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Public Health

A PILOT STUDY TO ASSESS THE EFFECTIVENESS OF NURSE-LED HOME BASED DIABETES MANAGEMENT PROGRAM ON QUALITY OF LIFE (QoL) AND SELF MANAGEMENT OF PEOPLE LIVING WITH TYPE 2 DIABETES RESIDING IN RURAL AREAS OF AMBALA DIST, HARYANA

Uma J Deaver	Professor and Research Scholar, MM College of Nursing, Mullana, Ambala Dist, Haryana.
Jyoti Sarin	Principal, MM College of Nursing, Mullana, Ambala Dist, Haryana.
Dr Gaurav Singh*	MD PG student, MMIMS&R, Mullana, Ambala Dist, Haryana. *Corresponding Author

ABSTRACT The prevalence of diabetes in India is increasing day by day. The standards of diabetes care in rural areas of India needs strengthening and the desired goal of the country is still far from its achievement. **Aims:** The present study aims (1) to determine the effectiveness of Nurse Led Home Based Diabetes Management program (N-HBDMP) on people living with Type 2 diabetes (PLD) in terms of Self-management and Quality of life (2) To find relationship between self-management and quality of life of people living with Type 2 diabetes.(3) to determine the association of self management and Quality of life with the selected demographic and clinical variables of PLD **Method:** A quantitative research approach with a pragmatic Randomized Controlled Trial (RCT) was used. The pilot study was conducted from 15th March 2021 to 15th June, 2021 after obtaining ethical approval. **Procedure:** the data was collected on the 1st day and the 90th day using the DSMQ and the QOLID. Blood sample was taken and sent to Thyrocare lab for HbA1c and RBS was checked with glucometer. On the same day, intervention was given to intervention group. Every 15th day, the Intervention group were called on their phones and were reminded on their follow up and adherence to diabetes management. Control group received the routine care. **Result:** The data was analysed for 32 participants which showed there was significant increase in mean SD of diabetes self management score from 4.14(1.15) to 5.48(0.46) and the Quality of life score 100.4±(15.6) to 129.7±(9.41) in the intervention group (n-15), which means that the N-HBDMP intervention was effective in enhancing Self Management and improving the quality of life of people living with diabetes.

KEYWORDS : People living with diabetes, self management, Quality of life, Nurse led Home based Diabetes management program

INTRODUCTION

The prevalence of diabetes in India is day by day increasing. People living with diabetes are now in danger of developing micro and macro vascular diseases. They need to be prevented from these health issues. The standards of diabetes care in rural areas of India needs strengthening and the desired goal of the country is still far from its achievement.

Community health nursing or home based nursing care is not a new holistic care approach in the society. When there were no hospitals available during the ancient days, it was community health nursing that focused on providing care to the sick and the suffering at their homes. Diabetes has not been a disease in the past but now has spread as wildfire throughout the world and our country.

Need for the study

The standards of diabetes care in rural areas of India needs strengthening and the desired goal of the country is still far from its achievement. The highest prevalence was seen in South East Asia with 82 million people living with diabetes in 2017, Out of which 40.9 million people were suffering in India, and further nearly 69.9 million people are estimated to develop diabetes by 2025, and potentially 85 million by 2030. In addition, 35 million Indians are at risk for diabetes. 70 million of people are suffering from Diabetes. Another 100 million are estimated to suffer from Pre diabetes. About 1.1 million people die from diabetes related illnesses every year. From the onset of the disease until the symptoms developed, many people with undiagnosed diabetes already have complications such as chronic kidney disease, heart failure, retinopathy and neuropathy. Prevalence of diabetes increased in both rural and urban North India from 2.4% and 3.3% in 1972 to 15.0% and 19.0% respectively between the year 2015-2019.

