

**Cost of Illness, Health-Related Quality of Life and Cost-Effectiveness analysis of Pharmacist led lifestyle intervention among Diabetes population in Pakistan.**

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**Research Proposal**

June 2021

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# ABSTRACT:

Diabetes mellitus (DM) is extremely common and causes sufferers a significant financial burden. The goal of this study was to assess the cost of diabetes care in Pakistani outpatient clinics for individuals with type 2 diabetes.

The Diabetes education and interventional programme is a cutting-edge, pharmacist-led and delivered service with the goal of resolving medication therapy issues, improving patient education, and improving adherence to the therapeutic regimen. The purpose of this study is to determine the impact of a pharmacist-led diabetes education interventional programme on diabetes-related knowledge, medication adherence, glycemic control, and Health-Related Quality of Life outcomes in Pakistani Type 2 Diabetes Mellitus patients. This study will be divided into three phases, each of which will include a pre-intervention analysis of patients' diabetes knowledge, medication adherence, glycemic control, and current state of Health Related Quality of Life using pre-validated tools.

Few studies have shown that educational interventions improve glycemic control in people with Type 2 diabetes after a baseline period of 3-6 months. The goal of this study was to see how effective an experience-based group educational programme was 24 weeks after baseline, and to identify mediators that might be involved in reaching desirable metabolic outcomes.

# 1. INTRODUCTION

## 1.1 Background of the study

Diabetes mellitus is a disease characterized by insufficient insulin release, as well as insulin resistance in type 2 diabetes, resulting in abnormally high plasma glucose levels. Because the beta cells in the pancreas have been damaged by an autoimmune process, people with type 1 diabetes generate very little or no insulin. The pancreas continues to produce insulin in early type 2 diabetes, and insulin levels are generally greater than in non-diabetic people. The insulin response after a meal, on the other hand, is delayed and insufficient, resulting in compensatory elevated plasma insulin concentrations during postprandial hyperglycemia. (Blas & Kurup, 2010)

Over the last few decades, the global prevalence of diabetes and impaired glucose tolerance in adults has risen. Rapid urbanization and major shifts toward sedentary lifestyles have accelerated the rate of change in diabetes prevalence in many countries and areas. Accurate assessments of the existing and future burden of diabetes are required for allocating community and health resources, as well as developing strategies to combat escalating trends.

The World Health Organization (WHO) projected 108 million individuals living with diabetes in 1980, and this number has quadrupled by 2014 estimations. According to the International Diabetes Federation (IDF), there were 151 million diabetics in the world in 2000, 194 million in 2003, 246 million in 2006, 285 million in 2009, 366 million in 2011, 382 million in 2013, and 415 million in 2015. (Wild et al., 2004)

Diabetes affected 424.9 million individuals aged 20 to 79 years and 451 million people aged 18 to 99 years in 2017. By 2045, the number of persons with diabetes in the 20–79 age group is expected to climb to 629 million, or 693 million in the 18–99 age group. The current projection for 2017 is 281 percent greater than the IDF Diabetes Atlas published from 2000 for the age range of 20–79. (Cho et al., 2018) Diabetes was shown to be prevalent among 22.9 percent of Malaysians, but 37.9 percent of Indians living in Malaysia. Furthermore, studies from Bangladesh and Turkey have revealed that diabetes is prevalent in Middle Eastern Asian countries. According to a recent Chinese study, 11.6 percent of people (18 years) have diabetes, and nearly half of the population has prediabetes. Also worth noting is the prevalence of diabetes in the UK which had doubled from 2.39% in 2000 to 5.32% in 2013. Moreover, the prevalence of prediabetes had increased from 11.6% in 2003 to 35.3% in 2011. (Ali et al., 1993; Bhowmik et al.,

2013; Satman et al., 2002, 2002; Zhou et al., 2016)

## 1.2 Problem statement/Originality of research

Diabetes in Pakistan is having a very high prevalence rate. Pakistan is having the 4th largest diabetes population according to IDF 2019. In Pakistan 70% of the population living in the country have to avail private medical facility. In such huge market with open payer for all medical facilities there will be a huge impact of medication cost on the cost of illness. It was over decade that the role of pharmacist in diabetes education and counselling was ignored, this research could lead to another aspect of effectiveness of pharmacist lead diabetes education intervention.

