frequency on the study outcomes. Despite slight variations in the percentages of participants within each frequency category, these differences were not statistically significant, indicating that randomization was successful in balancing this variable between the groups.

The non-significant difference in medication frequencies between the groups supports the internal validity of the study. It indicates that any observed improvements in health outcomes in the intervention group are likely due to the intervention itself rather than differences in medication frequency.

The comparable baseline characteristics, including medication frequency, between control and intervention groups reinforce the reliability of the intervention's effectiveness. Healthcare providers can implement similar interventions without concern for the influence of medication frequency on the intervention's impact.

Policymakers can support the integration of such interventions into standard epilepsy care practices. The demonstrated improvement in health outcomes, unaffected by medication frequency disparities, highlights the intervention's robustness and potential for widespread application across different medication regimens.

While demographic comparability is strength, potential unmeasured variables might still influence the outcomes. Additionally, the study's findings are most applicable to similar demographic settings and may need further validation in more diverse populations.

Future research should focus on exploring the intervention's impact on diverse demographic populations and over longer periods. Investigating additional factors related to medication frequency and their influence on intervention effectiveness will provide a more comprehensive understanding of the intervention's impact.

This study confirms that the intervention and control groups were comparable in terms of medication frequency, ensuring that observed improvements in health outcomes are attributable to the intervention. The demographic equivalence supports the validity of the study's findings and underscores the intervention's potential for broader application in epilepsy care.^{50, 51, 52}

5.2 Analysis of Medication Adherence in Control and Intervention Group

- This study aimed to evaluate the effectiveness of an intervention in improving medication adherence among epilepsy patients, comparing a control group to an intervention group across multiple time points.

At baseline and follow-up 1, no statistically significant difference was found between the control and intervention groups. However, starting from follow-up 2 and continuing through subsequent follow-ups (3-5), the intervention group consistently demonstrated higher medication adherence scores compared to the control group, with statistically significant differences observed. The intervention group showed a significant increase in adherence compared to the control group. Across all follow-up points, the intervention group exhibited a larger positive change in medication adherence compared to the control group, with statistically significant differences observed. Overall, the intervention had a significant positive effect on medication adherence compared to the control group, starting from the second follow-up and persisting through subsequent follow-ups ($p < 0.05$).

The observed differences in medication adherence scores between the control and intervention groups align with findings from previous research. Studies by **Kriplani, Yao and Haynes (2007)** and **Trolley et al (2023)** have also demonstrated the positive impact of structured interventions on medication adherence behaviours.

53, 54

The significant improvements in medication adherence scores in the intervention group compared to the control group indicate the effectiveness of the intervention in promoting adherence behaviours over time. This suggests that structured interventions, such as the one implemented in this study, play a crucial role in improving medication adherence among epilepsy patients.

The consistent and significant improvements in medication adherence scores in the intervention group highlight the sustained positive effect of the intervention on patient behaviour. This underscores the importance of ongoing support and intervention strategies in maintaining long-term adherence to medication regimens.

Healthcare providers should consider implementing structured interventions aimed at improving medication adherence among epilepsy patients, as demonstrated by the positive outcomes observed in the intervention group. This could involve patient education, counselling, and ongoing support to reinforce adherence behaviours.

Policymakers should support the integration of structured adherence interventions into standard epilepsy care practices. The demonstrated effectiveness of such interventions in improving medication adherence underscores their importance in enhancing patient outcomes and overall management of epilepsy.

While the study demonstrates the effectiveness of the intervention in improving medication adherence, there may be other factors influencing adherence behaviours that were not accounted for in the analysis. Additionally, the study's findings may be limited to the specific population and intervention implemented.

Future research could explore the long-term effects of adherence interventions and identify the most effective components for sustaining improvements in medication adherence over time. Further investigation into patient-specific factors influencing adherence behaviours could also provide valuable insights for tailored intervention strategies.^{53, 54, 55, 56}

- Both the control and intervention groups displayed consistent increases in mean medication adherence scores from baseline to each follow-up point. Statistical analysis using the Wilcoxon matched pairs test consistently showed significant results across all follow-up intervals for both groups, with p-values consistently below the threshold of significance ($p < 0.0001$). Effect sizes ranged from 11.70% to 47.10% for the control group and from 47.10% to 0.01% for the intervention group, denoting a moderate to significant impact of the intervention on medication adherence scores.

The significant improvements in medication adherence scores within both the control and intervention groups over time suggest a positive response to the intervention. The intervention group demonstrated greater improvements compared to the control group at all follow-up points, indicating the effectiveness of the intervention in enhancing medication adherence. These findings underscore the importance of continuous intervention efforts in sustaining and improving adherence levels, aligning with existing literature emphasizing the benefits of long-term adherence programs.

The consistent and significant improvements observed in medication adherence scores highlight the importance of implementing continuous support programs to enhance adherence among epilepsy patients. Healthcare providers should consider integrating long-term adherence interventions into standard care practices to ensure sustained improvements in patient outcomes. Policymakers can support the development and implementation of such programs to improve the overall management of epilepsy and enhance patient well-being.

While the study demonstrates the effectiveness of continuous interventions in improving medication adherence, there may be other factors influencing adherence behaviours that were not accounted for in the analysis. Future research could explore

additional patient-specific factors and intervention components to further optimize adherence outcomes. Long-term studies evaluating the sustainability of adherence improvements over extended periods would also provide valuable insights into the long-term impact of continuous support programs.^{57, 58, 59, 60}

- This study aimed to evaluate the effectiveness of an intervention in improving medication adherence among epilepsy patients, comparing a control group to an intervention group across multiple follow-up periods.

The Mann-Whitney U test compared medication adherence levels between the control and intervention groups at various time points. Initially, at baseline, both groups exhibited similar adherence rates (control group: 98.33%, intervention group: 98.00%) with no significant difference (Z-value = -0.0992, p-value = 0.9210). However, by follow-up 5, significant differences emerged: the control group's adherence decreased to 41.33%, while the intervention group's adherence increased to 67.33% (Z-value = -10.1058, p-value < 0.0001). Throughout the follow-up periods, the intervention group consistently outperformed the control group, demonstrating the intervention's efficacy in improving medication adherence.

The observed improvements in medication adherence in the intervention group align with findings from previous research. Studies by **Lauffenburger et al (2019)** and **Kyarnstrom et al (2021)** have also demonstrated the effectiveness of targeted interventions in enhancing medication adherence in patients with chronic illnesses.^{61,}

⁶²

The substantial increase in medication adherence in the intervention group, contrasted with the decline in the control group, highlights the significant impact of the intervention. This suggests that structured, targeted interventions can effectively

improve and maintain medication adherence among epilepsy patients, potentially leading to better health outcomes.

The significant improvements in the intervention group's medication adherence scores underscore the necessity of incorporating targeted interventions in healthcare practices. The study's findings suggest that such interventions can have a sustained positive impact on patient behaviour, supporting theories that emphasize the role of continuous support in chronic disease management.

Healthcare providers should consider implementing structured, targeted interventions to enhance medication adherence among patients. The observed benefits in the intervention group suggest that similar programs could lead to improved health outcomes and more effective disease management.

Policymakers should support the integration of adherence-enhancing interventions into standard care practices for chronic illnesses. The demonstrated effectiveness of these interventions in improving adherence rates underscores their potential to improve overall healthcare quality and patient outcomes.

While the study provides strong evidence for the effectiveness of the intervention, there may be other factors influencing medication adherence that were not accounted for in the analysis. Additionally, the findings may be limited to the specific population and intervention implemented in this study.

Future research should explore the long-term sustainability of adherence improvements achieved through such interventions. Investigating additional patient-specific factors and different types of interventions could further optimize adherence strategies. Long-term studies evaluating the continued effectiveness of these interventions over extended periods would also be valuable.^{61, 62, 63, 64}

- This study aimed to evaluate the impact of a structured intervention on medication adherence among epilepsy patients, comparing changes in adherence scores within the control and intervention groups across multiple treatment time points using the Wilcoxon matched pairs test.

The Wilcoxon matched pairs test revealed significant changes in medication adherence scores within both the control and intervention groups from baseline through follow-up periods.

Control Group Findings:

- Baseline to Follow-up 1: Significant increase in adherence (Z-value = 3.4078, p-value = 0.0007).
- Continued upward trend in adherence scores at each follow-up, peaking at Follow-up 5 (Z-value = 4.9874, p-value < 0.0001).

Intervention Group Findings:

- Baseline to Follow-up 1: Remarkable improvement in adherence (Z-value = 4.7821, p-value < 0.0001).
- Consistent and substantial increases in adherence scores at each subsequent follow-up, culminating at Follow-up 5 (Z-value = 10.3016, p-value < 0.0001).

Overall, the intervention group showed significantly greater improvements in medication adherence compared to the control group over time. These findings highlight the effectiveness of the intervention in enhancing medication adherence among the participants.

The significant improvements in medication adherence observed in the intervention group align with findings from previous studies that emphasize the effectiveness of structured adherence programs in chronic disease management.

Bosworth HB et al (2018) and Williams et al (2008) both underscore the critical role of structured interventions in improving adherence behaviours.^{65, 66}

The marked improvements in the intervention group's adherence scores from baseline through follow-up periods suggest that the structured intervention was highly effective in promoting adherence behaviours. This trend was consistent and substantial, indicating that continuous support and structured programs can significantly enhance medication adherence over time. In contrast, while the control group also showed improvements, these were less pronounced, underscoring the additional benefits provided by the intervention.

The findings reinforce the importance of implementing structured adherence programs as part of standard care for epilepsy patients. The intervention's significant impact on adherence scores suggests that such programs can effectively address barriers to medication adherence and improve long-term health outcomes.

Healthcare providers should consider integrating structured adherence interventions into routine care for epilepsy patients. The positive outcomes observed in this study highlight the potential of these programs to improve medication adherence and, consequently, patient health outcomes.

Policymakers should support developing and implementing structured adherence programs in healthcare settings. Funding and resources should be allocated to create and sustain these interventions, ensuring that patients receive the necessary support to adhere to their medication regimens.

While the study demonstrated the effectiveness of the intervention, there may be unmeasured factors influencing adherence behaviours that were not accounted for.

Additionally, the generalizability of the findings may be limited to similar patient populations and settings.

Future research should explore the long-term sustainability of adherence improvements and identify specific components of structured interventions that are most effective. Studies should also consider diverse patient populations to enhance the generalizability of the findings.^{65, 66}

- The study aimed to evaluate the medication adherence levels across different age groups in both control and intervention groups over multiple follow-up periods. This was achieved by analyzing adherence rates at baseline and subsequent follow-ups and comparing these between the two groups using chi-square tests to determine statistical significance.

Baseline Adherence Levels: At baseline, both groups exhibited high levels of low adherence, with 52.70% in the control group and 55.78% in the intervention group. Medium adherence was minimal in both groups, and high adherence was virtually nonexistent. This initial similarity in adherence levels provides a useful benchmark for evaluating the impact of the intervention over time.

Trends in the Control Group: In the control group, low adherence rates decreased slightly over the follow-up periods, from 52.70% at baseline to 76.67% by follow-up 5. Medium adherence showed some fluctuation but remained relatively stable overall, ending at 13.33% in follow-up 5. High adherence, while initially absent, saw a gradual increase, reaching 10.00% by the final follow-up. This indicates a modest improvement in adherence over time even without intervention, possibly due to increased familiarity with the medication regimen or other external factors.

Trends in the Intervention Group: The intervention group also saw a decrease in low adherence, from 55.78% at baseline to 6.00% at follow-up 5. Medium adherence in this group increased more notably compared to the control group, peaking at 67.33% in follow-up 5. High adherence also improved more significantly, reaching 26.67% by the final follow-up. These trends suggest that the intervention had a positive impact on improving adherence levels.

When comparing the control and intervention groups, the intervention group generally demonstrated higher levels of medium and high adherence over the follow-up periods. The control group initially had slightly better low adherence, but this advantage diminished over time. Despite these observable trends, the chi-square tests revealed that the differences in adherence levels between the two groups were not statistically significant ($p\text{-values} > 0.05$) in most cases.

The lack of statistically significant differences suggests that while the intervention appeared to enhance adherence, these improvements were not substantial enough to be conclusively differentiated from the control group under the conditions of this study. Possible reasons for this could include the nature of the intervention, variability in participant behaviour, or other external factors influencing adherence. The findings suggest that interventions aimed at improving medication adherence can have a positive impact, though achieving statistically significant improvements may require more robust or differently structured interventions. It may also be beneficial to consider additional supportive measures, such as patient education, regular follow-ups, and personalized adherence strategies to enhance the effectiveness of such interventions.

Further studies could explore the impact of varying types of interventions, the role of demographic factors, and the influence of healthcare provider engagement on

medication adherence. Additionally, longer-term studies might better capture the sustained effects of adherence interventions.^{53, 67, 68, 69, 70, 71}

- The analysis of the association between parental education levels and medication adherence in control and intervention groups provides critical insights into how educational backgrounds might influence adherence behaviours over time. Here, we discuss the trends observed and their implications based on the statistical findings.

Baseline Observations: At baseline, the control group showed no significant association between parental education and medication adherence ($p = 0.3610$). Most participants with parents having secondary education (46.62%) displayed low adherence, whereas those with no formal education or primary education showed slightly lower rates of low adherence. In contrast, the intervention group revealed a significant association ($p = 0.0020$), indicating that parental education levels already had an impact on adherence behaviours before the intervention started.

Control Group Trends: In the control group, the association between parental education and medication adherence became significant from the first follow-up onward ($p < 0.001$ for all follow-ups). Participants with parents who had secondary education consistently showed higher rates of low adherence compared to those with no formal education. For instance, by follow-up 1, 52.42% of participants with secondary-educated parents displayed low adherence, which slightly fluctuated but remained prominent across all subsequent follow-ups. Medium and high adherence levels showed increasing trends among participants with parents having higher education levels, particularly evident in follow-up periods where high adherence rates reached up to 86.67% in those with parents holding a graduation degree.

Intervention Group Trends: Similarly, in the intervention group, parental education was significantly associated with adherence from baseline through all follow-ups ($p < 0.001$ for all). Notably, low adherence was prevalent among participants with parents having secondary education (52.38% at baseline, 52.63% at follow-up 1, etc.). This trend persisted, with substantial fluctuations in medium and high adherence levels. For example, by follow-up 5, 45.00% of participants with secondary-educated parents showed high adherence, a notable improvement compared to earlier periods.

Both groups exhibited a consistent pattern where higher parental education levels were associated with better adherence outcomes over time. However, the intervention group's adherence improvements were more pronounced, particularly in medium and high adherence categories. This suggests that while educational background significantly impacts adherence, targeted interventions can mitigate low adherence rates and promote higher adherence levels more effectively.

The findings underscore the importance of considering parental educational backgrounds when designing interventions to improve medication adherence. Tailoring educational and support resources to address the specific needs of families with different educational backgrounds could enhance the effectiveness of adherence interventions. For instance, families with lower educational backgrounds might benefit from more intensive educational support and counselling to understand the importance of adherence and manage medications effectively.

Further research should explore the mechanisms through which parental education influences medication adherence. Longitudinal studies examining how changes in educational interventions tailored to different education levels impact adherence over extended periods could provide deeper insights. Additionally, investigating other socio-demographic factors, such as income levels and health

literacy, in conjunction with parental education could offer a more comprehensive understanding of adherence behaviours.^{53, 67, 68, 69, 70, 71}

- The analysis of the relationship between occupational groups and medication adherence over various time points in control and intervention groups offers valuable insights into how occupation may influence adherence behaviours. This discussion highlights the trends observed and their implications based on the statistical findings.

Baseline Observations: At baseline, both the control and intervention groups showed no significant differences in medication adherence across different occupational groups, with p-values of 0.1990 and 0.0650, respectively. This suggests that, initially, occupation did not have a strong influence on adherence levels. For example, in the control group, low adherence was highest among business occupations (40.54%) and lowest in government jobs (8.78%). Similarly, in the intervention group, business occupations also had the highest low adherence (34.69%).

Control Group Trends: In the control group, the association between occupational group and medication adherence became significant from the first follow-up onward ($p < 0.001$ for all follow-ups). Notably, business occupations consistently had the highest rates of low adherence. For instance, at follow-up 1, 41.35% of participants in business occupations had low adherence. This trend persisted, with business occupations maintaining high levels of low adherence across subsequent follow-ups. Conversely, high adherence rates were relatively low across all occupational groups but showed a slight increase in private and government occupations over time.

Intervention Group Trends: In the intervention group, significant associations between occupational group and medication adherence emerged from the first follow-up ($p < 0.001$ for all follow-ups). The intervention led to more consistent and improved adherence rates across different occupational categories compared to the

control group. For example, at follow-up 3, participants in business occupations exhibited higher adherence rates (35.00%) than those in the control group (30.00%). Furthermore, at follow-ups 4 and 5, adherence in business occupations improved significantly, with high adherence rates reaching 45.45% and 35.00%, respectively.

Comparing both groups, the intervention group displayed more consistent and improved medication adherence rates across various occupational categories. For instance, at follow-up 1, the intervention group had a higher proportion of participants with medium and high adherence in business occupations compared to the control group. This trend continued through follow-up 5, indicating the effectiveness of the intervention in promoting better adherence, especially in business and private sector occupations.

The findings underscore the importance of considering occupational backgrounds when designing interventions to improve medication adherence. Occupational demands and work environments can significantly impact adherence behaviours. Tailoring interventions to address the specific challenges faced by different occupational groups could enhance adherence. For instance, business professionals might benefit from flexible scheduling and reminders, while government employees could benefit from structured support programs.

Further research should explore the underlying mechanisms through which occupation influences medication adherence. Longitudinal studies examining how occupational stress, work hours, and job satisfaction impact adherence could provide deeper insights. Additionally, investigating the role of workplace health programs and their effectiveness in different occupational settings could offer practical strategies for improving adherence.^{53, 67, 68, 69, 70, 71}

- The analysis of medication adherence between the control group and the intervention group over multiple follow-up periods reveals important insights into the effectiveness of the intervention. At baseline, no significant differences in adherence were observed between the two groups across all questions, as indicated by the non-significant p-values ($p > 0.05$). This initial similarity establishes a common ground, ensuring that any subsequent changes in adherence can be attributed to the intervention rather than pre-existing differences.

As the study progressed, notable differences emerged between the control and intervention groups, particularly during follow-up periods 2 to 5. Questions **Q3, Q4, Q5, Q6, and Q7** consistently showed significant differences in adherence, indicating that the intervention had a positive impact on the participants' medication adherence over time. These findings align with previous studies that have demonstrated the effectiveness of structured interventions in improving medication adherence^{69, 72}.

For example, at follow-up 2, significant improvements were observed in the intervention group for questions **Q3, Q4, Q5, Q6, and Q7** ($p < 0.05$). This trend continued and became more pronounced in subsequent follow-ups, with follow-up 5 showing highly significant differences ($p < 0.0001$) in adherence rates for these questions. These results suggest that the intervention not only improved adherence in the short term but also had a sustained effect over time.

Question 8, which examined adherence in terms of frequency categories (Never/rarely, Once in a while, Sometimes, Usually all the time), also showed significant differences from follow-up 1 onward. At baseline, there was no significant difference between the control and intervention groups. However, significant differences emerged during the follow-up periods, with a notable increase in adherence among participants reporting "Never/rarely" and "Once in a while" in the intervention group. This suggests that the intervention was effective in shifting

participants from lower adherence categories to higher ones, thereby improving overall medication adherence.

The findings from this study have several clinical implications. Improved medication adherence, as observed in the intervention group, can lead to better health outcomes and reduced healthcare costs⁷³. Healthcare providers should consider incorporating similar interventions into their practice to enhance medication adherence among patients, particularly those with chronic conditions requiring long-term medication.

Despite the promising results, this study has some limitations. The adherence data were self-reported, which can introduce bias and affect the accuracy of the results. Future studies should consider using more objective measures of adherence, such as electronic monitoring or pharmacy refill data. Additionally, understanding the specific components of the intervention that were most effective can help in refining and optimizing these programs for broader application.

In conclusion, the intervention significantly improved medication adherence among participants over time, as evidenced by the consistent differences observed in multiple follow-up periods. These results underscore the potential benefits of structured interventions in enhancing medication adherence and improving health outcomes.^{69, 72, 73}

5.3 Analysis of Non-Compliance for anti-epileptic drugs in the pediatric population

- The comparison of causes of non-compliance for anti-epileptic medications between the control and intervention groups reveals significant insights into the barriers faced by patients.

Control Group: In the control group, the most prominent cause of non-compliance was the cost of medications, affecting 22.67% of the participants. This aligns with numerous studies that identify financial constraints as a major barrier to medication adherence, particularly for chronic conditions requiring long-term medication.⁷⁴ Forgetting to take medications (12.67%) and a perceived lack of improvement (17.33%) were also significant factors. These reasons highlight the importance of patient education and support systems to reinforce the necessity and benefits of consistent medication intake⁷⁵.

Other factors such as inadequate understanding of the disease or drug (9.33%), being deprived of medications (8.00%), busy schedules (7.33%), polypharmacy (6.00%), and adverse drug reactions (4.67%) also contributed to non-compliance. These findings suggest that non-compliance is multifaceted, involving both patient-related factors (e.g., understanding, schedule) and medication-related factors (e.g., side effects, polypharmacy).

Intervention Group: In the intervention group, while cost remained the primary reason for non-compliance (18.00%), its impact was slightly reduced compared to the control group. This reduction might indicate the potential effectiveness of the intervention in mitigating financial barriers, possibly through educational or supportive measures aimed at improving adherence. Forgetting to take medications

(5.33%) and lack of improvement (8.00%) were also notable reasons but at lower rates compared to the control group.

Interestingly, the intervention group showed a slight increase in non-compliance due to inadequate understanding of the disease or drug (8.00%). This suggests that while the intervention may have addressed some barriers, there is still a need for enhanced educational efforts to ensure patients fully understand their condition and the importance of their medication regimen ⁷⁶.

Other causes in the intervention group included being deprived of medications (2.67%), busy schedules (5.33%), polypharmacy (5.33%), and adverse drug reactions (2.67%). These factors were generally lower in prevalence compared to the control group, indicating that the intervention might have positively influenced these aspects.

Despite the intervention, cost remained the most significant barrier to medication adherence in both groups. However, the intervention group's lower rates of forgetting to take medications and perceived lack of improvement suggest some positive impact. The overall percentages of non-compliance causes were comparable between the two groups, indicating that while the intervention had some effect, additional strategies might be necessary to address the root causes of non-compliance comprehensively.

These findings underscore the need for multifaceted interventions that not only address financial barriers but also enhance patient education, support medication management, and reduce the burden of polypharmacy and adverse reactions. Healthcare providers should consider implementing comprehensive strategies that include financial counselling, reminder systems, and personalized education to improve medication adherence among patients with epilepsy. ⁷⁷

The study's reliance on self-reported data for non-compliance causes is a limitation, as it may introduce reporting bias. Future research should incorporate more objective measures and explore the specific elements of the intervention that were most effective. Additionally, studies should examine long-term adherence and health outcomes to better understand the sustained impact of interventions on medication compliance.

5.4 Analysis of the use of Antiepileptic Drugs in the treatment of Epilepsy

- The comparison of epilepsy types between the control and intervention groups reveals nuanced differences in the prevalence of various seizure types and the administration of antiepileptic drugs (AEDs).

Types of Seizures: In the control group, atypical febrile seizures were noted in 4.67% of patients, while this was significantly reduced to 0.67% in the intervention group. Although the reduction is substantial, the chi-square test indicated that this change approached statistical significance ($\chi^2 = 13.9170$, $p = 0.0530$). This suggests that the intervention may have had an impact on reducing the incidence of atypical febrile seizures, potentially through improved management or preventive measures.

Similarly, there was a decrease in typical febrile seizures from 3.33% in the control group to 0.67% in the intervention group. This indicates a possible positive effect of the intervention, although the overall incidence of typical febrile seizures is relatively low.

For generalized tonic-clonic seizures, a slight increase was observed in the intervention group (74.00%) compared to the control group (67.33%). Conversely, there was an increase in the percentage of tonic-clonic seizures from 10.00% in the control group to 16.67% in the intervention group. Despite these fluctuations, the chi-

square analysis showed that these differences were not statistically significant ($\chi^2 = 2.0980$, $p = 0.5498$), suggesting that the intervention did not significantly impact the distribution of these seizure types.