People living with Diabetes are 25 times more likely to become legally blind than are people without diabetes. One out of ten people with diabetes have Diabetic retinopathy. Diabetic neuropathy accounts for about 54% among 1, 00,000 people per year and it's the third most common neurological disorder. People with diabetes usually experience silent heart attack. 83.3% people with diabetes die of cardiovascular disease.[,6,7]

The biggest question arises "What has changed in the last 40 yrs". The answer is the essential multifactorial which is real and large "FOOD "and "EXERCISE". Fast food has replaced the usual homemade foods and thanks to "Murdoch Phenomenon" establishment of cable TV which made people to lead a very sedentary life e.g. watching TV for hours.[8] Home based diabetes management program is an initiative to help

people living with diabetes to become aware of importance of diet and exercise which can reduce obesity and reverse the insulin resistance which is the root cause of type 2 diabetes, thereby the people living with diabetes can lead a diabetes free Quality of life.[9]

The present study aims to assess the effectiveness of Nurse Led Home Based Diabetes Management program in terms of glycemic control and QOL of people living with diabetes.

Problem Statement:

"A pilot study to assess the effectiveness of Nurse led-Home based diabetes management program on Quality of life (QoL) and self management of people living with type 2 diabetes residing in rural areas of Ambala, Haryana."

Objectives of the study were:

1. To determine the effectiveness of Nurse led Home based Diabetes Management program on people living with Type 2 diabetes in terms of
   - Self-management[10]
   - Quality of life[11]

2. To find relationship between self-management and quality of life of people living with Type 2 diabetes.
3. To determine the association of self management and QoL score with the selected demographic and clinical variables of people living with diabetes.

Hypotheses

All hypotheses were tested at 0.05 level of significance.

H_1: The mean self-management score of people living with type 2 diabetes in the interventional group will be significantly higher than those in the control group

H_2: The mean quality of life score of people living with type 2 diabetes in the interventional group will be significantly higher than those in the control group

H_3: The mean HbA1c value among type 2 diabetes patients in the intervention group will be significantly lower than those in the control group

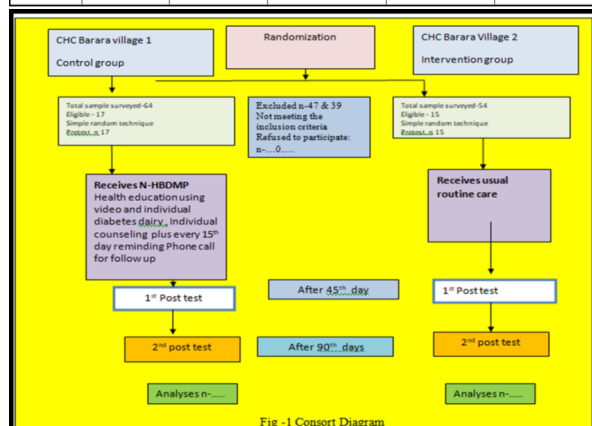H_4: There will be significant relation between self management and QoL of PLD in both group

H_5: There will be significant association between self management and QoL with the selected demographic and clinical variables of PLD

METHODS

Table 1 depicts the research methodology used in this study

Table 1: Research Methodology

RESEARCH APPROACH	SAMPLE RANDOMIZATION TECHNIQUE & SETTING	INTERVENTIONAL VARIABLES	DATA COLLECTION INSTRUMENTS & ETHICAL CONSIDERATION	DATA COLLECTION PROCEDURE	DATA ANALYSIS
APPROACH : •Quantitative Approach DESIGN : •RCT , Prospective Randomized trial with parallel groups	SAMPLE: •PLD of age 18-65 yrs RANDOMIZATION TECHNIQUE •Simple Random technique SEQUENCE GENERATION •Research randomizer online random number generator SETTING CHC Barara[(2 different villages) Adhoya control group & barara intervention group]	INDEPENDENT VARIABLE N-HBDMP: 1. Health Education with Videos and Demonstrations 2. Individual counseling 3. Telephone calls OUTCOME VARIABLES •Self Management and QoL of PLD	TOOL1 : Socio Demographic & Clinical Parameters TOOL2: Diabetes Self Management Questionnaire DSMQ (std) TOOL3: QOLID for QoL ETHICAL CONSIDERATION •Institutional Ethical Committee Approval •Clinical trial registration •Chief Medical Officer, Civil Hospital Ambala •Written consent from PLD	Eligibility Assessment Informed consent Enrolment Randomization Pretest Intervention for Intervention group Regular care for control group Post test after 3 months Analysis	SOFTWARE IBM SPSS DESCRIPTIVE STATISTICS •Frequency percentage •Mean , Median and SD •Normality of the data were checked using Shapiro-Wilk test. INFERENTIAL STATISTICS Pearsons coefficient correlation and Chi-square was used

