ORIGINAL ARTICLE

A Randomized controlled trial to assess the effectiveness of group-based Diabetes Self-Management Education (DSME) program on glycemic control and self-care activities among type-2 diabetics in South-East Delhi

Farishta Hannah D Singh[1], Farzana Islam[2], Aqsa Shaikh[3], Rambha Pathak[4], Sunil Kohli[5], Varun Kashyap[6]

[1]Senior Resident, Department of Community Medicine, Hamdard Institute of Medical Sciences and Research, New Delhi; [2]Professor and Head, Department of Community Medicine, Hamdard Institute of Medical Sciences and Research, New Delhi; [3]Associate Professor, Department of Community Medicine, Hamdard Institute of Medical Sciences and Research, New Delhi; [4]Professor and Head, Department of Community Medicine, Government Institute of Medical Sciences, Greater Noida; [5]Professor, Department of Medicine, Hakeem Abdul Hameed Centenary Hospital, New Delhi; [6]Assistant Professor, Department of Community Medicine, Hamdard Institute of Medical Sciences and Research, New Delhi

Abstract | Introduction | Methodology | Results | Conclusion | References | Citation | Tables / Figures

Corresponding Author

Farishta Hannah D. Singh, B-06, Dept of Community Medicine, Hamdard Institute of Medical Sciences and Research, New Delhi 110062
E Mail ID: farishtasingh@gmail.com

Citation

Singh FHD, Islam F, Shaikh A, Pathak R, Kohli S, Kashyap V. A Randomized controlled trial to assess the effectiveness of group-based Diabetes Self-Management Education (DSME) program on glycemic control and self-care activities among type-2 diabetics in South-East Delhi. Indian J Comm Health. 2022;34(3):402-407. https://doi.org/10.47203/IJCH.2022.v34i03.015

Source of Funding: ICMR New Delhi **Conflict of Interest:** None declared

Article Cycle

Received: 17/11/2021; **Revision:** 20/05/2022; **Accepted:** 12/07/2022; **Published:** 30/09/2022

Abstract

Introduction: India has the second-largest population of diabetes globally. The long-term complications due to poor glycemic control are concerning. Diabetes Self-Management Education (DSME) is a fundamental component in managing diabetes better. **Objectives**: This study was conducted to compare the effectiveness of group-based DSME in achieving glycemic control and improving self-care practices among people with type-2 diabetes as against the usual care. **Methods**: A non-blinded parallel-arm RCT among adults (≥ 30 years) diagnosed with Type-2 DM. Written informed consent was taken from each patient before enrollment. The sample size is estimated to be 85 in each arm according to the formula for equivalence design for an RCT. Randomization was done using a computer-generated random number table. The control arm received usual care, while the intervention group received group-based DSME in addition to usual care. At the end of 6 months, the change in glycemic control and self-care activity scores were compared between the two arms. **Results**: A total of 139 individuals (intervention =69; control =70) were analyzed. The proportion of females (62.1%) was higher than males (37.9%). There was no statistically significant difference at baseline. At end line, HbA1c showed a reduction from 9.3% to 6.9% in the intervention arm (P<0.001), which was greater than that in the control arm (p=0.017). All the self-care components showed a statistically significant improvement, except the medication score. **Conclusions**: Group-based DSME effectively increases self-care practices among people with diabetes, resulting in better glycemic control.

Keywords

DSME; Glycemic Control; Indian Adults; RCT; Self-Care Activities; Type-2 DM

Introduction

Globally, diabetes is a significant public health problem, with nearly 537 million (10.5%) adults living with diabetes in 2021 and projected to increase to 643 million (11.3%) by 2030 as per the International Diabetes Federation (IDF). (1) India hasn't been far behind, with nearly 8.9% of the adult population making it the second-highest prevalence. (2) The chronic nature of diabetes and the lack of glycemic control has made it one of India's leading causes of mortality and morbidity. (3) As much of the care plan of this disease is interwoven with daily life behaviours, thus diabetic individuals have the greatest responsibility for adequate control and management of the disease. Apart from the pharmacological options

available for managing diabetes, Diabetes Self-Management Education (DSME) is recognized as a fundamental component of diabetes care. (4)

Previous studies have shown that group-based DSME can be used to sensitize patients to efficient disease management. Since it is less expensive and offers the extra benefit of allowing patients to interact with one another, it is better accepted. (5) Although a large number of studies have been conducted in developed countries to support the efficacy of DSME interventions in improving diabetes-related health outcomes, very few studies have been conducted in India. (6,7,8) A dearth of studies investigating the impact of the DSME delivery format on diabetes health-related outcomes.