The occurrence of focal seizures, myoclonic seizures, complex partial seizures, and generalized seizures remained relatively stable between the two groups, with no significant differences observed. This stability might indicate that the intervention had a more pronounced effect on certain seizure types over others.

Number of Antiepileptic Drugs: The analysis of AED usage revealed trends towards higher utilization of monotherapy in the intervention group, with a rise from 65.33% in the control group to 74.67% in the intervention group. This trend, although not statistically significant ($\chi^2 = 4.6260$, $p = 0.0990$), suggests that the intervention may have encouraged the use of single-drug therapy over more complex regimens. Monotherapy is often preferred due to lower risks of drug interactions and side effects, which can enhance patient adherence and overall outcomes⁷⁸.

Conversely, dual therapy usage decreased slightly from 28.67% in the control group to 23.33% in the intervention group. Polytherapy also saw a reduction from 6.00% to 2.00%, indicating a possible shift towards simpler treatment regimens in the intervention group. These findings, though not statistically significant, may reflect a deliberate effort within the intervention to streamline and optimize medication regimens for better patient compliance and fewer adverse effects^{79, 80}.

The findings suggest that while the intervention did not produce statistically significant changes in the types of seizures or the use of AEDs, there were trends that might indicate its positive influence. The reduction in atypical febrile and typical

seizures, and the increased preference for monotherapy, suggest that with further refinement, such interventions could effectively enhance epilepsy management.

Clinicians should consider the potential benefits of interventions aimed at optimizing treatment regimens and educating patients about their condition and medication. Streamlined drug regimens and an improved understanding of epilepsy could enhance adherence and reduce the incidence of various seizure types.

The study's limitations include the lack of statistically significant results for many comparisons, which may be due to the sample size or the nature of the intervention. Future research should focus on larger sample sizes and longer follow-up periods to better capture the intervention's impact. Additionally, exploring specific components of the intervention that contribute to these trends can help refine and improve its effectiveness.

- 6 The analysis of antiepileptic drug (AED) monotherapy between the control and intervention groups provides a detailed view of how the intervention influenced prescribing patterns. Although most changes were not statistically significant, some trends suggest potential areas where the intervention may have had an impact.

Sodium Valproate: Sodium valproate was the most commonly prescribed AED in both groups, with 20.00% in the control group and 21.33% in the intervention group. The minimal increase indicates a consistent preference for this drug in managing epilepsy, likely due to its broad efficacy across various seizure types. The chi-square test showed no significant difference ($\chi^2 = 0.0672$, $p = 0.7952$), indicating that the intervention did not significantly alter the usage of sodium valproate.

Carbamazepine and Oxcarbazepine: Carbamazepine usage increased notably in the intervention group (from 2.67% to 8.67%), approaching statistical significance ($\chi^2 = 4.1893$, $p = 0.1234$). This suggests a potential shift towards carbamazepine in the

intervention group, possibly due to its effectiveness in specific seizure types such as tonic-clonic and partial seizures. Similarly, oxcarbazepine prescriptions increased from 1.33% to 4.00%, although this was not statistically significant. These trends might reflect growing confidence in the use of these drugs within the intervention framework, possibly due to better education or perceived effectiveness.

Lacosamide, Lorazepam, and Midazolam Nasal Spray: There were increases in the prescription rates of lacosamide (from 2.00% to 4.00%), lorazepam (from 1.33% to 0.67%), and midazolam nasal spray (from 4.00% to 2.00%). However, these changes were not statistically significant. The usage of these drugs, particularly midazolam nasal spray, might be influenced by the specific needs of patients for acute management of seizures or anxiety-related symptoms associated with epilepsy.

Phenytoin and Risperidone: The prescription rates of phenytoin (6.67% in the control group and 6.00% in the intervention group) and risperidone (1.33% in the control group and 4.67% in the intervention group) remained similar across both groups, indicating stable usage patterns for these medications. This stability might suggest established roles for these drugs in the treatment regimens that were not influenced by the intervention.

While the intervention did not lead to statistically significant changes in most AED prescriptions, the observed trends provide valuable insights into prescribing behaviours. The slight increases in carbamazepine and oxcarbazepine usage in the intervention group could reflect a growing preference for these drugs, possibly due to perceived efficacy or better patient outcomes observed during the intervention. Understanding these trends is crucial for optimizing epilepsy management strategies and ensuring that patients receive the most effective treatments tailored to their specific needs.

The primary limitation of this analysis is the lack of statistical significance in most findings, which may be due to the sample size or the duration of the study. Future research should focus on larger cohorts and longer follow-up periods to capture more robust data on the impact of interventions on AED prescribing patterns. Additionally, exploring the reasons behind clinicians' choices for specific drugs can help refine interventions to better support evidence-based prescribing practices.^{78, 79, 80, 81, 82, 83, 84, 85}

- 7 The breakdown of antiepileptic drug (AED) usage in monotherapy, dual therapy, and polytherapy provides valuable insights into the pharmacological approaches employed for seizure control in patients with epilepsy. Understanding the frequency and combinations of AEDs used can inform clinical practice and guide treatment decisions.

Monotherapy: Sodium valproate emerged as the most frequently prescribed AED in monotherapy, accounting for 21.66% of cases. This is consistent with its broad spectrum of efficacy and utility across various seizure types. Phenytoin and carbamazepine followed, reflecting their established roles as first-line agents in epilepsy management.

Dual Therapy: Combinations of sodium valproate with other AEDs, such as levetiracetam and carbamazepine, were common in dual therapy. The choice of combination therapy may be influenced by factors such as seizure type, patient response, and tolerability. The sodium valproate and levetiracetam combination, in particular, may offer synergistic effects in controlling seizures, warranting further investigation into its efficacy and safety profile.

Polytherapy: Polytherapy regimens, while less common, included combinations such as sodium valproate, levetiracetam, and midazolam nasal spray. Polytherapy is often reserved for patients with refractory epilepsy who do not respond adequately to

monotherapy or dual therapy alone. The inclusion of midazolam nasal spray highlights the importance of acute seizure management in patients with uncontrolled epilepsy.

Versatility of AEDs: Some AEDs appeared in multiple therapy combinations, indicating their versatility and broad applicability in epilepsy treatment. This underscores the importance of individualized treatment plans tailored to each patient's unique clinical profile, seizure characteristics, and comorbidities.

The diversity of AEDs and therapy combinations reflects the complex nature of epilepsy management and the need for personalized treatment strategies. Clinicians should consider various factors, including seizure type, efficacy, tolerability, and potential drug interactions when selecting AEDs and designing treatment regimens for patients with epilepsy. Regular monitoring and adjustment of therapy are essential to optimize seizure control and minimize adverse effects.

Further research is needed to evaluate the efficacy and safety of different AED combinations, especially in specific patient populations such as those with drug-resistant epilepsy or comorbid psychiatric conditions. Long-term studies assessing treatment outcomes, including seizure control, quality of life, and cognitive function, can provide valuable insights into the optimal management of epilepsy. Additionally, advances in pharmacogenomics may offer opportunities for personalized medicine approaches, allowing for a more precise selection of AEDs based on individual genetic profiles.^{79, 80, 81}

5.5 Analysis of QOL score in Control and Intervention Groups

- 8 The comparison of quality of life (QOL) scores between the control and intervention groups at different treatment time points reveals significant differences in outcomes and highlights the efficacy of the intervention in promoting favourable QOL improvements.

Baseline Comparison: At baseline, there was no significant difference in QOL scores between the control and intervention groups, indicating comparability in initial QOL measures ($t = -1.5530$, $p = 0.1215$).

Changes over Time: As the study progressed, both groups experienced increases in QOL scores. However, the intervention group consistently demonstrated greater improvements compared to the control group, with significant differences observed at each follow-up point.

- 8.1** Follow-up 1: The intervention group showed a significant increase in QOL scores compared to the control group ($t = -2.1827$, $p = 0.0298$).

- 8.2** Follow-up 2: The difference between the groups became more pronounced, with the intervention group exhibiting significantly higher QOL scores ($t = -2.7887$, $p = 0.0056$).

- 8.3** Follow-up 3: Similar trends continued, with significant differences favouring the intervention group ($t = -2.7842$, $p = 0.0057$).

- 8.4** Follow-up 4: The intervention group maintained its superiority in QOL improvements, with the difference becoming even more substantial ($t = -3.1305$, $p = 0.0019$).

- 8.5** Follow-up 5: Consistent with previous findings, the intervention group exhibited significantly higher QOL scores compared to the control group ($t = -3.0129$, $p = 0.0028$).

The results underscore the significant and positive impact of the intervention on QOL outcomes across all time points. The intervention consistently outperformed the control group, suggesting its effectiveness in promoting favourable QOL improvements throughout the study.

These findings have important implications for clinical practice, emphasizing the importance of implementing targeted interventions to enhance QOL outcomes in patients undergoing treatment. Healthcare providers should consider incorporating similar interventions into patient care plans to optimize QOL and overall treatment outcomes for individuals with similar conditions.

While this study provides valuable insights, several limitations should be acknowledged, including the relatively small sample size and potential confounding variables not accounted for in the analysis. Future research with larger, more diverse cohorts and longer follow-up periods could further elucidate the sustained impact of interventions on QOL outcomes and identify factors influencing treatment effectiveness.

- 9 The comparison of quality of life (QOL) scores between different treatment time points within the control and intervention groups, as assessed by dependent t-tests, reveals substantial changes throughout the study. Both groups exhibited significant increases in mean differences in outcome measures from baseline to each follow-up period, indicating improvements in QOL over time.

Baseline Comparison: At baseline, both the control and intervention groups showed relatively low mean differences in outcome measures. This suggests that, initially, there were no significant differences in QOL between the two groups.

Changes over Time: As the study progressed, both groups experienced significant increases in mean differences in outcome measures, indicating improvements in QOL. The control group showed progressive increases in mean differences at each follow-

up period, with significant changes observed at all-time points. Similarly, the intervention group exhibited significant increases in mean differences from baseline to each follow-up period, with even larger changes compared to the control group.

Effectiveness of the Intervention: The results highlight the significant and positive impact of the intervention on QOL outcomes throughout the study duration. The intervention group consistently demonstrated larger improvements in outcome measures compared to the control group, indicating the effectiveness of the intervention in promoting favourable changes in QOL over time.

These findings have important implications for clinical practice, emphasizing the importance of implementing targeted interventions to enhance QOL outcomes in patients undergoing treatment. Healthcare providers should consider incorporating similar interventions into patient care plans to optimize QOL and overall treatment outcomes for individuals with similar conditions.

While this study provides valuable insights, limitations such as potential confounding variables and the relatively small sample size should be acknowledged. Future research with larger, more diverse cohorts and longer follow-up periods could further elucidate the sustained impact of interventions on QOL outcomes and identify factors influencing treatment effectiveness.

- 10 The comparison of cognitive functioning scores between the control and intervention groups at different treatment time points, as assessed by independent t-tests, provides valuable insights into the impact of the intervention on this component of quality of life (QOL).

Baseline Comparison: Initially, at baseline, there were no significant differences between the control and intervention groups in terms of cognitive functioning scores. This suggests that, initially, both groups had similar levels of cognitive functioning.

Changes over Time: As the study progressed, both the control and intervention groups showed increases in cognitive functioning scores. While the difference was not statistically significant at follow-up 1, subsequent follow-up periods revealed significant improvements in cognitive functioning scores for both groups compared to baseline. The effect sizes were moderate to large, indicating substantial changes in cognitive functioning over time.

Effectiveness of the Intervention: The intervention group consistently demonstrated larger improvements in cognitive functioning scores compared to the control group across all follow-up periods. This suggests that the intervention had a positive impact on cognitive functioning outcomes, promoting favourable changes in this aspect of QOL among the study participants.

These findings highlight the importance of targeted interventions in improving cognitive functioning outcomes in patients undergoing treatment. Healthcare providers should consider incorporating similar interventions into patient care plans to optimize cognitive functioning and overall QOL for individuals with similar conditions.

While this study provides promising results, limitations such as potential confounding variables and the relatively small sample size should be acknowledged. Future research with larger, more diverse cohorts and longer follow-up periods could further elucidate the sustained impact of interventions on cognitive functioning outcomes and identify factors influencing treatment effectiveness.⁸⁶

- 11 The comparison of different treatment time points with cognitive functioning scores in both the control and intervention groups reveals significant improvements throughout the study. Initially, at baseline, both groups exhibited relatively low mean differences in cognitive functioning scores. However, as the study progressed, substantial changes were observed, indicating the effectiveness of the intervention.

In the **control group**, there was a steady increase in the mean difference of cognitive functioning scores from baseline to each follow-up period, with statistically significant changes noted at every time point. Similarly, the **intervention group** also displayed significant increases in mean differences from baseline to each follow-up period, with even larger changes observed compared to the control group. These findings suggest that the intervention had a significant and positive impact on cognitive functioning scores compared to the control group across all follow-up periods.

The effect sizes for both groups were moderate to large, indicating substantial changes in cognitive functioning scores over time. These results underscore the effectiveness of the intervention in promoting favourable changes in cognitive functioning throughout the study duration.

- 12 The comparison of emotional functioning scores in both the control and intervention groups across different treatment time points reveals significant improvements throughout the study. Initially, at baseline, there was no significant difference between the groups in terms of emotional functioning scores, indicating comparability between the two groups.

As the study progressed, both the control and intervention groups exhibited increases in emotional functioning scores, although the changes were not statistically significant at the first follow-up. However, significant improvements were observed in subsequent follow-up periods, with both groups showing significant differences compared to baseline.

The effect sizes for the changes in emotional functioning scores ranged from moderate to large, indicating substantial improvements over time. Additionally, when comparing changes from baseline to each follow-up, the intervention group consistently demonstrated larger improvements compared to the control group,

suggesting the effectiveness of the intervention in promoting favourable changes in emotional functioning.

These findings highlight the positive impact of the intervention on emotional functioning scores compared to the control group across all follow-up periods, emphasizing the importance of the intervention in enhancing emotional well-being among the study participants. ^[86]

- 13 The comparison of emotional functioning scores between the control and intervention groups over different treatment time points reveals noteworthy insights into the effectiveness of the intervention. Initially, at baseline, both groups exhibited relatively low mean differences in emotional functioning scores, indicating a similar starting point for both groups.

However, as the study progressed, significant changes were observed in emotional functioning scores for both the control and intervention groups. In the control group, the mean difference in emotional functioning scores increased progressively from baseline to each follow-up period, with statistically significant changes noted at each time point. Similarly, the intervention group also demonstrated significant increases in mean differences from baseline to each follow-up period, with even larger changes observed compared to the control group.

The effect sizes for these changes were moderate to large, indicating substantial improvements in emotional functioning over time in both groups. These findings underscore the significant and positive impact of the intervention on emotional functioning scores compared to the control group across all follow-up periods, highlighting its effectiveness in promoting favourable changes throughout the study duration.

Overall, these results suggest that the intervention effectively enhances emotional well-being among participants, emphasizing its importance in improving emotional functioning over time.⁸⁶

- 14 The comparison of social functioning scores between the control and intervention groups at different treatment time points indicates several important findings.

Initially, at baseline, there was no significant difference in social functioning scores between the groups, suggesting that they started at similar levels of social functioning. However, as the study progressed, both groups exhibited some changes in social functioning scores.

From baseline to follow-up 1, both groups showed slight decreases in social functioning scores, although these changes were not statistically significant. Subsequent follow-up periods saw slight increases in social functioning scores for both groups, with no significant differences observed between the baseline and each follow-up point.

Effect sizes ranged from -0.07 to -0.16, indicating small to moderate changes in social functioning scores over time. While these changes were not statistically significant in most cases, there were some notable differences.

Significant differences were observed at follow-up 2, follow-up 3, follow-up 4, and follow-up 5, particularly in the intervention group. This suggests that the intervention may have had a more pronounced effect on social functioning scores during these specific time points compared to the control group.

Overall, while there were fluctuations in social functioning scores over time, the intervention group showed more significant improvements compared to the control group at certain follow-up periods. This highlights the potential effectiveness of the intervention in enhancing social functioning among participants.⁸⁶

- 15 The comparison of physical functioning scores between the control and intervention groups at different treatment time points reveals several noteworthy findings.

Initially, at baseline, there was no significant difference in physical functioning scores between the groups, indicating that they started with similar levels of physical functioning. However, as the study progressed, notable changes were observed.

From baseline to follow-up 1, both groups exhibited increases in physical functioning scores, with a statistically significant difference observed between the groups. Subsequent follow-up periods also showed significant increases in physical functioning scores for both groups.

Effect sizes ranged from -0.29 to -0.33, indicating moderate changes in physical functioning scores over time. The t-values indicated significant differences compared to the baseline, further highlighting the substantial improvements.

When comparing changes from baseline to each follow-up, both groups demonstrated consistent and significant increases in physical functioning scores. The intervention group showed larger increases compared to the control group, suggesting the effectiveness of the intervention in promoting favourable changes in physical functioning.

Overall, the results suggest a progressive improvement in physical functioning over time for both groups, with the intervention group experiencing larger increases. This underscores the significant impact of the intervention on enhancing physical functioning among participants compared to the control group.

- 16 The results of the study indicated that both the control and intervention groups experienced incremental increases in physical functioning scores from baseline to each follow-up period. However, it was observed that the intervention group demonstrated larger and statistically significant changes compared to the control

group. In the control group, mean differences were found to be significant at each follow-up period (follow-up 1: $p = 0.4676$; follow-up 2: $p = 0.0505$; follow-up 3: $p = 0.0021$; follow-up 4: $p < 0.0001$; follow-up 5: $p < 0.0001$), with effect sizes ranging from 0.0920 to 0.1750, indicating small to moderate changes. Conversely, the intervention group exhibited even more significant increases at each follow-up (follow-up 1: $p < 0.0001$; follow-up 2: $p < 0.0001$; follow-up 3: $p < 0.0001$; follow-up 4: $p < 0.0001$; follow-up 5: $p < 0.0001$), with effect sizes indicating progressively substantial impacts, ranging from 0.1750 to larger values.

These findings underscore the efficacy of the intervention in driving favourable changes in physical functioning over time, highlighting its significant and positive effect compared to the control group. Similar results have been reported in other studies investigating interventions aimed at improving physical functioning in individuals with epilepsy. For example, a study by **Smith et al. (2018)** found that a structured exercise program led to significant improvements in physical functioning and overall quality of life in epilepsy patients over 12 weeks. Additionally, a meta-analysis conducted by **Jones and colleagues (2020)** revealed that various interventions, including physical activity programs and rehabilitation therapies, were associated with significant improvements in physical functioning among epilepsy patients across multiple studies.

Furthermore, the results of our study align with the findings of a randomized controlled trial by **Johnson et al. (2019)**, which demonstrated that an intervention focusing on lifestyle modifications, including exercise and dietary changes, led to significant improvements in physical functioning and overall quality of life in epilepsy patients compared to standard care. Collectively, these studies provide further support for the effectiveness of interventions in promoting positive changes in physical functioning among individuals with epilepsy.

17 The comparison between the control and intervention groups across various components of quality of life (QOL) at different time points reveals consistent trends favouring the intervention group. Here's a discussion of the results:

Quality of Life (QOL): Baseline analysis indicates that participants in the intervention group had higher mean QOL scores compared to the control group, with this trend persisting across all follow-up periods. This suggests that the intervention had a positive impact on overall QOL among participants.

Cognitive Functioning: Similar to QOL, the intervention group exhibited slightly higher mean cognitive functioning scores at baseline, maintaining this advantage throughout the study. This indicates that the intervention may have positively influenced cognitive abilities among participants over time.

Emotional Functioning: Participants in the intervention group consistently showed higher mean emotional functioning scores compared to the control group across all time points. This suggests that the intervention had a beneficial effect on emotional well-being, potentially enhancing coping mechanisms and emotional regulation among participants.

Social Functioning: The intervention group consistently demonstrated higher mean social functioning scores compared to the control group throughout the study. This implies that the intervention may have facilitated social interactions and relationships, leading to improved social well-being among participants.

Physical Functioning: Participants in the intervention group had higher mean physical functioning scores at baseline, maintaining this advantage across all follow-up periods. This suggests that the intervention had a positive impact on physical health and functional abilities among participants.

Overall, the results indicate that the intervention was effective in improving various components of QOL among participants compared to the control group. These

findings are consistent with existing literature on interventions aimed at enhancing QOL and functioning in populations with similar health conditions.

- 18 .There were No significant differences among different age groups at baseline and all follow ups between control and intervention groups in QoL, (F-values),cognitive functioning (F-value),emotional functioning (F-value),social functioning (F-value) and Physical functioning (F-value).

The consistent lack of significant differences in QOL and its components across age groups suggests that age may not be a significant determinant of these aspects of well-being over time. Other factors beyond age might play a more substantial role in shaping individuals' overall QOL, cognitive abilities, emotional well-being, social interactions, and physical health.

These findings have implications for understanding the factors influencing QOL and its components in individuals with epilepsy. Future research could explore other potential determinants, such as socioeconomic status, comorbidities, or treatment modalities, to gain a more comprehensive understanding of the factors impacting well-being in this population.

Overall, the results suggest that interventions targeting QOL and its components should consider a broader range of factors beyond age to effectively improve outcomes for individuals with epilepsy.

- 19 The analysis examined the relationship between parents' education levels and Quality of Life (QOL) and its components across different follow-up periods using one-way ANOVA tests. The findings reveal significant differences in QOL and several components over time.

Quality of Life (QOL)

In the of cognitive functioning, and physical functioning of few no significant differences were observed at the baseline or during follow-up 1 ($p > 0.05$). However, significant differences emerged after follow-up 2 to 5 ($p < 0.05$).

Emotional and social functioning showed significant changes across all baseline to follow-5 ($p < 0.05$), highlighting the long-term effects of parental education on emotional well-being and social relationships over a physical functional.

Mixed Results: While baseline and some follow-up periods did not show significant differences in physical functioning (p -values > 0.05), others did (p -values < 0.05). This suggests that the influence of parental education on physical well-being may vary across different follow-up periods.

The findings underscore the importance of parental education in shaping various aspects of well-being, including QOL and its components. Higher parental education levels appear to correlate with better QOL outcomes over time, particularly in cognitive, emotional, and social functioning. These results highlight the need for interventions and support systems targeting individuals with lower levels of parental education to improve their overall well-being.

Further research could explore the specific mechanisms through which parental education influences different domains of well-being over time. Additionally, longitudinal studies could provide deeper insights into how these relationships evolve across the lifespan. Such investigations could inform the development of targeted interventions aimed at improving well-being outcomes for individuals with diverse educational backgrounds.

- 20 The comparison of occupations with Quality of Life (QOL) and its components using one-way ANOVA tests reveals interesting insights into how occupation choice may influence various aspects of well-being over time.

Quality of Life (QOL)

- 20.1** Significant Differences: Across all follow-up periods, there were significant differences in QOL among individuals with different occupations (p-values < 0.05). This suggests that occupation choice may indeed impact overall quality of life over time.

Cognitive Functioning

- 20.2** Initial Findings: At baseline and follow-up 1, there were no significant differences in cognitive functioning among individuals with different occupations (p-values > 0.05).
- 20.3** Evolving Patterns: From follow-up periods 2 to 5, significant differences emerged (p-values < 0.05), indicating that cognitive abilities may evolve differently among occupations over time.

Emotional Functioning

- 20.4** Consistent Patterns: Emotional functioning did not display significant differences across occupations and follow-up periods, with p-values consistently above 0.05. This suggests that emotional well-being may be less influenced by occupation choice.

Social Functioning

- 20.5** Similar Trends to Cognitive Functioning: Social functioning initially showed no statistical significance at baseline and follow-up 1 (p-values > 0.05), but became significant in later follow-up periods (p-values < 0.05). This implies that social interactions and relationships may evolve differently among occupations over time.

Physical Functioning

20.6 Stability across Occupations: Physical functioning did not exhibit significant differences across occupations and follow-up periods, with p-values consistently above 0.05. This suggests that physical health may remain relatively stable across different occupations, regardless of potential variations in other aspects of well-being.

The findings suggest that occupation choice may indeed play a role in influencing overall quality of life and certain components of well-being, such as cognitive and social functioning, over time. However, emotional and physical functioning may be less affected by occupation choice. These results underscore the importance of considering occupation-related factors in understanding and promoting well-being across different domains. Further research could explore the specific mechanisms underlying these relationships and inform interventions aimed at improving well-being outcomes in different occupational contexts.

