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Anon-International Data Collection Study Todetermine Therole of Usage of Multivitamins Capsules in Diabetic Patient as an Add-On Therapy

S.S.V.S. Swetha*,Ch. Bindu Sri*, Aseem Nazia.Shaik, A. Lakshmi Gnapika
**Associate Profeesor,Hod Of Pharmacology, Nri College Of Pharmacy, Pothavarappadu*
Iv Year B. Pharmacy Students, Nri College Of Pharmacy, Pothavarappadu

Date of Submission: 05-08-2024 Date of Acceptance: 15-08-2024

ABSTRACT: Diabetes management often involves multiple strategies to maintain blood glucose levels and prevent complications. While the primary treatments include lifestyle modification and pharmacotherapy, the addition of multivitamins may offer further benefits. This non-interventionaldata collection study aims to assess the role of multivitamins capsules as an add- on the therapy in diabetic patients i.e., the impact of multivitamins capsules as an adjunct therapy in diabetic patients. The research categorized 20 patients into two groups. Group A included 10 patients with a diabetic history who took multivitamins tablets as an adjunct therapy, while group B, also comprising 10 patients, did not use multivitamins. Researches gathered and analysed the past medical and medication histories of both groups. In Group A, multivitamins consumption among the diabetic population reached 100%. Conversely, Group B had a 0% consumption rate of multivitamins. The mean quality of life score in Group A was 15.2%, indicative of the benefits of multivitamins uses. In Group B, the mean quality of life score was 3.6%, reflecting the absence of multivitamins use. The study concluded that diabetic patients who included multivitamins as an adjunct therapy enjoyed a notably better quality of life compared to those who did not. This finding highlighted the potential advantages of multivitamins supplementation in enhancing the quality of life for individuals with diabetes.

KEYWORDS: -Multivitamins,Supplementation, Blood glucose levels, Adjunct, Diabetes mellitus,Quality life

I. INTRODUCTION

MULTIVITAMIN: -

A multivitamin is a preparation intended to serve as a dietary supplement with vitamins, dietary minerals, and other nutritional elements. Such preparations are available in the form of tablets, capsules, pastilles, powders, liquids or injectable formulations.

Multivitamins are most commonly used by the people with poor nutrition or those at high risk of macular degeneration.

DIABETES MELLITUS:

Decreased or absent insulin activity results in diabetes mellitus, a condition of high sugar level [hyperglycaemia]. There are mainly two types of this disease i.e.; Diabetes Mellitus Type – 1 & Diabetes Mellitus type – 2.

In Diabetes Mellitus type-1:

The beta cells are destroyed by an autoimmune reaction so that insulin can no longer be synthesized or be secreted into the blood.

In Diabetes Mellitus Type-2:

The destruction of beta cells is less pronounced than in type-1, & is not due to an autoimmune process. Instead, there is accumulation of amyloid in the pancreatic islets, which likely disrupts their anatomy & physiology.

Insulin was the first peptide hormone which was discovered. Frederick Banting & Charles Herbert-Best, working in the laboratory of J.J.R. Macleod at the University of Toronto, where the first to isolate insulin from dog pancreas in 1921.

Frederick Sanger sequenced the amino acid structure in 1951, which made insulin the first protein to be fully sequenced. The crystal structure of insulin in the solid state was determined by Dorothy -Hodgkin in 1969.

Insulin is also the first protein to be chemically synthesized & produced by DNA recombinant technology. It is on the WHO Model List of Essential Medicines, the most important medications needed in a basic health system.[1]

