**Study Protocol**

The impact of pharmacist’s intervention in medication therapy management (MTM) program for asthma on the Quality of life, Cost of treatment, Adherence with medications, Pharmacovigilance and clinical outcomes of asthma.

**Research Synopsis**

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| Study Title | The impact of pharmacist’s intervention in medication therapy management (MTM) program for asthma on the Quality of life, Cost of treatment, Adherence with medications, Pharmacovigilance and clinical outcomes of asthma. |
| Study Population | Physician diagnosed asthma patients (non-smokers) |
| Study Design & Procedure | Prospective randomized controlled study  Total sample size = 600 subjects  Total hospitals selected= 3 hospitals  Each hospital = 200 subjects  Each hospital control group = 100 study subjects  Each hospital interventional group = 100 study subjects  Total sampling population is 600 asthma patients for three different hospitals. Study subjects would be divided into two groups i.e., Control Group and Interventional Group.  A follow-up of One year will be conducted for both groups.   1. **Control Group:** It comprises of the adult asthma outpatients receiving treatment from asthma management clinics in three selected hospitals. It will include 50% of the total sample population i.e., 300 asthma patients. 2. **Interventional Group:** It comprises of the adult asthma outpatients receiving treatment from asthma management clinics along with the pharmacist led educational intervention (MTM for asthma program) in three selected hospitals. It will include 50% of the total sample population i.e., 300 asthma patients. |
| General Objective | This study is aimed to evaluate the asthma control and quality of life of adult asthmatic patients with and without the involvement of pharmacists in hospital settings. |
| Specific Objectives | Specific objectives are stated below:   1. To assess the asthma control and asthma exacerbations in asthmatic patients with and without the involvement of pharmacist through MTM program for asthma, in different hospitals. 2. To observe and compare the clinical outcomes (Spirometry, FEV1, FEV/FVC, BMI) of asthma patients with and without the pharmacist’s involvement through MTM program for asthma. 3. To observe and compare the Quality of life (QOL) of asthmatic patients with and without the involvement of pharmacists through MTM program for asthma, in selected hospitals. 4. To observe and compare the cost of treatment (hospitalization in case of acute asthma exacerbations) in asthmatic patients with and without the pharmacist involvement in selected hospitals. 5. To observe and compare the Adherence with medication of asthmatic patients with and without the involvement of pharmacists through MTM program for asthma, in selected hospitals. 6. To observe and compare the adverse drug reactions (ADRs) associated with medication of asthmatic patients with and without the involvement of pharmacists through MTM program for asthma, in selected hospitals. |
| Study Outcomes | 1. **The study will evaluate the effect of pharmacist involvement through MTM program for asthma on asthma control and asthma exacerbations in study subjects recruited from different hospitals.**   i.e. asthma is controlled by proper management of asthma. This study would access the impact of Pharmacist involvement in control of asthma exacerbations. Does asthma control in interventional group show better results? If yes, then how much asthma control improvement is observed by pharmacist involvement through MTM program for asthma.  For example, if a patient has severe asthma from past few years. During the allergens season, the patient’s asthma control is reduced with increased asthma exacerbations. This patient was enrolled in MTM program for asthma and was provided educational intervention by pharmacist at regular intervals during the course of treatment. Does this pharmacist led intervention would improve the asthma control of patient? If so, how much improvement in asthma control and asthma exacerbations are observed in that particular patient?   1. **This is a multi-centered study and it will evaluate the clinical outcomes (Spirometry, Pulmonary function tests PFTs including FEV1, FEV/FVC as well as BMI) of asthma patients from different hospitals.** Asthma is a chronic disease with highest prevalence worldwide. The clinical outcomes of asthma patients (control group) would be compared with the clinical outcomes of patients undergone MTM program for asthma with pharmacist’s involvement (interventional group). Therefore, the current study would present the effect of pharmacist involvement through MTM program of asthma on clinical outcomes of asthma in different hospitals. 2. **This prospective study would evaluate the Quality of life (QOL) of asthmatic patients with and without the involvement of pharmacists through MTM program for asthma, in selected hospitals.** This study would further elaborate the role of MTM program is enhancing the QOL of patients.   For example, A young patient has asthma from past few years due to which his QOL has been effected greatly. The patients has been provided pharmacists based educational intervention through MTM program for asthma from past few months. Does this program improves patient’s QOL? If yes, then up to what extent the QOL of patient is improved? Furthermore, the domain of health that has been majorly influenced would be evaluated. The present study would evaluate the influence of MTM program of asthma on 5 general domains of health; mobility, ability to self-care, ability to undertake usual activities, pain and discomfort & anxiety and depression.   1. **The current study would access the cost of treatment in asthma patients from different hospitals.** The cost of treatment including the hospitalization (in case of acute asthma exacerbations) in asthmatic patients would be compared with and without the pharmacist involvement in selected hospitals.   For example, A patient has severe asthma from past few years and spends 20% of his income on management of asthma. On average, he is hospitalized every 2 months, due to severe asthma exacerbations. After being involved in MTM program for asthma, does the cost of treatment is reduced? This current study would evaluate and compare the cost of treatment for the patients enrolled in MTM program for asthma, along with the patients who were not provided medication therapy management consultation. Moreover, the extent of hospitalization in case of severe asthma exacerbations would be accessed and compared between the two groups.   1. **This study would observe the adherence with medication of asthmatic patients with the involvement of pharmacists through MTM program for asthma, in selected hospitals**. Non-compliance with medication results in treatment failure. This study will evaluate the role of pharmacist led intervention in enhancing the patient’s adherence with medication.   For example, A patient has un-controlled asthma from past few years. He often gets severe asthma attacks due to non-compliance and non-adherence with asthma medication. Does educational intervention by pharmacist (through MTM program) regarding medication use, improve medication adherence? If yes, up to what extent adherence and compliance is improved? This study will evaluate and compare the extent of adherence by patients (with and without the involvement of pharmacists through MTM program by asthma).   1. **The present study would observe the adverse drug reactions (ADRs) associated with medication of asthmatic patients.** Majority of the ADRs occur due to irrational use of medication. This study would evaluate the role of pharmacist involvement through MTM program for asthma, in reducing ADRs associated with asthma medication.   For Example, A patient has been diagnosed with asthma recently. Does pharmacist’s involvement regarding rational use of medication plays a positive role in ADR reduction? If yes, then up to what extent the ADRs have been reduced or avoided? This study would evaluate and compare the ADRs associated with asthma medication, with and without the involvement of pharmacists through MTM program for asthma, in selected hospitals. |
| Sample Size | Total number of participants from 3 hospitals is 600 subjects.  (Each hospital = 200 subjects)  Out of those 200 subjects, 100 subjects will be selected from asthma clinics as control group and 100 subjects will be selected from MTM for asthma departments as intervention group according to inclusion criteria. i.e.  Control group in each hospital = 100  Intervention group in each hospital = 100 |
| Study Duration | One year follow up will be conducted for both control and intervention group in all three selected hospitals.  June 2023- June 2024 |