Assessment of Dietary Compliance among Patients with Type II Diabetes Mellitus Receiving Text Message (SMS) Reminders for improving adherence to healthy diet in Pakistan: A Randomized Control Trial

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Abstract

Background

Motivating patients through text message (SMS) reminders can improve adherence to a healthy diet and can lead to better diabetes control. This study was carried out to assess the difference in dietary adherence in patients with Type II diabetes, who were sent dietary text message reminders vs. those provided standard care.

Methods

A block randomized control trial was conducted at the Aga Khan University Hospital in Karachi, Pakistan. Patients (n=249), diagnosed with Type II diabetes were invited to participate in the study. At baseline, dietary guidelines were provided to all the study participants. In the intervention arm, three dietary text message reminders were sent per week for 3 months. Adherence to diet was measured by assigning a score to the dietary intake assessed by the Food Frequency Questionnaire (FFQ) both at baseline and after follow-up.

Results

Mean age of participants in the intervention arm and the control arm was 49.7 (SD =9.94) and 51.3 (SD 9.79) years respectively. The results of the study showed no change in diet quality score from baseline till 3 months of the follow up in the intervention arm compared to the control arm. Odds ratio and confidence interval for the intervention was 1.04(0.96 – 1.14) compared to the control arm. However, diet quality score of overweight participants was 17% (OR: 0.83 CI: 0.70-0.99) less than that of normal weight participants. Each additional score points at baseline resulted in an almost 20% (OR: 1.20 CI: 1.07-1.34) increase in the adherence score at follow-up.

Conclusion

Findings of the study suggest that there is no effect of dietary text message reminders on
the dietary adherence of patients with Type II diabetes in a three months duration study. However, adherence to a healthy diet is better in patients who had a healthy diet to begin with and those who were obese.

Trial Approval and Registration

Approval for this study was obtained from the Ethical Review Committee (ERC NO: 1981-CHS-ERC-11) of the Aga Khan University Hospital. This trial was registered on “Australian New Zealand Clinical Trials Registry”. Trial registration number is: “ACTRN: ACTRN12612000538842”

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Background
Diabetes has been an important public health problem and is one of the four non-communicable diseases (NCDs) targeted for action by world leaders. Diabetes mellitus of all types can lead to many health related complications and increase the risk of dying prematurely (1). Both, the number of cases and the prevalence of diabetes have been steadily increasing over the past few decades, and according to the World Health
Organization (WHO), diabetes will be the 7th leading cause of death in 2030 (2)

The prevalence of diabetes has risen faster in low- and middle-income countries than in high-income countries (1). The percentage of deaths attributable to diabetes that occurs prior to age 70 is higher in low- and middle-income countries than in high-income countries (1). This could be the reason of less resources in terms of health care and management. The prevalence of diabetes mellitus in Pakistan ranges from 6.3% to 13.14% (3-6) and over 7 million cases of diabetes mellitus were reported in Pakistan in 2015 (7). Type II diabetes is a growing epidemic in South Asians and there is a higher prevalence among them as compared to other ethnicities around the world. This predisposition is due to both genetic and environmental factors associated with the disease (8). Type II diabetes cannot be cured permanently however various methods are available worldwide to manage this disease. An integrated approach including, improved physical activity, diet, and medicine (oral medications and insulin) are required to control blood sugar levels of patients.

Eating a healthy diet is an essential part of managing diabetes, however more counseling and motivation is needed for patients to adhere to this lifestyle (9, 10). Dietary adherence among patients with diabetes has been poor and has remained an obstacle in managing blood sugar levels. Therefore there is a strong need for dietary guidelines to be clear and understandable (11).

It is evidenced from the literature that in developed countries, text messages have been successfully used to improve the health of individuals, while there are only a few examples of such use of technology in developing countries, especially Pakistan. Use of mobile phones is very common and cost effective in Pakistan (12) and text messages can be used to remind people about effective dietary guidelines to help manage their disease. The present study assessed the difference in dietary adherence in patients with Type II
diabetes, attending outpatient clinics at a tertiary care hospital, who were sent text message reminders about dietary guidelines as compared to those who were receiving standard care.

Methods

This study was conducted at the Aga Khan University Hospital (AKUH) in Karachi, Pakistan. AKUH is a private, university hospital, focusing on the delivery of the highest quality health care in Pakistan for over 30 years since 1985.