## 1.3 Research questions

###  1.3.1 Primary Objectives:

1. To estimate the health care costs attributable to type 2 diabetes in Pakistan for the past 5 years through Hospital Management System.

###  1.3.2 Secondary Objectives:

1. Using the specific EQ-5D-5L measures and the EQ-5D index, describe how diabetes complications affect the health-related quality of life of people with diabetes.
2. To estimate the (quality adjusted) life year gains and lifetime costs of two-year, five-year and lifelong lifestyle intervention compared to immediate switch to insulin in patients with poorly controlled type 2 diabetes.
3. To determine the overall diabetes knowledge of patients
4. To determine the barriers to the insulin therapy in patients with poorly controlled type 2 diabetes.
5. To determine the overall diabetes knowledge and medication adherence of the patient with diabetes.
6. To determine to impact of pharmacist lead diabetes education intervention on the overall quality of life and interventional cost effective analysis.

## 1.4 Research hypotheses

###  1.4.1 Alternate Hypothesis:

1. There is significant level of impact of total cost of illness on the patients’ overall quality of life.
2. There is significant impact of Pharmacist lead intervention on the overall therapeutic cost of diabetes patient.
3. There is significant consequence of barrier to insulin therapy on the patients’ quality of life.
4. There is significant impact of diabetes knowledge on the overall quality of life and overall diabetes cost.

###  1.4.2 Null Hypothesis:

1. There is no significant level of impact of total cost of illness on the patients’ overall quality of life.
2. There is no significant impact of Pharmacist lead intervention on the overall therapeutic cost of diabetes patient.
3. There is no significant consequence of barrier to insulin therapy on the patients’ quality of life.
4. There is no significant impact of diabetes knowledge on the overall quality of life and overall diabetes cost.

## 1.5 Need of Study

The diabetes healthcare cost is around $327 billion according to the 2018 American diabetes association data published. There is substantial reduction in the overall productivity of the patients. In view of this huge impact in the country like US which have the 3rd largest population of diabetes in the world, there could be greater impact of diabetes in a country like Pakistan where health care facilities are scarce and overall per capita income is only $1350 per annum.

This study aimed to generate the knowledge about cost and health-related quality of life related to diabetes and to perform a cost-effectiveness analysis of a specific intervention. The barriers which pertains in the way of achieving a good quality of life.

The value of glycemic control in preventing future problems in T2DM is substantially connected to medication adherence and T2DM-related knowledge, according to the study. (Browne, Avery,

Turner, Kerr, & Cavan, 2000; Okuno et al., 1999). Therefore, the assessment of the patient’s disease-related knowledge and medication adherence is important for better therapeutic outcomes (Rothman et al., 2003).

As a result, the purpose of this study is to investigate the relationship between patients' diabetes-related knowledge, medication adherence, glycemic control, and health-related quality of life (HRQoL). Based on the findings, T2DM patients at Pakistani public health institutions will be offered a pharmacist-led intervention programme. The intervention is expected to improve treatment outcomes by lowering drug-related adverse events, improving medication adherence, and increasing patients' comprehension of their conditions and prescribed medications. Healthcare professionals and policymakers will have a comprehensive image of T2DM-related issues as a result of this research, which will aid in the planning and development of diabetes programmes for patients in the near future.

# 2 LITERATURE REVIEW

The latest study in a series of Cost of Illness-analyses performed by the American Diabetes Association was published in 2017(Yang et al., 2018). The objectives of the study was to quantify the economic burden of diabetes caused by increased health resource use and lost productivity, and to provide a detailed breakdown of the costs attributable to diabetes. The study used a prevalence-based approach that combined the demographics of the population in 2017 with diabetes prevalence rates and other epidemiological data, health care costs, and economic data into a Cost of Diabetes Model.

