Effectiveness of diabetes self-care education at primary health care centres in Saudi Arabia: A pragmatic randomized trial in Tabuk

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Abstract

Objective: The present trial aimed to assess the effectiveness of the structured Information, Education, and Communication provided by trained health educators at primary care on the mean body mass index, waist circumference, fasting blood glucose, and the level of blood pressure, among patients with type 2 diabetes mellitus. Research Methods: This was a 12-month pragmatic clustered randomized trial where 180 patients with type 2 diabetes mellitus were enrolled in 2020. Five primary health care centres were randomly allocated to either the intervention or control arm. Results: There was a comparable significant reduction in the mean scores of waist circumference among participants in the intervention versus control arm over 12 months: I = 108.7 cm (P value = 0.001), I = 109.2 cm (P value = 0.001), and I = 105.6 cm (P value = 0.001) in the first, sixth, and twelfth months, respectively. A significant reduction in the mean scores of body mass index in the intervention versus control arm only in the first month: I = 31.7 cm (P value = 0.001). However, there was a comparable significant reduction in the mean scores of fasting blood glucose in the intervention versus control arm over 12 months: I = 2016.5 mmol/l (P value = 0.011), I = 207.4 mmol/l (P value = 0.002), and I = 2012.7 mmol/l (P value = 0.001) in the first, sixth, and twelfth months, respectively. Conclusions: The delivery of structured diabetes self-care education for diabetics by trained health educators at primary health care has a beneficiary effect on reducing the mean body mass index, waist circumference, and blood glucose. Similarly, it decreases high blood pressure.

Keywords: Diabetes, health educator, pragmatic trial, primary health care, self-education

Introduction

The global incidence of diabetes is rising, and almost half of deaths among elderslies are due to diabetes mellitus.[1] Diabetes Self-care Education (DSCE) is an ongoing process of facilitating the knowledge and abilities necessary for self-care.[2] There is scarcity in randomized trials addressing DSCE worldwide and in the Gulf region, in particular.[3,4] DSCE is recommended for better care.[5-8] Therefore, a new model of care is suggested by the Saudi Ministry of Health.[9-12]

This study aimed to assess the effectiveness of the structured Information, Education, and Communication (IEC) provided by trained health educators at primary care centres in Saudi Arabia.
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Research Methods

This was a 12-month pragmatic randomized clustered trial, where 180 patients with T2DM attending primary health care clinics at governmental health care centres were enrolled in 2020. Five primary health care centres were randomly allocated to either the intervention or control arm. After randomization, participants were invited to participate and start follow-up with the study in both intervention and control arms [Figure 1].

It is a registered trial in the ClinicalTrials.gov database. Identifier: NCT04847856: https://clinicaltrials.gov/ct2/show/NCT04847856.

The study population was patients with T2DM of both genders attending primary health care centres, irrespective of their duration of disease and the types of medication currently received. The participants were adults aged 18 years and above. Children and young adults with juvenile diabetes mellitus were excluded. Also, severely ill patients and patients with mental disorders were excluded.

The participants were interviewed at the start of the study to collect the baseline data as BMI, WC, FBG, and BP. Similarly, participants were interviewed to collect end-line data and similar measurements at the end of the first month, sixth month, and the twelfth month at the end of the trial.

Typical family physicians and nurse staff who are working in diabetes and chronic care clinics were nominated to receive training of trainer's workshop organized as on-the-job training. A pre-and-post reflection on the gained knowledge, practice, and competencies on self-care education for a patient with T2DM is accomplished. At the end of the mentoring and training session, a small training manual was given to enhance further reading and preparation for practical applications.

Intervention, trial arms, and primary outcomes

The intervention was a structured IEC on diabetes self-care education delivered to the participants by trained health educators at the selected primary health care centres. It is composed of sessions of training and education and the participants were planned to attend four structured sessions on diabetes self-care at months: 1, 3, 5, and 7. After each session, the participants were provided with a single-page checklist, i.e. a to-do list of activities and simple advice that covering the various aspects of diabetes self-care. The IEC materials were adapted from John Hopkins University studies on self-care education for a patient with T2DM. Frequent telephone contact on weekly basis was conducted to make sure that the participants were adhering to the given instructions.

The comparators or control arm were patients with T2DM of both genders attending the selected primary health care centres that provide routine care for diabetes including instructions from relevant health care providers. They were interviewed at the start of the trial to collect the baseline data on BMI, WC, FBG, and BP at the same time frame of the enrolment in the intervention arm.

The primary outcome measures were to compare the mean differences in BMI, WC, and FBG in addition to comparing the proportion of high and normal BP between the intervention and control arm over 12 months’ duration.