This was a hospital based single blinded, block randomized controlled trial with one intervention and one control arm. Participants were recruited from all endocrine clinics at AKUH. Participants aged 30 to 70 years old who had been diagnosed with Type II diabetes in the last 2 to 15 years, with an HbA1c of more than 7% and who were on oral hypoglycemic medication were included in the study. Moreover, participants who owned mobile phones, and who could read and respond to text messages written in Urdu were included in the study. Those participants who had serious chronic conditions like diabetic ketosis, diabetic foot, nephropathy, neuropathy, retinopathy, chronic renal failure and liver cirrhosis, pregnant mothers, those who were involved in any other study and those who did not give informed consent were excluded from the study. Recruitment of the study participants started on the 21st June 2012 and ended on the 12 June 2015. The overall follow up period for each participant was 3 months.

Potential participants were identified from endocrine clinics at the AKUH by obtaining information about the status of the disease from both hospital online records and medical record files. WHO criterion was used to diagnose diabetes; which is fasting blood glucose $\geq 126\text{mg/dl or }7\text{mmol/l and }2\text{ hours random sugar }\geq 200\text{mg/dl or }11.1\text{mmol/l. Recent HbA1c (})$ level and fasting blood sugar (mg/dl) were recorded from the electronic laboratory records. Each eligible participant was given detailed information about the
study. A written informed consent was taken from all the willing participants. Consent form was composed of both English and Urdu. Data collectors were provided proper training for administration of the questionnaires. Questionnaires were explained in detail to the data collectors and description of how to collect data for each variable was formulated in a manual of operations. At baseline an interview was conducted with each participant to obtain information about their socio-demographic status, social and psychological support and dietary intake using validated questionnaires. Anthropometric measurements including height and weight were measured in order to assess the body mass index by using weight and height scales respectively. Waist and hip circumference were recorded using measuring tapes to assess the waist to hip ratio. Dietary intake information was assessed using semi quantitative validated food frequency questionnaires (FFQ) both at baseline and after the follow-up period of three months. This FFQ contained both traditional and mixed food dishes eaten in Karachi. Mobile phone numbers of each participant were recorded. All participants were provided with dietary guidelines and explained in detail, so it would help maintain their blood glucose level. Randomization was performed by block randomization strategy with an uneven varying block size of 2 and 4. Alphabet “A” was assigned to intervention arm while “B” was considered as control arm. There were only two possible combinations of A&B for block size 2, while for block size 4, there were 6 possible combinations. These were generated by the primary investigator. Each combination was put in an opaque envelop, which was selected for randomization by a third person. After randomization, identification numbers (different for intervention and control arm) were assigned to each participant. Dietary text message reminders were sent to participants three times a week using the Frontline Short Message Service (SMS) software. These were automated messages, similar for all the participants in the intervention arm, and were sent at the same time. Each
time, different templates of messages were used. These dietary text messages as well as dietary guidelines were developed based on suggestions provided by the “American Diabetes Association Complete Guide to Diabetes”(13), as well as with advice given by a local expert nutritionist and other investigators of the study. Messages were based on 8 food components; vegetables, fruits, cereals, starch and whole grain foods, nuts and legumes, dairy products, fish, poultry and eggs, meat products and sweets and drinks. Dietary adherence was the main outcome of interest and was measured using the FFQ. Frequency of intake of each food item falling under the 8 food components was recorded in one of the 9 categories which were: Never, ≤ once/month, 1-3 times/month, 1 time /week, 2-4 times/ week, 5-6 times/ week, 1 time/ day, 2-3 times/day, 4-5 times/ day and ≥ 6 times/day. Mean daily intake of each component was compared with the daily intake recommended in the dietary guidelines. This was done by converting the frequency of intake into “intake per day” and then multiplying it with the amount of food consumed at one time. After adjusting for the amount of intake, mean daily intake for each food component was calculated in order to consider the number of food items in each food component. Diet quality scores were assigned to each component (range was from 0 to 2). If the consumption of the food component was exactly equal to the dietary guidelines, it was given a score of “2”. If the consumption was greater or lesser than the dietary guidelines, a score of “1 and 0” was given based on the food group’s effect on the level of glucose management. If the food is beneficial in terms of management of glucose level in the body and consumed greater than the prescribed amount, we assigned 1 and if consumed less than the mentioned amount we assigned 0. However, if the food could increase the blood glucose level and could be unhealthy for diabetic patients and the participant consumed more than the amount assigned, we gave 0 score and for less consumption we assigned 1.
In addition, a fortnightly two-item questionnaire was sent to assess the dietary intake of specific food components in both the groups of participants i.e. fruits and vegetables. Two questions were designed in a text message. It was stated as: in the last 24 hours how many fruits do you have? If yes write the number of fruits if no, please write zero. Same question was asked for the vegetables as well. Participants responded back to questions via text message. For this response credit was transferred through easy loads to each participant. This approach also helped in the reduction of loss to follow-up in the control arm as well as give us an idea of compliance to text messages.