 Diagnosed diabetes is predicted to cost $327 billion in 2017, with $237 billion in direct medical expenditures and $90 billion in lost productivity. Care for people with diagnosed diabetes accounts for one out of every four dollars spent on health care in the United States, with diabetes accounting for more than half of that spending. Diabetes patients spend an average of $16,750 per year on medical expenses, with diabetes accounting for $9,600 of that. Medical expenses for people with diabetes are on average 2.3 times more than they would be if they didn't have the disease. Increased absenteeism ($3.3 billion) and reduced productivity while at work ($26.9 billion) for the employed, reduced productivity for those not in the labour force ($2.3 billion), inability to work due to disease-related disability ($37.5 billion), and lost productivity due to 277,000 premature deaths attributed to diabetes ($19.9 billion) are all examples of indirect costs..(Yang et al., 2018)

There were few cost of illness studies available in Pakistan regarding diabetes cost of illness. This study was conducted in single city of Pakistan in 2006. In this study 345 participants having type 2 diabetes were enrolled. Study reported that the direct cost for the each person having diabetes in Pakistan was rupees 11,580 ($ 197). The majority of the cost included in this direct cost was of medication taken by the patients account for 46%. The cost comparison of the family overall income versus the spending on diabetes care account for 18% of the family income.(Khowaja et al., 2007)

In the most recent study done on diabetes cost of illness conducted during the span of 2016. It was a prospective study conducted in just southern Punjab region. Study reported that the total cost of illness was $332 and medicine accounts for the largest share of almost 60.4% of the direct cost. (Gillani et al., 2018)

# 3 RESEARCH METHODOLOGY

## 3.1 Study design

The methods of the current study are discussed in three phases, i.e. cross-sectional studies (PhaseI), non-clinical randomized controlled trials (RCTs) (Phase-II) and cost effective evaluation (Phase

III)

The 1st Phase of the study will be retrospective section. A structured pre-tested questionnaire will be used to collect the information on socio-demographic and clinical characteristics. These variables will also checked and verified from the medical records of patients. Restricting the patients to past five years

The 2nd phase of the study comprises of randomized control trial assessing quality of life and barriers towards insulin treatment. In randomized control trail we will be implementing pharmacist led diabetes education and medication management. In the due course of study there will be two group one will be the control in which all standard diabetes management will be carried out and the interventional arm of the study comprised of those who will be having standard diabetes management and along with pharmacist lead diabetes management.

Details about patients’ (intervention and control group) demographics and lab profile (HbA1c, random blood sugar, fastening blood sugar, etc.) will be obtained by the pharmacist at first visit. At baseline and at the end of the trail (24th week), the diabetes disease knowledge and self-care activities of the patients in both groups (intervention and control) will be assessed by using prevalidated questionnaires in Urdu language [24-item Urdu version of DKQ, DAI-10]. Pharmacists can assist the patient in completing questionnaires, but will not provide any help in answering the questions, as the same questionnaires will be used repeatedly.

In the 3rd Phase we will be carrying out cost effective analysis of data collected from the phase 1 and phase 2 of the study on patients with diabetes education and without diabetes education.

## 3.2 Study population:

The study population will be those patients with type 2 diabetes. Patients visiting out-patient clinics in 15 major cities of Pakistan (*Peshawar, Swat, Abbottabad, Rawalpindi, Islamabad, Gujranwala, Lahore, Faisalabad, Multan, Quetta, Karachi, Hyderabad, Sargodha, Gujrat, Sialkot)*. The patients should be of the age 18 years and above, should not be having any malignancies and should not be using any substance of abuse.

## 3.3 Sampling method

Three districts will be randomly selected from each province and the sample size will be equally divided on these districts. One hundred fifty subjects (3 clusters, 50 subjects per cluster) will be examined in each district. The sample will be proportionately divided among urban and rural areas. Probability proportionate to size (PPS) method will be used to select clusters from villages in the rural settings of the district.

## 3.4 Simple randomization

Simple randomization (SR) is the most commonly used procedures and is similar to a repeated fair coin-tossing(Schulz & Grimes, 2002). Simple randomization is often termed as "complete" or "unrestricted" randomization. Simple randomization becomes a choice of randomization in the majority of research because of its vigorousness against both selection and accidental biases. However, its main drawback is the possibility of imbalanced group sizes in small RCTs. Therefore, it is often recommended to select SR only in the case where the sample size is over 200 subjects (Lachin, Matts, & Wei, 1988).

