Effectiveness of Telephonic Adherence Programme on Diet and Lifestyle Modifications on Metabolic Control in Type 2 Diabetes Mellitus Patients

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1. Introduction

Diabetes Mellitus is one of the non - communicable disease which is the largest global health emergencies of 21st century. The International Diabetes Federation have quoted approximately 463 million adults (from the age of 20 to 79 years) are affected with diabetes in the year 2019.[1] India is home to the second largest number (77 million) of adults with diabetes worldwide.[2]

Type 2 Diabetes Mellitus is a diet dependent disease which requires dietary changes and lifestyle modifications. These are the two important landmarks which is to be achieved by patients of T2DM. Individualized approach to maintain the metabolic control in T2DM patients through diet and lifestyle modifications is one of the best methods followed as the non - pharmacological method. Thus, the researcher plans to adhere the modified diet and lifestyle regimen and expects the individual to follow the plan in the further life for the adequate metabolic control.

Therefore, in the present study, to provide individualized approach the researcher has aimed to develop an 'Telephonic Adherence Programme' on diet and lifestyle modification to manage the metabolic control in T2DM patients. Telephonic medium was chosen by the researcher to maintain the social distancing precaution due to COVID - 19 pandemic guidelines.

With this context, the present study is proposed to observe the effectiveness of the individualized approach through Telephonic Adherence Programme (TAP) on the metabolic control in the T2DM patients in Indian setting. The study is intended to note the difference in the dietary pattern with the improvement in body mass index, increased physical activities, smoking cessation and improvement in psychosocial aspects, under the lifestyle modifications.

2. Material and Methods

In this study, quasi experimental design was adopted and participants were selected by using purposive sampling technique on the patients who met the inclusion criteria. Data was collected by using the demographic profile, Modified United Kingdom Diabetes Diet Questionnaire (MUKDDQ) [3], Diabetes Distress Scale (DDS) [4]and Diabetes Adherence Log sheet. Population under the study was Type 2 Diabetes Mellitus patients who attended medicine OPD of KGMU, Lucknow.

Study Duration: The period of study was from 01/03/2021 to 15/04/2021.

Sample size: 44

Sample size calculation:

Sample size is calculated by using the following statistical formula:

$$n = \frac{\left(z_\alpha + z_\beta\right)^2 \left(\sigma_1^2 + \sigma_2^2\right)}{d^2}$$

Where σ_1 = 2.4, The SD of fasting blood glucose before the programme.
σ_2 = 1.9, The SD of fasting blood sugar after the programme.
d= mean (σ_1, σ_1) the difference considered to be clinically significant
Type I error α = 5% corresponding to 95% confidence level
Type II error β = 20% for detecting results with 80% power of study

So the required sample size was
n =22 in each group
The calculated sample size was 44 (22 in each group)

Subjects & selection method:
The study conducted among the patients who were diagnosed with Type 2 Diabetes Mellitus and attended medicine OPD of King George Medical University Lucknow, Uttar Pradesh.

Inclusion criteria:
It includes participants who met following criteria:
- Diabetic client who are willing to participate in the study.
- Diabetic client who are able to understand Hindi & English.
- Diabetic client with the availability of telephone.
- Diabetic client who are available during the period of data collection.
- Age of patient should be more than 18 years.

- Patient should be diagnosed with Type 2 Diabetes mellitus for more than 12 months with at least one follow - up in previous 3 months.

Exclusion criteria:
It excludes participants who met following criteria:
- Diabetic client who have musculoskeletal deformity.
- Diabetic client who were diagnosed with secondary or gestational diabetes, chronic non - cardio - metabolic diseases (systemic lupus erythematous, rheumatoid arthritis, chronic obstructive pulmonary disease), or any mental illness or incapability.
- Diabetic clients who are diagnosed with Cardio - vascular Diseases (CVD).

Procedure of data collection:
Ethical permission from IEC and administrative permission from Registrar, KGMU were obtained. Informed consent from participants taken before initiating the study. Demographic data was collected through self - structured tool which was validated by the experts. Dietary pattern was assessed with the help of United Kingdom Diabetes Diet Questionnaire (UKDDQ). The reliability of the tool was 0.88 (split - half reliability (odd even) Pearson formula). The psychosocial assessment was done through Diabetes Distress Scale (DDS). The reliability of DDS was 0.920 (Cronbach's Alpha value). The adherence to the Telephonic Adherence Programmewas assessed with the help of self - structured tool which was validated by experts. The reliability of tool after collecting the post - test data of 22 subjects was 0.82.