Aims & Objectives

To assess the effectiveness of group-based DSME on glycemic control and self-care activities as compared to routine care.

Material & Methods

Study design & setting: This was a non-blinded parallel-arm randomized controlled clinical trial conducted from March 2019 to May 2020 among individuals with uncomplicated type-2 Diabetes Mellitus (DM), diagnosed at least six months before the start of the study. The study was conducted at Hamdard Institute of Medical Sciences and Research (HIMSR), New Delhi.

Study population: The study population comprised individuals 30-70 years with uncomplicated type-2 Diabetes meeting the inclusion criteria.

Inclusion criteria included those who were able and willing to provide informed consent, give the requisite information, undergo investigation, and participate in activities, had no plans to move out of the area within the 12-month study period and had access to a mobile phone.

Exclusion Criteria: Individuals diagnosed with other types of diabetes, diabetes-related complications, and anemia at the last hemoglobin count since these would confound the results.

Diabetes-related complications were screened based on the last laboratory check-up (tested within the previous three months) of their kidney function test, the latest eye check-up, and the clinical notes from their family physician, excluding any neuropathic symptoms or symptoms of other complications.

The Individual's giving consent to participate in the study, with no plans to move out during the study period, and having access to a mobile phone were included in the study. While, those with type-1 DM, severe complications, or on glucocorticoid therapy for at least 3 months, on any other weight loss program or pregnant women, were excluded from the study. In case any woman became pregnant or if any individual developed complications during the study, they were discontinued from the same.

Sample size: The sample size was calculated based on the formula for equivalence design for an RCT (9) and was estimated to be 67.82, where p (response rate in the standard treatment group) was taken to be 0.21, based on a previous study. (8) Considering a drop-out rate of 20%, the total sample size was calculated to be 85 in each arm. After assessing eligibility and enrolling the participants, the enrolled patients were randomly allocated into the intervention and control arms.

Study intervention:

Standard Care: The control arm received the usual care which included standard assessment and care in the OPD, blood glucose monitoring, and medications follow-up. It entailed a 20–30 min standard doctors' consultation where the recent HbA1c level and medication compliance were reviewed, and a brief informal patient-tailored diabetes education was offered. This enabled the individual an opportunity to learn about self-management flexibly and informally. There was no structure to it and the information was offered according to what the patient requested to know as well as what the doctor thought would have been important for the patient to know, during that consultation. Print, audio-visual and online patient education materials were used depending on the provider.

Diabetes self-management education: The intervention arm received DSME along with the usual care. The DSME program had 6 sessions of 30 minutes each, delivered once a month by a single educator in a group of 6-7 members. Each session had a guided discussion to emphasize key messages towards diabetes management, self-care activities and prevention of long-term effects of diabetes. Direct instruction by a doctor, personalized goal-setting, self-monitoring, feedback, and problem-solving for building self-management skills and positive- peer reviews were the strategies used.

Patients were called telephonically and invited to attend the sessions. Usually, the sessions were conducted at the time the patient had a scheduled visit to the OPD for their routine check-up so that it did not incur any extra cost or time. The sessions were conducted in a separate room having good seating for at least 15 people at a time. Education materials, in the form of flipcharts, were used to educate the patients. Each patient was given a chart to record their adherence to diet, exercise, medications, and blood glucose readings. The sessions included discussions on the epidemiology of diabetes, appropriate dietary practices, emphasis on adequate physical activity, medication adherence, the importance of glucose monitoring, and foot care.

Endline assessment was done after a period of 6- months in both the intervention and control arms.

