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Effectiveness of mobile phone text messaging in improving glycaemic control among persons with newly detected type 2 diabetes

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ABSTRACT

Aims: The aim of the study was to evaluate the effect of text messaging as a tool to improve glycaemic control among newly diagnosed T2D patients in a 2 year period.

Methods: This is a multicentric, randomised controlled trial conducted in 2 states of India. The primary outcome was improvement in glycaemia measured by an HbA1c value of ≤7% (53 mmol/mol) with intervention. The secondary outcomes were changes in biochemical, dietary parameters and physical activity. Acceptability of text messages was assessed. Persons having HbA1c value of ≥6.5% (48 mmol/mol) at diagnosis were enrolled. A total of 248 participants with a mean age of 43.3 ± 8.7 years were recruited. Participants in the control group (n = 122) received standard care, the intervention group (n = 126) received customized text messages thrice a week. Both groups received personal advice at the beginning of the study.

Results: Baseline characteristics were similar in both groups. At 24 months, both groups showed significant reduction in blood pressure and glycaemic variables in comparison to the baseline values. The intervention group showed significant lowering of LDLc also. Multivariate analysis showed that reduction in HbA1c was associated with intervention.

Conclusion: Text messaging can lead to improvement in glycaemic control through personal empowerment and sustained behavioural changes.

1. Introduction

Patient empowerment is important for effective management of type 2 diabetes (T2D), the burden of which is increasing worldwide [1]. Long term prospective studies have also shown that good glycemic management prevents development of complications to a large extent and its benefits are sustained for longer periods [2]. Diabetes education involving healthy lifestyle changes, early treatment strategies, regular monitoring and good compliance to medication is helpful in modifying behaviour whereby glycated hemoglobin A1c (HbA1c) is lowered.

Although education is effective at the initial stages, the benefits diminish over time as shown by the Diabetes

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Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) programme. Improved HbA1c levels were seen at twelve months but not at three years [3]. There are data suggesting that compliance to treatment is low in people with established T2D [4].

There is evidence that the benefits may be sustained, if the educational programme is reinforced periodically. A major barrier to implement personal education programmes is its cost and is offered only to a small proportion of patients, even in developed countries. Attendance at educational sessions is also difficult, as it requires taking time off work or being away from the family, or if the venue is considered inaccessible. To overcome these challenges, efforts have been underway to seek, develop and test, new, less expensive tools using mobile technology.

Short messaging service (SMS) via mobile phones is relatively inexpensive and potentially scalable as shown by a primary prevention study of diabetes in India [5]. Studies from different countries have shown that mobile phone short messaging service (SMS) is an effective tool to educate patients on diabetes management and reinforce adherence to the treatment advised by the physicians [6,7]. Mobile phone ownership is high in India and large proportion of the population has smart phones and/or home computers.

However there is paucity of data on the effectiveness of SMS for longer periods of time from randomized controlled trials [7]. Evidences show that strict adherence to the treatment from the initial stage, not only improves the glycaemic status at that time, but also provides sustained benefits such as prevention of vascular complications of diabetes [8,9].

The present study was designed to assess the effectiveness of SMS as an educational tool to improve the glycaemic status in newly diagnosed Asian Indian persons with T2D.

2. Material and methods

2.1. Study design and participants

This is a hospital based multicentric, prospective, parallel group, randomized controlled clinical trial done in newly diagnosed patients with T2D.