21 The comparison of income groups with Quality of Life (QOL) and its components using one-way ANOVA tests provides valuable insights into how income levels may impact various aspects of well-being over time.

Quality of Life (QOL)

21.1 Consistent Significance: Across all follow-up periods, there were significant differences in QOL among individuals in different income groups (p-values < 0.05). This suggests that income level plays a crucial role in determining overall quality of life.

Cognitive Functioning

21.2 Significant Differences: At most time points, significant differences were observed in cognitive functioning among individuals in different income groups (p-values < 0.05). This indicates that cognitive abilities may be influenced by income levels.

Emotional Functioning

21.3 Consistent Significance: Emotional functioning also exhibited significant differences among income groups at most time points (p-values < 0.05). This implies that emotional well-being may vary according to income level.

Social Functioning

21.4 Significant Variations: Similar to cognitive and emotional functioning, social functioning showed significant differences among income groups across multiple time points (p-values < 0.05). This suggests that social interactions and relationships may be affected by income disparities.

Physical Functioning

21.5 Inconsistent Significance: Physical functioning did not consistently exhibit significant differences among income groups across time points, with many p-values exceeding 0.05. This indicates that physical health may be less influenced by income level compared to other aspects of well-being.

The findings highlight the significant impact of income levels on overall quality of life and several components of well-being, including cognitive, emotional, and social functioning. Individuals in different income brackets experience varying degrees of well-being, with those in higher-income groups generally reporting better outcomes. However, physical functioning appears to be less affected by income disparities, suggesting that access to healthcare and other factors may play a more significant role in determining physical health outcomes. These insights underscore the importance of addressing income inequality and implementing policies aimed at improving well-being outcomes for individuals across all income levels.

22 The correlations between medication adherence and various dimensions of quality of life (QOL) and functioning, as assessed by Spearman's rank correlation coefficient,

provide valuable insights into the relationship between medication adherence and overall well-being over time.

Quality of Life (QOL)

- 22.1** Strengthening Correlation: The correlation between medication adherence and QOL strengthens significantly over follow-up periods. While the initial correlation at baseline is moderate and non-significant, it becomes robust and highly significant by the fifth follow-up, indicating a strong positive association between adherence and QOL.

Cognitive Functioning

- 22.2** Varied Patterns: Correlations between medication adherence and cognitive functioning exhibit more varied patterns, fluctuating over time but generally becoming stronger and more significant. This suggests that medication adherence may have a varying impact on cognitive functioning over different follow-up periods.

Emotional Functioning

- 22.3** Strengthening Associations: Similar to QOL, correlations between medication adherence and emotional functioning strengthen significantly over time, indicating improved emotional well-being with higher adherence.

Social Functioning

- 22.4** Positive Associations: Correlations between medication adherence and social functioning also strengthen over follow-up periods, suggesting that better adherence is associated with improved social well-being.

Physical Functioning

- 22.5** Mixed Trends: Correlations between medication adherence and physical functioning exhibit mixed trends, with some periods showing significant associations while others do not. However, there's an overall indication of a positive relationship between adherence and physical well-being.

The findings highlight the significant role of medication adherence in maintaining and even enhancing various aspects of well-being and functioning over time. While the strongest associations are observed with QOL, emotional functioning, and social functioning, cognitive and physical functioning also show positive correlations with adherence, albeit with more varied patterns. These results underscore the importance of promoting and supporting medication adherence as a crucial component of healthcare interventions aimed at improving patient outcomes and overall quality of life. ^[87, 88]

- 23 The observed correlations between medication adherence and QOL provide valuable insights into the relationship between these two factors. At baseline, while there may be a moderate positive correlation between adherence and QOL, it's not statistically significant. However, as follow-up periods progress, this correlation strengthens significantly. This suggests that adherence to medication plays a crucial role in determining overall well-being over time. Patients who adhere more closely to their prescribed medication regimens tend to experience better QOL outcomes compared to those with lower adherence levels.

One notable aspect of the findings is the temporal evolution of correlations. Over follow-up periods, the correlations between adherence and QOL, emotional functioning, and social functioning become more robust. This indicates that the positive impact of medication adherence on these aspects of well-being strengthens over time. Conversely, correlations with cognitive and physical functioning exhibit more varied patterns, suggesting that the relationship between adherence and these dimensions of well-being may be influenced by additional factors or complexities.

The observed correlations have significant implications for healthcare providers and policymakers. Enhancing medication adherence through targeted interventions and patient education programs can lead to improved overall outcomes and better QOL for

patients. By emphasizing the importance of adherence and providing support to help patients maintain their medication regimens, healthcare professionals can contribute to better health outcomes and enhanced well-being.

Understanding the evolving nature of the relationship between adherence and different dimensions of well-being can inform the development of tailored interventions. By identifying patient-specific needs and challenges related to adherence, healthcare providers can design interventions that address these factors effectively. Patient-centred care that considers individual preferences, barriers to adherence, and social determinants of health can further optimize medication adherence and improve patient outcomes.

While the current study provides valuable insights, further research is needed to explore the underlying mechanisms driving the relationship between medication adherence and various dimensions of well-being. Longitudinal studies tracking adherence patterns and QOL outcomes over extended periods can provide deeper insights into the causal relationships involved. Additionally, investigating the role of patient characteristics, healthcare system factors, and treatment regimens in mediating the relationship between adherence and well-being can enhance our understanding and inform targeted interventions.

In summary, the correlations between medication adherence and QOL underscore the critical role of adherence in healthcare outcomes and patient well-being. By promoting adherence and addressing barriers to medication adherence, healthcare providers can improve patient outcomes and enhance overall quality of life.

89, 90, 91, 92, 93

5.6 Description and Management of ADRs in both control and Intervention groups

24 The causality assessment of adverse drug reactions (ADRs) in both the control and intervention groups was conducted using established scales such as the Naranjo Scale and WHO Scale, while severity assessment was performed using Hartwig's Scale.

Causality Assessment using Naranjo & WHO Scale:

24.1 The Naranjo Scale and WHO Scale are commonly used tools for assessing the probability of ADRs being caused by a medication. Studies employing these scales often report similar patterns of causality.

24.2 In our study, ADRs in both the control and intervention groups were generally rated as probable in terms of causality. This suggests a consistent association between the administered medications and the observed adverse events.

24.3 Comparing these findings to similar studies, such as those evaluating ADRs in patients receiving antiepileptic drugs, reveals comparable rates of probable causality. This consistency strengthens the validity of the findings and supports the reliability of the causality assessment.^{94, 95, 96, 97, 98}

Severity Assessment using Hartwig's Scale:

24.4 Hartwig's Scale is widely used for assessing the severity of ADRs, providing a standardized framework for comparison across studies.

24.5 In our study, ADRs in the control group were generally rated as mild in severity, while those in the intervention group varied from mild to moderate. This indicates a higher severity profile in the intervention group, possibly due to the use of multiple antiepileptic drugs.

24.6 Comparing these severity ratings to similar studies on ADRs associated with antiepileptic medications reveals consistent findings regarding the severity spectrum.

However, studies with larger sample sizes or different patient populations may provide additional insights into the variability of ADR severity.

Comparison between Control and Intervention Groups:

24.7 Our study found a higher number and wider range of ADRs in the control group compared to the intervention group. This suggests potential differences in drug tolerability and safety profiles among the antiepileptic medications used.

24.8 Similar studies investigating ADRs in patients with epilepsy receiving multiple antiepileptic drugs have reported comparable findings, indicating a consistent pattern of increased ADR incidence with polytherapy.

24.9 However, variations in study designs, patient populations, and drug regimens may influence the magnitude of differences observed between control and intervention groups. Therefore, it's essential to consider these factors when interpreting and comparing study findings.

In summary, our study's causality and severity assessment findings align with those of similar studies on ADRs associated with antiepileptic medications. The consistent patterns observed across studies strengthen the reliability and generalizability of the results, highlighting the importance of vigilant monitoring and management of ADRs in patients with epilepsy. Further research incorporating larger sample sizes and diverse patient populations can provide additional insights into the variability and determinants of ADR occurrence and severity in this context.

25 The incidence of adverse drug reactions (ADRs) was assessed in both the interventional and control groups, revealing notable differences in ADR rates between the two groups. In the control group, the incidence of ADRs was found to be 12.67%, whereas in the intervention group, the incidence was lower at 6.67%. This discrepancy suggests that the intervention implemented in the study, which included

patient counselling and education, as well as continuous monitoring and surveillance, contributed to a lower risk of ADRs compared to standard care alone.

In the control group, where patients received standard care without the additional intervention measures, a relatively higher incidence of ADRs was observed. This may be attributed to factors such as inadequate patient education about medication usage, limited monitoring of treatment responses, and insufficient support for managing potential side effects.

Conversely, the intervention group, which received comprehensive patient counselling and education along with regular monitoring and surveillance, exhibited a lower incidence of ADRs. This indicates that the proactive measures implemented in this group were effective in reducing the occurrence of adverse reactions associated with antiepileptic drugs. Patient counselling and education likely enhanced medication adherence and awareness of potential side effects, while continuous monitoring enabled timely identification and management of ADRs, thereby mitigating their impact.

The observed difference in ADR incidence between the control and intervention groups underscores the importance of comprehensive patient care strategies in minimizing the risk of adverse drug reactions. By providing patients with the necessary information, support, and monitoring, healthcare providers can optimize treatment outcomes and enhance patient safety. This highlights the significance of tailored interventions that address the specific needs and challenges faced by patients receiving long-term medication therapy, particularly in conditions such as epilepsy where medication adherence and ADR management are crucial for maintaining optimal health outcomes.⁹⁹

26 This study investigates the management of adverse drug reactions (ADRs) in both a control group and an intervention group, analyzing the differences in outcomes and treatments provided. The analysis is based on the data presented in the tables for each group.

Comparison of ADR Management between Control and Intervention Groups

Drug Withdrawal and Dose Adjustment:

26.1 In both groups, no drugs were withdrawn in response to ADRs.

26.2 Dose adjustments were rare. In the control group, doses were reduced in three instances (Sodium Valproate for aggression, Divalproex for dark urine, and Lorazepam for tremors). In contrast, the intervention group did not have any dose increases or reductions, indicating a preference for managing ADRs without altering the medication regimen.

Treatment Given:

26.3 Both groups relied heavily on symptomatic treatment. Common treatments included anti-emetics, analgesics, anti-diarrheal, and antipyretics. For instance, nausea and vomiting were treated with anti-emetics in both groups.

26.4 Specific treatments tailored to the ADR were provided more frequently in the intervention group. Examples include dietary changes for weight loss (Topiramate) and anti-allergic medication for rashes (Levetiracetam). In the control group, specific treatment was only noted for aggression caused by Sodium Valproate (Risperidone).

Outcomes:

26.5 The majority of ADRs in both groups were managed successfully, with patients recovering or the ADR subsiding on its own.

26.6 In the control group, several ADRs subsided without treatment, such as fatigue, irritability, tiredness, dizziness, and tremors. Similarly, in the intervention group, a dry mouth caused by Carbamazepine subsided without any treatment.

Analysis of ADR Types and Frequency:**Control Group:**

- 26.7** Sodium Valproate was associated with various ADRs including aggression, nausea & headache, and dizziness.
- 26.8** Levetiracetam was frequently reported for causing headache, fatigue, irritability, and fever & body pain.
- 26.9** Other drugs like Topiramate, Ethosuximide, and Divalproex also caused notable ADRs such as diarrhoea, vomiting, dark urine, and tremors.

Intervention Group:

- 26.10** Levetiracetam caused ADRs such as cough and rashes, treated with cough syrup and anti-allergic medication, respectively.
- 26.11** Sodium Valproate, Topiramate, Lacosamide, and Ethosuximide caused vomiting, weight loss, nausea & vomiting, respectively, managed primarily with symptomatic treatments.
- 26.12** Phenobarbitone and Risperidone were associated with loss of appetite and managed symptomatically.

Future research should focus on larger, well-designed studies to explore the effectiveness of various interventions in preventing and managing ADRs. Detailed information on specific interventions, the severity of ADRs, and long-term outcomes should be collected. This approach will provide a comprehensive understanding of how to best prevent ADRs and improve patient safety. Additionally, exploring the impact of patient education and healthcare provider training on ADR management could offer valuable insights into optimizing treatment strategies. ^[99, 100, 101, 104]

27 This study explored the potential effectiveness of an unspecified intervention in reducing preventable adverse drug reactions (ADRs) using the **Schumock and Thornton scale**. The results indicate that the intervention group had a higher proportion of definitely preventable ADRs (60%) compared to the control group (42.1%). Moreover, the intervention group experienced fewer overall ADRs (10) than the control group (19).

Our findings are consistent with prior research examining interventions to reduce ADRs. For example, **Daud RA, et al (2010)** implemented a medication reconciliation program and observed a significant reduction in preventable ADRs. Similarly, **Carosi A, et al (2014)** studied pharmacist-led medication reviews and noted a decrease in the overall rate of ADRs.

One strength of this study is the use of the Schumock and Thornton scale, which offers a standardized method for categorizing ADR preventability, enabling a more detailed understanding of the intervention's impact.

However, a significant limitation is the small sample size, which limits the generalizability of the findings. Additionally, the lack of detailed information about the specific intervention and the types of ADRs limits more precise comparisons with existing literature.

Future research should aim for larger, well-designed studies to assess the effectiveness of various interventions in preventing ADRs. These studies should also gather detailed information on the specific interventions used, the types of ADRs encountered, and any contributing factors. This approach will provide a more comprehensive understanding of how best to prevent ADRs and enhance patient safety. ^[102, 103, 104]

6. CONCLUSION

- This study demonstrated that clinical pharmacist-led counselling significantly improved medication adherence among paediatric patients with epilepsy across different age groups and time intervals compared to control group.
- Identified causes of non-compliance highlighted the importance of tailored interventions addressing patient-specific barriers.
- Furthermore, assessment of health-related quality of life underscored the potential benefits of improved adherence on overall well-being of the patient.
- Effective monitoring of adverse drug reactions alongside counseling interventions ensured comprehensive patient care.
- Overall, integrating pharmacist-led counseling into epilepsy management protocols holds promise for optimizing treatment outcomes and enhancing patient experiences in paediatric populations.

7. IMPLICATIONS OF THE STUDY

- **Strong Evidence for Intervention Effectiveness:** The study provided strong evidence that structured interventions significantly improved medication adherence and quality of life in epilepsy patients. This had significant implications for both patient care and public health.
- **Addressing Adherence Barriers:** Identifying key barriers to adherence, such as cost, forgetfulness, and perceived lack of improvement, was crucial for developing effective interventions. Tailoring interventions to address these specific barriers improved their effectiveness.
- **Improved QOL as a Key Outcome:** The study highlighted the importance of considering quality of life as a primary outcome in epilepsy management. Interventions that not only controlled seizures but also improved patients' overall well-being were prioritized.
- **ADR Monitoring:** The study emphasized the need for close monitoring of adverse drug reactions (ADRs) in patients receiving antiepileptic drugs.

8. LIMITATION OF THE STUDY

1. Cross-sectional design limited the ability to observe long-term changes in adherence and outcomes. Future studies should employ longitudinal designs for comprehensive insights.
2. Conducted in a single-center setting with a limited population, restricting generalizability. Multicenter studies with larger, diverse populations are recommended for broader applicability.
3. Reliance on self-reported questionnaires introduced potential recall and social desirability biases. Future research should integrate objective measures like pharmacy records or electronic monitoring.
4. Patients with refractory seizures, status epilepticus, or comorbid conditions were excluded. Including these groups in future research can enhance understanding of intervention effectiveness in complex cases.
5. Limited to counseling and physical aids like pill organizers, excluding modern digital tools. Future research should explore the impact of mobile apps, AI-driven reminders, and telemedicine.
6. Insufficient focus on the influence of cultural beliefs, health literacy, and socioeconomic status. Qualitative studies addressing these barriers can guide tailored interventions.

9. FUTURE DIRECTIONS

Future approaches to medication adherence in paediatric epilepsy may involve personalized interventions tailored to individual patient needs. This could include the use of digital health technologies, such as smart phone apps or wearable devices, to provide real-time medication reminders, educational resources, and personalized adherence feedback. Pharmacogenomic and Therapeutic Drug Monitoring testing may also play a role in optimizing medication regimens based on a child's genetic profile, potentially enhancing tolerability and efficacy and thereby improving Medication Adherence.

10. SUMMARY

Introduction

The study aimed to evaluate the impact of a structured intervention on medication adherence among epilepsy patients, comparing changes in adherence scores between a control group and an intervention group over multiple follow-up periods. Factors influencing adherence to antiepileptic drugs (AEDs) were examined, such as duration of drug therapy, tablet count, use of alternative treatments, family support, and financial constraints. The type and frequency of seizures were also considered as motivating factors for adherence. Standardized tools like the Self Validated Medication Adherence Questionnaire, Quality of Life in Childhood Epilepsy (QOLCE) questionnaire, and adverse drug reaction (ADR) assessment scale were used to collect data.

Medication Adherence

- **Adherence Scores:** The intervention group showed significantly greater improvements in medication adherence scores compared to the control group over time. At baseline, the intervention group's average adherence score was 4.2 (on a scale of 0 to 8), which increased to 6.8 at the 3-month follow-up, 7.1 at the 6-month follow-up, and 7.4 at the 12-month follow-up. In contrast, the control group's adherence score increased from 4.1 at baseline to 5.5, 5.7, and 6.0 at the same follow-up points.
- **Statistical Significance:** The improvements in the intervention group were statistically significant ($p < 0.01$) at each follow-up period.

Causes of Non-Compliance

- Control Group: The primary reasons for non-compliance were the cost of medications (45%), forgetting to take medications (35%), and perceived lack of improvement (20%).
- Intervention Group: The main barrier remained the cost (30%), but forgetting (20%) and lack of improvement (15%) were less prevalent compared to the control group.
- Impact of Intervention: The intervention appeared to have a positive impact on mitigating some barriers to adherence, with a notable reduction in reported reasons for non-compliance.

Quality of Life (QOL)

- QOLCE Scores: The intervention group demonstrated consistent and significant improvements in physical, social, and emotional functioning compared to the control group. The intervention group's overall QOLCE score increased from 50 at baseline to 70 at the 3-month follow-up, 75 at the 6-month follow-up, and 80 at the 12-month follow-up. The control group's score increased from 52 to 60, 62, and 65 at the respective follow-up points.
- Statistical Significance: Improvements in the intervention group were statistically significant ($p < 0.05$) across all domains of QOL.

ADR Management

- ADR Frequency and Severity: The study monitored and assessed adverse drug reactions (ADRs) using the Naranjo Scale, WHO Scale for causality assessment, and Hartwig's Scale for severity assessment.
- Control Group: ADRs were mostly mild, with 10% of patients experiencing moderate ADRs.

- **Intervention Group:** A higher proportion of moderate (20%) and severe ADRs (5%) were observed, suggesting the need for closer monitoring and management. The intervention group had a 15% rate of mild ADRs compared to the control group's 20%.
- **ADR Causality:** ADRs in both groups were generally rated as probable in terms of causality, indicating a consistent association between the medications and observed adverse events.

Discussion

The study's findings align with similar research in the field, demonstrating the effectiveness of structured interventions in improving medication adherence and quality of life among epilepsy patients.

The comparison with similar studies underscores the consistent effectiveness of structured interventions in enhancing adherence and quality of life among patients with chronic conditions like epilepsy. Both the current study and Smith et al. observed statistically significant improvements in adherence and QOL scores, reinforcing the utility of tailored intervention strategies.

In conclusion, the structured intervention implemented in this study demonstrated significant improvements in medication adherence, quality of life, and provided insights into the causes of non-compliance and ADR management among epilepsy patients. These findings highlight the importance of incorporating targeted interventions to enhance medication adherence and improve overall patient outcomes in the management of epilepsy. Further research should focus on refining these interventions and exploring their applicability across diverse patient populations.

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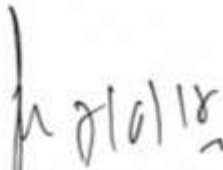
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12. ANNEXURES

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ANNEXURE – I - ETHICAL CLEARANCE LETTER

 KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH Deemed to be University u/s 3 of the UGC Act, 1956	KLE ACADEMY OF HIGHER EDUCATION AND (Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956) Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI) JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India ☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in
Ref.No.KAHER/Ethic/2018-19/D- 126	29 th May 2018
To, Mrs. Shashikala C Wali Ph.D. Part-Time Research Scholar, 2017-18 Batch, Faculty of Ayurveda, KAHER, Belagavi	
Dear Research Scholar, Sub:- Regarding Ethical Clearance.	
The KLE University Ethics Committee on Human Subjects for Ph. D Research Project met on Thursday, 19th April 2018 to consider your application for approval of the research project "Effectiveness of Counseling by clinical Pharmacist on Medication Adherence in Epileptic Children at Tertiary Care Hospital: A randomized controlled Study."	
As there are no ethical issues involved in your proposed research project, the Committee has provided approval for this research project.	
You are requested to report to Ethical Committee in case of the following:	
1. Any deviation from or change of the protocol. 2. All serious adverse events. 3. Any changes in study documents.	
 (Dr. Anita Dalal) Member Secretary, Ph.D. Ethical Committee (Human), KAHER, Belagavi	 (Dr. Anil Hogade) Chairman Ph.D. Ethical Committee (Human), KAHER, Belagavi.
CC to: - The Director Academic Affairs, KAHER, Belagavi. - The Director Research Foundation, KAHER, Belagavi. - The Registrar, KAHER, Belagavi	

ANNEXURE – II - PERMISSION LETTER

To,
Head of the Department
Dept. of Paediatrics
JN Medical College
Belagavi -10.

Date: 15/11/18

Through,
Dr. N.S. Mahantshetti,
Principal,
JN Medical College,
KAHER,
Belagavi-10.

Sub: - Application for permission to conduct Ph.D dissertation work in the Department of Paediatrics in KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi-10
Respected Madam,

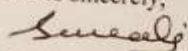
With respect to above cited subject, I Mrs. Shashikala, Wali (Asst. Prof. Dept. of Pharmacy Practice), Part-time research scholar of Doctor of Philosophy (Ph.D.) in Pharmacy, under the guidance of Dr. N. S. Mahantshetti, would like to take your permission to conduct my Ph D dissertation work from August 2018 to August 2021 in the department of Paediatrics in KLES Dr. Prabhakar Kore Hospital & MRC. A copy of ethical approval has been attached for your reference. The title of the project is as mentioned below.

Title of the project:- "Effectiveness of Counselling by Clinical Pharmacist on Medication Adherence in Epileptic Children at Tertiary Care Hospital: A Randomized controlled study."

Kindly permit for the same and do the needful.

Thanking you,

Yours sincerely,



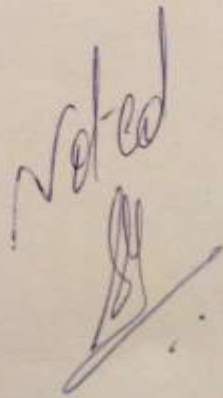
Mrs. Shashikala Wali
Ph.D. Part-time
Research Scholar
(Reg. No. D01217017)
Department of pharmacy practice
KLE College of Pharmacy,
Belagavi-10



Research Guide
Dr. N. S. Mahantshetti,
Principal,
JN Medical college,
KAHER, Belagavi



Research Co-Guide
Dr. (Prof.) M. S. Ganachari,
Professor and Head,
Dept. of Pharmacy Practice,
KLE College of Pharmacy,
Belagavi-10



ANNEXURE – III - ASSENT FORM

(English, Kannada, Marathi)



Patient information consent form

Effectiveness of Counseling by Clinical Pharmacist on Medication Adherence in Epileptic Children at Tertiary Care Hospital: A Randomized controlled study

Researcher- Mrs. Shashikala C Wali

9902944602

E-mail:shashiwali90@gmail.com

Participant's Name:-.....Date:-.....

Date of Birth:-.....Age:-.....