Randomization: The research assistant invited all the eligible patients for participation, and randomized them equally into two groups based on computer-generated random numbers, and informed them of the assigned group. The randomization allocation sequence remained concealed from the principal investigator and physicians

to further eliminate conscious or unconscious selection bias. After recruitment, the patients completed their demographic and medical history information on a standard data collection form. Evaluation of self-care activities was done using the Summary of Diabetes Self-care Activities scale (SDSCA). (10) It assessed the frequency with which a patient followed a diabetes routine over the past 7 days in five domains. Scores were calculated for each of the five regimen areas assessed by the SDSCA: Diet, Exercise, Blood-Glucose Testing, Foot Care, and Smoking Status.

The required anthropometric measurements were measured using standard devices. Biochemical evaluations included the measurement of Fasting and Postprandial Blood Sugar (FBS & PPBS), and HbA1c were conducted using standard methods.

Data analysis: The data was anonymized and entered into MS Excel. Analysis was done using SPSS Ver. 26. The test of normality of our data was done by using the Kolmogorov-Smirnov test. Socio-demographic variables were calculated as a percentage of frequencies observed and continuous variables were represented as mean ± SD. Z-test for the difference in two proportions was done to test the significance of the difference of an event in two groups. An independent t-test was performed to test the difference between two means in the case of quantitative variables. Before applying an independent t-test, Levine's test for equality of variances was performed to assess the variability between the two groups. A paired t-test was performed to test the difference between two means of the same group at two different points of time. Non-parametric tests were performed to analyze the data which did not follow a normal distribution assumption. The difference was considered significant if the p-value was less than 0.05.

Ethical consideration: The Jamia Hamdard Institutional Ethics Committee (JHIEC) approved the study, and the trial was registered in the Clinical Trial Registry of India with registration number CTRI/2019/02/017589. All the participants provided written informed consent before participating in the study. A patient information sheet was provided to all the patients in English and Hindi. Good clinical practices were followed throughout the study

Results

A total of 215 patients were screened for eligibility and 169 met the eligibility criteria. Eighty-four were randomized into the intervention arm and 85 in the control arm of whom 77 and 81 individuals completed the baseline assessments in the respective arms. After a six-month follow-up, complete data were available for 139 patients (87.9%) and that was used for final analysis. The loss to follow-up was significantly more common in the usual care group than the intervention group (41% vs. 21%; p = 0.005). The patient recruitment and follow-up flow diagram is shown in (Figure 1)

The mean age of the study participants was 50.0 ± 9.9 years, with a higher proportion of female participants (62.1%) as compared to males (37.9%). Only 55.5% of them had received some formal education with the majority having studied up to middle school (24%). According to the Modified Kuppuswamy scale 2019, 48.7% belonged to the upper-lower class, 27.3% belonged to the lower-middle class, while the remaining 4.4% belonged to the upper-middle and upper socio-economic classes. There was no statistically significant difference observed between the two arms after randomization, based on age, gender, education status, or socio-economic class. (Table 1)

Baseline assessment revealed the mean duration of diabetes to be 4 years 8 months with a standard deviation of 4 years. Positive family history was found among 44.3% and about 92.4% were on medications. Nearly 82.9% of participants had unsatisfactory waist circumference, indicating a higher proportion of central obesity. Only 24.1% had an ideal BMI, while 16.4 % had satisfactory BMI and 59.4% had unsatisfactory BMI according to the ICMR BMI cut-offs for diabetic individuals.(11)

Glycemic Control: At baseline, the mean HBA1c was found to be 9.3% ± 2.2%, and the median was 9.05% with the minimum being 5.2% and the maximum being 15.4%. Among the 158 study participants, 24.7 % had good glycemic control while 75.3 % had poor glycemic control.

Although at baseline there was no statistically significant difference in the glycemic control measures between the two arms, a statistically significant reduction was observed at the end line in both the arms, as can be appreciated in (Table 2). Further, the difference of the improvements from baseline to end-line was greater in the intervention arms as compared to the control arm (p=0.002).