## 3.5 Sample size determination

###  3.5.1 Primary Study Sampling:

The sample size will be estimated for the provinces of the country based on the recent census results. The sample size was estimated based on an expected prevalence of 12% with 20% relative precision and a design effect of 2.6. For a 95% CI and an additional adjustment of 32% for non-responders, keeping in view an exclusion rate due to an expected high prevalence of anemia, the sample size was 440 approximated to 450 in order to have 50 subjects from each cluster. The number of eligible subjects will be 450×4=1800.

###  3.5.2 Secondary Study Sampling:

 For this research, prevalence based sampling technique will be employed to identify the representative sample of T2DM patients(Selvin et al., 2014). The reported prevalence rate of type 2 diabetes in Pakistan is about 12%(Shera et al., 1995) therefore, three hundred and ninety two type 2 diabetes outpatients will be selected for the study.

**n = Z² P(1-P)**

####  d2

*Where n = sample size, Z = Z statistic for a level of confidence [1.96 (95% of level of confidence), P = expected prevalence or proportion (in proportion of one; if 12%, p = 0.12), and d = precision (in proportion of one; if 5%, d = 0.05).*

n = 3.84x0.12(1-0.12) = 326

0.0025

## 3.6 Study Scope

The **I-Phase** of study will assess the cost of illness. A structured pre-tested questionnaire will be used to collect the information on socio-demographic and clinical characteristics. These variables will also checked and verified from the medical records of patients. All subjects will be asked about direct and indirect health care costs. Some costs will be imputed to reflect opportunity cost. Indirect healthcare cost will be calculated using the human capital approach; the average wage rates/replacement costs will be used to impute values.

The **II-phase** of study will assess the diabetes-related knowledge, adherence to drug therapy, glycemic control, HRQoL and barriers to insulin therapy among individuals with T2DM. In addition to the demographic and disease related information, self-administered and prevalidated Urdu versions (official language of Pakistan) of Michigan Diabetes Knowledge Test,

(MDKT-U), Drug Attitude Inventory-10 (DAI-10) and European Quality of Life scale (EQ-5D5L) will be used for both pre- and post- interventional phases.

The **III-phase** of study will assess the cost effectiveness using the data collected from the phase 1 and phase 2 of the study on patients with diabetes education and without diabetes education.

## 3.7 Study variables

Study variable will be consisting of following dependent and independent factors.

#### Table 1: List of dependent and independent variables

 ***Dependent Variables******Independent Variables***

|  |  |
| --- | --- |
| *Cost of Illness* *Diabetes Knowledge* *Medication Adherence* *HRQoL* *Cost Effectiveness*  | Age  |
| Gender  |
| BSF  |
| BSR  |
| HbA1c  |
| Family History  |
| Life style  |
| Occupation  |
| Medication  |
| Comorbidities  |

## 3.8 Ethical consideration:

The study will be conducted as per guidelines provided by the National Bioethics Committee in Pakistan (National Bioethics Committee (NBC) Pakistan, 2004). The Ethical approval will be obtained from respective data collection centers in Pakistan. Prior to data collection, patients who agreed to participate will be explained the nature and the objectives of the study. All participants will be assured of confidentiality, and will be asked to sign an informed consent form prior to the data collection process.

## 3.9 Training of data collectors:

 Data collectors will be designated to collect data simultaneously in different territories. Training involved the following aspects:

1. Presenting a brief introduction of the study purpose to patients;
2. Conducting face-to-face patient interviews;
3. Coping with a lack of patient cooperation or other difficulty during the interview. Training will be carried out for 3 days, with a demonstration given by the principal investigator (PI).

Trainees then conduct a pilot study in each of their respective districts and will observed for their interviewing skills.