a) In the present study only registered Type 2 Diabetes Mellitus patients attending medicine OPD will be taken in this study.
b) Patients will be given a telephonic call to come on the following day. Patients will give pre - test (experimental group) which includes Structured Demographic and Clinical Profile Data Sheet, Modified United Kingdom Diabetes Diet Questionnaire (MUKDDQ) and Diabetes Distress Scale (DDS).
c) Patient will go after pre - test and a diabetes adherence log sheet and clinical profile data sheet, for 45 - day record will be given to the patients.
d) Once a week on a telephonic call will be done by the researcher. TAP will be counselled to the subjects of experimental group. Call will last for 15 - 20 minutes.
e) A diabetes adherence and clinical profile log sheet will consist of name, age, sex, body mass index (BMI), category of BMI, fasting blood glucose before the intervention and fasting blood glucose after the intervention month (of which data is collected) with the parameters of assessment like -
  - Dietary pattern follow up
  - Physical activity
  - Number of cigarettes smoked.
f) Patient will fill the data in log sheet daily according to the lifestyle followed.
g) After 45 days patients will be called for post - test.
h) Patients of experimental group will bring their log sheet.
i) Patients of experimental group will be monitored for adherence of diet and lifestyle modifications. Patients with good adherence are expected to keep following the modifications.
j) Control group patients are also called after 45 days of normal regimen. These patients will also bring their fasting blood glucose.

Statistical analysis
In this study descriptive and inferential statistics will be used for analysis like Mean, Frequency percentage, Chi square test. The level $P < 0.05$ was considered as the cut - off value or significance.

3. Result

Section 1: Frequency and percentage distribution of demographic variables of both experimental group and control.
Results revealed that, majority of participants (43.2%) were in the age range of 50 - 65 years. There was equal percentage (50%) of male and female. Majority of participants were either of elementary level of education (40.9%) or were graduate and above (40.9%). Participants of married (86.4%) marital status was maximum. The majority participants had the monthly income above Rs10, 000 (38.6%). The participants were majority Hindu (79.5%) in number. Majority of participants were homemaker (36.4%). Majority of participants were of nuclear (52.3%) family type. Participants were in majority from urban (61.4%) place of residence. The majority participants had normal body mass index (45.5%) in experimental group.

Section 2: Frequency and percentage distribution of patient with type 2 Diabetes Mellitus on the basis of dietary pattern followed by the patients of experimental group and control group.

Table a: Frequency and percentage of subjects based on assessment of dietary pattern (n=44)

Category	Control (n_1=22)		Experimental (n_2=22)	
	Frequency	%	Frequency	%
Unhealthy Dietary Choices	0	0.00%	0	0.00%
Less - Healthy Dietary Choices	14	63.6%	14	63.6%
Healthy Dietary Choices	8	36.3%	8	36.3%

The findings indicate that the majority of subjects of control group and experimental group followed less healthy dietary choices (63.6%). The subjects of both control group and experimental group followed the healthy dietary choices (36.3%).

Section 3: Effectiveness of Telephonic Adherence Programme on Diet and Lifestyle Modification of Type 2 Diabetes Mellitus.
This section is further divided into four sub - sections:

(i) Comparison between pre - interventional Fasting Blood Sugar (FBS) levels of control group and experimental group.

Table b: Comparison between pre - interventional FBS levels in both groups (N=44)

Subjects	Control Group FBS Level (mg/dl)	Mean	SD	Experimental Group FBS Level (mg/dl)	Mean	SD
	Pre - interventional level of FBS					
1.	160mg/dl			179 mg/dl		
2.	139mg/dl			256mg/dl		
3.	228mg/dl			132mg/dl		
4.	165mg/dl	166.27	43.34	220mg/dl	206.27	60.04
5.	220mg/dl			310mg/dl		
6.	220mg/dl			180mg/dl		
7.	160mg/dl			132mg/dl		
8.	170mg/dl			206mg/dl		
9.	300mg/dl			180mg/dl		
10.	140mg/dl			178mg/dl		
11.	180mg/dl			150mg/dl		
12.	150mg/dl			280mg/dl		
13.	120mg/dl			241mg/dl		
14.	145mg/dl			146mg/dl		
15.	172mg/dl			310mg/dl		
16.	132mg/dl			232mg/dl		
17.	118mg/dl			180mg/dl		
18.	176mg/dl			252mg/dl		
19.	155mg/dl			142mg/dl		
20.	160mg/dl			132mg/dl		
21.	120mg/dl			310mg/dl		
22.	128mg/dl			190mg/dl		

The findings depict that the mean pretest FBS in control group it was 166.27±43.34while in experimental groups it was 206.27±60.04.