Self-care activities: The Summary of Diabetes Self-Care Activities Scale (SDSCA) is used to assess the number of days the participants had engaged in self-care activities under various domains, in the last 1 week. The scale is scored from 0 to 7 depending on the number of days the activity was done. The baseline and end line findings of the self-care activities scores are as shown in (Table 3). There was no statistically significant difference between the intervention and control arms at baseline. At the end-line, there was a significant difference observed between the intervention and control arms in almost all the domains except the medications score.

Further, the mean difference in the change in self-care activity scores from baseline to end line in the intervention and control arms is shown in (Figure 2). The difference was statistically significant in general diet (p=0.011), specific diet (p=0.006), exercise (p=0.014), blood sugar testing (p=0.04), foot care, and carbohydrate spacing (p<0.001). The medication adherence scores did show an improvement; however, the change was not statistically significant (p=0.404).

Discussion

The prevalence of diabetes mellitus is growing rapidly worldwide and India has earned the dubious distinction of being the diabetic capital of the world with nearly 77.0 million (8.9%) people living with diabetes. (2) Evidence-based, population-wide, cost-effective, and multisectoral interventions are recognized as key strategies to reduce the impact of diabetes. (12) The World Health Organization also recognizes the importance of educating patients to facilitate self-care to enhance the management of diabetes and prevention of complications. (13) This study found group-based diabetes self-management education to be effective in achieving glycemic control.

At baseline, the poor glycemic control found in our study was similar to other similar studies such as an RCT study conducted among low-income Latinos, where the mean baseline HbA1c was found to be 9.0% ±1.87 %. (8) similarly, in a longitudinal study conducted in the UK, the mean HbA1c was found to be 9.20 ±1.92%. (14) The poor glycemic control observed in our study at baseline, despite the majority of them being on medications, could be due to poor self-care practices such as lack of physical activity and poor dietary management.

Our study found a significant reduction in HbA1c and FBS levels after DSME which was similar to other studies such as that conducted among Mexican Americans, in 2002, which concluded to have a significant reduction in HbA1c after the intervention from 11.81±3.00 to 10.89±2.56 (p=0.016). (15) They also found a reduction in FBG from 213.01±64.06 to 194.95± 63.27(p=0.020). In the study conducted among low-income Latinos which assessed the effectiveness of a diabetes self-management intervention, they found a mean change of 0.88 (1.55 to 0.60) after 4-months and 0.46 (0.77 to 0.13) after 12-months in HbA1c, using a linear mixed-model. (8) Similar findings were reported from the study conducted in the UK wherein a mixed-methods longitudinal study found a significant reduction of 2.35% (p=0.03) in HbA1c from baseline to the 6-months follow-up. (14)

In a meta-analysis, conducted by Steinsbekk et al., in 2012 to assess the effectiveness of group-based DSME in achieving clinical, lifestyle, and psycho-social outcomes they found a significant reduction in HbA1c at 6 months (0.44%; p=0.0006) in 13 studies consisting of 1883 participants. (5) The reduction at 12 months was found in 11 studies, 1503 participants to be 0.46%; p=0.001). In three studies, 397 participants found a reduction of 0.87% (p<0.0001) after 2 years. Significant reductions in fasting blood glucose were seen in 12-months (1.26mmol/l; p<0.0001) in 5 studies with 690 participants. (5)

Our study found a statistically significant change in self-care activities in General diet, specific diet, and foot care scores after diabetes self-management education. This was similar to a study conducted in Mumbai, India, which after 6-months of a counselling intervention, found a statistically significant difference in the change in dietary practice (p=0.016), and foot care(p=0.009). Our study found exercise score also to have a statistically significant difference, however, the study in Mumbai found a non-significant change, exercise score (p=0.421). (16) The remarkable change in exercise scores in our study could be due to a majority of participants engaging in some form of physical activity after receiving education. Many individuals were employed in physically active jobs as well. The medication scores did not show any significant improvement after intervention in our study which was similar to the study conducted in Mumbai.