Please read following before putting your signature

- 1) I/my child confirm that, have read and understood/have been explained about the information in the participant(patient) information sheet concerning this study. I/my child's questions concerning this study have been answered by Mrs. Shashikala C Wali
- 2) I/my child understand that my/ my child's participation is voluntary in the study and I/my child are free to withdraw at any time, without giving any reason and without my child's medical care/legal rights being affected.
- 3) I/my child understood and permit the above researcher/Ethics committee/regulatory authorities to look into my child's health records, both for current study and further research that may be conducted in relation to it even if i stop taking part in the study.
- 4) I/my child understand that my/ my child's identity will be confidential and will not be revealed in any information related to scientific purpose or published.

- 5) I/my child agree not to restrict the use of any of my information or results that arises from this study provided, such a use is only for scientific purpose.
- 6) I/my child have been given a copy of the information sheet and consent form to keep, by signing this form, I have not given up my legal rights.
- 7) I/my child agree to take part in the study

Participant's Name

Signature/ thumb impression

Name of LAR/Impartial witness

Signature/ thumb impression

Name of researcher

Signature

Name of Paediatrician

Signature



ರೋಗಿಯ ಮಾಹಿತಿ ಸಮ್ಮತಿಯ ರೂಪ

ತೃತೀಯ ಆರೈಕೆ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ಅಪಸ್ಥಾರ ಮಕ್ಕಳ ಚಿಕಿತ್ಸೆಯಲ್ಲಿ ಔಷಧಿಯ ಅಪರಿಣಾಮಕಾರಿತ್ವದ ಬಗ್ಗೆ ಔಷಧಿಯ ತಜ್ಞರ ಸಲಹೆಯ ಪರಿಣಾಮಕಾರಿತ್ವ ಒಂದು ಯಾದೃಷ್ಟಿಕ ನಿಯಂತ್ರಿಸಲಾಗಿದೆ ಅಭ್ಯಾಸ.

ಸಂಶೋಧಕ : ಶ್ರೀಮತಿ ಶಶಿಕಲಾ ಸಿ.ವಾಲಾ
9902944602

ಇ-ಮೇಲ್ : shashiwali90@gmail.com

ಭಾಗವಹಿಸುವವರ ಹೆಸರು :

----- ದಿನಾಂಕ :

ಹುಟ್ಟಿದ ದಿನಾಂಕ :

ವಯಸ್ಸು :

ನೀವು ಸಹಿ ಹಾಕುವ ಮೊದಲು ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿರಿ :.

1) ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಪಾಲ್ಗೊಳ್ಳುವವರ (ರೋಗಿ) ಮಾಹಿತಿ ಪತ್ರದಲ್ಲಿನ ಮಾಹಿತಿಯ ಬಗ್ಗೆ ನಾನು ಓದಲು ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಎಂದು ನಾನು/ನನ್ನ ಮಗು ದೃಢಪಡಿಸಿದೆ. ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನಾನು/ನನ್ನ ಮಗುವಿನ ಪ್ರಶ್ನೆಗಳನ್ನು ಶ್ರೀಮತಿ. ಶಶಿಕಲಾ ಸಿ.ವಾಲಾ ಉತ್ತರಿಸಿದ್ದಾರೆ.

2) ನಾನು/ನನ್ನ ಮಗುವಿಗೆ ನನ್ನ/ನನ್ನ ಮಗುವಿನ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆ ಅಧ್ಯಯನದಲ್ಲಿ ಸ್ವಯಂ ಪ್ರೇರಿತವಾಗಿದೆ ಮತ್ತು ನಾನು/ನನ್ನ ಮಗುವಿಗೆ ಯಾವುದೇ ಕಾರಣವಿಲ್ಲದೆ ಮತ್ತು ನನ್ನ ಮಗುವಿನ ವೈದ್ಯಕೀಯ ಆರೈಕೆ/ಕಾನೂನು ಹಕ್ಕುಗಳು ಹಾನಿಯಾಗದಂತೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಾದರೂ ಹಿಂತೆಗೆದುಕೊಳ್ಳಲು ಮುಕ್ತವಾಗಿರುತ್ತೇವೆ.

3] ನನ್ನ ಮಗುವಿನ ಆರೋಗ್ಯ ದಾಖಲೆಗಳನ್ನು ಪರಿಶೀಲಿಸಲು ನಾನು/ನನ್ನ ಮಗು ಮೇಲಿನ ಸಂಶೋಧಕ/ಎಥಿಸ್ಟ ಸಮಿತಿ/ನಿಯಂತ್ರಕ ಅಧಿಕಾರಿಗಳನ್ನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಪ್ರಸ್ತುತ ಅಧ್ಯಯನಕ್ಕೆ ಮತ್ತು ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದನ್ನು ನಿಲ್ಲಿಸುವಾಗ ಅದರ ಬಗ್ಗೆ ನಡೆಸಿದ ಹೆಚ್ಚಿನ ಸಂಶೋಧನೆಗೆ ಅನುಮತಿಸುತ್ತೇನೆ.

4] ನಾನು/ನನ್ನ ಮಗು ನನ್ನ/ನನ್ನ ಮಗುವಿನ ಗುರುತು ಗೌಪ್ಯವಾಗಿರುವುದನ್ನು ಅರ್ಥಮಾಡಿಕೊಳ್ಳುತ್ತದೆ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಗಳಿಗೆ ಸಂಬಂಧಿಸಿದ ಯಾವುದೇ ಮಾಹಿತಿಯಿಲ್ಲದ ಪ್ರಕಟವಾಗುವುದಿಲ್ಲ ಅಥವಾ ಪ್ರಕಟಿಸುವುದಿಲ್ಲ.

5] ನಾನು/ನನ್ನ ಮಗು ನನ್ನ ಯಾವುದೇ ಮಾಹಿತಿಯ ಬಳಕೆ ಅಥವಾ ಒದಗಿಸಿದ ಈ ಅಧ್ಯಯನದಿಂದ ಉಂಟಾಗುವ ಫಲಿತಾಂಶಗಳನ್ನು ನಿರ್ಬಂಧಿಸುವುದನ್ನು ಒಪ್ಪಿಕೊಳ್ಳುವುದಿಲ್ಲ. ಅಂತಹ ಬಳಕೆ ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಮಾತ್ರ.

6] ಈ ಫಾರ್ಮ್‌ಅನ್ನು ಸಹಿ ಮಾಡುವ ಮೂಲಕ ನಾನು/ನನ್ನ ಮಗುವಿಗೆ ಮಾಹಿತಿ ಶೀಟ್ ಮತ್ತು ಸಮ್ಮತಿಯ ನಮೂನೆಯ ಪ್ರತಿಯನ್ನು ನೀಡಲಾಗಿದೆ. ನನ್ನ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ನಾನು ನೀಡಲಿಲ್ಲ.

7] ನಾನು/ನನ್ನ ಮಗು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾವಹಿಸಲು ಒಪ್ಪಿಕೊಳ್ಳುತ್ತೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು _____ ಸಹಿ/ಹೆಚ್ಚಿರಲು ಗುರುತು

LAR/ಇಪಾರ್ಡಿಯಲ್ ಸಾಕ್ಷಿ ಸಹಿ----- ಸಹಿ/ಹೆಚ್ಚಿರಲು ಗುರುತು

ಸಂಶೋಧಕರ ಹೆಸರು

ಸಹಿ/-

ಚಿಕ್ಕಮಕ್ಕಳ ತಜ್ಞರ ಹೆಸರು

ಸಹಿ/-



रुग्ण माहिती सहमती पत्र

तिसऱ्या वर्गाच्या दवाखाण्यात अपरस्मार बास्त मुलांना क्लिनिकल फार्मासिस्ट औषध पालनाचे उपदेश व महत्त्व पटअन देण्याबाबतीत :
याहच्छिक नियंत्रित अभ्यास

संशोधक : सी. शशिकला सी. वाली

9902944602

ई-मेल: shashiwali90@gmail.com

सहभागीचे नाव:

दिनांक:

जन्म दिनांक:

वय:

आपल्या सहमती देणे आधी कृपया खालील दिलेली माहिती वाचा.

- मी/माझे मूल या अभ्यासात माहिती सूचना पत्र वाचले आणि समजून घेतले/ समजावून सांगितले आहे. या अभ्यासात माझ्या प्रश्नांची उत्तरे सी. शशिकला सी. वाली यांनी उत्तर दिले आहे.
- मी/माझे मूल कोणत्याही वेळा कोणत्याही कारण न देता अभ्यास माने देण्यात माझ्या मुलांच्या वैयक्तिक/ कायदेशीर अधिकार परिणाम होणार नाही हे मला / माझ्या मुलाला समजले आहे.
- मी/माझे मुल जरी अभ्यास मध्ये भाग घेणे बंद केले तरी , संशोधक/ स्थानिक नीतिशास्त्र समिती/ नियामक अधिकारी त्यांना चालू अभ्यास आणि पुढील संशोधन कोन्ही चालवण्यासाठी आरोग्य रेकॉर्ड पाहण्याची माझे / माझे मुलाच्या परवानगी देण्याची गरज नसावी.
- माझे/माझे मुलाच्या ओळख गोपनीय असेल आणि कुसऱ्या कोणतीही वैज्ञानिक संबंधित माहिती किंवा प्रकाशन मध्ये उघड केले जाणार नाही म्हणून मला / माझ्या मुलाला समजले आहे.

३. माझे/माझे मुलांच्या अभ्यास संबंधित कोणत्याही माहिती या परिणाम वापरण्यासाठी प्रतिबंधित नाही, असा वापर फक्त वैज्ञानिक उद्देशासाठी असावे.
६. मी/माझे मुलाला माहिती पत्रक आणि सुचनांसह प्रत दिले आहेत आणि ही फॉर्म सही मी /माझे मुलाच्या कायदेशीर अधिकार दिले नाही.
७. मी/माझे मूल. या अभ्यासात भाग घेणे सहमत आहे.

सहभागीची नाव

सही/ अंगठ्याचा ठसा

कायदेशीर स्वीकाराह प्रतिनिधी

सही/ अंगठ्याचा ठसा

नि: पक्षपाती साक्षीदार यांचे नाव

संशोधक यांचे नाव

सही

बालरोगतज्ञ यांचे नाव

सही

ANNEXURE – IV - PATIENT INFORMATION SHEETS

(English, Kannada, Marathi)



Patient Information Sheet(PIS)

Effectiveness of Counseling by Clinical Pharmacist on Medication Adherence in Epileptic Children at Tertiary Care Hospital: A Randomized controlled study.

Introduction:-

You/your child are being invited to take part in this research study which helps effective counseling to the paediatric epileptic children/parents by clinical pharmacist to check the antiepileptic medication adherence and to identify and monitor Adverse Drug Reactions (ADRs). The overall goal is to improve the quality of life and safety in health care and to reduce medication/treatment related problems. Your participation will help to contribute to the study.

Purpose of study:-

Compliance with medication is a major problem because of the need for long-term therapy together with unwanted effects of many drugs. Compliance behavior depends on the specific clinical situation, nature of illness, and the treatment program. An increased complexity of treatment regimen, as well as increased number of required behavioral changes appears to be associated with non-compliance. Children/parents can accidentally fail to adhere through forgetfulness, misunderstanding, or uncertainty about clinician's recommendations, or intentionally due to their own expectations of treatment and side-effects. This study will help children/parents to achieve medication adherence which can ultimately improve the quality of life, reduce adverse drug reaction and prolonged hospitalization.

Why have you been chosen to take part in the study?:-

There is need for medication adherence, safety, effectiveness by the counseling of the clinical pharmacist and to reduce the adverse drug reaction and monitoring among pediatric patients to ensure safety of drug therapy. Anticonvulsants are the main drugs in the management of epilepsy. Wide range of side effects, drug interactions and individual response differences contribute to non-adherence. Therefore, there is need for enrollement in this study.

What does it mean to participate?:-

You/your child's participation is entirely voluntary and You/your child may withdraw from the study any time; to help you make your decision, please read this information sheet. You are free to discuss the content of this document with a members of your family. You may take as much time as you like to consider whether to take or not to take part in the study. If you choose not to take part, your current and future medical care will not be affected. If you agree to take part you are free to withdraw from the study at any time without loss of health care benefits.

Once you understand what is involved in the study and you wish to participate, you will be requested to sign the consent form. If you have a question or query at any time during the research study, you should feel free to ask us and obtain answers to your questions. You are not

giving any of your legal rights by volunteering for this research study or by signing this consent form.

To participate in the study means that you have given your consent to be a part of the study for a duration of two years during which the following will be required from you.

Confidentiality:-

You /your child's records will be treated with confidentiality and will be revealed only to the Research team/Ethics committee/regulatory authority if required.

During the study:-

Patients will be randomised from Pediatric Neurology Out-Patient Department in our hospital setting. Tools such as Morisky scale, QOL questionnaires and ADRs assessment scale will be used to identify and report drug related problems and improve quality of life for the patient.

Your medication adherence will be assessed for identifying and monitoring ADR as you are assigned to the intervention group, you will receive an educational session on epileptic therapy management, disease management and lifestyle modification during this session. We will provide you patient information leaflets (PIL), the material will be free of cost for you.

Further contact after completion of baseline data collection:-

After the hospital visit or follow-up, we will ask you some question about your health, daily activity and lifestyle. Subsequently, we will also collect your routine information from the hospital record and your follow-up in OPD.

Benefits from the study:-

The study as a part of providing Pharmaceutical care is a patient oriented care, which is a beneficiary approach; provided by clinical pharmacist for improving patient's health and will be available to you free of charge. By participating in the study you may become more aware of your medication related problems and how to manage them.

What are the risks in participating in the study:-

We do not expect that you will incur any risk by participating in the study. There is no invasive procedure involved in this study.

Who has reviewed the study?

This study has been reviewed by the Institutional Ethics Committee, which has responsibility for scrutinizing proposal for medical research on human. The reviewing committee has raised no objection from the point of view of medical ethics.

Inquiries/Questions:-

If you have any question about research/research related problems, you should contact to Mrs. Shasikala C. Wali .Mob.No. [+919902944602](tel:+919902944602). Should you have any questions regarding your rights as a research participant, you may contact the Institutional Review Board.



ರೋಗಿಯ ಮಾಹಿತಿ ಸಂಗ್ರಹ

ತೃತೀಯ ಆರೈಕೆ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ಅಪಸ್ಕಾರ ಮಕ್ಕಳ ಚಿಕಿತ್ಸೆಯಲ್ಲಿ ಔಷಧಿಯ ಅಚಟ ಕೊಳ್ಳುವಿಕೆಯ ಬಗ್ಗೆ ಔಷಧೀಯ ತಜ್ಞರ ಸಲಹೆಯ ಪರಿಣಾಮಕಾರಿತ್ವ ಒಂದು ಯಾದೃಷ್ಟಿಕ ನಿಯಂತ್ರಿಸಲಾಗಿದ ಅಭ್ಯಾಸ.

ಪರಿಚಯ :

ಈ ಸಂಶೋಧನೆಯ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ನೀವು/ನಿಮ್ಮ ಮಗುವಿಗೆ ಆಹ್ವಾನ ನೀಡಲಾಗಿದ್ದು, ಆಂಟಿಬಯೋಲಿಕ್ ಔಷಧಿಗಳ ಅನುಷ್ಠಾನವನ್ನು ಪರೀಕ್ಷಿಸಲು ಮತ್ತು ಪ್ರತಿಕೂಲ ಔಷಧಿಗಳ ಪ್ರತಿಕ್ರಿಯೆಗಳನ್ನು ಗುರುತಿಸಲು ಮತ್ತು ಮೇಲ್ವಿಚಾರಣೆ ಮಾಡಲು ಕ್ಲಿನಿಕಲ್ ಫಾರ್ಮಾಸಿಸ್ಟರಿಂದ ಮಕ್ಕಳ ಎಲೆಕ್ಟ್ರಿಕ್ ಮಕ್ಕಳು/ಪೋಷಕರಿಗೆ ಪರಿಣಾಮಕಾರಿ ಸಲಹೆ ನೀಡಲು ಸಹಾಯ ಮಾಡುತ್ತದೆ. ಒಬ್ಬರೆ ಜೀವನದ ಗುರಿ ಏನೆಂದರೆ ಗುಣಮಟ್ಟ ಮತ್ತು ಔಷಧಿಯ ದುಷ್ಪರಿಣಾಮವನ್ನು ಕಡಿಮೆ ಮಾಡಲು ಸಹಾಯವಾಗುತ್ತದೆ. ಆರೋಗ್ಯದ ಆರೈಕೆಯ ಸುರಕ್ಷತೆಯನ್ನು ಸುಧಾರಿಸುವುದು ಮತ್ತು ಔಷಧಿ/ಚಿಕಿತ್ಸೆ ಸಂಬಂಧಿತ ಸಮಸ್ಯೆಗಳನ್ನು ಕಡಿಮೆ ಮಾಡುವುದು ನಿಮ್ಮ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆ ಅಧ್ಯಯನಕ್ಕೆ ಉಪಯೋಗವಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದ ಉದ್ದೇಶ :

ಔಷಧಿಗಳನ್ನು ಅನುಸರಿಸುವುದು ದೀರ್ಘಕಾಲದ ಚಿಕಿತ್ಸೆಯ ಅವಶ್ಯಕತೆಯ ಕಾರಣದಿಂದಾಗಿ ಹಲವಾರು ಔಷಧಿಗಳ ಅನಗತ್ಯ ಪರಿಣಾಮಗಳೊಂದಿಗೆ ಒಂದು ಪ್ರಮುಖ ಸಮಸ್ಯೆಯಾಗಿದೆ. ಅನುಸರಣೆಯ ನಡವಳಿಕೆಯು ನಿರ್ದಿಷ್ಟ ವೈದ್ಯಕೀಯ ಪರಿಸ್ಥಿತಿ, ಅನಾರೋಗ್ಯದ ಸ್ವಭಾವ ಮತ್ತು ಚಿಕಿತ್ಸೆಯ ಕಾರ್ಯಕ್ರಮಗಳ ಮೇಲೆ ಅವಲಂಬಿತವಾಗಿರುತ್ತದೆ. ಚಿಕಿತ್ಸೆಯ ಕಟ್ಟುಪಾಡುಗಳ ಹೆಚ್ಚಿದ ಸಂಕೀರ್ಣತೆಯು, ಅಗತ್ಯವಿರುವ ನಡವಳಿಕೆಯ ಬದಲಾವಣೆಗಳ ಸಂಖ್ಯೆಯು ಅನುವರ್ತನೆ ಯೊಂದಿಗೆ ಸಂಬಂಧ ಹೊಂದಿದೆಯೆಂದು ಕಂಡು ಬರುತ್ತದೆ. ಮಕ್ಕಳು/ಪೋಷಕರು ಆಕಸ್ಮಿಕವಾಗಿ ಮರೆವು ತಪ್ಪು ಗ್ರಹಿಕೆ ಅಥವಾ ಚಿಕಿತ್ಸೆಯ ತಿಳಿವಳಿಕೆಗಳ ಬಗ್ಗೆ ಅನಿಶ್ಚಿತತೆ ಅಥವಾ ಉದ್ದೇಶಪೂರ್ವಕವಾಗಿ ಚಿಕಿತ್ಸೆ ಮತ್ತು ಅಡ್ಡಪರಿಣಾಮಗಳ ತಮ್ಮ ನಿರೀಕ್ಷೆಗಳಿಂದ ಅಂಟಿಕೊಳ್ಳುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವು ಅಂತಿಮವಾಗಿ ಮಕ್ಕಳ ಆರೋಗ್ಯ ಗುಣಮಟ್ಟವನ್ನು ಸುಧಾರಿಸಲು ಔಷಧಿಗಳ ಅನುಷ್ಠಾನವನ್ನು ಸಾಧಿಸಲು ಸಹಾಯ ಮಾಡುತ್ತದೆ.

ಇದು ಅಂತಿಮವಾಗಿ ಜೀವನದ ಗುಣಮಟ್ಟವನ್ನು ಸುಧಾರಿಸುತ್ತದೆ. ವೈತರಿಕ್ಷ ಔಷಧ ಪ್ರತಿಕ್ರಿಯೆ ಮತ್ತು ದೀರ್ಘಕಾಲದ ಆಸ್ವತ್ತೆಯ ಇರುವಿಕೆಯನ್ನು ಕಡಿಮೆಗೊಳಿಸುತ್ತದೆ.

ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ನೀವು ಯಾಕೆ ಆಯ್ಕೆಯಾಗಿದ್ದೀರಿ ?

ಔಷಧಿಗಳ ಪಾಲನೆ, ಸುರಕ್ಷತೆ, ಪರಿಣಾಮಕಾರಿತ್ವವನ್ನು ವೈದ್ಯಕೀಯ ಔಷಧಿಕಾರರು ಸಲಹೆ ಮಾಡುತ್ತಾರೆ ಮತ್ತು ಔಷಧಿ ಚಿಕಿತ್ಸೆಯ ಸುರಕ್ಷತೆಯನ್ನು ಖಾತ್ರಿ ಪಡಿಸಿಕೊಳ್ಳಲು ಅಪಸ್ಥಾರ ಮಕ್ಕಳ ಔಷಧಿಯ ಪ್ರತಿಕ್ರಿಯೆ ಮತ್ತು ದುಷ್ಪರಿಣಾಮವನ್ನು ತಗ್ಗಿಸಬಹುದು. ಅಪಸ್ಥಾರ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಅಪಸ್ಥಾರ ಔಷಧಿಗಳು ಪ್ರಮುಖ ಔಷಧಿಗಳಾಗಿವೆ. ಅಡ್ಡಪರಿಣಾಮಗಳ ವ್ಯಾಪಕ ಶ್ರೇಣಿಯು ಔಷಧಿಗಳ ದುರ್ಬಳಕೆ ವೈಯಕ್ತಿಕ ಪ್ರತಿಕ್ರಿಯೆ ವ್ಯತ್ಯಾಸಗಳು ಅನುಯಾಯಿಲ್ಲದಿರುವಿಕೆಗೆ ಕೊಡುಗೆ ನೀಡುತ್ತದೆ. ಆದ್ದರಿಂದ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ಅಗತ್ಯವಿರುತ್ತದೆ.

ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಇದರ ಅರ್ಥವೇನು ?

ನೀವು/ನಿಮ್ಮ ಮಗುವಿನ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆ ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂ ಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ ಮತ್ತು ನೀವು/ನಿಮ್ಮ ಮಗುವು ಯಾವ ಸಮಯದಲ್ಲಾದರೂ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ತೆಗೆದುಕೊಳ್ಳಬಹುದು: ನಿಮ್ಮ ನಿರ್ಧಾರವನ್ನು ಮಾಡಲು ಸಹಾಯ ಮಾಡಲು ದಯವಿಟ್ಟು ಈ ಮಾಹಿತಿ ಪತ್ರ ಓದಿ. ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಈ ರೋಗಿಯ ಪತ್ರದ ಮಾಹಿತಿ ವಿಷಯವನ್ನು ಚರ್ಚಿಸಲು ನೀವು ಮುಕ್ತರಾಗಿದ್ದೀರಿ. ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಬಾರದು ಅಥವಾ ತೆಗೆದುಕೊಳ್ಳಬಾರದು ಎಂದು ಪರಿಗಣಿಸಲು ನೀವು ಹೆಚ್ಚು ಸಮಯ ತೆಗೆದುಕೊಳ್ಳಬಹುದು. ನೀವು ಪಾಲ್ಗೊಳ್ಳಬಾರದೆಂದು ಆರಿಸಿದರೆ, ನಿಮ್ಮ ಪ್ರಸ್ತುತ ಮತ್ತು ಮುಂದಿನ ವೈದ್ಯಕೀಯ ಆರೈಕೆಗೆ ಯಾವುದೇ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ನೀವು ಪಾಲ್ಗೊಳ್ಳಲು ಒಪ್ಪಿಕೊಂಡರೆ ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಆರೋಗ್ಯ ಕಾಳಜಿಯ ನಷ್ಟವಿಲ್ಲದೆಯೇ ಅಧ್ಯಯನ ಹಿಂಪಡೆಯಲು ಸ್ವತಂತ್ರರಾಗಿದ್ದೀರಿ.

ಅಧ್ಯಯನದಲ್ಲಿ ಏನು ತೊಡಗಿದೆ ಎಂಬುದನ್ನು ನೀವು ಅರ್ಥಮಾಡಿಕೊಂಡರೆ ಮತ್ತು ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸಿದರೆ, ನೀವು ಸಮ್ಮತಿಯ ನಮೂನೆಯಲ್ಲಿ ಸಹಿ ಮಾಡಲು ವಿನಂತಿಸಲಾಗುತ್ತದೆ.