Fig 1: Consort Diagram

Analysis of Data:
IBM Statistical Package for Social Sciences (SPSS) software (SPSS 2007) version 15.0 was used for data analysis. Descriptive statistics such as frequency, percentage (for categorical variables) and mean, median/standard deviation were used for summarizing the data. Normality of the data was examined using Shapiro-Wilk test. Inferential statistics, the level of significance was set at 5% ($p < 0.05$) for all comparisons, pearsons coefficient correlation 'r' for correlation and Chi-square was used for association.

Organization of Analysis
The Analysis And Interpretation Of The Data Are As Follows
Section I: Description of characteristics and clinical variables of the study participants

Section II: Description of the baseline self-management status & quality of life

Section III: Effect of N-HBDMP intervention on self-management status

Section IV: Effect of N-HBDMP intervention on quality of life

Section V: Effect of N-HBDMP intervention on HbA1c

Section VI: Relationship between self-management and quality of life

Section VII: Association of Self Management and Quality of life of people living with diabetes with their demographic and clinical variables

RESULTS:
Section I: Demographic and Clinical Variable
This section deals with the socio-demographic and clinical characteristics of the participants randomized to the intervention group (n=15) and control group (n=17).

Section I.1. Description of Socio-demographic Characteristics
The frequency and percentage distribution of socio-demographic characteristics of study participants are presented in Table1. The majority of the participants (66.7%) were in the age group of 41-60 years. There was a preponderance of females in the study with 82.3 % and 73.3% of participants in intervention and control group resp. Most of the participants had a high school level of education (73 %). Type of occupation was skilled workers job of study participants (46.1%) in the intervention group and (47.1%) in control group. Majority of the participants were living with diabetes for a period of less than 5 yrs. Majority of the participants were vegetarian 73.3% in intervention group and (82.4%) in control group. Both the intervention and control group had between 40-60% family history of diabetes.. The computed chi-square values for the selected demographic variables of the PLD in the intervention and control group were found to be non significant at 0.05 level of significance. Hence, it can be concluded that the PLD in both the intervention and control groups were homogenous and comparable in terms of their selected demographic variables.

Section 1.2. Description of Clinical Characteristics
Specific details on the proportions of clinical characteristics of participants in intervention and control group are summarized in Table 2.

Table 2 Clinical Variables Of The Study Population (N=32)

Sr No	Variables	Control group n-17		Intervention group n-15		df	χ^2	'p' value
		f	%	f	%			
1	BMI							
	Under weight<18.0 kg/m^2	00	00	00	0.00			
	Normal weight 18.1-22.9 kg/m^2	01	5.9	01	6.67	2	1.722^{ns}	0.05
	Overweight 23.0-24.9 kg/m^2	04	23.5	01	6.67			
	Obesity > 25 kg/m^2	12	70.6	13	86.67			
4	Systolic Blood pressure							
	<120	01	5.88	03	20			
	121-140	09	52.94	06	40	2	1.558^{ns}	0.05
	>141	07	41.17	06	40			
5	Diastolic Blood pressure							
	< 80	03	17.64	07	46.66			
	81-90	10	58.88	07	46.66	2	3.819^{ns}	0.05
	>91	04	23.52	01	6.67			
6	HbA1c							
	<6.5	0	0	4	26.66			
	6.6-8.5	3	17.64	4	26.66	3	8.685^{ns}	0.05
	8.6-10.5	9	52.94	2	13.33			
	>10.6	4	23.52	5	33.33			
7	RBS	n-16		n-15				
	<140mg/dl	0	0	1	6.67			
	141-180mg/dl	2	12.5	1	6.67	2	1.340^{ns}	0.05
	>181mg/dl	14	87.5	13	86.66			