The drop-out rate observed in our study was calculated to be 18.2%, which was similar to other interventional studies, as observed by Carpenter et al. who conducted an integrative review of diabetes-self management intervention studies in 2018 and found that among 64% of studies who had a drop-out rate of <20%, 39% had 10%-20% attrition. (17) The high attrition rate in our study could be attributed to the lockdown imposed due to the CoVID-19 pandemic at the time of end-line data collection. Some of the limitations of this study are, firstly the possibility of social-desirability bias, as the self-care activities scale was a self-reported measure. Secondly, HbA1c could not be tested for all participants due to various constraints; hence FBS was used as a marker for glycemic control. Thirdly, this study could not account for extraneous factors such as diabetes education from other sources, which could not be monitored in the control group, hence they too could have received education from elsewhere during the study period.

Conclusion

In conclusion, the study showed that group-based DSME played an important role in increasing self-care practices among diabetics. The adherence to self-care activities resulted in better glycemic control which made patients more confident. The group-based approach acts as a tool to bring people of different backgrounds with diabetes together, enabling them to interact and share their views and opinions. It provided an opportunity to learn from the success stories and good practices of their peers. The myths & barriers related to the causation and management of diabetes could be addressed, which reflected in achieving better glycemic control. Thus, Diabetes Self-Management Education empowers the individuals living with diabetes to better achieve glycemic control even when it may be difficult to access healthcare professionals for various reasons such as frequent travelling, migratory population, and even unexpected events such as the CoVID-19 pandemic.

Recommendation

Based on the findings of this study, it is recommended to initiate diabetes self-management education in the community to achieve better glycaemic control.

Developing a culturally tailored program would be easier to implement and better accepted. The instruction can be disseminated through platforms such as the Anganwadi or health and wellness centres.

Limitation of the study

Most of the scales were self-reported so it could be prone to social-desirability bias. Extraneous factors such as diabetes education from other sources could not be monitored in the control group; hence they too could have received instruction from elsewhere during the study period. This study could not account for such factors.

Relevance of the study

This study is relevant to the present scenario as it provides information on the effectiveness of the DSME program in the community. During Covid, when several patients were cut off from accessing physicians', thus being self-reliant and being aware about managing their diabetes is a good tool to ensure glycemic control. The effect of enhancing self-care practices and its acceptability in the Indian setting is better understood now.

Authors Contribution

FHDS: Concept, design, the definition of intellectual content, literature search, data acquisition, data analysis, statistical analysis, manuscript preparation, editing, and review. AS: Concept, design, the definition of intellectual content, literature search, statistical analysis, manuscript preparation, editing, and review. FI: Concept, design, the definition of intellectual content, manuscript preparation, editing, and review. RP: Concept, design, definition of intellectual content, manuscript preparation, manuscript editing and manuscript review. SK: Concept, design, the definition of intellectual content, manuscript preparation, editing, and review. VK: Concept, design, statistical analysis, manuscript editing, and review.

Acknowledgement

I want to extend gratitude to all the participants who participated in the study and contributed to enhancing the research. I would also like to thank the health center staff who supported me through every activity and session planned for DSME.