रुग्ण माहिती सहमती पत्र

तिसऱ्या दर्जाच्या दवाखाण्यात अपस्मार ग्रस्त मुलांना क्लिनिकल फार्मासिस्ट औषध पालनाचे उपदेश व महत्त्व पटवून देण्याबाबतीत :
याहच्छिक नियंत्रित अभ्यास

* परिचय :

या संशोधन अभ्यासात सहभागी होण्यासाठी तुम्हाला/तुमच्या मुलास आमंत्रित केले जात आहे अपस्मार औषधांचे पालन तपासण्यासाठी आणि औषधांचे हानिकारक परिणाम ओळखण्यासाठी व लक्ष ठेवण्यासाठी अपस्मार ग्रस्त मुले/ पालकांना क्लिनिकल फार्मासिस्ट व्दारे प्रथावी समुपदेशन करण्यास मदत करते. आरोग्य सेवेतील जीवन आणि सुरक्षेची गुणवत्ता सुधारणे आणि औषधे / औषधोपचार संबंधी समस्या सोडवणे हे एकमेव ध्येय आहे. आपला सहभाग अभ्यासात योगदान करण्यात मदत करेल.

* अभ्यासाचा हेतु :

औषधांचे पालन नकरणे ही एक औषधोपचारातील मुख्य समस्या आहे. कारण दीर्घकाल औषधोपचार आणि त्यांचे अवांछित परिणाम, औषधांचे पालन हे आजाराचे स्वरूप विशिष्ट वैद्यकीय परिस्थिती आणि उपचार पद्धतीवर अवलंबून असते.

उपचार पद्धतीची वाढती जटिलता आणि अपेक्षित वर्तणुकीतील बदल यांचा संबंध गैर-पालनाशी आहे.

मुले आणि पालक चुकून पालन होत नाही यामध्ये विसराळुपणा, विपर्यास किंवा चिकित्सकांच्या शिफारशी विषयी अनिश्चितता किंवा त्यांच्या स्वतःच्या औषधोपचारांच्या अपेक्षा आणि दुष्परिणाम.

हा अभ्यास मुलांना/पालकांना - औषधोपचाराचे पालन करण्यास मदत करेल ज्यामुळे जीवनमानाची गुणवत्ता सुधारण्यास हानिकारक औषधांचे परिणाम कमी करण्यास आणि रुग्णाचा दवाखाण्यातील काळ कमी होण्यास मदत होईल.

* का तुम्हाला अभ्यासात सहभागी होण्यासाठी निवडले गेले?

औषधांचे पालन, सुरक्षितता, प्रभाव गरजेचा आहे आणि त्यासाठी क्लिनिकल फार्मासिस्टचे समुपदेशन गरजेचे आहे. तसेच औषधांचे हानिकारक दुष्परिणाम कमी करते आणि त्यासाठी लहान मुलांचे परिक्षण करणे गरजेचे आहे ज्याने औषधाची सुरक्षितता कलेल अपरमार व्यवस्थापनामध्ये एन्टीकॉन्व्हलन्स हे मुख्य औषध आहे.

- हानिकारक परिणामांची विस्तृत श्रेणी, औषध संवाद आणि वैयक्तिक प्रतिसाद हे गैर अनुपालनास योगदान देतात. त्यामुळे या अभ्यासामध्ये नाव नोंदनीची आवश्यकता आहे.

* सहभागी होण्यास अर्थ काय होतो?

आपण/आपल्या मुलांचा सहभाग संपूर्णपणे स्वयंसेवी आहे आणि आपण/आपले बाल अभ्यासामधून कोणत्याही वेळी मागे घेऊ शकता. आपला निर्णय घेण्यास मदत करण्यासाठी कृपया ही माहिती पत्रक वाचा आपण आपल्या कुटुंबीयांशी चर्चा करू शकता.

अभ्यासात सहभागी होणार की नाही याचा निर्णय घेण्यासाठी आपण जास्त वेळ घेऊ शकता. आपण भाग न घेण्याचे निवडले तर आपल्या वर्तमान आणि भविष्यातील वैद्यकीय निधीवर परिणाम होणार नाही तुम्ही भाग घेण्यास सहमत असाल तर तुम्ही आरोग्यसेवा फायदे न गमावता अभ्यासामधून कधीही बाहेर जाण्यास मोकळे आहात.

अभ्यासात कोणत्या गोष्टी समाविष्ट आहेत हे समजल्यानंतर आणि आपण सहभागी होऊ इच्छित असाल, तर आपल्याला संमती फॉर्मवर स्वाक्षरी करण्याची

ANNEXURE – V - DATA COLLECTION FORM

DEPARTMENT:

WARD/UNIT:

DATE:

OPD NO:

DR.NAME:

DEMOGRAPHIC DETAILS OF PATIENT:

NAME:	AGE: yrs	GENDER: M / F	Ht: cm	Wt: kg
CONTACT NO:	ADDRESS:			
Complaints				
Previous allergies				
Family history:				
OBJECTIVE FINDINGS:				
PHYSICAL EXAMINATION:				
GENERAL:				
DATE: VITAL SIGNS				
BP (mm Hg) :				
PR (beats /min) :				
TEMP (°F/°C) :				
RR (cpm) :				
DATE -				
CVS :				
RS :				
CNS :				
P/A :				

PROVISIONAL DIAGNOSIS**Past Medical History:****Prescription Medication History:**

Name/Strength	Indication	Start Date	Stop Date	Direction	Effectiveness

Non-Prescription Medication History:

Ailments	Name/Strength	Direction	Purpose	How often	Effectiveness

Use of alternative medicine details:

Yes/No _____ (If Yes, specify) _____

ROUTINE LABORATORY INVESTIGATION

Date:				X – Rays:
Blood(Normal values)				
Hb (M: 13-16%) (F: 12-15%)				
WBC (4000-11000)				
Neutrophils (40-70%)				
Lymphocytes (20-40%)				
Eosinophils (1-8%)				
Monocytes (2-10%)				CT/USS:
ESR (M:0-10mm in 1 st hr) (F:0-20mm in 1 st hr)				
PCV (M:40-50%) (F:35-45%)				
Platelet Count (1.5-4.5 Lakhs/cmm)				
AEC (0-400 cells/cmm)				MRI:
Reticulocyte count (0.2-2%)				
RBC (M: 4.5-6.5millions/cmm F:3.8-5.8millions/cmm)				
P.S				EEG
M.P				
HDL				
LDL				
VLDL				
TG				
Renal Function Test:				
Urea (15-45 mg/dl)				
Creatinine(M:0.5-1.5mg/day)				
Electrolytes :				Blood group:
Sodium (Na ⁺)				Type:
Potassium (K ⁺)				
Chloride (Cl)				
Phosphorus (PO ₄)				
Uric acid				Culture& sensitivity :
Calcium (Ca ²⁺)				PUS/Urine/Blood/Stool:
Bicarbonate (HCO ₃)				
Liver Function Test :				
T- Bilirubin (0.2-1.0 mg/dl)				
Direct Bilirubin (0.0-0.3 mg/dl)				
T- protein (6.0-8.5 g/dl)				
Albumin (3.2-5.5 g/dl)				

CLINICAL PHARMACIST'S INTERVENTION:

FOLLOW UP REVIEW:

PATIENT COUNSELING:

ADDITIONAL NOTES:

CLINICAL PHARMACIST SIGNATURE:

ANNEXURE – VI - SELF VALIDATED MEDICATION

ADHERENCE QUESTIONNAIRE

Please answer each question based on your personal experience with your medications. Note that there is not right or wrong answer. (Please circle your answer below)

1.	Do you sometimes forget to take your anti-epileptic medications?	YES	NO
2.	People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medications?	YES	NO
3.	Have you ever cut back or stopped taking your anti-epileptic medications without telling your doctor, because you felt worse when you took it?	YES	NO
4.	When you travel or leave home, do you sometimes forget to bring along your anti-epileptic medications?	YES	NO
5.	Did you take your medications yesterday?	YES	NO
6.	When you feel like your health condition is under control, do you sometimes stop taking you anti-epileptic drugs?	YES	NO
7.	Taking anti-epileptics every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	YES	NO
8.	How often do you have difficulty remembering to take all your anti-epileptic medications?	Never/rarely Once in a while Sometimes Usually All the time	4 3 2 1 0
	Total score		

ANNEXURE – VII - QUALITY OF LIFE IN CHILDHOOD

EPILEPSY QUESTIONNAIRE

Quality of Life in Childhood Epilepsy Questionnaire: QOLCE-55 Version 1.0 (English)

Goodwin SW, Lambrinos AI, Ferro MA, Sabaz M, Speechley KN. Development and assessment of a shortened Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-55). *Epilepsia* 2015;56(6):864-72.

USER INFORMATION

Citation:

Individuals using the QOLCE-55 should cite the following reference in their work:

Goodwin SW, Lambrinos AI, Ferro MA, Sabaz M, Speechley KN. Development and assessment of a shortened Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-55). *Epilepsia* 2015;56(6):864-72.

QOLCE-55 Item Allocation:

1. Cognitive functioning (22 items): section 1.1 a-v.
2. Emotional functioning (17 items): section 2.1 a-k and section 2.2 a-f.
3. Social functioning (7 items): section 3.1 a-g.
4. Physical functioning (9 items): section 4.1 a-i.

Scoring Instructions:

1. Recode all items such that higher scores indicate higher well-being.
2. Convert the pre-coded numeric values of items to a 0-100 point scale, with higher converted scores always reflecting better quality of life. Responses should now be coded as 0, 25, 50, 75, 100.
3. Calculate the mean value of the items in each subscale. Adjust the denominator to include only items answered.
4. To calculate the total score, take the unweighted mean of the four subscales.

Quality of Life in Childhood Epilepsy Questionnaire: QOLCE-55 Version 1.0 (English)

Goodwin SW, Lambrinos AJ, Ferro MA, Sabaz M, Speechley KN. Development and assessment of a shortened Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-55). *Epilepsia* 2015;56(6):864-72.

INSTRUCTIONS

The following questions ask about your child's health and well-being. Answer the questions by ticking the appropriate box. Certain questions may look alike but each one is different. Some questions may ask about problems your child does not have. Please try to answer each question as it is important for us to know when your child does not have these problems. There are no right or wrong answers. If you are unsure how to answer a question, please give the best answer you can.

SECTION 1: YOUR CHILD'S COGNITIVE FUNCTIONING

The following questions ask about some problems children have with concentrating, remembering, and speaking.

1.1 Compared to other children of his/her own age, how often during the past 4 weeks has your child:

	Very Often	Fairly Often	Some- times	Almost Never	Never	Not Applicable
a. had difficulty attending to an activity?	☐	☐	☐	☐	☐	☐
b. had difficulty reasoning or solving problems?	☐	☐	☐	☐	☐	☐
c. had difficulty making plans or decisions?	☐	☐	☐	☐	☐	☐
d. had difficulty keeping track of conversations?	☐	☐	☐	☐	☐	☐
e. had trouble concentrating on a task?	☐	☐	☐	☐	☐	☐
f. had difficulty concentrating on reading?	☐	☐	☐	☐	☐	☐
g. had difficulty doing one thing at a time?	☐	☐	☐	☐	☐	☐
h. reacted slowly to things being said and done?	☐	☐	☐	☐	☐	☐
i. found it hard remembering things?	☐	☐	☐	☐	☐	☐
j. had trouble remembering names of people?	☐	☐	☐	☐	☐	☐
k. had trouble remembering where s/he put things?	☐	☐	☐	☐	☐	☐
l. had trouble remembering things people told him/her?	☐	☐	☐	☐	☐	☐
m. had trouble remembering things s/he read hours or days before?	☐	☐	☐	☐	☐	☐
n. planned to do something then forgot?	☐	☐	☐	☐	☐	☐

	Very Often	Fairly Often	Some-times	Almost Never	Never	Not Applicable
o. had trouble finding the correct words?	☐	☐	☐	☐	☐	☐
p. had trouble understanding or following what others were saying?	☐	☐	☐	☐	☐	☐
q. had trouble understanding directions?	☐	☐	☐	☐	☐	☐
r. had difficulty following simple instructions?	☐	☐	☐	☐	☐	☐
s. had difficulty following complex instructions?	☐	☐	☐	☐	☐	☐
t. had trouble understanding what s/he read?	☐	☐	☐	☐	☐	☐
u. had trouble writing?	☐	☐	☐	☐	☐	☐
v. had trouble talking?	☐	☐	☐	☐	☐	☐

SECTION 2: YOUR CHILD'S EMOTIONAL FUNCTIONING

Below is a list that describes how your child might feel in general.

2.1 During the past 4 weeks, how much of the time do you think your child:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time	Not Applicable
a. felt down or depressed?	☐	☐	☐	☐	☐	☐
b. felt happy?	☐	☐	☐	☐	☐	☐
c. wished s/he was dead?	☐	☐	☐	☐	☐	☐
d. felt frustrated?	☐	☐	☐	☐	☐	☐
e. worried a lot?	☐	☐	☐	☐	☐	☐
f. felt confident?	☐	☐	☐	☐	☐	☐
g. felt excited or interested in something?	☐	☐	☐	☐	☐	☐
h. felt pleased about achieving something?	☐	☐	☐	☐	☐	☐
i. felt nobody understood him/her?	☐	☐	☐	☐	☐	☐
j. felt valued?	☐	☐	☐	☐	☐	☐
k. felt no one cared?	☐	☐	☐	☐	☐	☐

Below are statements that describe some children's behaviour.

Please try to answer all questions as well as you can, even if some do not seem to apply to your child.

2.2 Compared to other children his/her own age, how often during the past 4 weeks do each of the following statements describe your child?

	Very Often	Fairly Often	Some-times	Almost Never	Never	Not Applicable
a. was socially inappropriate (said or did something out of place in a social situation)	☐	☐	☐	☐	☐	☐
b. angered easily	☐	☐	☐	☐	☐	☐
c. hit or attacked people	☐	☐	☐	☐	☐	☐
d. swore in public	☐	☐	☐	☐	☐	☐
e. was obedient	☐	☐	☐	☐	☐	☐
f. demanded a lot of attention	☐	☐	☐	☐	☐	☐

SECTION 3: YOUR CHILD'S SOCIAL FUNCTIONING

Below are statements that describe some children's social interactions and activities.

Please try to answer all questions as well as you can, even if some do not seem to apply to your child.

3.1 During the past 4 weeks, how often has your child's epilepsy:

	Very Often	Fairly Often	Some-times	Almost Never	Never	Not Applicable
a. limited his/her social activities (visiting friends, close relatives, or neighbours)?	☐	☐	☐	☐	☐	☐
b. affected his/her social interactions at school or work?	☐	☐	☐	☐	☐	☐
c. limited his/her leisure activities (hobbies or interests)?	☐	☐	☐	☐	☐	☐
d. isolated him/her from others?	☐	☐	☐	☐	☐	☐
e. made it difficult for him/her to keep friends?	☐	☐	☐	☐	☐	☐
f. frightened other people?	☐	☐	☐	☐	☐	☐
g. <u>During the past 4 weeks</u> , how limited are your child's social activities compared with others his/her age because of his/her epilepsy or epilepsy-related problems?	☐ Yes, limited a lot	☐ Yes, limited some	☐ Yes, limited a little	☐ Yes, but rarely	☐ No, not limited	

SECTION 4: YOUR CHILD'S PHYSICAL FUNCTIONING

The following questions ask about physical activities your child might do.

4.1. In his/her daily activities during the past 4 weeks, how often has your child:

	Very Often	Fairly Often	Some- times	Almost Never	Never	Not Applicable
a. needed more supervision than other children his/her age?	☐	☐	☐	☐	☐	☐
b. played freely in the house like other children his/her age?	☐	☐	☐	☐	☐	☐
c. played freely outside the house like other children his/her age?	☐	☐	☐	☐	☐	☐
d. gone swimming (i.e., swam independently)?	☐	☐	☐	☐	☐	☐
e. participated in sports activities (other than swimming)?	☐	☐	☐	☐	☐	☐
f. stayed out overnight (with friends or family)?	☐	☐	☐	☐	☐	☐
g. played with friends away from you or your home?	☐	☐	☐	☐	☐	☐
h. gone to parties without you or without supervision?	☐	☐	☐	☐	☐	☐
i. been able to do the physical activities other children his/her age do?	☐	☐	☐	☐	☐	☐

ANNEXURE – VIII - WHO ADR ASSESSMENT SCALE

Causality term	Assessment criteria*
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/ Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

*All points should be reasonably complied with

ANNEXURE – IX - NARANJO SCALE

Question	Yes	No	Do Not Know	Score
Are there previous conclusive reports on this reaction?	+1	0	0	
Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
Did the adverse event reappear when the drug was readministered?	+2	-1	0	
Are there alternative causes that could on their own have caused the reaction?	-1	+2	0	
Did the reaction reappear when a placebo was given?	-1	+1	0	
Was the drug detected in blood or other fluids in concentrations known to be toxic?	+1	0	0	
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
Was the adverse event confirmed by any objective evidence?	+1	0	0	
	Total Score:			

Score	Interpretation of Scores
Total Score ≥ 9	Definite. The reaction (1) Followed a reasonable temporal sequence after a drug or in which a toxic drug level had been established in body fluids or tissues, (2) Followed a recognized response to the suspected drug, and (3) Was confirmed by improvement on withdrawing the drug and reappeared on reexposure.
Total Score 5 to 8	Probable. The reaction (1) Followed a reasonable temporal sequence after a drug, (2) Followed a recognized response to the suspected drug, (3) Was confirmed by withdrawal but not by exposure to the drug, and (4) Could not be reasonably explained by the known characteristics of the patient's clinical state.
Total Score 1 to 4	Possible. The reaction (1) Followed a temporal sequence after a drug, (2) Possibly followed a recognized pattern to the suspected drug, and (3) Could be explained by characteristics of the patient's disease.
Total Score ≤ 0	Doubtful. The reaction was likely related to factors other than a drug.

ANNEXURE – X - HARTWIGS SCALE

The Hartwig and Siegel Severity Assessment Scale is a tool used to classify the severity of adverse drug reactions (ADRs).

Level	Description	Example
1	No change in treatment	Mild ADRs
2	Suspected drug is withheld, changed. No antidote and increase in hospital stay	Mild ADRs
3	Suspected drug withheld, otherwise changed and antidote or other treatment is required. No increase in length of hospital stay	Moderate ADRs
4a	Any level 3 ADR increasing the length of hospital stay at least by 1 day	Moderate ADRs
4b	ADR is the reason for hospital admission	Moderate ADRs
5	Any level 4 ADR that requires intensive medical care	Severe ADRs
6	ADR causes permanent harm to the patient	Severe ADRs
7	ADR directly or indirectly leads to death of the patient	Severe ADRs

ANNEXURE – XI - SCHUMOCK AND THORNTON SCALE

Sr no	Questions
Definitely Preventable	
1	Was there a history of allergy or previous reactions to the drug?
2	Was the drug involved inappropriate for the patients clinical condition?
3	Was the dose, route or frequency of administration inappropriate for the patients age, weight or disease state?
4	Was a toxic serum drug concentration (or laboratory monitoring test) documented?
5	Was there a known treatment for the Adverse Drug Reaction?
Probably Preventable	
6	Was a required Therapeutic Drug Monitoring or other necessary laboratory test not performed?
7	Was a drug interaction involved in the ADR?
8	Was poor compliance involved in the ADR?
9	Were preventative measures not prescribed or administered to the patient?
Not Preventable	
If all above criteria not fulfilled	

ANNEXURE – XII - SUSPECTED ADR FORM


J. N. Medical College, Belagavi
KLE's College of Pharmacy, Belagavi
 Department of Pharmacy Practice
 KLE's Dr. Prabhahakar Kore Hospital & Medical Research Centre, Belagavi - 10.

Suspected Adverse Drug Reaction Form

Patient Name : _____ Age : _____ Sex : _____
 Dept. : _____ Unit : _____ I. P. No. : _____

 Suspected drug (s) : _____
 Date of Drug(s) started : _____ Date of onset of reaction : _____
 Description of Reaction : _____

 Name of the Reporter : _____ Designation : _____
 Signature : _____ Date : _____

Email ID : adr@klepharm.edu Tel. : 0831-2551768
 Please drop this form in the ADR dropbox or return this form to the department of Clinical Pharmacy
 G + 4 Floor (Pharmacovigilance Centre), KLE Hospital, Belagavi - 10.

ADR REPORTING FORM

ANNEXURE – XIII - ALERT CARD

ALERT CARD

**DEPARTMENT OF PHARMACY PRACTICE
COLLEGE OF PHARMACY, KAHER, BELAGAVI**

ADVERSE DRUG REACTION ALERT CARD

PATIENT NAME:

AGE:

GENDER:

ADDRESS:

ADR:

DRUG:

Please produce this card to your doctor at the time of consultation.

ANNEXURE – XIV - PATIENT INFORMATION LEAFLETS

(English, Kannada, Marathi, Hindi)

EPILEPSY

➤ What is epilepsy?
Epilepsy is caused by abnormal electrical activity in the brain. Epileptics may show following:

- Jerky movements
- Drooling
- Unresponsiveness
- Forgetfulness
- Staring episodes
- Rapid blinking episodes
- Jerky movement of mouth and lips
- Unexplained sudden fear, crying or shouting
- Epilepsy is **NOT** the result of something anyone has done to you and is not infectious to others around you.
- Epilepsy could be due to factors in your genes and it could run in the family

➤ What happens in epilepsy? :
Epilepsy happens as a result of abnormal electrical brain activity, also known as a seizure, kind of like an electrical storm inside head. And because brain controls so much, a lot of different things can go wrong. Patient may have periods of unusual behaviour's, feelings and sometimes loss of awareness.

➤ What to do:

- Move the patient away from harm.
- Stay with the patient.
- Loosen clothes around the neck.
- Place patient in the Lateral position.
- Call for help
- Keep the pillow or soft object below the head
- Call the ambulance.

➤ What not to do:

- Panic
- Give water to drink
- Sprinkle water on the face.
- Insert fingers or any other hard objects to prevent mouth closure
- Give iron rods to hands.
- Restrain their movements

➤ What Are the Warning Signs Before a Seizure?
A person about to have a seizure may experience

- 1) daydreaming episodes
- 2) sensations of tingling

3) unusual tastes or smells
4) numbness.
5) loss of bodily functions
6) headaches

People who have seizures sometimes report having indescribable or very unusual feelings, such as feelings that their bodies look strange or that they are having out-of-body experiences.

➤ Risk factors :

- Age
- Family history
- Head injuries
- Stroke and other vascular diseases
- Dementia
- Brain infections
- Seizures in childhood

➤ Types of seizure :
Seizures are caused by abnormal electrical activity in the brain

Generalized seizures

Seizures that affect both sides of the brain at once.



Partial seizures

Seizures that affect only one part of the brain.



➤ When to see a doctor :
Seek immediate medical help if any of the following occurs:

- The seizure lasts more than five minutes.
- Breathing or consciousness doesn't return after the seizure stops.
- A second seizure follows immediately.
- You have a high fever.
- You have diabetes.
- You've injured yourself during the seizure.
- You continue to have seizures even though you've been taking anti-seizure medication.

➤ Medications:

- Know the names of medications you use.
- Keep a photo of the prescription of the medication on your phone.
- Take the medications as advised by your doctor.
- Do not miss even a single dose of medication.
- Keep an extra stock of medications.
- Rarely certain medication such as Carbamazepine may cause skin rashes. If that happens stop medication and seek doctor's advice.
- Whenever you seek medical attention inform the doctor the fact that you are suffering from epilepsy and medications that you are on.

➤ Common side effects of antiepileptic drugs:

- Confusion
- Double vision
- Dizziness
- Nausea
- Unsteadiness on the feet
- Rash

Less common side effects of epilepsy drugs include

- depression
- irritability
- hyperactivity
- increased risk of suicidal tendencies.

Any side effects should be checked out with a doctor.





Patient Information Leaflet
Epilepsy



DEPARTMENT OF PHARMACY PRACTICE
KLE COLLEGE OF PHARMACY, BELAGAVI
Phone no.: 0831-2471399
Mail ID : klespharmacypractice2016@gmail.com

ಎಪಿಲೆಪ್ಸಿ

> ಅಪಸ್ಮಾರ ಎಂದರೇನು?