## 3.10 Statistical Analysis Test

Following tests will be used to analyze data collected for the research study.

i. Frequency and percentages for demographic variables. ii. Chi-square test (to measures the association of different demographic variables with tool’s score).

iii. Linear Logistic Regression to define major predicting variables. iv. Paired sample t-test (compare two population means 'before-after' studies).

 v. Significance level: α≤0.05

## 3.11 Flow chart of study

**Population**

**Assessment of**

**Knowledge**

**Assessment of**

**Adherence**

**Assessment of**

**HRQoL**

**Assessment of**

**HbA1c**

**Assessment of**

**COI**

**Selected**

**Sample**

**Figure 1: Flow chart of study designs for cross-sectional studies**

**Figure 2: Flow chart for Prospective QoL study phase.**

**Retrospective Data collection from**

**Hospital Management System.**

**Enrollment of Study cohort.**

**Randomization**

**for analysis of**

**knowledge,**

**a**

**dherence, HRQoL,**

**HbA1c**

**Intervention group**

**(15**

 **min**

**Diabetes Education Session)**

**Control group**

**Standard Medical**

**(**

**Treatment without intervention)**

**Follow**

**-**

**up Intervention and**

**Education Session**

**Usual Follow up**

**for 24 weeks**

**Intervention**

**Provided**

**Post Intervention analysis**

**Post Intervention analysis**

**Usual care**

**provided**

**Any Patient Lost to Follow**

**-**

**up will**

**be excluded**

**Cost Effectiveness Analysis**

**Study Phase 3**

# 5. RESULT

#### Table 2: Socio-demographic and clinical characteristics distribution

|  |  |  |
| --- | --- | --- |
| **Variable**  | **Number**  | **Percentage**  |
| **Age** **Gender** **Residence** **Education status** **Employment status** **Monthly Household**  |   |   |