ns-non significant

Majority of the participants in the intervention (86.6%) and control group(70.6%) had BMI more than 25 kg/m^2 which shows in obesity category. The waist and neck circumference for male and female was more than the normal level in both intervention and control group. The blood pressure ranged 121-140 and 81-90 Hg of mm for both the groups. In the intervention group, more than half 52.9% of the participants had HbA1c level between 8.6-10.5% and in the control group less than half (33.3%) of the participants had HbA1c level more than 10.6%. Both the intervention (86.6%)and control group (87.5%) had RBS more than 180mg/dl. Chi-square test was applied to check the homogeneity between the groups. The computed chi-square values for the clinical variables of the PLD in the intervention and control group were found to be non significant at 0.05 level of significance. Hence, it can be concluded that the PLD in both the intervention and control groups were homogenous and comparable in terms of their selected clinical variables.

### Section II: Description of the baseline self-management status & quality of life
The Mean diabetes self-management score among people living with

type 2 diabetes in interventional group and control group were 19.5 (5.21) and 25.8 (7.93) resp. Mean quality of life score among People living with type 2 diabetes patients in both Interventional group and control group were 115 (31.4) and 100.4(15.6) respectively. To assess the homogeneity of all outcome variables at baseline, independent 't' test was used and it revealed that participants in both the interventional and control group did not vary at their baseline measures (p>.05).

Section III: Effect of N-HBDMP intervention on self-management status

The Mean SD, MD and t test analysis of Diabetes self management scores within the Intervention and Control group. The overall mean SD posttest score of diabetes self management 5.48 (0.46) was higher than mean SD pretest score of diabetes self management 4.14 (1.15) in intervention group with the mean difference of 1.34. The computed't' value (t=4.39) was found to be statistically significant at 0.05 level of significance. Whereas the overall mean SD posttest score of diabetes self management **3.76 (1.30)** was lower than mean SD pretest score of diabetes self management **4.04(1.32)** in control group with the mean difference of -0.27. The computed't' value (t=0.736) was found to be statistically non significant at 0.05 level of significance.

The increase in diabetes self management score was highly significant, which means that the N-HBDMP intervention was effective in enhancing Self Management of people living with diabetes in the intervention group. Hence the null hypothesis (H_{01}) was rejected and research hypothesis (H_{01}) was accepted. The change in DSMQ score depicted in figure 2.
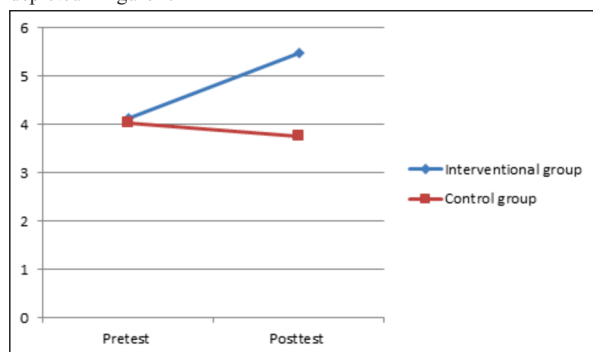
Figure 2: Profile Plot Showing Mean Self Management Value

Section IV: Effect of N-HBDMP Intervention on Quality of Life

Table 3 Mean, Standard Deviation (SD) And 95% Confidence Interval (CI) of QOL Scores Of PLD   **N-32**