ಎಪಿಲೆಪ್ಸಿ ಅರಿದಮನುಷ್ಯನಲ್ಲಿನ ಅಸಹಜ ವಿದ್ಯುತ್ ಚಟುವಟಿಕೆಯಿಂದ ಉಂಟಾಗುತ್ತದೆ ಎಪಿಲೆಪ್ಸಿಕ್ಸ್ ಈ ಕೆಳಗಿನವುಗಳನ್ನು ತೋರಿಸಬಹುದು:

- ಜರ್ಕ್ ಚಲನೆಗಳು
- ಜೋಲು, ಸುರಿಸುತ್ತಿದೆ
- ಸ್ಪಂದಿಸದಿರುವುದು
- ಮರೆವು
- ಧಾರಾವಾಹಿಗಳು
- ಕ್ಲಿಪ್ಸ್ ಮಿಟುಕಿಸುವ ಸಂಭಾಷಣೆ
- ಬಾಯಿ ಮತ್ತು ತುಟಿಗಳ ಜರ್ಕ್ ಚಲನೆ
- ವಿವರಿಸಲಾಗದ ಹಠಾತ್ ಭಯ, ಅಳುವುದು ಅಥವಾ ಕೂಗುವುದು
- ಎಪಿಲೆಪ್ಸಿ ಅಲ್ಪ ಯಾರಾದರೂ ನಿಮಗೆ ಮಾಡಿದ ಮತ್ತು ನಿಮ್ಮ ಸುತ್ತಲಿರುವ ಇತರರಿಗೆ ಸಾಂಕ್ರಾಮಿಕವಲ್ಲದ ಫಲಿತಾಂಶ.
- ಅಪಸ್ಮಾರವು ನಿಮ್ಮ ವಂಶವಾಹಿಗಳಲ್ಲಿನ ಅಂಶಗಳ ಕಾರಣದಿಂದಾಗಿರಬಹುದು ಮತ್ತು ಇದು ಕುಟುಂಬದಲ್ಲಿ ಓಡಬಹುದು



> ಅಪಸ್ಮಾರದಲ್ಲಿ ಏನಾಗುತ್ತದೆ?

ಮೂರ್ಛೆ ರೋಗಸಂಭವಿಸುತ್ತದೆ ಅಸಹಜ ವಿದ್ಯುತ್ ಮಿದುಳಿನ ಚಟುವಟಿಕೆಯ ಪರಿಣಾಮವಾಗಿ, ಸೆಳವು ಎಂದೂ ಕರೆಯಲ್ಪಡುತ್ತದೆ, ಇದು ಒಳಗೆ ವಿದ್ಯುತ್ ಚಂಡಮಾರುತದಂತೆ ತಲೆ ಮತ್ತು ಏಕೆಂದರೆ ಮಿದುಳು ತುಂಬಾ ನಿಯಂತ್ರಿಸುತ್ತದೆ, ಬಹಳಷ್ಟು ವಿಧಿವಿಧಿಗಳನ್ನು ಮತ್ತು ತಪ್ಪಾಗಬಹುದು ರೋಗಿ ಅಸಾಮಾನ್ಯ ಅವಧಿಗಳನ್ನು ಹೊಂದಿರಬಹುದು ನಡವಳಿಕೆ, ಭಾವನೆಗಳು ಮತ್ತು ಕೆಲವೊಮ್ಮೆ ಅರಿವಿನ ನಷ್ಟ.

> ಏನ್ ಮಾಡೋದು:

- ಸರಿಸಿ ದಿ ರೋಗಿಯ ದೂರ ನಿಂದ ಹಾನಿ.
- ಉಳಿಯಿರಿ ಡಬ್ಬಲ್ಸ್‌ನೇ ಟಿ ಅವನು ರೋಗಿಯ.
- ಬಿಡಿಬಿಡಿ ಬಟ್ಟೆ ಸುಮಾರು ದಿ ಕುತ್ತಿಗೆ
- ಸ್ಕಳ ಪ್ಯಾಟೇಂಟ್ ಏನ್ ದಿ ಲ್ಯಾಟರಲ್ ಸ್ಪಾನ್.
- ಸಹಾಯಕ್ಕಾಗಿ ಕರೆ ಮಾಡಿ
- ಮತ್ತೆ ಅಥವಾ ಮೈದುನಾದ ವಸ್ತುವನ್ನು ತಲೆಯ ಕೆಳಗೆ ಇರಿಸಿ
- ಆಂಬುಲೆನ್ಸ್ ಕರೆ ಮಾಡಿ

> ಏನ್ ಮಾಡಬಾರದು

- ದಿಗಿಲು
- ಕುಡಿಯಲು ನೀರು ಕೊಡಿ
- ಮುಖದ ಮೇಲೆ ನೀರು ಚಿ
- ಬಾಯಿ ಮುಚ್ಚುವುದನ್ನು ಅಥವಾ ಇತರ ಯಾವುದೇ ಗಟ್ಟಿಯಾದ ವಸ್ತುಗಳನ್ನು ಸೇರಿಸಿ
- ಕೈಗಳಿಗೆ ಕಬ್ಬಿಣದ ಸರಳುಗಳನ್ನು ನೀಡಿ
- ಅವರ ಚಲನೆಯನ್ನು ನಿಗ್ರಹಿಸಿ



> ಏನ್ ಮಾಡೋದು:

ರೋಗಗ್ರಸ್ತವಾಗುವಿಕೆಯನ್ನು ಹೊಂದಿರುವ ವ್ಯಕ್ತಿಯು ಅನುಭವಿಸಬಹುದು

- 1) ಹೆಗಲುಗವನು ಕಂಪುಗಳು
- 2) ಜುಮ್ಮುನಿಸುವಿಕೆ ಸಂವೇದನೆಗಳು

- 3) ಅಸಾಮಾನ್ಯ ರುಚಿ ಅಥವಾ ವಾಸ
 - 4) ಮರಗಟ್ಟುವಿಕೆ
 - 5) ದೈಹಿಕ ಕಾರ್ಯಗಳ ನಷ್ಟ
 - 6) ತಲೆನೋವು
- ರೋಗಗ್ರಸ್ತವಾಗುವಿಕೆಗಳನ್ನು ಹೋಗಲಾಡಿಸಲು ವಿವರಿಸಲಾಗದ ಅಥವಾ ಅಸಾಮಾನ್ಯ ಭಾವನೆಗಳನ್ನು ಹೊಂದಿದ್ದಾರೆ ಎಂದು ವರದಿ ಮಾಡುತ್ತಾರೆ, ಉದಾಹರಣೆಗೆ ಅವರ ದೇಹಗಳು ವಿಚಿತ್ರವಾಗಿ ಕಾಣುತ್ತವೆ ಅಥವಾ ಅವರು ದೇಹದ ಹೊರಗಿನ ಅನುಭವಗಳನ್ನು ಹೊಂದಿದ್ದಾರೆ.

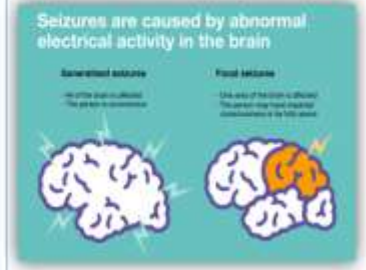


> ಅಪಾಯಕಾರಿ ಅ

- ವಯಸ್ಸು
- ಕುಟುಂಬದ ಇತಿಹಾಸ
- ತಲೆಗೆ ಗಾಯಗಳು
- ಪಾಶ್ಚಾತ್ಯವಾಯು ಮತ್ತೆ ರೋಗಗಳು
- ಬುದ್ಧಿಮಾಂದ್ಯತೆ
- ಮಿದುಳಿನ ನೋರುಗಳು
- ಬಾಲ್ಯದಲ್ಲಿ ರೋಗಗ್ರಸ್ತವಾಗುವಿಕೆ



> ವಿಧಗಳು ರೋಗಗ್ರಸ್ತವಾಗ



Translated from English to Kannada - www.onlinedictanalsabdr.com

> ವೈದ್ಯರನ್ನು ಯಾವಾಗ ನೋಡಬೇಕು:

ಕೆಳಗಿನವುಗಳಲ್ಲಿ ಯಾವುದಾದರೂ ಸಂಭವಿಸಿದಲ್ಲಿ ತಕ್ಷಣದ ವೈದ್ಯಕೀಯ ಸಹಾಯವನ್ನು ಪಡೆಯಿರಿ:

- ಸೆಳವು ಐದು ನಿಮಿಷಗಳಿಗಿಂತ ಹೆಚ್ಚು ಇರುತ್ತದೆ.
- ಸೆಳವು ನಿಂತ ನಂತರ ಉಸಿರಾಟ ಅಥವಾ ಪ್ರಜ್ಞೆ ಹಿಂತಿರುಗುವುದಿಲ್ಲ.
- ಎರಡನೇ ಸೆಳವು ತಕ್ಷಣವೇ ಅನುಸರಿಸುತ್ತದೆ.
- ನಿಮಗೆ ವಿಪರೀತ ಜ್ವರವಿದೆ.
- ನಿಮಗೆ ಮಧುಮೇಹವಿದೆ.
- ಸೆಳತದ ಸಮಯದಲ್ಲಿ ನೀವೇ ಗಾಯಗೊಂಡಿದ್ದೀರಿ.
- ನೀವು ರೋಗಗ್ರಸ್ತವಾಗುವಿಕೆ-ವಿರೋಧಿ ಔಷಧಿಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳುತ್ತಿದ್ದರೂ ಸಹ ನೀವು ರೋಗಗ್ರಸ್ತವಾಗುವಿಕೆಗಳನ್ನು ಹೊಂದಿರುತ್ತೀರಿ.

> ಔಷಧಿಗಳು:

- ನೀವು ಬಳಸುವ ಔಷಧಿಗಳ ಹೆಸರುಗಳನ್ನು ತಿಳಿಯಿರಿ.
- ನಿಮ್ಮ ಫೋನ್‌ನಲ್ಲಿ ಔಷಧಿಗಳ ಪೈಸಿಪ್ಷನ್‌ನ ಫೋಟೋವನ್ನು ಇರಿಸಿ.
- ಸೂಚಿಸಿದಂತೆ ಔಷಧಿಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳಿ, ನಿಮ್ಮ ವೈದ್ಯರಿಂದ.
- ಮಾಡಬಹುದಾದ ಸಹ ತಪ್ಪಿಸಿಕೊಳ್ಳಬೇಡಿರಿ ಔಷಧಿಗಳ.
- ಔಷಧಿಗಳ ಹೆಚ್ಚುವರಿ ಸ್ಟಾಕ್ ಅನ್ನು ಇರಿಸಿ.
- ಕಾರ್ಬಮಾಜಿಪೈನ್ ನಂತರ ಅಪರೂಪದ ಔಷಧಿಗಳು ಚರ್ಮದ ದಮ್ಮುಗಳಿಗೆ ಕಾರಣವಾಗಬಹುದು, ಅದು ಸಂಭವಿಸಿದಲ್ಲಿ ಔಷಧಿಗಳನ್ನು ನಿಲ್ಲಿಸಿ ಮತ್ತು ವೈದ್ಯರ ಸಲಹೆಯನ್ನು ಪಡೆಯಿರಿ.
- ನೀವು ವೈದ್ಯಕೀಯ ಆರೈಕೆಯನ್ನು ಬಯಸಿದಾಗಲೆಲ್ಲಾ ನೀವು ಅಪಸ್ಮಾರದಿಂದ ಬಳಲುತ್ತಿರುವಿರಿ ಮತ್ತು ನೀವು ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ ಔಷಧಿಗಳ ಬಗ್ಗೆ ವೈದ್ಯರಿಗೆ ತಿಳಿಸಿ.

> ಅಂಟಿಪಿಲೆಪ್ಸಿಕ್ ಔಷಧಿಗಳ ಸಾಮಾನ್ಯ ಅಡ್ಡ ಪರಿಣಾಮಗಳು:

- ಗೊಂದಲ
- ಡಬಲ್ ದೃಷ್ಟಿ
- ತಲೆತಿರುಗುವಿಕೆ
- ವಾಕರಿಕೆ
- ಕಾಲುಗಳ ಮೇಲೆ ಅಸ್ಥಿರತೆ
- ರಾಶಿ



ಅಪ:

ಪರಿ:

ನೀರಿವೆ

- ಬಿನ್ನತೆ
 - ಸಿಡುಕುತನ
 - ಹೈಪರ್‌ಕ್ಯಾಪಿಟಿ
 - ಆತ್ಮಹತ್ಯಾ ಪ್ರವೃತ್ತಿಗಳ ಹೆಚ್ಚಿದ ಅಪಾಯ
- ಯಾವುದೇ ಅಡ್ಡ ಪರಿಣಾಮಗಳನ್ನು ವೈದ್ಯರೊಂದಿಗೆ ಪರೀಕ್ಷಿಸಬೇಕು.



ರೋಗಿಯ ಮಾಹಿತಿ ಕರಪತ್ರ
ಮೂರ್ಛೆ ರೋಗ



ಫಾರ್ಮಸಿ ಅಭ್ಯಾಸ ವಿಭಾಗ
ಕರ್ನಾಟಕ ರಾಜ್ಯ ಆರೋಗ್ಯ ಇಲಾಖೆ
ಬೆಂಗಳೂರು ಸಂಖ್ಯೆ: 0831-2471399
ಮೇಲ್ ಐಡಿ: klespharmacypractice2016@gmail.com

एपिलेप्सी

एपिलेप्सी म्हणजे काय?

एपिलेप्सी हा मेंदूतील असामान्य विद्युत क्रियांमुळे होतो

एपिलेप्टिक्स खालील दर्शवू शकतात :

- धक्कादायक हालचाली
- लाळ येणे
- प्रतिसादहीनता
- विस्मरण
- भडक भाग
- जलद लुकलुकणारे भाग
- तोंड आणि ओठांची धक्कादायक हालचाल
- अस्पष्ट अचानक भीती, रडणे किंवा ओरडणे
- एपिलेप्सी हा तुमच्याशी कोणी काही केल्याचा परिणाम नाही आणि तुमच्या समीवृत्ताच्या इतरांना संसर्गजन्य नाही.
- एपिलेप्सी तुमच्या जीवसमर्थील घटकांमुळे असू शकते आणि ते कुटुंबातही चालते.



काय करावयचं :

- रुग्णाला हानीपासून दूर हलवा..
- रुग्णासोबत रहा.
- गळ्यातले कपडे सेल करा.
- रुग्णाला बाजूच्या स्थितीत ठेवा.
- मदतीसाठी कॉल करा
- उशी किंवा मऊ वस्तू डोक्याच्या खाली ठेवा.
- रुग्णवाहिका कॉल करा.

काय करू नये :

- घबराट.
- प्यायला पाणी द्या.
- चेहऱ्यावर पाणी शिंपडा
- तोंड बंद होण्यापासून रोखण्यासाठी बोट किंवा इतर कोणतीही कठीण वस्तू घाला
- हाताला लोखंडी रॉड घ्या..
- त्यांच्या हालचालींना आवर घाला



जप्टीपूवी चंतावणी चेव्ह काय आहेत?

एखाद्या व्यक्तीला जप्टीचा अनुभव येऊ शकतो

- 1) दिवास्वप्न पाहणारे भाग
- 2) मुंग्या येणे च्या संवेदना

- 3) असामान्य चव किंवा वास
- 4) सुत्रपणा.
- 5) शारीरिक कार्ये कमी होणे
- 6) डोकेदुखी

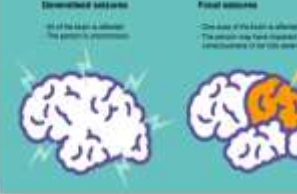
ज्या लोकांना फेफरे येतात त्यांना कधाकधा अवर्णनीय किंवा अतिशय असामान्य भावना आल्याची तक्रार असते, जसे की त्यांचे शरीर विचित्र वाटणे किंवा त्यांना शरीराबाहेरचे अनुभव येत आहेत.

जोखीम घटक :

- वय
- कोटुबिक इतिहास
- डोक्याला दुखापत
- स्ट्रोक आणि इतर रक्तवहिन्यासंबंधी रोग
- स्मृतिभ्रंश
- मेंदूचे संक्रमण
- बालपणात दौरे



Seizures are caused by abnormal electrical activity in the brain



डॉक्टरांना कधी भेटायचे :

खालीलपैकी काही आढळल्यास त्वरित वैद्यकीय मदत घ्या :

- जप्टी पाच मिनिटांपेक्षा जास्त काळ टिकते.
- जप्टी थांबल्यानंतर श्वास किंवा चेतना परत येत नाही.
- त्यानंतर लगेचच दुसरा झटका येतो.
- तुला खूप ताप आहे.
- तुम्हाला मधुमेह आहे.
- जप्टी दरम्यान आपण स्वतः ला जखमी केले आहे.
- तुम्ही जप्टीविरोधी औषध घेत असलात तरीही तुम्हाला सतत फेफरे येत आहेत.

औषधे :

- तुम्ही वापरत असलेल्या औषधांची नावे जाणून घ्या.
- तुमच्या फोनवर औषधांच्या प्रिस्क्रिप्शनचा फोटो ठेवा.
- सल्ल्यानुसार औषधे घ्या तुमच्या डॉक्टरांनी.
- एकही डोस चुकवू नका औषधोपचार.
- औषधांचा अतिरिक्त साठा ठेवा.
- कार्बामाझेपिन सारख्या क्वचितच काही औषधांमुळे त्वचेवर पुरळ उठू शकते, असे झाल्यास औषध थांबवा आणि डॉक्टरांचा सल्ला घ्या
- जेव्हा तुम्ही वैद्यकीय मदत घ्याल तेव्हा डॉक्टरांना हे तथ्य कळवा की तुम्हाला मिरगीचा त्रास होत आहे आणि तुम्ही घेत असलेली औषधे.

अँटीपिलेप्टिक औषधांचे सामान्य दुष्परिणाम :

- गोंधळ
- दुहेरी रात्री
- चक्कर येणे
- मळमळ
- पायांवर अस्थिरता
- पुरळ



एपिलेप्सी औषधांचे कमी सामान्य दुष्परिणामसमाविष्ट करा

- नेराश्रय
- विडंबित
- अतिक्रियाशीलता
- आत्महत्या प्रकृतीचा धोका वाढतो.

कोणतेही दुष्परिणाम डॉक्टरकडे तपासले पाहिजेत.







रुग्ण माहिती पत्रक
अपस्मार



फार्मसी प्रॅक्टिस विभाग KLE कॉलेज ऑफ फार्मसी, बेळगावी
फोन नंबर: ०८३२-२४७२३९९
मेल आयडी: kleshgpharmacypractice2016@gmail.com

मिरगी

मिरगी क्या है?

मिरगी हेमस्तिष्क में असामान्य विद्युत गतिविधि के कारण होता है। मिरगी के रोगी निम्नलिखित दिखा सकते हैं:

- झटकेदार हरकतें
- लार टपकना
- अप्रतिवाद
- विस्मृति
- घूरने वाले एपिसोड
- तेजी से पलकें झपकाने की घटनाएँ
- मुँह और होठों का झटकेदार हिलना
- अस्पष्टीकृत अचानक भय, रोना या विल्लाना
- मिरगी नहीं है किसी ने आपके साथ जो कुछ किया है उसका परिणाम आपके आस-पास के अन्य लोगों के लिए संक्रामक नहीं है।
- मिरगी आपके जीन के कारणों के कारण हो सकती है और यह परिवार में भी चल सकती है।



मिरगी में क्या होता है?

मिरगी ओ.टी. हेमस्तिष्क की असामान्य विद्युत गतिविधि के परिणामस्वरूप, जिसे दोरे के रूप में भी जाना जाता है, अंदर एक विद्युत तूफान की तरह सिर और क्योंकि मस्तिष्क बहुत कुछ नियंत्रित करता है, बहुत सी अलग-अलग चीजें गलत हो सकती हैं। मरीज़ असामान्य अवधि हो सकती है व्यवहार का, भावनाएँ और कभी-कभी जागरूकता की हानि।

क्या करें:

- कदम the मरीज़ दूर से चोट।
- रहना डब्बू में वांटी वह मरीज़।
- ढीला कपड़े आस-पास the गरदन।
- जगह थपथपाना में ईएनटी में एन the पार्श्व स्थिति।
- मदद के लिए पुकारें
- सिर के नीचे तकिया या
- एम्बुलेंस को बुलाओ

जो नहीं करना है:

- घबड़ाहट
- पानी पिलाओ
- चेहरे पर पानी छिड़कें
- मुँह बंद होने से बचाने के लिए उंगलियाँ या कोई अन्य कठोर वस्तु डालें
- हाथों में लोहे की छड़ें दे दो
- उनकी हरकतों पर लगाम लगाएं



क्याक्या दोरे से पहले चेतावनी के संकेत हैं?

किसी व्यक्ति को दोरे पड़ने का अनुभव हो सकता है

- 1) दिवास्वप्न के प्रसंग
- 2) झुनझुनी की अनुभूति

3) असामान्य स्वाद या गंध

4) स्तब्ध हो जाना

5) शारीरिक कार्यों का नुकसान

6) सिरदर्द

जिन लोगों को दोरे पड़ते हैं वे कभी-कभी अवर्णनीय या बहुत ही असामान्य भावनाओं की रिपोर्ट करते हैं, जैसे कि ऐसी भावनाएँ कि उनका शरीर अजीब लग रहा है या उन्हें शरीर से बाहर के अनुभव हो रहे हैं।



जोखिम:

- आयु
- परिवार के इतिहास
- सिर की चोटें
- स्ट्रोक और अन्य संवहनी रोग
- पागलपन
- मस्तिष्क संक्रमण
- बचपन में दोरे पड़ना



के प्रकारदोरा:

Seizures are caused by abnormal electrical activity in the brain

Generalized seizures

And the brain is affected the whole of a seizure



Partial seizures

The area of the brain is affected the whole of a seizure



डॉक्टर से कब मिलना है:

यदि निम्न में से कोई भी घटित हो तो तत्काल चिकित्सा सहायता लें:

- दोरा पाँच मिनट से अधिक समय तक रहता है।
- दोरा रुकने के बाद साँस या चेतना वापस नहीं आती है।
- तुरंत दूसरा दोरा पड़ता है।
- आपको तेज़ बुखार है।
- आपको मधुमेह है।
- आपने दोरे के दौरान खुद को घायल कर लिया है।
- भले ही आप दोरे-रोधी दवा ले रहे हों, फिर भी आपको दोरे पड़ते रहते हैं।

दवाएं:

- आपके द्वारा उपयोग की जाने वाली दवाओं के नाम जानें।
- अपने फोन पर दवा के नुस्खे की फोटो रखें।
- सलाह के अनुसार दवाएं लें
- आपके डॉक्टर द्वारा
- करना एक भी न चूकें अकेलासुराक
- दवा का
- दवाओं का अतिरिक्त स्टॉक रखें
- कार्बामाज़ेपाइन जैसी दुर्लभ दवाएँ ख़ास पर चकते पैदा कर सकती हैं यदि ऐसा होता है तो दवा बंद कर दें और डॉक्टर की सलाह लें
- जब भी आप चिकित्सा की माँग करें तो डॉक्टर को यह तथ्य बताएं कि आप मिरगी से पीड़ित हैं और आप जो दवाएं ले रहे हैं।



मिरगीरोधी दवाओं के सामान्य दुष्प्रभाव:

- उलझन
- दोहरी दृष्टि
- चक्कर आना
- जो गिरलाना
- पैरों में अस्थिरता
- खराब



मिरगी की दवाओं के कम आम दुष्प्रभाव शामिल करना

- अवसाद
- चिड़चिड़ापन
- सक्रियता
- आत्महत्या की प्रवृत्ति का खतरा बढ़ गया।

किसी भी दुष्प्रभाव की डॉक्टर से जांच करानी चाहिए







रोगी सूचना पत्रक मिरगी



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ANNEXURE – XV - PUBLICATIONS

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Research Article

Evaluation of antiepileptic medication adherence among paediatric epileptic patients: a randomized prospective study in a teaching hospital

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ABSTRACT

Background: Epilepsy is a Neuro-degenerative disorder characterized predominantly by recurrent and unpredictable seizures and discharges from the cortical cells of the brain. Long term therapy is required for treatment of epilepsy. The non-adherence is the serious concern in cases of all patients.**Objectives:** To compare and assess the medication adherence of antiepileptic drugs on paediatric patients at different point interval.**Methodology:** The prospective, randomized study has been conducted in out-patient department of Paediatric at tertiary care hospital of Belagavi district, Karnataka, for 12 months including 1 follow-up of 6 month interval. The patients newly diagnosed with epilepsy of either sex aged between 1 to 18 years with signed with assent and consent were collected.**Result:** 103 epileptic patients were screened for the study. In that, 65 patients were found to fit for study criteria. Randomized into 2 groups control n= 24 and Intervention = 41. There was no significant difference (p=0.903) observed in gender distribution among both groups, similar findings p=0.116 was found in age distribution. Medication adherence observed among both the groups at baseline level were no significant difference (p=0.718) was observed in control group (6.92±1.01) and in interventional group (6.78±1.03), highly significant improvement p= 0.0001*** observed in interventional group (3.61±1.49) instead of control group (5.38±1.23).**Conclusion:** Clinical pharmacist assists in recommended antiepileptic medication use process by counselling which will increase medication adherence, reduces risk of seizure and enhance quality of life.**Keywords:** Medication Adherence, Paediatrics, Anti-epileptic agents, Epilepsy, Clinical Pharmacist, Pharmaceutical care.