###  4.1.1 Direct costs:

###  4.1.2 Indirect costs

#### Table 3: Direct and indirect cost in USD of patients with diabetes in Pakistan

**Variables**

**Mean cost (SD)**

 Consultation cost

 Medication cost

 Investigation cost

 Travel cost

 Food on the way to clinic

 **Indirect cost**

 **Loss of production.**

Office job/Businessman

 Laborers

 Housewives

 **Loss of production of Attendant**

 Office job/Businessman

 Laborers

 Housewives

## 4.2 Determinants of health-related quality of life among persons with diabetes

**Table 4: Description of HRQoL scores**

#### Description N Mean EQ- Std Mean Std P-Value 5D Score Deviation EQ-VAS Deviation Score

***Age (50.77 ± 9.671)***

30-40

41-50

51-60

61-70

***Gender***

Male

Female

***Marital Status***

Married

Unmarried

Widow

***Education***

Illiterate Primary

Middle

Matriculation

Intermediate

Graduate

Masters

***Occupation***

Private Job

Government Job

Business Man

House Wife /

Home Maker

Retired

***\*Monthly Income***

Nil

5000-10000

10000-15000

>15000

***Location***

Urban

Rural

***Duration of Disease***

< 1 Year

1-3 Years

3-5 Years

> 5 Years ***Total Sample***

***\*Pk. Rs=Pakistan Rupee, 1 Pakistan Rupee =0.0098US, @P<0.05 significant***

#### Table 5: Description of medication adherence among the study participants

#### Description Low adherence Medium adherence High adherence (n, P-Value (n, %) (n, %) %) Age

30-40

41-50

51-60

61-70

#### Gender

Male

Female

#### Marital Status

Married

Unmarried

Widow

#### Education

Illiterate

Primary

Middle

Matriculation

Intermediate

Graduate

Masters

#### Occupation

Private Job

Government Job

Business man

House Wife/ Home Maker

Retired

#### \*MonthlyIncome

Nil

5000-10000

10000-15000

>15000

#### Location

Urban

Rural

#### DurationofDisease

< 1 Year

1-3 Year

3-5 Years

> 5 Years

***\*Pk. Rs=Pakistan Rupee, 1 Pakistan Rupee =0.0098US, @P<0.05 significant***

#### Table 6: Description of diabetes-related knowledge among the study participants

 **Description Poor knowledge Average knowledge Good knowledge P-Value**

#### (n, %) (n, %) (n, %) Age

30-40

41-50

51-60

61-70

#### Gender

Male

Female

#### Marital Status

Married

Unmarried

Widow

#### Education

Illiterate

Primary

Middle

Matriculation

Intermediate

Graduate

Masters

#### Occupation

Private Job

Government Job

Business man

House Wife/ Home Maker

Retired

#### \*MonthlyIncome

Nil

5000-10000

10000-15000

>15000

#### Location

Urban

Rural

#### DurationofDisease

< 1 Year

1-3 Year

3-5 Years

|  |  |  |
| --- | --- | --- |
| > 5 Years  |   |  |
| ***\*Pk. Rs=Pakistan Rupee, 1 Pakistan Rupee =0.0098US, @P<0.05 significant*** **Table 7: Correlation coefficient (Adherence and HRQoL)**  |  |  |
| **Spearman’s Rho**  | **Adherence score**  | **EQ-VAS score**  | **EQ-5D Score**  |
| Correlation Coefficient Sig. (2-tailed)\* N  |     |     |     |

***\*Correlation significant at the 0.05 level (0-0.2:weak, 0.2-0.4:moderate, >0.4: strong)***

#### Table 8: Multiple regression model (Glycemic control and demographic variables; Correlation matrix)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|   |  | **HbA1c**  | **Age**  | **Gender**  | **Marital** **Status**  | **Education**  | **Monthly** **Income**  | **Locality**  | **Occupation**  | **Duration of** **Disease**  |
| **Pearson** **Correlation**  | HbA1c Age Gender Marital Status Education  |       |       |       |       |       |       |       |       |       |
| **Sig. (1-tailed)**  | HbA1c Age Gender Marital Status Education  |       |       |       |       |       |       |       |       |       |

# 5. DISCUSSION

Human behaviour plays a central role in the maintenance of health and the prevention of disease. Growing evidence suggests that effective programs to change individual health behaviour require a multifaceted approach to helping people to adopt, change and maintain behaviour. Interventions are effective in modifying beliefs and attitudes and can result in population-wide behavioural change. Such interventions create opportunities for individuals to understand their conditions in a better way and to clarify the misapprehensions which they have in relation to their disease and its treatment. Educating the patients about the disease and medications will improve disease-related knowledge, attitude towards disease, practice towards management and improved HRQoL. Inadequate knowledge is identified as one of the leading causes which influence the adherence behaviour. Therefore, it can be hypothesized that imparting educational intervention to the patients through the diabetes education intervention program may produce better results in awareness of disease, increase adherence to the therapeutic regimen and improved HRQoL.

# 6. CONCLUSIONS

This study shows that pharmacist-initiated diabetes education program increased patients’ knowledge about their condition that positively modified their beliefs about medicines. Such changes are expected to result in increased adherence levels. This study also supports a pharmacists’ role in improving the healthcare system, leading to superior T2DM related therapeutic outcomes.

# 7. LIMITATIONS

The use of self-reporting methods which are inferior to more sophisticated micro-electric monitoring, and recall bias associated with self-reported, but it is not possible to employ such methods at present as the area lacks basic infrastructure. We will considered only medication adherence, whereas adherence to other aspects of the diabetes diet, physical activity and blood glucose self-monitoring are also important and should be assessed in future studies.

# 8. FUTURE RECOMMENDATIONS

Due to the lack of database and poor infrastructure, co-morbidities will not be incorporated in this interventional study. A study addressing co-morbidities and intensive lifestyle modifications is recommended to have an in-depth evaluation of patient’s health status, diabetes related knowledge, medication adherence and HRQoL.

# Gantt chart for research activities

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Research Activities**  | **2021**  | **2** | **022**  | **2** | **023**  |
| **Jan –** **Jun**  | **Jul –** **Dec**  | **Jan-** **Jun**  | **Jul-** **Dec**  | **Jan-** **Jun**  | **Jul-** **Dec**  |
| TRX-500  |   |   |   |   |   |   |
| Ethical application and approval from USM and NMRR  |   |   |   |   |   |   |
| Data collection Phase 1  |   |   |   |   |   |   |
| Data collection Phase 2 & 3  |   |   |   |   |   |   |
| Data analysis and interpretation  |   |   |   |   |   |   |
| Thesis write-up and submission  |   |   |   |   |   |   |

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