After 3 months of the intervention period, another FFQ was administered to measure dietary adherence from both groups via telephone calls. The outcome assessor was blinded to the randomization status of the participants i.e. whether they belonged to the intervention arm or the control arm. Full trial protocol is available on ANZCTR website. Text message reminders and dietary guidelines are attached in the supplementary material.

Statistical Analysis

A total of 112 subjects in each arm were required to achieve 80% power for the parent study with 5% level of significance, range of compliance score of 0-16 and expected mean difference in the dietary compliance score of 1.5 between the two groups for the complete duration of follow-up. After considering 10% loss to follow-up an additional sample of 12 participants in each arm was decided to recruit in the study.

Total scores for all FFQ were then calculated by adding diet quality scores of all 8-food components. The overall possible scoring for FFQ ranged from 0 to 16.

Means and standard deviations were calculated for normally distributed continuous data, while median and inter quartile range were computed for skewed data. Frequencies and proportion were computed for categorical variables. We were unable to conduct the
planed analysis because we ended up with count data for compliance score and because of less variability in the dietary score. Hence Poisson regression was conducted to see the association between dietary text message reminders and the adherence score for dietary guidelines while adjusting for different variables such as age, gender, body mass index (BMI), education and household income. We also checked the interaction between different variables while building the final model. SPSS version 19 was used to conduct the analysis.

Results

We approached to 6256 participants. Out of these 5145 participants were not eligible and 862 participants refused. We were able to enroll 249 participants in our study and randomized 126 to the intervention arm and 123 were in the control arm and two participants were loss to follow-up. (figure.1). Two participants were loss to follow-up in the intervention group. We were unable to contact them to conduct the follow-up interview. The number loss to follow-up was small so we did intention to treat analysis. There was no significant difference between the two groups with respect to baseline characteristics. More than 50% of the participants were employed in both groups. 6.3% of the participants in the intervention group had a normal BMI while 93.7% of the participants were either overweight or obese. Similarly, 9.8% of the participants in the control group had a normal BMI while 90.2% were either overweight or obese. Furthermore, 29.4% and 30.9% of the participants had a history of anxiety in the intervention group and control group respectively. (Table 1)

With respect to the association between the dietary text message reminders and the diet quality score, the adherence was increased by 4% (OR: 1.04 CI: 0.95-1.14) among those
who received dietary text message reminders as compared to the control group while adjusting for sex, BMI, education, no of physician visits, HbA1c at baseline and compliance score at baseline. However, this association was not significant. We observed that BMI and baseline diet quality score were significantly associated with the diet quality score at follow-up. Diet quality score of overweight participants was 17% (OR: 0.83 CI: 0.70-0.99) less than the diet quality score of normal weight participants and the results were statistically significant, hence, obese participants are less compliant compared to normal weight participants. (Table 2).

Additionally, we found that each additional score of diet quality at baseline resulted in an almost 19% (OR: 1.199 CI: 1.07-1.33) increase in diet quality score at follow-up. (Table 2).

Discussion

This was the first mobile health study done in Pakistan to assess dietary adherence to dietary guidelines by sending dietary text message reminders to people with Type II diabetes. Our study found that the diet quality score increased by 4% among those who received text message reminders as compared to the control group. However, the results were not found to be significant. These results suggest that dietary text message reminders have no significant effect in the improvement of dietary compliance score among people with Type II diabetes in a study with a three months follow-up period.

In a similar study done to see the effect of text message reminders on weight reduction in obese participants in the Philippines (14), it was found that there was no significant difference in dietary adherence in the two groups, despite there being an improvement in knowledge about diet and physical activity in the intervention arm. Likewise, a pilot study done on people with diabetes in India (n=215), with a secondary objective of improving dietary adherence by sending text message reminders, found no significant improvement in the dietary adherence at follow up and reported that a small sample size could be a
reason for this association(15). However in studies done by Kim and Oh (11), Wong et al (16) and Nesari M et al (17), where telephone calls were made to assess glycemic control and dietary adherence, results at follow up reported a significant reduction of mean HbA1c (1.2%, 2.9% and 2.86% respectively) in the intervention arm after 12 weeks of follow-up compared to the control. Nesari M et al also suggested that in the intervention arm, dietary adherence was significantly higher compared to the control arm. Mean adherence score was improved by 17.6 points from baseline to follow-up in the intervention arm while it was increased by 5.3 points in the control arm (17). Another study using internet and SMS reminders conducted by Yoon and Kim (18) showed a significant decrease in HbA1c levels after 12 months of follow-up and an improvement in adherence to diet and medications. Franklin VL et al (19) reported that SMS reminders are associated with an improvement in diabetes self-efficacy, self-reported adherence and reduction in HbA1c. Majority of the studies support that telemedicine is an inexpensive and effective intervention in management of diabetes.