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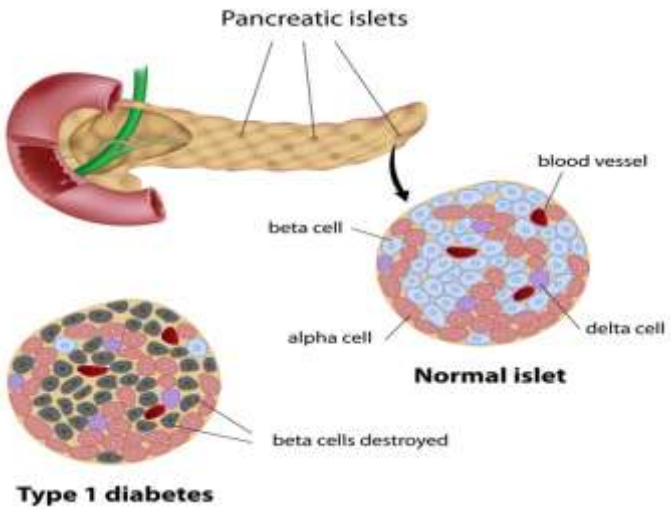
FIGURE:-1



BACKGROUND OF THE STUDY:
Multivitamins are the most common supportive therapy for diabetes mellitus patients & the current study is designed to determine the role & usage of multivitamin as an add on therapy.

Rationale of study:
This study is mainly used to determine the percentage of patients who are having good activity & good quality of life compared in diabetic patients who are not consuming any add on therapy.[3]

Study objective:
The study objective is to prove role & usage of multivitamins as an add on drug in diabetic patients.

STUDY DESIGN:
This study is designed to collect the patients in a single visit & the following data will be captured.

- The acceptance of the patient to give their data in the form of informed consent form.
- Patient past medical history will be collected.

The patient's data will be collected in 2 groups.

Group-1:
Data:
The patient's data will be categorised in two groups.
In group-1 the patient should use enough multivitamin as an add on therapy &should be diabetic patient.

Group-2:
Data:
In group-2 the patient should not use multivitamin as an add on drug & they should be diabetic patients.[4]

INSTITUTIONAL ETHICS COMMITTEE REVIEW

Before the start of the study protocol, ICF, and any other essential documents will be submitted to the institutional ethics committee with a cover letter or form listing the documents submitted their dates and versions of issue for which approval is sought.

As per institutional requirements, the study protocol & any other appropriate documents will be submitted to scientific committee for approval. The study team will also keep the documentation of study approval by internal scientific committee as per institutional requirements.

CONFIDENTIALITY

If patient's name appearson any other document collected, the name must be obliterated before the document is transmitted into CRF subjects will be informed that all personal information made available for the inspection will be handled in the strictest confidence & in accordance with all state, local &federal data protection.

CASE REPORT FORMS

The study case report form[CRF] is the primary source of the data collection of the study.All the data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not

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asked, write "N/D". if the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. All such changes should be initiated & dated.[5]

DO NOT ERASE OR WHITE OUT ERRORS.
For clarification of illegibly or uncertain entries, print the clarification above the item, then initial & date it.

INFORMED CONSENT FORM:
The basic requirement of the study to prove the acceptance of the patient or the participant to give their volunteer acceptance to participate in the study.[6]

Sample size & the statistical analysis plan:
The total sample size calculated for the study in two groups was twenty
Group 1: n = 10
Group 2: n = 10
Total n No. of patient's data planned to collect in the study was 20.

Publication Policies:
All information collected in the study will be published on the name of students& on behalf of Guide.

TABLE:-1

ANNEXURES:

Annexure – 1	Informed consent form
Annexure – 2	Case report form
Annexure – 3	Patient quality of life questionnaires

TABLE:-2

PROTOCOL SYNOPSIS:-

PROTOCOL TITLE	**"A NON-INTERNATIONAL DATA COLLECTION STUDY TO DETERMINETHE ROLE OF MULTIVITAMIN COMSUMPTION BY DIABETIC PATIENTS AS AN ADD-ON THERAPY"**
protocol id	NRI/03/2022
Version and date	Version no 1.0, dated: 01/03/2022
Data collection centres	01
Study period	1 month
Total no of population selected for data collection	20 patients non – international data collection
No of study visits	01
No of groups	02
Study type	Non-international data collection
Study objective	The objective of the study is to determine the role of multivitamins consumption by diabetic patients as an add-on therapy
Primary end points	No of patients having their improvement of quality of life.
Secondary end points	Difference of activity in diabetic patients comparing patient who consuming not consuming multivitamins as an add- on therapy
Study population	Male and female of age 18 yrs. and above who are diagnosed with diabetic mellitus type 1 and diabetic mellitus type 2.
Inclusion criteria	Patients of age 18 years and above who are diagnosed with diabetic mellitus type 1 and diabetic mellitus type 2.
Exclusion criteria	Non diabetic patients Diabetic patient who are on insulin therapy patients of low BMI

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	Patients who suffering from severe chronic diseases
Data capturing	paper CRF patient quality of life questionnaires

FIGURE:-2

ANU HOSPITALS ETHICS COMMITTEE

To,
Batch-3,
NRI College of pharmacy.