(ii) Comparison between post - interventional Fasting Blood Sugar (FBS) levels of control group and experimental group.

Table c: Comparison between post - interventional FBS levels in both groups (N=44)

Subjects	Control Group FBS Level (mg/dl)	Mean	SD	Experimental Group FBS Level (mg/dl)	Mean	SD
	Post - interventional level of FBS					
1.	140mg/dl			104 mg/dl		
2.	128mg/dl			120mg/dl		
3.	200mg/dl			102mg/dl		
4.	175mg/dl	153.59	42.49	160mg/dl	116.23	21.39
5.	200mg/dl			186mg/dl		
6.	145mg/dl			120mg/dl		
7.	140mg/dl			108mg/dl		
8.	176mg/dl			115mg/dl		
9.	280mg/dl			106 mg/dl		
10.	120mg/dl			120mg/dl		
11.	184mg/dl			98mg/dl		
12.	145mg/dl			104mg/dl		
13.	110mg/dl			105mg/dl		
14.	124mg/dl			96mg/dl		
15.	210mg/dl			107mg/dl		
16.	105mg/dl			114mg/dl		
17.	110mg/dl			110mg/dl		
18.	165mg/dl			125mg/dl		
19.	140mg/dl			100mg/dl		
20.	150mg/dl			102mg/dl		
21.	122mg/dl			115mg/dl		
22.	110mg/dl			140mg/dl		

Table c depicts that the mean post - test FBS in experimental groups was 116.23±21.39 while in control group it was 153.59±42.49. The highly significant difference was found in mean post - testFBS score between experimental and control group (p=0.001). It was relatively less in experimental group.

(iii) Comparison between pre - interventional and post - interventional Fasting Blood Sugar (FBS) levels of experimental group.

Table d: Comparison between pre and post interventional FBS level of experimental group (N=22)

Group	Pre - interventional FBS Mean	SD	Post - interventional FBS Mean	SD	t - value[a]	p - value*
Experimental	206.27	60.04	116.23	21.39	2.50	0.012

[a]Paired t - test, * (p<0.05)

Table d represents the comparison between pre - interventional and post - interventional Fasting Blood Sugar (FBS) levels of experimental group. The findings depict that the pre interventional FBS mean in experimental group was 206.27±60.04 and in post - interventional FBS mean was 166.27±43.34 with the p value of 0.012. Thus the mild significant difference was found in mean FBS score in experimental group between pre - interventional and post - interventional scores (p=0.012).

(iv) Comparison between pre - interventional and post - interventional Fasting Blood Sugar (FBS) levels of control group and experimental group.

Table e: Comparison between pre and post interventional FBS levels of both groups. (N=44) (p<0.05)

Group	Pre - interventional FBS Mean	SD	t - value	p - value	Post - interventional FBS Mean	SD	t - value	p - value
Control Group	166.27	43.34	2.53	0.015	153.59	42.49	- 3.68	0.001
Experimental Group	206.27	60.04			116.23	21.39		

Table e depicts the findings in pre - interventional scores depicts that the experimental group mean was 206.27±60.04 while control group mean was 166.27±43.34 with the p value of 0.015. The findings of post - interventional FBS mean of experimental group was 116.23±21.39 and in control group the mean was 153±42.49 with the p value of 0.001. Thus, the overall results showed that there was significant difference in score of pre - interventional and post - interventional fasting blood sugar level. P - value was highly significant in post - interventional scores (p=0.001).

Section 4: Frequency and percentage distribution of patients with Type 2 Diabetes Mellitus based on compliance to Telephonic Adherence Programme.

Assessment of the compliance to Telephonic Adherence Programme on Diet and Lifestyle Modification in patients of experimental group is measured with the help of Diabetes adherence log sheet. The results depicted that there was high adherence to Telephonic Adherence Programme (TAP) in the patients of experimental group (90.9%) and moderate adherence to TAP (9%) in experimental group subjects. The mean adherence level of experimental group to TAP was 110.36±15.31.

Section 5: Frequency and percentage distribution of patient based on psychosocial issues associated with Type 2 Diabetes Mellitus.

Assessment of psychosocial issues associated with Type 2 Diabetes mellitus is assessed with the help of Diabetes Distress Scale. The result depicted the frequency and percentage distribution of patient based on psychosocial issues associated with Type 2 Diabetes Mellitus. The results showed that the percentage of patients of experimental group who showed moderate distress was 77.2% and in control group percentage of subjects with moderate distress were 22.7%. The percentage of greater distress in experimental and control group showed 50% in both the groups.