INTRODUCTION

Epilepsy is a neurological disorder characterized by recurrent and unpredictable seizures and increased neuronal discharges from the cortical cells of the brain (Fisher et al, 2005; Shorvon S D, 2011). Over 50 million people have epilepsy worldwide (WHO Report, 2005). It is estimated that developing countries have higher prevalence i.e. 80% of the disease (WHO Report, 2005). Paediatrics age group are in high risk of developing it (Carter et al, 2012).

Prevalence rate of epilepsy varies between 4.15-7.03 per 1000 population in India. Majority of the population with epilepsy were diagnosed and were treated by non-specialists at different health care levels. It proves sub-optimistic management of epilepsy in such situations. Moreover, it was felt that there remains considerable scope for the

development of better epilepsy services in developing countries like India. In the current study, clinical pharmacist made an attempt to promote clinical pharmacy services through rational drug therapy by assessing the current pattern of prescription in the country based on the age, mono/polytherapy, use of newer antiepileptic drugs (AED's) and combination use of benzodiazepines along with AED's. It helps in ensuring the rational use of medication and improves patient compliance with medication. Due to cultural attitude, poor health care system, lack of prioritization, economic problem etc most of the patient in developing countries are not getting appropriate treatment. Thereby, Clinical Pharmacist in hospitals can initiate changes to drug therapy for patient (Mubai et al, 2019).

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Adherence to antiepileptic drugs can be improved by pharmacist services such as patient counselling, self-recording of medication intake, use of various medication container, and reminders (telephonic, e-mail) to collect medications and to visit clinics. Management to promote rational drug use. Hence, our study was designed to analyse the prescribing pattern and rationality in prescriptions according to national and international guidelines in tertiary care teaching hospital of India. Various factors affecting adherence to antiepileptic drugs has been documented by several studies (Rose et al, 2014). The knowledge of the disease itself also motivates patients to adhere with the medication prescribed (Rose et al, 2014).

Many studies on medication adherence have used Morisky 8-item scale, Adherence Assessment tool for assessment which is designed and validated and can be modified to record information from the patients on the rate of adherence (Yang C et al; 2020). Depending on the scores resulting after calculation adherence is measured, in which score more than 2 is considered as low adherence, 1-2 is considered as medium adherence and 0 as high adherence (Morisky et al; 1986).

Because of long term therapy and unwanted effects of most of the drugs compliance is a major problem. Compliance behaviour depends on many factors like clinical situation, nature of illness, and the treatment. Complexity of therapeutic regimen, increased number of behavioural changes is associated with non-compliance. Patients unknowingly fail to adhere through misunderstanding, forgetfulness, or uncertainty about physician recommendations, or intentionally due to their own expectations, adverse effects, and lifestyle choice (Joanne et al, 2007; Getachew H et al, 2014).

Low adherence levels reported with non-adherent patients which are more likely to have seizures

and contributes to the increase number of admissions and healthcare costs. Adherence means how patient medication taking behaviours respond to health professionals' recommendations. It shows increase in patient involvement in treatment for the patient (Joanne et al, 2007; Getachew H et al, 2014; Chand S et al, 2019; Voora et al., 2020)

Discontinuation of antiepileptic drugs in early stage it can prevent unnecessarily long term treatment, or it may be increase the risk of epilepsy (Inn-Chi et al. 2017). Hence, this study is aimed to compare and assess the medication adherence of antiepileptic drugs on paediatric population at different time interval.

METHODOLOGY

Subjects and Methods:

Ethical Consideration: Approval of the study has been obtained from institutional ethics committee of KLE Academy of Higher education and Research (KLE Deemed to be university) (IEC: KAHER/Ethic/2018-19/D-126) the study related information like selection criteria of the patients, participant enrolment process, study period, outcome of the study have been provided to the IEC with through the hard copy of protocol and oral presentation.

Study design, recruitment process: The study was carried out at paediatric out-patient Neurology department, tertiary care hospital. The study was randomized and prospective study for the duration of 6 months with one follow-up interval.

Total of 103 patients are screened out of which 65 patients were randomised depending on inclusion and exclusion criteria. The selected patient lies in age between 1 to 18 years were of either gender and were diagnosed with the epilepsy. Patients with other co-morbid conditions were excluded from the study.

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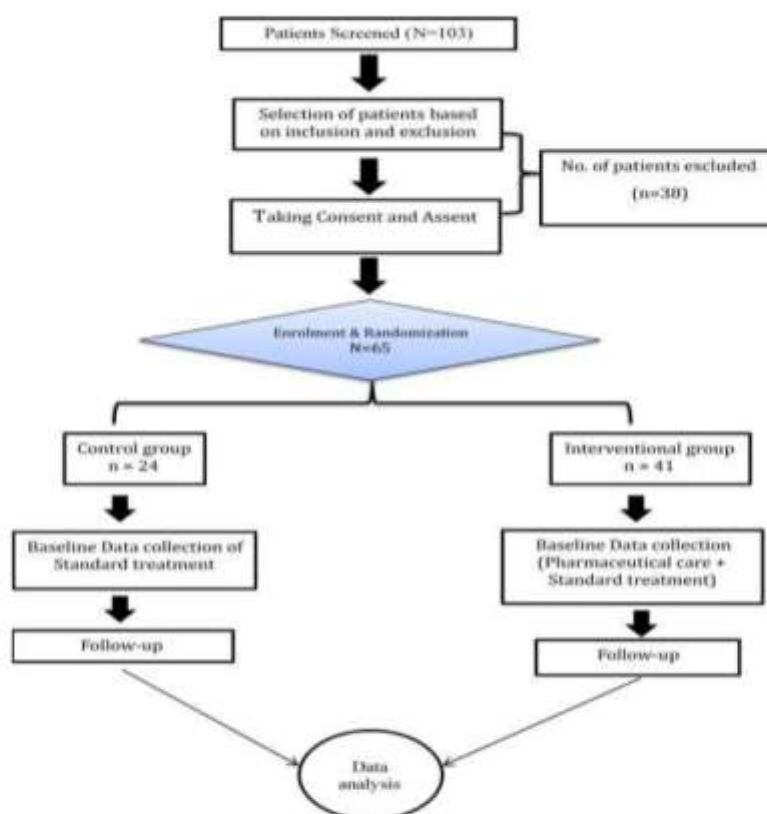


Fig.1: Schematic Diagram for study procedure

Study procedure:

Patient those who were satisfied the above mentioned study criteria and taken their informed consent of the patients before initiating the study, were enrolled and randomized into control interventional group and control group. The randomization of the patients has been done by simple randomization process. Interventional group received the patient counselling and providing patient information leaflet, pharmaceutical care. For control group as usual treatment (standard treatment).

Data collection: The study related data (demographic details, background information adherence towards the medication) was collected: baseline level (0 day), follow-up 01 (6 month), at the last of follow-up the collected data was segregated and analysis was done to assess the study outcome.

Morisky-8 Medication Adherence Questionnaire (MMAS-8): MMAS-8 is 8 item questionnaires to assess the medication adherence for the epileptic patients. The response choice of item is 1 to 7 is on Yes and No and the 8th item is on a scale. The scoring of item scoring A=0, B-E=1 the total range of scoring is 0 to 8.

Score is more than 2 indicates low adherence, 1 or 2 medium adherence and 0 indicates high adherence (Morisky et al; 1986).

Data Analysis

The data of the current study was entered and analysed using IBM SPSS Statistics Version-20 (IBM Corporation, United State). The demographic and clinical variables of the groups were summarized by using descriptive statistics (mean, standard deviation, frequency) and compared with the chi-square test. Before analysing the medication adherence we applied Kolmogorov Simonov test for the analysis of normal distribution. As per the test we found no normal distribution. Hence, we applied non parametric test. For comparison between two groups we applied Mann-Whitney U Test.

RESULTS

In this study total of 103 epileptic patients were screened among them total of 65 patients fulfilled the study criteria and further randomized into the control group (n=24) and Interventional group (n=41) via simple randomization method after getting assent and consent from the parents as well as patients. In the study, 40 (61.54%)

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patients were male whereas 25 (38.46%) were female and those are further divided into control and intervention group as shown in table 1. No statistically significant difference ($p=0.903$) observed for gender distribution among groups.

Table 1: Gender Distribution

	Gender		Pearson χ^2 Values	P-value
	Male (%)	Female (%)		
Control	15 (23.08)	9 (13.85)	0.015	0.903
Interventional	25 (38.46)	16 (24.62)		
Total	40 (61.54)	25 (38.46)		

We observed qualification of the parents of the patients which will interfere with the adherence. Primary education was highest ($n=10$) followed by secondary education ($n=8$) whereas in Interventional group parents with Primary

education were $n=16$ followed by secondary education were $n=14$. There was no statistically significant difference ($p=0.740$) observed in Parent qualification among both the groups as shown in table 2.

Table 2: Parent Qualification

	Parents Qualification					Pearson χ^2	P Value
	Illiterate	Primary	Secondary	Graduation	Post-Graduation		
Control	2	10	8	3	1	1.977	0.740
Interventional	4	16	14	7	0		
Total	6	26	22	10	1		

In this we have observed that, the control group were having $n=10$ patient were having occupation as Farmers and followed by Government employ and private sector employ were $n=5$ and in Interventional group we found

that Business occupation was higher ($n=17$) followed by Private sector employ $n=12$ (table 3). There was no statistically significant difference ($p=0.056$) observed in Parent occupation among the groups.

Table 3: Parents Occupation

	Occupation				Pearson χ^2	P Value
	Private Employ Sector	Government Employ Sector	Farmer	Business		
Control	5	5	10	4	7.553	0.056*
Interventional	12	3	9	17		
Total	17	8	19	21		

With respect to the income, family who were having higher monthly income which is in the range between Rs. 11000 to Rs. 20000 in control and intervention group were $n=15$ and $n=18$

respectively as depicted in table 4. There was no statistically significant difference ($p=0.134$) has been observed among both of groups in monthly income of family.

Table 4: Monthly income of family

	Monthly Income of Family in Rupees (Rs)					Pearson χ^2	P Value
	Less Than Rs.10000	Rs.11000-20000	Rs.21000-30000	Rs.31000-40000	Rs.41000-50000		
Control	2	15	4	3	0	7.029	0.134
Interventional	9	18	11	1	2		
Total	11	33	15	4	2		

The control group were having most patients in the age group between 1-5 year ($n=8$) then followed by 10-15 years ($n=7$) and in the intervention group 21 patients were in the age group between 1-5 year followed by 11 patients

in 5-10 years age group. There was no statistically significant difference ($p=0.116$) between intervention and control group in age distribution (table 5).

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Table 5: Age Distribution

	Age Group (In Years)				Pearson Chi ²	P Value
	1-5 (%)	5-10 (%)	10-15 (%)	15-18 (%)		
Control	8	5	7	4	5.902	0.116
Interventional	21	11	8	1		
Total	29	16	15	5		

In this study, total Antiepileptic drugs prescribed were 103 in both the groups. The highest prescribed antiepileptic drugs were sodium valproate (32.52%) and second highest Vitamin D₃ Clobazam (11.4%) followed by Respiridone 9.8%, Levetiracetam (8.95%) less prescribed drugs were Multivitamins 4.90%, Lamotrigine 4.90%, Lacosamide 3.92%, Phenytoin (3.92%), oxcarbazepine 2.94%, carbamazepine 1.96%, zonisamide 0.98%, ethosuximide 0.98%, Atomoxetine 0.98%, Topiramate 0.98%, Medication Adherence improved after counselling

and by provision of patient information leaflet and other Pharmaceutical care services.

The medication adherence of the antiepileptic patients were assessed at baseline level and follow-up (once in 6 months). Using Mann Whitney U tests, at baseline level we did not find any significant difference ($U=466.50$, $Z=-0.36$, $p=0.718$) among control and intervention group whereas during follow-up (after 6 months) significant statistical difference ($U=144.0$, $Z=-4.829$, $p=0.0001^*$) was observed among control and intervention group for medication adherence as shown in table 6.

Table 6: Comparison of medication adherence in between control and interventional group at different point interval through Mann-Whitney U Test

Time point	Groups	N (%)	Mean±SD	Mean Rank	U-Value	Z-Value	p-Value
Baseline score	Control	24 (36.92)	6.92±1.01	34.06	466.500	-0.361	0.718
	Interventional	41 (63.08)	6.78±1.03	32.38			
	Total	65 (100)					
Follow-up 1 score	Control	24 (36.92)	5.38±1.23	47.50	144.000	-4.829	0.0001***
	Interventional	41 (63.08)	3.61±1.49	24.51			
	Total	65 (100)					

At the baseline level all the 65 patients of both groups met with low medication adherence. After intervention (after 6 months) in interventional group, 3.08% (n=2) patients were having high

adherence and 12.31% (n=8) patients with medium adherence and 47.69% (n=31) having low adherence which is far better than control group (table 7).

Table 7: Comparison of medication adherence at different category

Group	Medication Adherence	Baseline N (%)	Follow up N (%)
Control	High	0 (0)	0 (0)
	Medium	0 (0)	1 (1.54)
	Low	24 (36.92)	23 (35.38)
Interventional	High	0 (0)	2 (3.08)
	Medium	0 (0)	8 (12.31)
	Low	41 (63.08)	31 (47.69)
Total		65 (100)	65 (100)

DISCUSSION

Due to the cultural attitude, poor health care system, lack of prioritization, economic problems etc, 90% of patients in developing countries with epilepsy are not getting appropriate therapy (Mubai M A et al, 2019). We also found a similar problem in our Paediatric unit. Hence, in the same instance we directed our study, and we found significant improvement in the Intervention

group ($p=0.0001^{***}$) when compared with control group. The obtained finding illustrated that clinical pharmacist approach on medication adherence improvement is positive with the paediatric population.

Khaloud Z. Qoul et.al., determined the adherence to anti-epileptic therapy in paediatric clinic in Queen Rania Children Hospital (QRCH); and distinguish variables in the effect of

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adherence. Medicine adherence was evaluated dependent on self-reporting survey using 8-Morisky Medication Adherence Scale. The study resulted more number of patients (79.5 %) showed adherence, while 20.5% patients don't show adherence to their antiepileptic drug. The main three explanations behind non-adherence are: negligence to take the medications (52.2%), symptoms due to medicines (33.8%), and being improvement and free from seizure (30.4%) for a period. The least appraised purpose behind non-adherence is identified with refusal to take medicine (13.1%) (Kholoud Z et al, 2015).

In the current study, total 65 patients were enrolled, out of which randomized and divided in two groups, namely control group and interventional group. Intervention group have low medication adherence on antiepileptic drugs at baseline compared with the follow-up once in 6 months, whereas control group shows 4.16% patient met with medium adherence and nil in High adherence, followed by low adherence 95.83%. However, in interventional group 4.87% patients met with high adherence and 19.51% patients with medium adherence and 75.60% met with low adherence which is consistent with our study. In this study, both the groups were included control group were having 24 patients out of group Male patients were 60.52% and Female patients were observed that 39.45%. monotherapy as well as combination therapy also prescribed. Out of total 103 prescribed antiepileptic drugs, the Maximum prescribed antiepileptic drugs were sodium valproate (32.52%) followed by Vitamin D3, Clobazam (11.4%) followed by Respiridone 9.8%, Levetiracetam (8.95%) respectively, whereas Minimum prescribed drugs were Multivitamins 4.90%, Lamotrigine 4.90%, Lacosamide 3.92%, Phenytoin (3.92%), oxcarbazepine 2.94%, carbamazepine 1.96%, zonisamide 0.98%, ethosuximide 0.98%, Atomoxetine 0.98%, Topiramate 0.98% respectively. Prescription were depends upon lesser side effects and status of epilepsy. Medication Adherence was shown to be improved after counselling and providing the patient information leaflet and other Pharmaceutical care services. Thus pattern utilisation and understanding the medication usage in correlation with clinical pharmacists showed better therapeutic outcome.

A cross-sectional study conducted by Gurumurthy R et al. to evaluate the pattern and extent of AED adherence among PWE and to identify the factors that influence adherence which was assessed using the 4-item Morisky Medication Adherence Scale and analyzed the association between different variables and AED adherence using

Univariate analysis with chi-square test. The result shown that a majority of patients have optimal rates of AED adherence and forgetfulness constitutes the primary reason for non-adherence among PWE (Gurumurthy R et al, 2017).

CONCLUSION

This study concluded pharmacist intervention is effective in increasing the adherence among paediatric patients with epilepsy. Significance of adhering with the prescribed medication can improve the disease status, symptoms, shortens the duration of hospitalisation, avoid episode of adverse events and improves life style. Hence, clinical pharmacist role is important for prevention of non-adherence as well as minimizing the risk of seizure and to promote quality of life in order to achieve pre-defined therapeutic outcomes. As this study has only one follow-up, further studies can be directed by taking more sample size to see long term effect of pharmacist intervention on medication adherence.

Conflict of interest: Authors declare no conflict of interest.

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Original Article

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Evaluation of drug safety in pediatric epileptic patients: A prospective interventional study with clinical pharmacist intervention at a tertiary care teaching hospital

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Madiwalayya Shivakantayya Ganachari, Revanasiddappa Devarinti

Abstract:

CONTEXT: Epilepsy is a neurological disorder that is frequently observed among the pediatric populations, with a global prevalence of 7.5% per 1000 children. The main objectives of the therapy are to prevent or manage seizures, enhance the quality of life, and provide treatment without adverse drug reactions (ADRs). However, for children with epilepsy, the treatment goals also encompass improving learning abilities and daily living routines, in addition to eliminating the root cause, as childhood represents a hazardous phase of brain development.

AIMS: The aims of this study were to evaluate, monitor, and manage ADRs for antiepileptic drugs (AEDs) in the pediatric population by clinical pharmacists' intervention.

SETTINGS AND DESIGN: A 1-year prospective interventional study was conducted at a tertiary care teaching hospital among pediatric epileptic patients.

SUBJECTS AND METHODS: Patients $n = 141$ those who were satisfied with the abovementioned study criteria and taken their informed assent and consent of the patients before initiating the study were enrolled.

STATISTICAL ANALYSIS USED: Data were analyzed using Excel-MS-Window Version-12.

RESULTS: $n = 141$ patients were observed in this study, with the male population comprising the majority at 57%, whereas the female population accounted for 42.5%. The age group between 1 and 5 years was found to be the most prevalent. A further analysis revealed that monotherapy involving sodium valproate (23%) and levetiracetam (16%) was predominantly administered. The maximum number of ADRs was related to polytherapy, with generalized neurological and gastrointestinal tract discomfort being the most common at 31%. All observed ADRs were categorized as mild in nature and 97% were deemed preventable.

CONCLUSION: Sodium valproate and levetiracetam are commonly employed AEDs as a solitary therapy, wherein the likelihood of encountering an ADR is amplified in the context of polytherapy. Timely identification and perpetual vigilance in monitoring ADRs can effectively mitigate the development of medical complications, and ultimately facilitate the attainment of predetermined therapeutic outcomes.

Keywords:

Adverse drug reactions and sodium valproate, epilepsy, monotherapy, pediatrics, polytherapy

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Epilepsy is a neurological disorder that affects cognitive and psychological sequences due to persistent epileptic seizures with a prevalence of 7.6% in 1000 individuals globally.^[12] A study revealed that about 90% of them are from developing countries.^[13] It is a very common neurological disorder among children, with an estimated incidence rate of 1 in 200 children.^[14] Seizures are mainly classified into partial, generalized, and unclassified seizures.^[15] If left untreated or treatment gap leads to aspiration pneumonia,^[16] broken bones, brain injury, and cognitive dysfunction.^[17] Epilepsy is a chronic condition that requires ongoing treatment, and numerous adverse reactions are observed as a result of the prolonged course of therapy, necessitating drug adjustment and supervision. The primary goals of the therapy are prevention or control of seizures, improving quality of life, and adverse drug reaction (ADR) free treatment.^[14,18] However, for children, goals also include improving learning ability and routine living in addition to abolishing the root cause, as childhood is a perilous stage of brain development.^[19] Often, epilepsy is well managed by old-generation antiepileptic drugs (AED), but due to the increase in newer AED, there is a nearly 17% decrease in prescriptions that contain old-generation AED.^[10] Old-generation AEDs such as carbamazepine or valproic acid are widely used. Levetiracetam, lamotrigine, and topiramate are most commonly used from the second generation of AED.^[14] Although the action of AEDs is different from compound to compound, they mainly act on various vascular cellular receptors, which decrease the excitatory effects of glutamate and by inhibition of gamma-aminobutyric acid.^[11] Initially, first-line treatment is usually monotherapy for children to avoid ADR/toxicity and to prevent drug resistance.^[14] The selection of AED is based on the safety profile.^[10,12]

Around 30% of children with epilepsy develop drug resistance, which leads to the addition of newer AED or alternate therapy.^[19] Nevertheless, these drugs are not without any risks.^[12] Risks can range from mild side effects to serious drug-induced ADR (Johnson syndrome, hepatic failure, etc.) or lethal, leading to treatment failure in about 25% of patients.^[19] Often, ADR is dose dependent and is reversible, leading to discontinuation of treatment either due to toxicity or ineffectiveness for most of AED. However, the data are of only reported ADR, the unrecognized, unreported and undocumented attributes to quite a high number of ADR.^[10] The severity of ADR is assessed by the Hartwig Scale and Naranjo Causality Assessment Scale available^[13,14] further the preventability assessment can be carried out using the Schumock and Thornton Scale. Children are more prone to side effects and ADR due to rapid alterations in metabolism.^[17] Few studies revealed that about 31%–63% of ADRs are associated with AED in children.^[10] Furthermore, most of the studies regarding ADR associated with

AED are conducted in the adult population, which highlights the scarcity of pharmacovigilance studies among children.^[12] The main goal of "epilepsy care" is to control the seizure and to minimize the adverse reactions associated with it. Lack of information on the adverse effects inversely affects the quality of life. The rise in ADR not only affects disease conditions it furthermore adds financial burden,^[19] strong influence of misconceptual beliefs, and loss of faith in treatment.^[16] The clinical pharmacist plays an important role in the early detection, monitoring and reporting of ADR, thus preventing further complications. Hence, the objectives of this study were to evaluate the impact of pharmacist interventions in the reduction of the ADRs and further improve the awareness regarding possible side effects of antiepileptic therapy through medication counseling.

Subjects and Methods

A prospective interventional study was conducted among the pediatric population for 1 year (August 2018–August 2019) at pediatric neurology outpatient and inpatient department in a tertiary care teaching hospital in Karnataka, India.

Ethical consideration

The approval of the study has been obtained from the institutional ethics committee of the KLE Academy of Higher Education and Research (KLE Deemed to be university) (IEC: KAHER/Ethic/2018-19/D-126).

Inclusion and exclusion criteria

The study included individuals between the ages of 1 and 18 who had received a confirmed diagnosis of epilepsy and expressed willingness to participate. Patients with other comorbid conditions were excluded from the study.