19 MAR 2022

Project ID: NRI/03/2022

Project Title: A non-interventional data collection study to determine the role of multivitamin consumption by diabetic patients as an add-on therapy.

Subject: Approval Letter to conduct clinical Study.

Dear Students of Batch No-3,

The Institutional Ethics Committee of Anu Hospital, held's its meeting on Date 19-03-2022 at 3:00 pm to 4:00 pm at Anu hospitals, Kovelamudivari street, Suryaraopet, Vijayawada Krishna district – 520002, Andhra Pradesh, India.

The Following Documents are reviewed in the meeting.

Sno	Name of the document reviewed	Version no and date
1	Project protocol	Version No 1.0, Dated: 01/03/2022
2	Draft Case report form	Version No 1.0, Dated: 01/03/2022
3	Patient questionnaires	Version No 1.0, Dated: 01/03/2022

No member had any conflict of interest for the trail discussed in the meeting.

After due consideration EC has given approval for the above-mentioned study on 19-03-2022 at 6:00 pm.

Yours Sincerely,
17/3/2022
19 MAR 2022
Jessie Kopelli- Member Secretary
Institutional Ethics Committee, Anu Hospitals
Vijayawada-520002, Andhra Pradesh, India.
Member Secretary
(IEC-AH)

CONTROLLED COPY

Kovelamudivari St., Suryaraopet, VIJAYAWADA - 520 002
Tel : 0866 - 2436881, 2436889, Fax : 0866 - 2434655, Email : anuhospitalsec@gmail.com

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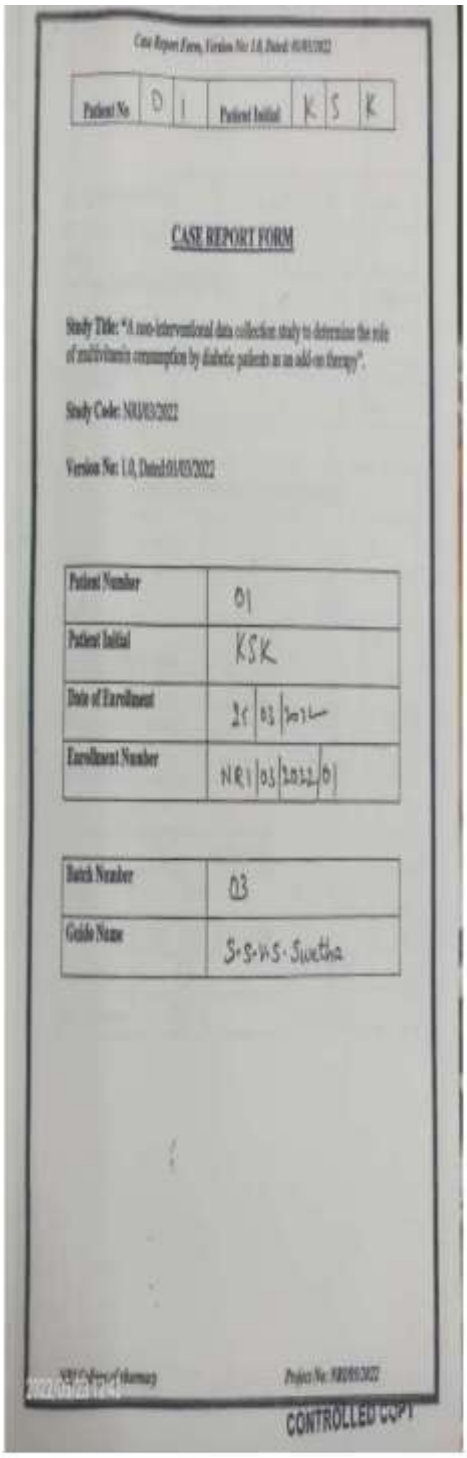
FIGURE:-3



Case Report Form, Version No: 1.0, Dated: 01/03/2022

Patient No: 01 Patient Initial: K S K

CASE REPORT FORM

Study Title: "A non-interventional data collection study to determine the role of multivitamin consumption by diabetic patients as an add-on therapy".