As randomization was per cluster, participants in the trial were allocated to either the intervention or the control arm within the randomization cluster. The Random Number Generator software was used from https://www.random.org/ and the randomization was held centrally by the research team. As a result, each trial arm was divided into three health centres to receive the intervention, and two health centres to receive routine care [Figure 1]. The selected health centres were identified before the starting date of the trial, and they were maintained throughout the trial, i.e. no change was allowed. The principal investigator had maintained contact with the selected health centre authorities to obtain permission for trial implementation. A sample of 195 participants for the two trial arms with an average cluster sample (m) of about 39 participants per cluster is calculated using the STATA clustersampsi command. This is by specifying the total number of clusters (k) = 5, the mean for control sample1 as (m1) = 0.6, the mean for experimental sample2 (m2) = 0.27, the intra-class correlation coefficient (rho) = 0.01, at the power beta (0.8), and significant alpha level of (0.05).

Data analysis was conducted using the SPSS software version 21.
Results

Response rate

A total of 180 participants were enrolled in the study; there was a 91% response rate. The respondents were males (75, 41.4%) and females (105, 58%) with a mean age of 51.7 for both genders. Respondents were patients with T2DM who used to receive their medication in diabetes and chronic care clinic at the primary health care centre.

Comparing BMI, WC, and FBG between trial arms

The result of comparing the difference in the mean scores of BMI, WC, and FBG between the intervention and control arm shows an overall significant difference in most of the parameters. It also shows an overall significant reduction in most of the parameters in the intervention versus control arm over 12 months [Table 1].

The change in the mean scores of BMI was only significant in the first month, but not significant in the sixth and twelfth months.

There was improvement reflected as a gradual reduction in the mean scores of BMI among participants in the intervention (I) versus control (C) arm over 12 months as follow: mean scores of BMI: I = 31.7: C = 26.5 cm (P value = 0.001), I = 30.8: C = 29.9 cm (P value = 0.33), and I = 29.9: C = 30.4 cm (P value = 0.59) in the first, sixth, and twelfth months, respectively [Table 1], [Figure 2].

There was significant reduction in the mean scores of WC among participants in the intervention versus control arm over 12 months as follows: mean scores of WC: I = 108.7: C = 85.8 cm (P-value = 0.001), I = 109.2: C = 86.02 cm (P value = 0.001), and I = 105.6: C = 87.2 cm (P value = 0.001) in the first, sixth, and twelfth months, respectively [Table 1], [Figure 3].

A significant gradual reduction was observed in the mean scores of FBG among participants in the intervention versus control arm over 12 months as follows: mean scores of FBG: I = 2016.5:C = 185.3 mmol/l (P value = 0.012), I = 207.4:C = 186.04 mmol/l (P value = 0.002), and I = 212.7:C = 158.6 mmol/l (P value = 0.001) in the first, sixth, and twelfth months, respectively [Table 1], [Figure 4].

Figure 4: Difference in the proportion of high and normal blood pressure in the intervention versus the control arm.

This figure illustrates a gradual increase in the optimum normal BP among participants with T2DM in the intervention versus control arm over 12 months.

Figure 5: Difference in the proportion of high BP in the intervention versus the control arm.

This figure shows a gradual increase in the proportion of high BP among participants with T2DM in the control arm over 12 months, especially in the twelfth month at the end of the trial.

Figure 6: reflects improvement in the level of normal blood pressure in the intervention arm throughout the trial.

Table 1: Independent samples t-test, a comparison summary of mean scores

| Time frame | Variables          | Trial arms | n  | Mean  | Std. Deviation | Sig   |
|------------|--------------------|------------|----|-------|----------------|-------|
| 1st Month  | Body mass index    | Intervention | 102 | 31.7  | 6.4            | 0.001 |
|            |                    | Control     | 77  | 26.5  | 5              | 0.001 |
|            | Waist circumference| Intervention | 26  | 108.7 | 11.2           | 0.001 |
|            |                    | Control     | 52  | 85.8  | 15.2           | 0.001 |
|            | Fasting blood glucose| Intervention | 97  | 216.5 | 86.3           | 0.012 |
|            |                    | Control     | 77  | 185.3 | 73.2           | 0.011 |
| 6th Month  | Body mass index    | Intervention | 98  | 30.8  | 5.9            | 0.327 |
|            |                    | Control     | 62  | 29.9  | 5.9            | 0.327 |
|            | Waist circumference| Intervention | 22  | 109.2 | 11.97          | 0.001 |
|            |                    | Control     | 40  | 86.02 | 13.3           | 0.001 |
|            | Fasting blood glucose| Intervention | 81  | 207.4 | 69.7           | 0.002 |
|            |                    | Control     | 53  | 168.04 | 69.6          | 0.002 |
| 12th Month | Body mass index    | Intervention | 78  | 29.9  | 5.5            | 0.599 |
|            |                    | Control     | 55  | 30.4  | 6.4            | 0.607 |
|            | Waist circumference| Intervention | 18  | 105.6 | 10.5           | 0.001 |
|            |                    | Control     | 35  | 87.2  | 14.1           | 0.001 |
|            | Fasting blood glucose| Intervention | 75  | 212.7 | 77.3           | 0.001 |
|            |                    | Control     | 55  | 158.6 | 42.9           | 0.001 |
Finally, the result of the Chi-squared test in comparing normal and high BP in the intervention versus control arm is significant ($P$ value = 0.042) at a 5% level of significance.