Section 6: Association between compliance to Telephonic Adherence Programme on patient outcome with selected demographic variables.

Table f: Compliance to Telephonic Adherence Programme on patient outcome with selected demographic variables in experimental group, (N=22)

Selected demographic variables	Experimental Group	Highly Adherent	Moderately Adherent	Poorly Adherent	Chi square	p - value*
	Frequency	Frequency	Frequency	Frequency		
Age (in years)						
20 - 35 year	1	1	0	0		
35 - 50 year	5	3	2	0		
50 - 65 year	11	11	0	0	1.14	0.767
>= 65 year	5	5	0	0		
Sex						
Male	13	12	1	0	1.46	0.228
Female	9	8	1	0		
Education						
Elementary	7	6	1	0		
Secondary school	6	6	0	0	2.89	0.236
Graduate or above	9	8	1	0		
Marital status						
Married	19	17	2	0		
Unmarried	1	1	0	0	0.00	1.00
Widow/Widower	2	2	0	0		
Monthly Income						
< 5000	7	6	1	0		
5000 - 10000	6	6	0	0	0.40	0.819
>10000	9	8	1	0		
Religion						
Hindu	16	16	0	0		
Muslim	6	4	2	0	1.26	0.262
Others	0	0	0	0		
Occupation						
Homemaker	6	5	1	0		
Unskilled	6	6	0	0		
Skilled	1	1	0	0	14.37	0.002
Professional	9	8	1	0		
Type of family						
Nuclear	11	11	0	0	0.09	0.763
Joint	11	9	2	0		
Place of residence						
Rural	8	8	0	0		
Semi Urban	5	4	1	0	8.94	0.011
Urban	9	8	1	0		

Chi Square, *p<0.05

Table f depicts the association between the compliance to Telephonic Adherence Programme on patient outcome with selected demographic variables in experimental group. The distribution of subjects according to age revealed that maximum subjects (11) belong to the age group 50 - 65 years and were highly adherent to the programme. The age groups >= 65 years of frequency (5) were also highly adherent to the programme. Subjects from age group of 35 - 50 of frequency 5 that showed high adherence were 3 while those of moderate adherence were 2. No significant difference was found in proportion of various age groups and the p - value was 0.767.

4. Discussion

The findings of the study showed that there was significant difference in the fasting blood sugar stating the improvement in metabolic control in pre and post interventional FBS level. The p - value of 0.012 showed the significance of telephonic adherence programme in maintenance of the metabolic control in the experimental group. The comparison between pre - interventional and post - interventional fasting blood sugar of control group and experimental group depicted that the p - value calculated was 0.015 which was significant in the comparison of pre - interventional scores of both the groups. Some studies reported the results in line with the present study. Rupinderjeet Kaur, Krishan Singh Kajal et al (2015) conducted a randomized control trail study done on diabetics to see the impact of telephonic consultation on metabolic control, quality of life and patient compliance. The results revealed that there was significant difference in fasting blood glucose between two groups (p=0.0072).5A randomized control trail was conducted by Masumeh Hemmati Maslakpak et al (2017) to compare the effects of Face - to - Face and Telephone - Based Family - Oriented Education on Self - Care Behavior and Patient Outcomes in Type 2 Diabetes Mellitus. The results demonstrated that there was significant improvement in fasting blood glucose levels (p=0.0001) in control group which was intervened with telephonic based education.6
These above results show that consistent and frequent follow - ups through telephone is easier for the compliance to the regimen because of the easy accessibility of the nurse's guidance over the telephone. It improves compliance to programme with investigations and adherence to the diet and lifestyle suggestions like in the present study.

In the present study results of the compliance to the programme showed that there was high adherence to Telephonic Adherence Programme (TAP) in the patients of experimental group (90.9%). The percentage distribution of patients of experimental group who showed moderate distress was 77.2% whereas in control group it was 22.7%. The percentage of greater distress in experimental and control group showed 50% in both the groups.

The findings suggested that there is association of study findings with selected demographic variable to compliance to TAP with occupation (p=0.002) and place of residents (0.011) between the experimental group with the adherence programme.

5. Conclusion

From the findings of the study, it has been observed that the telephonic follow - up for diet and lifestyle modifications in Type 2 Diabetes Mellitus patients has proved to be beneficial in maintaining the metabolic control.

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