Study Code: NR/03/2022

Version No: 1.0, Dated 01/03/2022

Patient Number	01
Patient Initial	KSK
Date of Enrollment	25/03/2022
Enrollment Number	NR/03/2022/01

Batch Number	03
Guide Name	S.S.N.S. Swetha

CONTROLLED COPY

FIGURE:-4

Case Report Form, Version No: 1.0, Dated: 01/03/2022

Patient No: 01 Patient Initial: K S K

Date of Visit (DD/MM/YYYY)	25	03	2022
Did the Subject Sign Informed Consent Form? Yes/No	YES ✓	NO	
If yes, Date of consent signed (DD/MM/YYYY)	25	03	2022
If No Mention Reason?	NIL		
Subject Initials	K	S	K

DEMOGRAPHICS (TICK AS APPLICABLE)

Height	164	(cm)		
Weight	75	(kg)		
Date of Birth (DD/MM/YYYY)	05	01	1981	
Age	40 yrs	(yrs)		
Gender	Male ✓		Female	NIL

VITAL SIGNS

Pulse Rate	72			Beats per minute
Blood Pressure	130	SBP	80	DBP mmHg
Respiratory Rate	22			Breaths per minute
Body Temperature	98.6			Degree Fahrenheit

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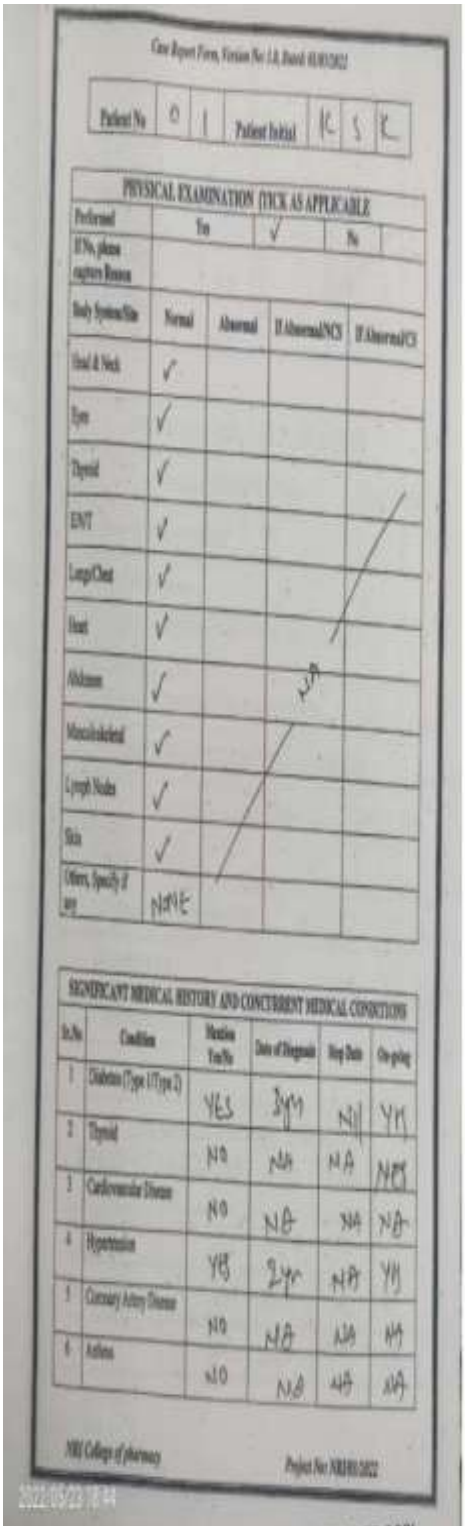
FIGURE:-5