However, in this study, this was not the case this might have been the case due to a variety of reasons including short duration of the intervention i.e. three months. In behavioral interventions, more time is required for the intervention to be effective(20). The frequency of text messages sent to participants has also varied among studies. While in other studies daily reminders were sent to the participants (21), Shetty AS et al (15) assessed participants acceptance of text messages per week and reported that on average participants acceptance of text message reminders was 2 times per week. In our study, three text message reminders were sent per week so that it would be easier for participants to remember and recall dietary tips. It is likely that if we would have sent daily reminders then the dietary score would have been better.

The strength of this study is that it is a randomized control trial, which is one of the
robust and rigorous research designs to conduct epidemiologic studies. This research
design is considered as a gold standard among all study designs to answer research
questions. It can adjust for both known and unknown confounders. Furthermore, the
outcome assessor was blinded to the assignment of the participants in order to reduce
self-introduce bias while assessing the outcome. Moreover, validated data collection tools
were used in this study. Dietary text messages were developed in the Urdu language and
tailored to the Pakistani population. Incentives were given in the form of detailed dietary
counseling at the time of interview. Experienced data collectors were hired and went
through rigorous training by the principal investigator in order to reduce interviewer bias.
One major limitation is that patients might not have read the dietary text messages in the
intervention arm. They could have just opened and deleted the messages without reading
them.

In the case of assessing dietary adherence, the best way is to use bio markers while in
this study the budget was limited for such a standard technique to apply.

Another limitation of this study could be the short duration of follow-up, which could have
resulted in the lack of improvement in dietary adherence. The minimum follow-up period
in most of studies was 6 months while the follow-up in this study was 3 months. A follow-
up after 3 months is not considered to be a sufficient amount of time to elicit behavioral
change, as behavioral interventions take a longer time to bring about a change in patients
with chronic disease (20).

There may have also been a recall bias and a response bias in the assessment of dietary
adherence. FFQ was used to interview the participants about their dietary intake, which
could have introduced a recall and response bias in the study. Patients may have had a
difficult time recalling their food intake and hence information taken from the participants
could be biased.
Moreover, the FFQ was administered through telephone calls for the assessment of outcomes while the baseline FFQ was conducted via face to face interviews. Two different modes were used to conduct the FFQ because of resource constraints; this could have also introduced a bias in the study. We used two different approaches for data collection because there were not enough incentives for the participants to invite at the clinic for the follow-up assessment.

Findings of the study suggest that there is no effect of dietary text message reminders on dietary adherence of people with Type II diabetes. However, participants with a normal BMI had a higher diet quality score compared to overweight individuals. Similarly, those who showed adherence at the baseline showed increased adherence after follow-up.

Conclusion

Findings of the study suggest that there is no effect of dietary text message reminders on dietary adherence of patients with Type II diabetes in a three months duration study. This is the first epidemiological study to assess dietary adherence in people with diabetes by sending dietary text message reminders in Pakistan. It can have important public health implications especially in low- and middle-income countries as it has the potential of lowering the use of healthcare resources while reaching out to a larger audience, and thereby improving health care delivery. Moreover, on a larger scale, more effective communication with patients can be achieved by text message interventions if messages are personalized and interactive, as it can improve health care delivery. Along with the work of primary health care providers, mobile health technology can work in conjunction with practices already in place to improve effective patient-provider communication, adherence to treatment and self-management ability.

Abbreviations
List of

Declarations

Ethics approval and consent to participate

Ethical approval is given by the Aga Khan University Ethical Review Committee (ERC NO: 1981-CHS-ERC-1). Participants are required to sign a consent form to indicate their willingness to participate. Voluntary participation and the right to ask any questions and to decline participation at any time was emphasized during the data collection.

Consent for publication

Not applicable

Availability of data and materials

Data and materials presented in this paper will be made available on request from the primary author.
Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

The study was conceptualized by GBA, RI and SIA. GBA prepared the first draft of the manuscript. SA, MI, NG and HK reviewed it several time before sharing with RI. RI, SIA, SK and JA finalized the last version of manuscript. All authors have contributed to this manuscript and reviewed and approved the final version of the paper.
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Figure And Table Legends

Figure 1: Flow chart describing the layout of the study
Table 1 Baseline Socio-demographic and clinical characteristics of the study participants

Table 2: Association of dietary text message reminder and dietary compliance score

Figures

Figure 1

Flow chart describing the layout of the study

Supplementary Files

This is a list of supplementary files associated with the primary manuscript. Click to download.

CONSORT 2010 Checklist.pdf
Tables.pdf
Dietary Guidelines.pdf