The study was initiated in December 2014 and the recruitment of patients was done in five different centres in two states of South India (two in Tamil Nadu and three in Andhra Pradesh) over a period of 18 months. Written permission was given by the heads of the participating centers. Informed written consent was also given by the study participants. Patients' physicians were informed of their participation in the study. Diagnosis of T2D was made using HbA1c (HbA1c $\geq$ 6.5%, 48 mmol/mol) according to the criteria of the World Health Organization (WHO) and American Diabetes Association (ADA) [10,11]. The study was approved by the Ethics Review Committee of the India Diabetes Research Foundation and Dr. A. Ramachandran's Diabetes Hospitals, Chennai, India. Participants were selected and enrolled as per the inclusion criteria (Fig. 1) by the study investigator of each centre. Persons with newly diagnosed T2D and treatment naïve, aged 20–60 years of both sexes with values of glycosylated haemoglobin (HbA1c) $\geq$ 6.5%, (48 mmol/mol) and were able to read and understand the messages were selected. Persons having type 1 diabetes, any major illness such as cardiovascular disease, chronic liver or kidney disease, cognitive impairment or other mental imbalance, physical disability, not able to read and understand SMS, pregnant and lactating mothers were excluded from the study.

Patients were randomised to the standard care (control group, n = 122) or to the intervention (SMS group, n = 126) by a central team not involved in the analysis of the data and were followed-up for 24 months. A computer generated randomisation sequence was used to allocate patients (1:1) to the study groups. The study investigators, research team members, statistician and laboratory personnel were masked to participant's group allocation until the end of the study. The study physicians were the care providers for the participants. Those involved in the clinical care and trial related activities of the participant were by necessity not masked. It was also ensured by the trial staff at each site that the participants in the intervention arm received and read the messages.

The details of the analysis were entered in an electronic case report form (eCRF). During the screening, details of demography, age, sex, medical history, family history of diabetes, anthropometric measurements, blood pressure, pulse rate, respiratory rate and clinical assessments were done and recorded.

The primary outcome was improvement in glycaemia as assessed by an HbA1c of $\leq$7% (53 mmol/mol) with intervention (i.e. treatment including education via SMS) versus the standard care.

Secondary outcomes were changes in fasting plasma glucose (FPG) and 2hr plasma glucose (2hPG), lipid parameters, body weight, waist circumference, blood pressure, physical activity, quality of life and dietary aspects. Acceptability of text messages was also assessed using a questionnaire developed and validated by the central research institute [5].

2.2. Study assessments

Anthropometric measurements and vital signs were measured at 3, 6, 12, 18 and 24 months reviews. Fasting, 2hr PG and HbA1c were estimated at these periods. Lipid profile was estimated annually. The 2hr PG represents the blood glucose level 2 h after a regular meal (non-standardized meal) by the patient.

Regular face-to-face follow-up visits of the study subjects were coordinated by a central study team. The dietician at each centre assessed the 24 h dietary pattern. FPG and 2hPG were estimated at the respective sites. All centres used glucose oxidase–peroxidase method for glucose estimations. Other biochemical parameters such as HbA1c by immunoturbidimetry (TINA-QUANT II; Roche Diagnostics Corporation, Germany); a procedure certified by the National Glycohemoglobin Standardization Program and lipid parameters were estimated at the central laboratory (Dr. A. Ramachandran's Diabetes Hospitals, Chennai, India).

Each participant was assessed individually for their dietary intake based on the 24 h recall method. This method enumerates what the subject has eaten during the past 24 h starting from morning till bed time. Energy and nutrient