Case Report Form, Version No: 1.0, Dated: 01/03/2022

Patient No: 0 1 Patient Initial: K S K

PHYSICAL EXAMINATION (TICK AS APPLICABLE)

Performed	Yes	✓	No	
If No, please capture Reason				

Body System/Site	Normal	Abnormal	If Abnormal/NCS	If Abnormal/CS
Head & Neck	✓			
Eyes	✓			
Thyroid	✓			
ENT	✓			
Lungs/Chest	✓			
Heart	✓			
Abdomen	✓			
Musculoskeletal	✓			
Lymph Nodes	✓			
Skin	✓			
Others, Specify if any	NAME			

SIGNIFICANT MEDICAL HISTORY AND CONCURRENT MEDICAL CONDITIONS

Sr.No	Condition	Medicine Yes/No	Date of Diagnosis	Stop Date	On-going
1	Diabetes (Type 1/Type 2)	YES	3yrs	NIL	YES
2	Thyroid	NO	NA	NA	NO
3	Cardiovascular Disease	NO	NA	NA	NA
4	Hypertension	YES	2yr	NA	YES
5	Coronary Artery Disease	NO	NA	NA	NA
6	Asthma	NO	NA	NA	NA

NRI College of pharmacy Project No: NRI/01/2022

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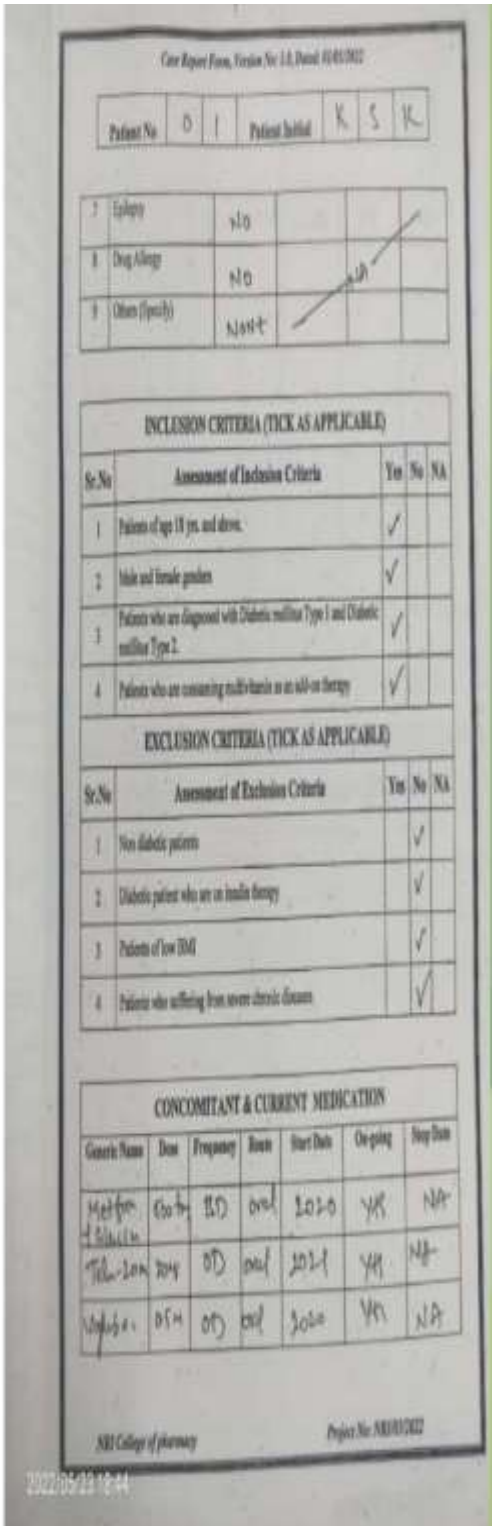
FIGURE: -6