Variable	items no	Pretest		Post Test	
Intervention group (n=15)		Mean±SD	CI 95%	Mean SD	CI 95%
Role limitation due to physical health	6	18.26± (4.47)	15.06-21.46	21.07± (6.04)	17.0-27.0
Physical Endurance	6	12.8± (7.02)	8.64-16.95	24.04± (1.1)	24.0-24.0
General health	3	6.93± (1.86)	5.59-8.26	12.0± (0.00)	12.0-12.0
Treatment satisfaction	4	11.06± (2.91)	8.70-13.4	14.9±(2.5)	12.0-16.0
Symptom botherness	3	7.60± (2.66)	5.86-9.33	12.2± (0.561)	12.0-12.0
financial worries	4	16.33± (4.63)	13.5-19.14	17.4± (3.04)	15.0-20.0
Emotional/ Mental health	5	18.9± (3.05)	16.3-21.5	20.5± (4.47)	19.0-22.0
Diet Satisfaction	3	8.46± (2.85)	7.01-9.91	18.26± (2.06)	6.0-12.0
Overall Quality of life	34	100.4± (15.6)	87.04-113.75	129.7± (9.41)	121.0-137.0
Control group (n=17)					
Role limitation due to physical health	6	23.88± (7.18)	20.87-26.89	19.6± (1.61)	18.5-21.5

Physical Endurance	6	19.94± (8.54)	16.04-23.84	22.0± (0.935)	22.0-23.0
General health	3	10.7± (2.99)	9.4-11.9	41.6± (2.178)	40.0-43.0
Treatment satisfaction	4	12.47± (5.48)	10.25-14.68	12.4± (0.795)	12.0-13.0
Symptom botherness	3	9.17± (3.74)	7.54-10.80	9.0± (0.00)	9.00-9.00
financial worries	4	15.00± (5.87)	13.3-17.64	14.5± (1.5)	13.0-16.0
Emotional/ Mental health	5	15.7± (6.15)	13.3-18.22	16.1± (0.60)	16.0-16.5
Diet Satisfaction	3	8.70± (2.66)	7.34-10.06	11.0± (0.00)	11.0-11.0
Overall Quality of life	34	115.6± (31.4)	103.1-128.1	146.3± (4.23)	143.5-149.5

Table 3 depicts the overall baseline and posttest mean (SD), [95 % CI] quality of life score was 100.4 (15.6) and 129.7±(9.41) in Intervention group resp and 115.64 (31.4) and 146.3±(4.23) in control group, which was against an overall possible score of 169. The intervention and control group had a slightly better QOL score at posttest than at baseline. The scores indicate that diabetes mellitus can have incapacitating effects on various domains of an individual's functioning and that quality of life of PLD can be improved with intervention or N-HBDMP is effective enough. The present intervention N-HBDMP shows significant improvement in the intervention group in all domains of the PLD.

The increase in Quality of Life score was highly significant, which means that the N-HBDMP intervention was effective in enhancing Quality of life of people living with diabetes. Hence the null hypothesis (H_{02}) was rejected and research hypothesis (H_{02}) was accepted.

Section V: Effect of N-HBDMP Intervention on HbA1c
Table 4 Mean SD, MD And T Test Analysis of HbA1c within the Intervention and Control Group   **N-32**

Test	Group	Mean	SD	MD	't'value	P value	Remark
Intervention	Pretest	8.96	2.81	0.64	1.33	0.202	Not Significant
	Post test	8.32	2.40				
Control	Pretest	9.49	3.01	0.31	0.57	0.57	Not Significant
	Post test	9.79	1.98				
* Significant at 0.05 level				table value-t(2.15)			