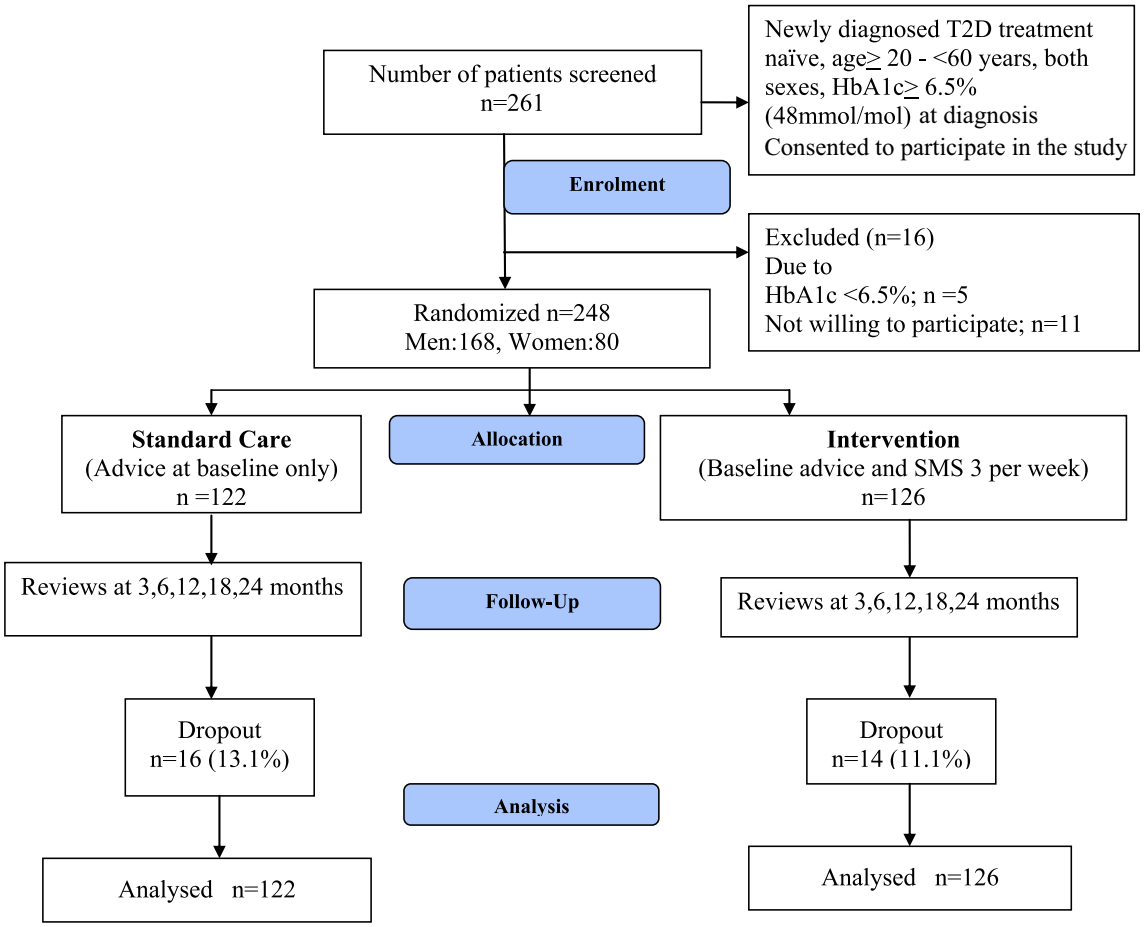

Fig. 1 – Enrolment, allocation and follow-up of study participants.

intake was calculated using guidelines by the National Institute of Nutrition, India.

Physical activity was measured using the Recent Physical Activity Questionnaire (RPAQ) developed by the MRC Epidemiology unit, Cambridge [12]. It refers to the recent physical activity which the participant has performed in the last 4 weeks and the duration of sleep.

European Quality of Life Questionnaire 5 Dimension (EQ5D) [13], diet assessment by 24 h recall method and text messages acceptability questionnaire were used to assess the physical activity, quality of life, dietary pattern and acceptability of text messages at 6, 12, 18 and 24 months.

The study participants were interviewed by trained study personnel at the beginning of the study. Participants were advised at an individual level on healthy behavioural changes to follow healthy diet pattern and physical activity. The intervention group received the above advice and in addition received 2–3 educatory text messages per week till the end of the study as reinforcement to healthy lifestyle practices and adherence to medication.

The text message contents were on the causes, principles of diabetes management and the associated complications of diabetes. Text messages on the benefits of healthy lifestyle, pros and cons of modifying and not changing the behavior; cues to initiate medication and to modify healthy lifestyle practices were delivered. The text messages were in English and three local languages (Hindi, Tamil, Telugu). The **Panel** shows the sample messages under various categories.