Case Report Form, Version No: 1.0, Dated: 01/03/2022

Patient No: 0 1 Patient Initial: K S K

7	Epilepsy	NO			
8	Drug Allergy	NO			
9	Others (Specify)	NONE			

INCLUSION CRITERIA (TICK AS APPLICABLE)

Sr.No	Assessment of Inclusion Criteria	Yes	No	NA
1	Patients of age 18 yrs. and above.	✓		
2	Male and female genders	✓		
3	Patients who are diagnosed with Diabetes mellitus Type 1 and Diabetic mellitus Type 2.	✓		
4	Patients who are consuming multivitamin as an add-on therapy	✓		

EXCLUSION CRITERIA (TICK AS APPLICABLE)

Sr.No	Assessment of Exclusion Criteria	Yes	No	NA
1	Non diabetic patients		✓	
2	Diabetic patient who are on insulin therapy		✓	
3	Patients of low BMI		✓	
4	Patients who suffering from severe chronic diseases		✓	

CONCOMITANT & CURRENT MEDICATION

Generic Name	Dose	Frequency	Route	Start Date	On-going	Stop Date
Metformin + Glibenclamide	500mg	BD	Oral	2020	YES	NA
Telmisartan	20mg	OD	Oral	2021	YES	NA
Multivitamin	DSM	OD	Oral	2020	YES	NA

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FIGURE:-7

FIGURE:-8

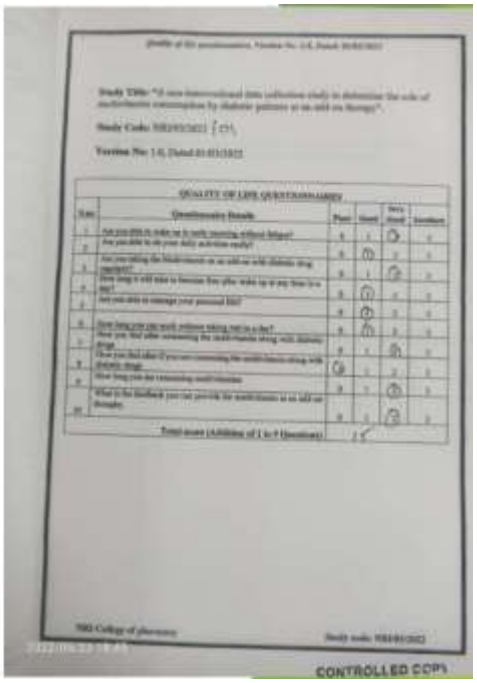


FIGURE:-9

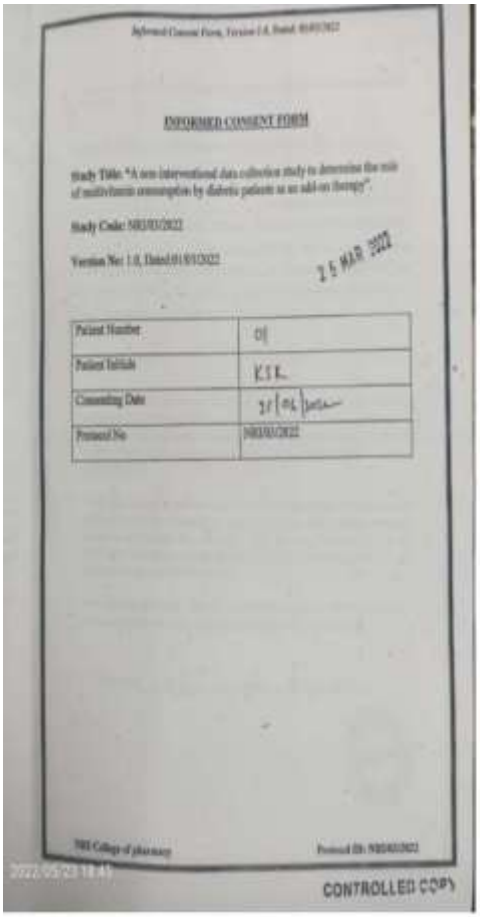
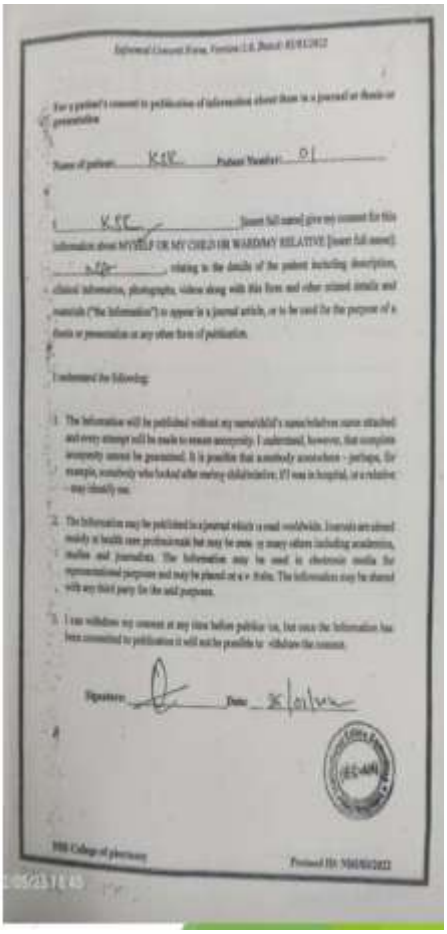