References

1. International Diabetes Federation. IDF Diabetes Atlas 10th Edition 2021. [Internet]. [Accessed on 15/09/2022]. Available from: https://diabetesatlas.org/idfawp/resource-files/2021/07/IDF_Atlas_10th_Edition_2021.pdf
2. International Diabetes Federation. IDF Diabetes Atlas 9th edition 2019. [Internet]. [Accessed on 15/09/2022]. Available from: https://diabetesatlas.org/en/
3. Tandon N, Anjana RM, Mohan V, Kaur T, Afshin A, Ong K, et al. The increasing burden of diabetes and variations among the states of India: the Global Burden of Disease Study 1990–2016. The Lancet Global Health. 2018;6(12):e1352–62.
4. Funnell MM, Brown TL, Childs BP, Haas LB, Hosey GM, Jensen B, et al. National Standards for Diabetes Self-Management Education. Diabetes Care. 2011;34(Supplement 1):S89–96.
5. Steinsbekk A, Rygg L, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Services Research. 2012;12(1):213.
6. Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the diabetes X-PERT Programme makes a difference. Diabet Med. 2006;23(9):944–54.
7. Wichit N, Mnatzaganian G, Courtney M, Schulz P, Johnson M. Randomized controlled trial of a family-oriented self-management program to improve self-efficacy, glycemic control and quality of life among Thai individuals with Type 2 diabetes. Diabetes Res Clin Pract. 2017;123:37–48.
8. Rosal MC, Ockene IS, Restrepo A, White MJ, Borg A, Olendzki B, et al. Randomized Trial of a Literacy-Sensitive, Culturally Tailored Diabetes Self-Management Intervention for Low-Income Latinos: Latinos en Control. Diabetes Care. 2011;34(4):838–44.
9. Zhong B. How to Calculate Sample Size in Randomized Controlled Trial? J Thorac Dis. 2009;1(1):51–4.
10. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care. 2000;23(7):943–50.
11. Indian Council of Medical Research. ICMR Guidelines for Management of Type- 2 Diabetes 2018. [Internet] [Accessed on 15/09/2022]. Available from https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_GuidelinesType2diabetes2018_0.pdf
12. United Nations. 2011 High Level Meeting on the Prevention and Control of Non-communicable Diseases [Internet]. United Nations; [Accessed on 15/09/2022]. Available from: https://www.un.org/en/ga/ncdmeeting2011/
13. World Health Organization. Global report on diabetes [Internet]. [Accessed on 15/09/2022]. Available from: https://www.who.int/publications-detail-redirect/9789241565257
14. Huxley C, Sturt J, Dale J, Walker R, Caramlau I, O'Hare JP, et al. Is it possible to predict improved diabetes outcomes following diabetes self-management education: a mixed-methods longitudinal design. BMJ Open. 2015;5(11):e008781.
15. Brown SA, Garcia AA, Kouzekanani K, Hanis CL. Culturally Competent Diabetes Self-Management Education for Mexican Americans: The Starr County Border Health Initiative. Diabetes Care. 2002;25(2):259–68.
16. Sriram M, Doke P, Dasila P. Impact of Communication on Self Care Management among Individuals with Diabetes Mellitus in an Urban Community in Mumbai. Int J Health Sci Res. 2020;10(7):1-11.
17. Carpenter R, DiChiacchio T, Barker K. Interventions for self-management of type 2 diabetes: An integrative review. International Journal of Nursing Sciences. 2019;6(1):70–91.

Tables

TABLE 1 BASELINE CHARACTERISTICS OF STUDY PARTICIPANTS IN THE INTERVENTION AND CONTROL ARM

	Category	Intervention Arm(n=77)	Control arm (n=81)	p-value*
		Frequency (%)	Frequency (%)	
Age	30-40	20(25.9)	13(16.1)	0.12
	41-50	25(32.5)	24(29.6)	0.69
	51-60	23(29.9)	33(40.7)	0.15
	61-70	9(11.6)	11(13.6)	0.71
Gender	Male	35 (58.3)	25(41.6)	0.058

	Female	42 (42.8)	56 (57.2)	0.058
Education status	Uneducated	34(47.2)	38 (52.7)	0.72
	Educated	43(50)	43(50)	0.72
Socio-economic status	Lower	12	18	0.28
	Upper-lower	40	37	0.42
	Lower-middle	20	23	0.72
	Upper-middle	3	3	0.95
	Upper	1	0	0.30
Mode of medication	Diet & exercise Oral/ Oral & insulin	7(9.1) 70(90.9)	5(6.1) 76(93.9)	0.49 0.49
	H/o Tobacco use	21(27.2)	18(22.2)	0.71
Duration of diabetes	<5yrs 5-10yrs >10yrs	48(62.3) 16(20.7) 13(16.8)	55(67.9) 17(20.9) 9(11.2)	0.46 0.97 0.29
		Mean(SD)	Mean(SD)	p#
	BMI	25.39(4.09)	26.4(5.2)	0.17
Blood Pressure(BP)	Systolic BP Diastolic BP	129.08(10.73) 83.11(7.48)	128.24(10.26) 83.74(6.84)	0.61 0.58
	HbA1c	9.35(2.12)	9.38(2.35)	0.93