**Discussion**

This study aims to assess the effectiveness of the structured information, education, and communication about self-care delivered by a trained health educator at a primary health care centre on promoting optimal BMI, WC, FBG, and BP among patients with T2DM attending primary health care centres.

The high response rate among the study participants at the start of the study reflects approach acceptability and convenience for both respondents and health educators. It also reflects the suitability of the primary health care centres as a preferred setting for participants to receive a structured IEC for diabetes self-care. The drop-out in the final total number of study participants could be attributed to the lack of patient–doctor rapport because of the frequent turnover of health educators in diabetes and chronic care clinics.

The study results in comparing differences in the mean scores of BMI across intervention, and control arms generate valuable information on the effectiveness of the intervention approach in optimizing BMI of patients with T2DM over time [Figure 2]. This finding matches that of previous study results.[13]

**Patient compliance to the intervention**

A finding of a linear reduction in the mean scores of WC in the intervention arm in comparison to the control arm [Figure 3], reflects the participants’ compliance with the provided IEC instructions. It also reflects the commitment to regular exercise at least 30 min a day, taking medications on time, and eating healthy food throughout the trial period, this finding is coherent with that of previous studies.[14]

Given this valuable effect of IEC intervention on the general health of a patient with T2DM, frontline health providers are superior and need to provide a deliberate, short, concrete, and effective self-care education message. This will foster nurse competencies in the self-care education process as stated in recent studies.[15]

**Improve self-care behavior**

The result of the progressively decreasing mean scores of FBG in the intervention arm in comparison with the control arm [Figure 4] could be explained by the effect of improvement in self-care behavior among participants in the intervention arm. This finding is similar to that of previous studies.[16]

The finding of a gradual fall in high BP in the intervention arm in comparison with the control arm [Figure 5] was possibly because of the commitment of participants to exercise regularly. This finding is consistent with other findings, which could be ascribed to a reduction in systolic and diastolic blood pressures due to aerobic exercise.[17]

Another possible explanation of the linear reduction in the high BP could be inferred to the protective effect of reduction in both
BMI and WC as the latter two parameters could affect BP. This finding is consistent with the study findings among the Chinese about the effect of BMI, WC, and other factors in predicting incident hypertension.[18]

**Conclusion**

The delivery of mindful, deliberate, and structured diabetic self-care education by trained health educators at primary health care has an everlasting effect on boosting and controlling BMI, WC, FBG, and BP among patients with T2DM.

Given the similarities in the sociodemographic status and health setting design, these trial findings deserved to be generalized to other primary health care settings.

**Recommendations**

Doctor–patient communication at the primary health care level is the key to patient compliance.

Self-care education training and mentoring for primary health care staff is crucial.

**Limitations**

The outbreak of SARS-Cov-2 during the data collection period forced the trial team to arrange telephone contact with the patient to collect end-line data from the study participants. Therefore, most of the medical check-ups for participants were performed in health facilities other than the allocated ones where no information is available about the standard operating procedures that followed.

**Ethical considerations**

Ethical approval for the protocol was obtained from the Institutional Review Board (IRB) at the Local Ministry of health, protocol number: TU-077/019/013. The proposal was also approved by the Research Ethics Committee in the Faculty of Medicine.

**Informed consent**

A written informed consent was obtained from each participant before randomization and before the participants had undergone any study intervention or data collection procedures. The informed consent was obtained by the primary health care physician in a special room at the health centre. The primary health care educator provided the information about the trial and as well ensures that the participant has understood the information. This was achieved through answering adequately the questions raised by participants; hence, the participants were encouraged to ask questions about the trial and were given adequate time to decide, voluntarily, either to participate in the trial or not. The health staff was trained to be deliberate and precise and when a participant requested more time to decide, then they requested to give another appointment to the participants.