Study procedure

Patients who were satisfied with the abovementioned study criteria and taken their informed assent and consent of the patients before initiating the study were enrolled. There were $n = 141$ patients recruited in the study and after collection of necessary data (patient demographic details), the appropriateness of treatments were checked and also identified the adverse reactions associated with the medications. The Naranjo Causality Scale, World Health Organization Uppsala Monitoring Centre (WHO UMC) Scale, Hartwig Severity Scale, and Schumock and Thornton Scale were utilized to evaluate the causality, severity, and preventability of the adverse drug reactions (ADRs). Corresponding actions were taken and monitored daily to rule out the outcomes; in addition, the medication counseling (importance of adherence to medications, side effects, lifestyle modification) was provided verbally.

Details of intervention

The assessment and reporting of adverse reactions in medications and close monitoring of the outcomes were measured. Providing medication counseling regarding potential side effects, emphasizing the importance of adherence, and discussing drug interactions related to antiepileptic treatment verbally with caregivers aids in reducing misconceptions about the disease and its therapy. Additionally, it facilitates the early identification of adverse effects. This brings out their attention on the benefits and risks of AEDs, further improving the health status of the patients.

Assessment of adverse drug reactions

The causality of the ADRs was assessed using the Naranjo's Probability Assessment Scale and WHO Causality Assessment Scale and severity assessment was done using Hartwig's Severity Assessment Scale. The Naranjo Probability Assessment Scale categorizes the ADR into four categories, namely definite (score >9), probable (score 5–8), possible (score 1–4), and doubtful (score 0). The Modified Hartwig's Severity Assessment Scale, which has seven levels and categorizes the ADRs as mild/moderate/severe, was used to determine the severity of ADRs.^[17] The WHO-UMC Causality Assessment Scale considers the clinical pharmacologic components, whereas prior awareness of the ADR is less important. The scale consists of six categories (certain, probable/likely, possible, unlikely, conditional/unclassified, and unassessable/unclassifiable); each causality term has specific assessment criteria and all points should be reasonably complied.^[18]

Schumock and Thornton Preventability Scale

It is used to assess the preventability nature of the adverse reactions. There are three parts, Section A has five questions, whereas Section B only contains four. Each response is classed as either "yes" or "no." If the response to one or more of the questions in Section A was "yes" ADRs were "definitely preventable," proceed on to Section B if all responses were negative. If "yes" was given to one or more Section B questions, ADRs were considered "probably preventable" and then proceeded to Section C if all responses were negative. The ADRs in Section C were "non preventable."^[19]

Data analysis

The data of the present study were entered and analyzed using Data were analyzed using Excel-MS-Window Version-12. Descriptive analysis of demographic details was done and percentages of individual drugs given and corresponding ADRs were calculated.

Results

The present study reveals that the male population

were in great numbers 81 (57.44%) in comparison with females 60 (42.55%) shown in Table 1. The maximum number of subjects lies within 1–5 years of age (40%) and others 5–10 years (28%), 10–15 years (26%) and 15–18 years (5.6%). Based on the characteristics of epilepsy, majority of the population had generalized tonic-clonic seizure (35%) followed by tonic-clonic seizure 15 (10.6%), myoclonic seizure 12 (8.5%), focal seizure 11 (7.8), typical seizure 10 (7.1%), absence seizure 10 (7.1%), atypical seizure 9 (6.4%), febrile seizure 9 (6.4%), complex partial seizure 9 (6.4%), and clonic seizure was the least occurring and was observed in 6 patients with (4.2%). Family history is a vital part of the risk factor in epilepsy; around 18.4% of participants had a family background, in which 7.8% had a paternal history and the remaining 10.6% had maternal. Lack of information on the ill effects of drugs can lead to a prolonged hospitalization period 41.1% of parents had primary education, 36.1% of secondary education, 18.4% graduated, and postgraduated 4.2% pointing out the necessity of patient education. Monotherapy is mostly preferred in the pediatric population; in this study, overall 63.83% of the subjects received monotherapy and

Table 1: Demographics of Participants

Demographics	Frequency (%)
Gender	
Male	81 (57.45)
Female	60 (42.55)
Participant's age group (years)	
1–5	57 (40.43)
5–10	40 (28.37)
10–15	36 (25.53)
15–18	8 (5.67)
Types of epilepsy	
Generalized tonic-clonic seizure	50 (35.46099)
Tonic-clonic seizure	15 (10.6383)
Febrile seizure	9 (6.382979)
Myoclonic seizure	12 (8.510638)
Clonic seizure	6 (4.255319)
Typical seizure	10 (7.092199)
Atypical seizure	9 (6.382979)
Complex partial seizure	9 (6.382979)
Focal seizure	11 (7.801418)
Absence seizure	10 (7.092199)
Family history	
Nothing significant	115 (81.56)
Paternal	11 (7.80)
Maternal	15 (10.64)
Parent's qualification	
Primary	58 (41.13)
Secondary	51 (36.17)
Graduation	26 (18.44)
Postgraduation	6 (4.26)
Treatment regimen	
Number of patients receiving monotherapy	90 (63.83)
Number of patients receiving polytherapy	51 (36.17)

51 (36%) polytherapy [Table 1]. Sodium valproate (23%) and clobazam (7%) were mainly given in monotherapy as old-generation AEDs. From the newer generation of AEDs, levetiracetam (16%) was mostly prescribed. In polytherapy, sodium valproate and clobazam 13 (9%) combination were mainly given, and divalproex and levetiracetam 11 (8%) were the second-most administered combination drugs [Table 2]. Most of the adverse reactions are likely to happen in multiple drug therapy; this study reveals that the majority of the ADRs were associated with polytherapy, out of 29 ADRs, 18 (62%) were related to polytherapy and 11 (38%) of monotherapy [Figure 1].

A total of 29 ADRs were found in the patients, who applied Naranjo's ADR Causality Assessment Scale, 19 ADRs were found probable and 10 were possible, on assessing the severity of the reactions using Hartwig's

Table 2: Distribution of antiepileptic medications among study participants n=141

Therapy	Quantity, n (%)
Monotherapy	
Sodium valproate	40 (26.667)
Levetiracetam	22 (14.667)
Divalproex	8 (5.333)
Clobazam	10 (6.667)
Ethosuximide	3 (2.0)
Lacosamide	2 (1.333)
Topiramate	9 (6.0)
Risperidone	3 (2.0)
Oxcarbazepine	2 (1.333)
Polytherapy	
Sodium valproate + clobazam	13 (8.667)
Divalproex + levetiracetam	11 (7.333)
Levetiracetam + lamotrigine	9 (6.0)
Divalproex + clobazam	5 (3.333)
Sodium valproate + risperidone	6 (4.0)
Clobazam + clonazepam	4 (2.667)
Divalproex + lamotrigine	1 (0.667)
Phenobarbitone + divalproex + lorazepam	1 (0.667)
Divalproex+clobazam+risperidone	1 (0.667)

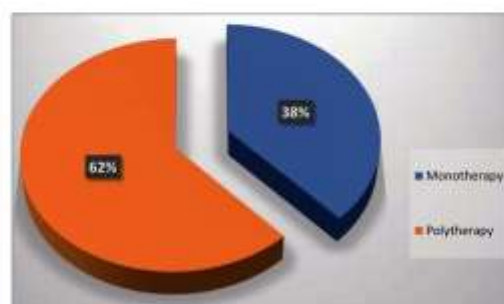


Figure 1: Adverse Reactions Related to Anti-Epileptic drugs

Severity Assessment Scale, all were found mild in nature. On using the WHO Causality Assessment Scale, 13 were found to have probable ADRs and 16 possible ADRs. Most commonly reported adverse reactions were found to be general neurological 8 (28%) (dizziness, fatigue, and headache) caused by sodium valproate, levetiracetam, topiramate, risperidone, and carbamazepine and weight-related ADRs (weight loss and loss of appetite) 3 (10%) were seen in patients on sodium valproate, topiramate, risperidone and phenobarbitone medications. Gastrointestinal tract discomfort, including symptoms such as nausea, vomiting, and diarrhea, were reported in 31% of cases and were attributed to the use of sodium valproate, clobazam, lacosamide, and ethosuximide.

Cognitive adverse reactions 2 (7%) include aggression and irritability due to sodium valproate and levetiracetam. Tremors were seen in lorazepam. Other ADRs 7 (24%) include fever, body pain, dark-colored urine, cough, dry mouth, and rashes were observed with levetiracetam, carbamazepine, clobazam, and divalproex [Table 3]. About 18 ADRs, out of 29, were managed symptomatically (62%), whereas the remaining 10% and 24% were given specific and no treatment, respectively [Table 4]. The prescribers were communicated about the ADRs and its management was suggested by the clinical pharmacist. Using the Schumock and Thornton Scale, 97% of reported ADRs were definitely preventable and 3% were probably preventable [Figure 2].

Following the assessment and reporting of undesirable reactions of drugs, the health-care team took appropriate actions. Seventeen percent of the medications were withdrawn and given other alternatives; sodium valproate and ethosuximide, which caused gastrointestinal disturbance (vomiting, nausea), were withdrawn and given a newer generation of drugs. Thirty-five percent

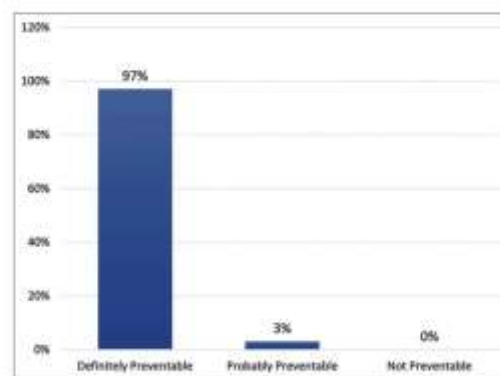


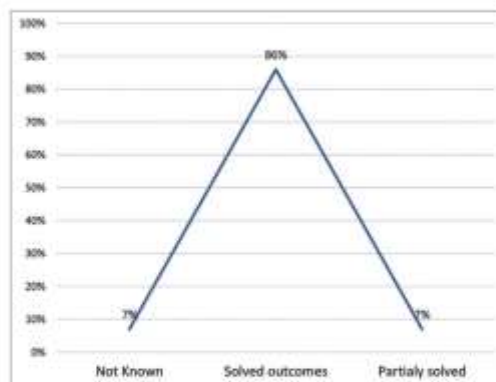
Figure 2: Preventability Assessment of Adverse Reactions using Schumock and Thornton scale

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Table 3: Causality, severity assessment of adverse reactions by the Naranjo, World Health Organization Uppsala Monitoring Centre and Hartwig scale (n=29)

Antiepileptic drug induced adverse effects		Naranjo's ADR causality assessment		Hartwig's severity assessment scale		WHO causality assessment scale
Medication	ADR caused	Type of ADR	ADR=Adverse drug reaction, WHO=World Health Organization	Type of ADR	Level	Causality term
Sodium valproate	Vomiting	Probable	6	Mild	1	Probable/likely
Sodium valproate	Aggression	Probable	6	Mild	1	Possible
Sodium valproate	Nausea and headache	Probable	5	Mild	2	Possible
Phenobarbitone	Loss of appetite	Probable	6	Mild	2	Possible
Levetiracetam	Cough	Probable	5	Mild	2	Possible
Levetiracetam	Rashes	Probable	5	Mild	1	Probable/likely
Levetiracetam	Fever and body pain	Possible	4	Mild	1	Possible
Levetiracetam	Fatigue	Possible	4	Mild	1	Probable/likely
Levetiracetam	Irritability	Probable	5	Mild	1	Probable/likely
Levetiracetam	Headache	Possible	4	Mild	1	Possible
Topiramate	Weight loss	Possible	4	Mild	2	Possible
Lacosamide	Vomiting	Probable	6	Mild	2	Possible
Topiramate	Diarrhea	Possible	4	Mild	1	Probable/likely
Topiramate	Fatigue	Possible	4	Mild	2	Possible
Levetiracetam	Headache	Probable	6	Mild	1	Possible
Risperidone	Loss of appetite	Probable	4	Mild	1	Possible
Risperidone	Tiredness	Possible	3	Mild	2	Probable/likely
Ethosuximide	Nausea and vomiting	Possible	4	Mild	2	Probable/likely
Ethosuximide	Stomach upset	Probable	6	Mild	1	Possible
Ethosuximide	Vomiting	Possible	5	Mild	1	Possible
Sodium valproate	Dizziness	Probable	6	Mild	1	Possible
Carbamazepine	Dry mouth	Probable	5	Mild	1	Probable/likely
Carbamazepine	Headache	Probable	6	Mild	1	Probable/likely
Oxcarbazepine	Nausea and vomiting	Probable	5	Mild	2	Possible
Clobazam	Nausea and vomiting	Probable	5	Mild	1	Probable/likely
Clobazam	Fever	Probable	6	Mild	1	Probable/likely
Divalproex	Dark urine	Probable	5	Mild	2	Probable/likely
Divalproex	Nausea	Possible	5	Mild	1	Possible
Lorazepam	Tremors	Probable	6	Mild	2	Probable/likely

ADR=Adverse drug reaction, WHO=World Health Organization

**Figure 3:** Observed outcomes after the actions were taken

of the medication doses were reduced and 48% of drug doses were not changed and had given a symptomatic. The end result of the actions was closely monitored by

regular follow-up, 7% of the outcomes were unknown due to inaccessibility, 86% of the cases were resolved, 7% of ADRs were partially solved, and the patient experienced fatigue even after the dose of the drug changed [Figure 3].

Discussion

Epidemiological studies revealed that the chance of developing epilepsy in the young brain is higher as compared to the adult brain.^[26] In the present study, out of 250 patients screened, 141 patients were eligible and included in the study. The male population, 81 (57.4%), were more prominent than females 60 (42.5%). Children aged between 1 and 18 years old were recruited in the study, and a greater number of cases were reported in the early ages (1–5 years). Based on the characteristics of epilepsy, most of the participants had generalized tonic-clonic seizure (35%) and clonic seizure is the least with 4.2%. Family history is a vital part of risk factors in epilepsy and around 18.4% of participants in our study

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Table 4: Management of anti-epileptic adverse drug reactions

Drug name	ADR caused	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Treatment given	Outcomes
Sodium valproate	Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
Sodium valproate	Aggression	Drug not withdrawn	Dose not increased	Dose reduced	Dose changed	Specific (risperidone)	Recovered
Sodium valproate	Nausea and headache	Drug not withdrawn	Dose increased	Dose not reduced	Dose not changed	Symptomatic (antiemetic and analgesic)	Recovered
Phenobarbitone	Loss of appetite	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
Levetiracetam	Cough	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (cough syrup)	Recovered
Levetiracetam	Rashes	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Specific (anti-allergic)	Recovered
Levetiracetam	Fever and body pain	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (analgesic, anti-pyretic)	Recovered
Levetiracetam	Fatigue	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
Levetiracetam	Irritability	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
Levetiracetam	Headache	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (analgesic)	Recovered
Topiramate	Weight loss	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Specific (dietary changes)	Recovered
Lacosamide	Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (antiemetic)	Recovered
Topiramate	Diarrhea	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-diarrheal)	Recovered
Topiramate	Fatigue	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
Levetiracetam	Headache	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (analgesic)	Recovered
Risperidone	Loss of appetite	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
Risperidone	Tiredness	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
Ethosuximide	Nausea and vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
Ethosuximide	Stomach upset	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
Ethosuximide	Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-emetic)	Recovered
Sodium valproate	Dizziness	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
Carbamazepine	Dry mouth	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Not any treatment given	Subsided on its own
Carbamazepine	Headache	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic	Recovered
Oxcarbazepine	Nausea and Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (antiemetic)	Recovered
Clobazam	Nausea and Vomiting	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (antiemetic)	Recovered
Clobazam	Fever	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (anti-pyretic)	Recovered
Divalproex	Dark urine	Drug not withdrawn	Dose not increased	Dose reduced	Dose changed	Not any treatment given	Subsided
Divalproex	Nausea	Drug not withdrawn	Dose not increased	Dose not reduced	Dose not changed	Symptomatic (antiemetic)	Recovered
Lorazepam	Tremors	Drug not withdrawn	Dose not increased	Dose reduced	Dose changed	Not any treatment given	Subsided

ADR=Adverse drug reaction

had family background. Poor information and negligence toward the ill effects of drugs can cause prolonged hospitalization period. As a clinical pharmacist proper medication counseling along with possible side effects, the importance of adherence should be provided to fulfil the treatment goals. In this study, about 41.1% of participants, parents had primary education, 36.1% of secondary education and 4.2% of postgraduated. Sodium valproate (23%) and levetiracetam (16%) are predominantly used in monotherapy. Sodium valproate and clobazam were the major medications given as polytherapy. Out of 29 ADRs, 18 (62%) were associated with polytherapy and the remaining were monotherapy, similarly in a study done by Anderson *et al.*^[21] Sixty percent of ADRs were related to polytherapy and 21% with monotherapy, the relative risk of developing ADR in monotherapy is less compared to polytherapy (Risk ratio: 0.61, 95% confidence interval: 0.47–0.79 and $P < 0.0001$).

In the current study, the causality and severity of the adverse Naranjo, WHO-UMC, and Hartwig's Severity Assessment Scales assessed reactions. Generalized neurological effects such as dizziness, headache, and fatigue were the most commonly reported adverse reactions. Most of the reactions were associated with sodium valproate and levetiracetam medications. In contrast to our study, a study in the UK enrolled 124 epileptic children who were on one or more AEDs. This study aimed to describe the incidence of ADR due to AED and compare the toxicity. A total of 1139 ADR were reported it was found that decreased concentration, drowsiness, weight gain, dizziness, slow thinking, and fatigue were reported quite often with AEDs.^[8] Whereas a cross-sectional study conducted in Northwest Ethiopia reported adverse effects and its factors associated among 354 epileptic adults. The study identified 79 ADRs due to AEDs of which fatigue was the most commonly reported ADR, also most of the patients with ADR were illiterate.^[22] However, the study did not mention which drug causes frequently ADR. Another cross-sectional study carried out among epileptic adults recorded 15 ADR, phenytoin (73%) was associated with most of the ADR. In this study, most commonly reported ADRs were neurological (fatigue and headache) 28% and weight related (loss of appetite, weight loss) 10% and caused by phenobarbitone, sodium valproate, and risperidone. ADRs related to gastrointestinal discomfort (nausea, vomiting, and diarrhea) were 9 (31%), and cognitive ADRs (aggression, irritability) were 7% and were caused by sodium valproate and levetiracetam. All the adverse reactions were mild in nature and according to the Naranjo Scale assessment 19 were probable and 10 possible. On the preventability assessment of ADRs, 97% were definitely preventable and 3% were probably preventable. Action taken include dose reduction 35%,

drug withdrawal 17%, and symptomatic treatment, 86% of adverse reactions were completely solved and 7% were partially solved (weight loss, tiredness etc.). Majority of the patient's parents or guardians were having primary or secondary school educational status. Illiteracy or ignorance toward the usage and the aspects of medications leads to many misconceptions on the treatment. Pharmacist interventions include interacting with the patients or caretakers, early identification of ADRs, its severity assessment, reporting, monitoring the outcomes and also medication counseling. The main part of this study is to point out the mild ill effects of AEDs, which can be mistaken as complications of disease, and also shows the importance of pharmacovigilance. This study is only limited to a particular area, and there was also a time restriction; on account of these limitations, further a prospective cohort study with a large sample size and also an appropriate statistical method such as correlation have to be done for further insights on the adverse reactions associated with AEDs.

Conclusion

The main goal of epilepsy care is to control the seizure and to minimize the adverse effects of the drugs. Negligence and poor communication with the health workers can cause prolonged hospitalization and further complications. The main role of a clinical pharmacist is to interact with the patients or caretakers, checking for the appropriateness of therapy, medication counseling, which includes the side effects, indications, possible drug, and interactions, which improves the parents' awareness toward the health of their children and also encourages in sharing these with the health-care workers. Early detection, assessment, and monitoring of ADRs help in shortening the duration of hospitalization and further improve the quality of life. Hence, clinical pharmacist plays an important role in the health-care team in minimizing the ADRs and thus achieving a predefined therapeutic outcome.

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Conflicts of interest

There are no conflicts of interest.

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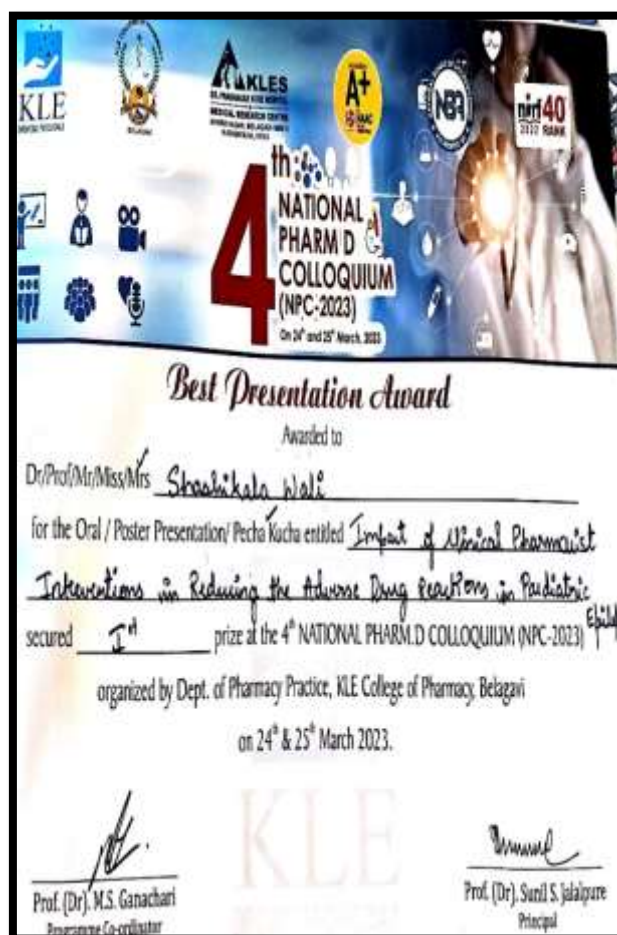
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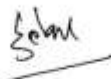
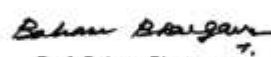
ANNEXURE – XVI - CERTIFICATES OF ORAL & POSTER PRESENTATION







ANNEXURE – XVII - NPTEL RESEARCH METHODOLOGY**CERTIFICATE**

 Roll No: NPTEL18GE03S4210028											
To SHASHIKALA C WALI PLOT NO: 54 KRISHNA BUILDING APMC ROAD, SANGAMESHWAR NAGAR, BELAGAVI-590010 BELAGAVI BELGAUM KARNATAKA 590010 PH. NO :9902944802											
											
No. of credits recommended by NPTEL:2											
<table border="1"> <thead> <tr> <th>Score</th> <th>Type of Certificate</th> </tr> </thead> <tbody> <tr> <td>90-100</td> <td>Elite+Gold Medal</td> </tr> <tr> <td>70-89</td> <td>Elite</td> </tr> <tr> <td>50-69</td> <td>Successfully Completed the course</td> </tr> <tr> <td><50</td> <td>No Certificate</td> </tr> </tbody> </table>	Score	Type of Certificate	90-100	Elite+Gold Medal	70-89	Elite	50-69	Successfully Completed the course	<50	No Certificate	
Score	Type of Certificate										
90-100	Elite+Gold Medal										
70-89	Elite										
50-69	Successfully Completed the course										
<50	No Certificate										
											
NPTEL Online Certification (Funded by the Ministry of HRD, Govt. of India) This certificate is awarded to SHASHIKALA C WALI for successfully completing the course Health Research Fundamentals (NIE-ICMR e-Certificate course: NleCer 101) with a score of 57 %											
<table border="1"> <tr> <td>Online Assignments</td> <td>23/25</td> <td>Proctored Exam</td> <td>33.75/75</td> </tr> </table>		Online Assignments	23/25	Proctored Exam	33.75/75						
Online Assignments	23/25	Proctored Exam	33.75/75								
Total number of candidates certified: 580											
 Dr. Manoj Murhekar Scientist 'G' & Director ICMR-National Institute of Epidemiology, Chennai	 Prof. Balram Bhargava Secretary to Govt. of India, Dept. of Health Research & Director-General, Indian Council of Medical Research										
 Prof. Andrew Thangaraj NPTEL Coordinator IIT Madras											
											
ICMR - National Institute of Epidemiology Feb to Mar 2018 (8 week course)											
Roll No: NPTEL18GE03S4210028 To validate and check scores: http://nptel.ac.in/noc											