z-test of proportions; # unpaired t-test

TABLE 2 CHANGE IN GLYCEMIC CONTROL FROM BASELINE TO ENDLINE

Outcome	Intervention Arm(n=69)			Control Arm (n=70)			Difference
	Baseline Median (Range)	**End-line Median (Range)**	**p-value***	**Baseline Median (Range)**	**End-line Median (Range)**	**p-value***	**p-value**
FBS **(mg/dl) (n=139)**	194 (82 -370)	116 (65 -234)	0.001	157 (78 -468)	120 (75 -351)	0.001	0.002
HbA1c **(%) (n=80)**	9.30 (5.2 -15.4)	6.9 (5.2-11.0)	0.001	8.7 (5.7-15.0)	7.2 (5.5-13.3)	0.001	0.017

** Wilcoxon-signed rank test*

TABLE 3 COMPARISON OF CHANGE IN SELF-CARE ACTIVITY SCORE AT BASELINE AND END LINE

Self-care activities (No. of days per week)	Baseline				End-line			
	Intervention arm	Control arm	Mean diff.	t-statistic (P value)	Intervention arm	Control arm	Mean diff.	t-statistic (P value)
General diet	3.99 (2.06)	4.01(2.01)	0.029	0.083 (0.934)	5.71 (0.97)	5.06 (1.22)	-0.653	-3.47 (<0.001)
Specific diet	2.65 (1.58)	2.50(1.35)	-0.152	-0.607(0.545)	4.38(1.28)	3.64(1.11)	-0.734	-3.59 (<0.001)
Exercise	3.19(2.86)	2.90(2.56)	-0.288	-0.625(0.533)	6.07 (1.52)	4.70(2.24)	- 1.37	-4.21 (<0.001)
Blood-sugar testing	1.01 (0.97)	1.00(1.21)	-0.014	-0.77(0.938)	1.55 (1.21)	1.06(0.61)	-0.494	-2.84 (0.005)
Foot-care	0.33 (1.19)	0.39(1.25)	0.06	0.252(0.802)	1.41 (1.28)	0.54(1.28)	-0.863	-3.96 (<0.001)
Carbohydrate spacing	4.39 (1.86)	4.80(1.40)	0.409	1.46(0.16)	5.97 (1.04)	5.50(0.95)	-0.471	-2.72 (0.006)
Medication	5.70 (2.50)	6.04(2.05)	0.347	0.894(0.373)	6.68 (1.33)	6.69(1.43)	0.005	0.01 (0.985)

Figures

FIGURE 1 PATIENT FLOW DIAGRAM

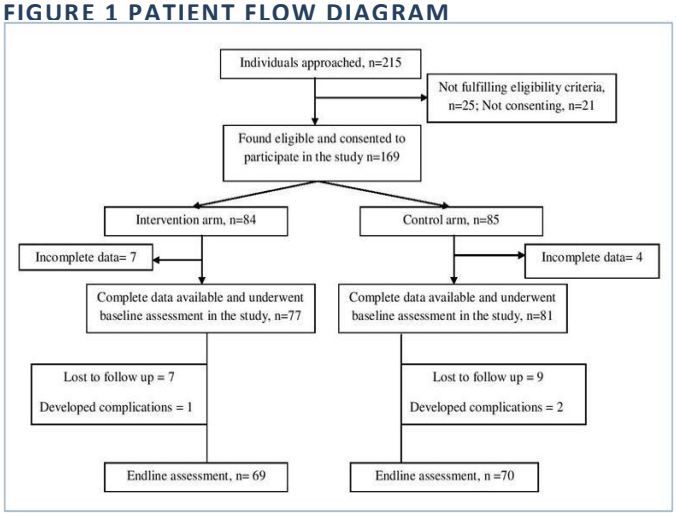

FIGURE 2 COMPARISON OF CHANGE IN SELF-CARE ACTIVITIES AT END-LINE BETWEEN THE INTERVENTION AND CONTROL ARMS