FIGURE:-10



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STUDY REPORT

Protocol Title:A non-international data collection study to determine the role of usage of multivitamins capsules in diabetic patient as an add-on therapy.

We have collected 20 patient's data with all required approvals prior to starting the data collection & we have used basic informed consent form of version no 1.0 dated: 01/03/2022 as a proof of acceptance from the patient to collect the required medical data from them in case report form of version no 1.0 dated: 01/03/2022.

We have divided the 20 patients into two groups & in group A we have collected the data of all 20 patientswith diabetic history & group A consuming multivitamins tablets as a add on therapy & group B was non consumers of multivitamin & the total past medical & medication history of both the groups is based on the data collected &post analysis we can observe in the following results.[8]

TABLE:-3MULTIVIATMINS CONSUMPTION

SUBJECT ID	GROUP A	SUBJECT ID	GROUP B
1	YES	11	NO
2	YES	12	NO
MVT CONSUMPTION			
3	YES	13	NO
4	YES	14	NO
5	YES	15	NO
6	YES	16	NO
7	YES	17	NO
8	YES	18	NO
9	YES	19	NO
10	YES	20	NO

TABLE:-4 Quality of life based on multivitamins consumption

PATIENTID	**MVT consumption**	**Quality of life**	**Patient id**	**MVT consumption**	**Quality of life**
1	**Yes**	**15**	**11**	**No**	**2**
2	**Yes**	**16**	**12**	**No**	**4**
3	**Yes**	**13**	**13**	**No**	**2**
4	**Yes**	**15**	**14**	**No**	**4**
5	**Yes**	**15**	**15**	**No**	**5**
6	**Yes**	**17**	**16**	**No**	**2**
7	**Yes**	**17**	**17**	**No**	**5**
8	**Yes**	**16**	**18**	**No**	**3**
9	**Yes**	**12**	**19**	**No**	**4**
10	**Yes**	**16**	**20**	**No**	**5**
Mean	**100%**	**15.2**	**Mean**	**0%**	**3.6**