Data in the table 4 reveals that mean HbA1c value of people living with type 2 diabetes during pre-test and post-test 1 at 3rd month measured respectively in both groups. There was significant reduction in HbA1c value in the interventional group (from 8.96 to 8.32 at 3rd month) and in control group slight increase in HbA1c value was observed (from 9.49 to 9.79 at 3 rd month). Hence the null hypothesis (H_{03}) was rejected and research hypothesis (H_{03}) was accepted. This indicates there is significant decrease in the mean post-test from pre-test HbA1c value among type 2 diabetes patients. Hence N-HBDMP was effective in reducing HbA1c value. The same is depicted in the figure 3.
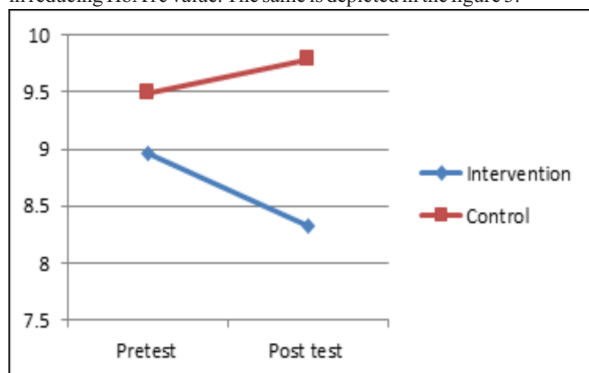
Figure 3: Profile plot showing mean Quality of life value

Section IV: Relationship Between Self-management and Quality of Life
The following null hypothesis was formulated to test the significant relationship between self-management scores and quality of life scores.

H_{03}: There will be no significant relationship between self-management scores and quality of life scores of people living with type 2 diabetes.

Table 5 Relationship Between Self-management and Quality of Life (post-test)   **N-32**

Variables	Group	Pearson's 'r' value	P-value
Self Management and Quality of Life	Intervention	0.246	0.377^{ns}
	Control	0.179	0.491^{ns}

Ns-Non Significant

Table 5 depicts the Pearson correlation coefficient calculated to find the relationship between self-management and quality of life. In interventional group the r =0.246 with p = 0.377 and in control group the r =0.179 with p = 0.491 since the p value was greater than 0.05 no significant relationship was evident between self management and quality of life of diabetes patients in both the group. Hence the null hypothesis (H_{03}) was accepted and research hypothesis (H_3) was rejected.

Section VII: Association of Self Management and Quality of Life Score with selected Demographic and Clinical Variables of PLD

There was no significant association found between Self Management scores and age (P=.485), gender (P=.200), religion (P=.1.00), education (P=.0.119), family History (P=.1.000), living with diabetes (P=0.719) and clinical items like BMI (P=.0.338), BP Systolic (P=.0.931), BP Diastolic (P=.0.312), HbA1c (P=.0.252) and RBS (P=.0.513)

There was no significant association found between Quality of Life scores and age (P=.0.290), gender (P=0.538), religion (P=.0.306), education (P=.0.085), family History (P=.0.082), living with diabetes (P=0.026) and clinical items like BMI (P=0.979), BP Systolic (P=.0.727), BP Diastolic (P=0.935), HbA1c (P=0.152) and RBS (P=0.508).

Hence the null hypothesis (H_{04}) was accepted and research hypothesis (H_3) was rejected

Until recently, clinical research interpretation was exclusively based on statistical significance. Results that are statistically significant may not be clinically significant or vice versa, hence clinical research focuses on the clinical utility of research findings . With the advent of evidence based nursing, it is imperative to utilize the findings which are not only statistically significant but also clinically meaningful.

In the present study, the clinical utility of HBDMP is discussed by providing the Percentage Change (PC) are discussed further.

Percentage Change (PC)

The Percentage change among the variables was calculated. A Percentage Improvement (PI) was calculated for the primary outcome - Quality of life. Percentage Reduction (PR) was calculated for other outcomes such as Qol &HbA1c of PLD.