All participants were newly diagnosed with (T2D) at study entry, hence were treatment naive. Medications for management of (T2D) were prescribed and modified if needed by the study physicians at each site during the interim visits.

An internal safety committee monitored the safety of the study participants and overall conduct of the study. Interim study outcomes were monitored by an external committee at 6 monthly intervals.

2.3. *Sample size calculation*

Considering a 15–45% difference in improvement in glycaemic control between the standard care and intervention group, the sample size required in each of the two groups was 121 with type 1 error of 5%, 80% power and allowing for a dropout rate of 20%.

The study was registered with ClinicalTrials.gov, number NCT02643277 and Clinical trial registry of India (CTRI) number CTRI/2016/03/006777.

Table 1 – Demographic and metabolic characteristics of the randomized persons at baseline and 24 months follow up.

Variables	Baseline		24 months Follow up		Inter Group			Intra Group	
	Control	Intervention	Control	Intervention	Baseline P value		Follow up P value	Control P value	Intervention P value
n	122	126	122	126					
Age (Years)	44.1 ± 8.9	42.4 ± 8.5	–	–	0.134		–	–	–
Male : Female	82:40	86:40	82:40	86:40					
Type of Occupation	n(%)				χ^2	P value			
Sedentary	44 (36.1)	48 (38.1)	–	–	0.040	0.842	–	–	–
Standing	19 (15.6)	17 (13.5)	–	–	0.081	0.776	–	–	–
Manual	9 (7.4)	9 (7.1)	–	–	0.030	0.862	–	–	–
Heavy manual Work	4 (3.3)	6 (4.8)	–	–	0.073	0.787	–	–	–
Not working	46 (37.7)	46 (36.5)	–	–	0.004	0.949	–	–	–
Weight (Kg)	73.4 ± 14.5	73.8 ± 12.7	74.3 ± 14.3	74.0 ± 12.6	0.830		0.861	**0.003**	0.255
BMI (Kg/m^2)	27.3 ± 4.7	27.2 ± 4.5	27.7 ± 4.6	27.2 ± 4.4	0.760		0.434	**0.002**	0.361
Waist Circumference (cm)	92.8 ± 8.7	93.2 ± 9.5	93.3 ± 8.9	93.2 ± 9.5	0.741		0.922	0.061	0.875
Blood Pressure (mmHg)									
Systolic	131.7 ± 15.0	129.5 ± 13.2	127.6 ± 11.8	124.1 ± 8.4	0.232		**0.007**	**0.004**	**<0.0001**
Diastolic	83.8 ± 9.8	83.2 ± 8.9	81.7 ± 6.5	81.8 ± 5.9	0.578		0.909	**0.017**	**0.048**
Plasma Glucose (mmol/l)									
Fasting	11.5 ± 3.9	10.9 ± 3.6	8.4 ± 2.8	7.5 ± 2.3	0.311		**0.007**	**<0.0001**	**<0.0001**
Post Prandial	17.2 ± 4.9	17.1 ± 4.6	12.7 ± 3.6	12.5 ± 3.3	0.877		0.593	**<0.0001**	**<0.0001**
HbA1c (%)	9.5 ± 1.9	9.5 ± 2.1	7.8 ± 1.5	7.4 ± 1.5	0.851		**0.044**	**<0.0001**	**<0.0001**
Lipid profile (mmol/l)									
Triglyceride *	1.8 (1.3–2.6)	1.9 (1.4–2.8)	1.9 (1.4–2.6)	1.8 (1.4–2.6)	0.403		0.565	0.889	0.534
Cholesterol	4.8 ± 0.9	4.8 ± 1.1	4.7 ± 1.0	4.6 ± 1.1	0.787		0.421	0.161	0.054
HDL-Chol	0.9 ± 0.3	1.0 ± 0.2	1.0 ± 0.2	1.0 ± 0.2	0.356		0.605	0.260	0.072
LDL-Chol	2.9 ± 0.9	2.8 ± 0.9	2.7 ± 0.9	2.6 ± 0.9	0.564		0.222	0.169	**0.029**

Values are mean ± SD, * Median (Inter quartile range).
P value used paired and unpaired *t* test.
P value used Mann-Whitney Test and Wilcoxon Signed Ranks Test.
P values <0.05 are considered statistically significant and are highlighted in bold.