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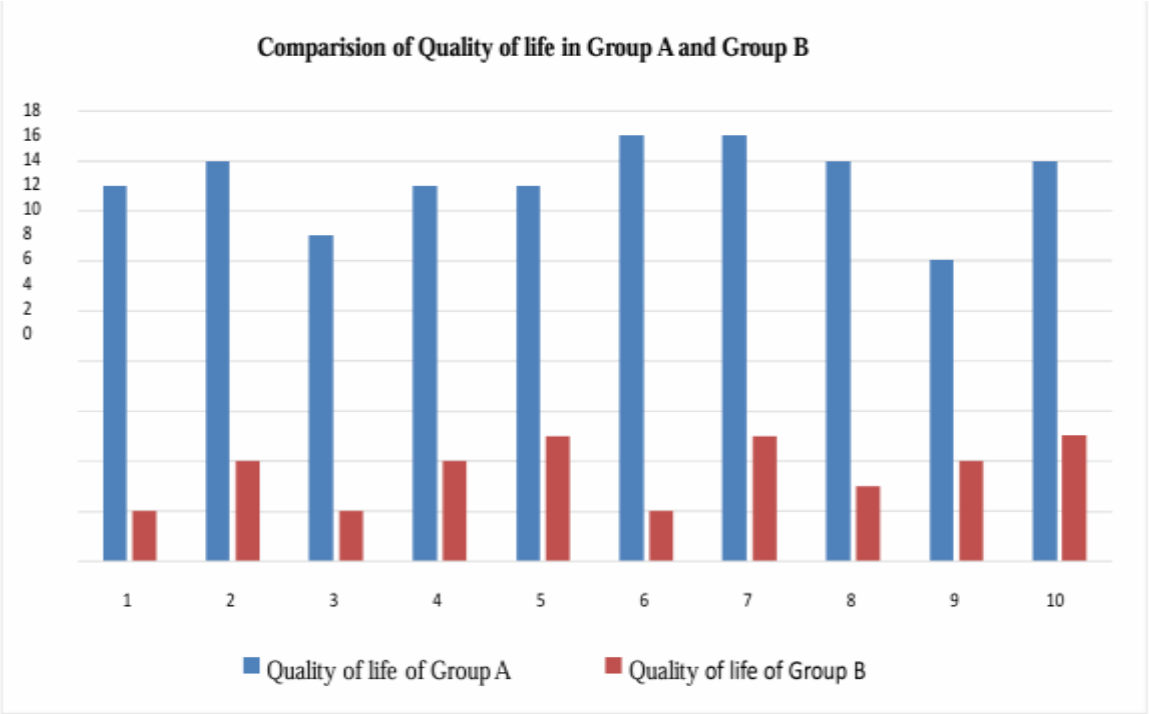
FIGURE:-11

QUALITY OF LIFE DIFFERENCE BETWEEN TWO GROUPS GRAPHIC REPRESENTATION



The bar chart compares the quality of life between two groups, labelled as Group A and Group B. the X-axis represents 10 different categories or intervals, while the Y-axis measures the quality-of-life scores. Group A, represented by the blue bars, consistently shows higher scores across all categories, ranging from approximately 12 to 17 in contrast, Group B depicted by the red bars, has significantly lower scores in every category, with values ranging from about 1 to 4. This graphical representation indicates a noticeable disparity in the quality of life between the two groups, with Group A having a substantially better quality of life than Group B across all measured categories**.**

FINAL DATA REPORT

TABLE: -5Comparison of quality of life between group A and group B population

GROUP-A		**GROUP-B**	
N no of population	**10**	**N no of population**	**10**
MVT consumption	**100%**	**MVT consumption**	**0%**
Quality of life	**15.2%**	**Quality of life**	**3.6%**

The table presents a comparison of the quality of life between two groups, Group A and Group B, both groups have an equal population size of 10 individuals. However, there is a stark contrast in their MVT (likely referring to multivitamins therapy or treatment) consumption: Group A has a 100% MVT consumption rate, while Group B has 0% consumption. This difference in MVT consumption appears to correlate with the reported quality of life in each group. Group A, with full MVT consumption, has a significantly higher quality of life score of 15.2%,whereas Group B, without any MVT consumption shows a much lower quality of life score of 3.6 %. this suggests a possible link between MVT consumption and an improved quality of life**.**

II. SUMMARY

In group A, no of population n= 10, we have observed that the mean value of consumption of MVT in diabetic population is 100% and in group B with the mean value of consumption of MVT in diabetic population is 0% and the mean value of quality of life in group A was 15.2% whoconsuming MVT as an add on therapy and mean value of quality of life in group B was 3.6% who wasnot consumed MVT as an add on therapy.

III. CONCLUSION

The final conclusion of the data collection was that all the diabetic population who are consuming multivitamin as an add on therapy were leading a good quality of life when compared to diabetic population who are not consuming the multivitamin as add on therapy.

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