**Key Messages:**

Health educators are superior and should attend to their patient’s needs while they are providing health care services at primary care clinics and diabetes centres.

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**Conflicts of interest**

There are no conflicts of interest.

**References**

1. Arokiasamy P, Salvi S, Selvamani Y. Global Burden of Diabetes Mellitus. Handbook of Global Health. 2020;1:44. 2. Ryan D, Burke SD, Litchman ML, Bronich ‑Hall L, Kolb L, Rinker J, Yehl K. Competencies for diabetes care and education specialists. The Diabetes Educator. 2020;46:384-97. 3. Chai S, Yao B, Xu L, Wang D, Sun J, Yuan N, et al. The effect of diabetes self-management education on psychological status and blood glucose in newly diagnosed patients with diabetes type 2. Patient Educ Couns 2018;101:1427–32. 4. Ali Slamah T, Nicholl BI, Alsailly FY, Melville CA. Self-management of type 2 diabetes in Gulf Cooperation Council countries: A systematic review. PloS One 2017;12:1–11. 5. American Diabetes Association. Facilitating behavior change and well-being to improve health outcomes: Standards of Medical Care in Diabetes—2020. Diabetes Care 2020;43(Suppl 1):S48–65. 6. Begum S. The impact of the NSF for Diabetes on patient empowerment. Br J Nurs 2010;19:887–90. 7. Ye W, Kuo S, Kieffer EC, Piatt G, Sinco B, Palmisano G, et al. Cost-effectiveness of a diabetes self-management education and support intervention led by community health workers and peer leaders: Projections from the racial and ethnic approaches to community health detroit trial. Diabetes Care 2021;44:1108–15. 8. Baviskar MP, Rangari S, Mishra S, Mohanta BS. Assessment of a group-based comprehensive diabetes management program to improve glycemic control, quality of life and self-care behavior in patients with type 2 diabetes mellitus in a primary healthcare setting of a metropolitan city in India: CDMP MUM Trial. Int J Diabetes Dev Ctries 2021;41:156–63. 9. Al Saffer Q, Al-Ghaith T, Alshehri A, Al-Mohammed R,
Elfakki, et al.: Self care education for patients with diabetes mellitus at primary care

Al Homidi S, Hamza MM, et al. The capacity of primary health care facilities in Saudi Arabia: Infrastructure, services, drug availability, and human resources. BMC Health Serv Res 2021;21:1-15.

10. Al Busaidi N, Shammugam P, Manoharan D. Diabetes in the Middle East: Government health care policies and strategies that address the growing diabetes prevalence in the Middle East. Curr Diab Rep 2019;19:8.

11. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: An extension of the CONSORT statement. BMJ 2008;337:a2390.

12. Aluhaymid YM, Alessa YA, Alhikan AA, Albalawi GA, Alrasheed WA, Aldawasari HK, et al. Educational interventions in type 2 diabetes mellitus patients in primary health care: Systematic review and meta-analysis. Ann Med Health Sci Res 2021;11:1217-21.

13. Wang Y, Min J, Khuri J, Xue H, Xie B, A Kaminsky L, et al. Effectiveness of mobile health interventions on diabetes and obesity treatment and management: Systematic review of systematic reviews. JMIR MHealth UHealth 2020;8:e15400.

14. Jiang XJ, Jiang H, Chen Y, Wu XA, Yu XL, Liu L, et al. The effectiveness of a self-efficacy-focused structured education program (SSEP) in improving metabolic control and psychological outcomes of type 2 diabetes patients: A 12-month follow-up of a multicenter randomized controlled trial. Diabetes Metab Syndr Obes Targets Ther 2021;14:305-13.

15. Teston EF, Spigolon DN, Maran E, de L. Santos A, Matsuda LM, Marcon SS. Nurses’ perspective on health education in Diabetes Mellitus Care. Rev Bras Enferm 2018;71:2735–42.

16. Samudera WS, Efendi F, Indarwati R. Effect of community and peer support based healthy lifestyle program (CP-HELP) on self care behavior and fasting blood glucose in patient with type 2 Diabetes Mellitus. J Diabetes Metab Disord 2021;20:193-9.

17. Park S, Kim J, Lee J. Effects of exercise intervention on adults with both hypertension and type 2 diabetes mellitus: A systematic review and meta-analysis. J Cardiovasc Nurs 2021;36:1–7.

18. Momin M, Fan F, Li J, Jia J, Zhang L, Zhang Y, et al. Joint effects of body mass index and waist circumference on the incidence of hypertension in a community-based Chinese population. Obes Facts 2020;13:245-55.