The Percentage Improvement (PI) will be calculated as follows

Improvement = Post Test – pretest ,
Percentage improvement = Improvement ÷ pretest × 100
If the answer is positive, there is a percentage improvement and if the answer is negative number then this is a percentage reduction.

The Percentage Reduction (PR) was calculated as follows

Reduction = Pretest – (Post Test)
Percentage reduction = Reduction ÷ pretest × 100
If the answer is positive, there is a percentage reduction and if the answer is a negative number then this is a percentage improvement.

Table 6 Percentage Change For The Outcome Variables.   **N-32**

Variable	Group	n	Pretest	Post-test	Improvement	PI %
Self Management	Intervention	15	19.5	29.1	9.6	49.2
	Control	17	25.8	28.4	2.6	10.7
Quality of life	Intervention	15	100.4	129.73	29.33	29.2%
	Control	17	115.64	146.35	30.71	26.55%
Variable	Group	N	Pretest	Post-test	Reduction	PR%
HbA1c	Intervention	15	8.96	8.32	0.64	0.07%
	Control	17	9.48	9.79	-0.31	-3.27%

Table 7 displays the percentage change calculated for the outcome variables. The data indicates that participants in the intervention group had greater percentage improvements in self diabetes management. The data also indicates that participants in the intervention group had greater percentage improvements in quality of life. The participants in the intervention group also exhibited greater percentage reductions in HbA1c, than participants in the control group.

It can be interpreted that, in comparison to the routine care the HBDMP intervention was effective in significantly improving the quality of life of people living with diabetes.

DISCUSSION

In this pilot study , the people living with diabetes residing in rural areas showed reduction of 0.07 % and 25.6% in the HbA1c and RBS resp in the intervention group. A study reported that an average drop in HbA1c for the entire sample was 0.57%, and the maximum drop was in the symptom management participants that received the telephone booster. Their HbA1c decreased by 0.76%[12]. Studies showed self-management were significantly related to QoL. But, Sidiq et al., (2018) found contrasting result which shown no relation between self-management and QoL [14].In the United Kingdom Prospective Diabetes Study (UKPDS; 1998) a decrease of 1% was found in HbA1c in patients with type 2 diabetes mellitus, which resulted in a 35% reduction in risk for micro vascular disease[15].

In the pilot study, there was significant effect on the quality of life of the people living with diabetes from small to large. (ηp0.54- 0.95). A Similar study have showed that effect of multicomponent intervention on duration of migraine had only a 'Moderate Effect' (ηp2 0.07).

Implications:
Nursing Practice

Nurses have maximum opportunity to interact, assess the condition of the patient, specially the community health nurses can utilize the current studies questionnaires and the intervention Home based Diabetes management program in creating awareness of self management among people living with type 2 diabetes and ways to sustain a good quality of life.

Nursing Education

It was evident in the present study that considerable number of type 2 diabetes patients had poor level of quality of life. Nursing curriculum needs periodical revision based on the professional and societal needs. Awareness on current changes in the clinical practice, education and patients' expectations will aid them to provide optimum level of nursing care.

Nursing Administration

The Nurse Administrators render their services across various settings like community, primary health centre, diabetic clinics, rehabilitation units etc where home based diabetes management program can be utilize in providing quality care.

Nursing Research

Future research can be focused to broaden the scope of current knowledge and forming various strategies to enhance the self-management ability and quality of life among type 2 diabetes patients.

CONCLUSION, LIMITATION, RECOMMENDATION:

The Nurse led Home Based Diabetes Management programme was effective in improving the quality of life of people living with diabetes by reducing the glycemic level to some extent. Only one follow up could be done as COVID 19 pandemic lockdown was going on during the pilot study. The people living with diabetes were also unable to meet many of their needs as informed to them by the researcher. For the final study, more emphasis can be given on the dietary pattern and the physical activity for better results for glycemic control and there by quality of life improvement. The people living in the urban areas can also undergo similar research as the prevalence is also more among them.

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