Table 2 – Glycemic parameters at baseline and during the follow up visit in the control and intervention groups.

Variables	Group	Visits					
		Baseline	3rd month	6th month	12th month	18th month	24th month
		Mean ± SD					
HbA1c (%)	Control	9.5 ± 2.0	7.9 ± 1.8[a]	7.6 ± 1.5 [a]	7.7 ± 1.6 [a]	7.9 ± 1.7 [a]	7.8 ± 1.5 [a]
	Intervention	9.5 ± 2.1	7.8 ± 1.6 [a]	7.6 ± 1.4 [a]	7.6 ± 1.6 [a]	7.5 ± 1.5 [a]	7.4 ± 1.5 [a,b]
FBG (mmol/l)	Control	11.5 ± 3.9	8.0 ± 3.1 [a]	8.1 ± 3.0 [a]	8.5 ± 3.1 [a]	8.5 ± 3.1 [a]	8.4 ± 2.8 [a]
	Intervention	10.9 ± 3.6	7.9 ± 2.6 [a]	7.8 ± 2.4 [a]	8.1 ± 2.9 [a]	7.7 ± 2.6 [a,c]	7.5 ± 2.3 [a,d]
PPBG (mmol/l)	Control	17.2 ± 4.9	11.8 ± 4.2 [a]	12.2 ± 4.0 [a]	12.7 ± 4.0 [a]	12.4 ± 4.2 [a]	12.7 ± 3.6 [a]
	Intervention	17.1 ± 4.6	12.3 ± 4.1 [a]	12.4 ± 3.6 [a]	12.8 ± 4.0 [a]	12.1 ± 4.2 [a]	12.5 ± 3.3 [a]

Control and Intervention group.
Baseline Vs Follow up: a, $p < 0.0001$.
Control Vs Intervention at 24 months.
HbA1c: b, $p = 0.044$.
FBG: d, $p = 0.007$.
FBG at 18 months: c, $p = 0.028$.

2.4. *Statistical analysis*

Statistical analysis was performed using SPSS version 21.0. An intention-to-treat analysis was performed. The last observed values were carried forward for final analysis. Mean and SD were reported for continuous variables, median and inter quartile range for skewed variables. Inter and intra group comparisons were done by paired or unpaired Student's *t* test or Mann Whitney or Wilcoxin Rank test as relevant. Multiple logistic regression analysis was done with HbA1c at 24 months as the dependent variable and age, BMI, BP and the components of dietary principles and the study groups (intervention Vs control) as the independent variables.

3. Results

At the end of the 24 months follow-up, the number of persons available was 106 and 112 in the control and intervention groups respectively. The analyses were carried out using intention-to- treat method, thus values at the last available visit (control group, n = 122 and SMS group, n = 126) were carried forward to the end of study visit (Fig. 1).

Table 1 shows the demographic, metabolic and biochemical characteristics of the randomized persons at baseline and at 24 months follow- up. The control and intervention groups had similar demographics and equal distribution of occupational categories.

At the baseline, the two groups had similar anthropometric and biochemical characteristics. During the follow- up no significant change in the anthropometric variables occurred in the intervention group. Weight and BMI increased significantly in the control group.

The treatment reduced HbA1c from baseline to the end of the study in both the groups ($p < 0.0001$). Inter-group analysis of HbA1c, showed a significantly lower value in the intervention group when compared with the control group (HbA1c 7.4, 57 mmol/mol ± 1.5% Vs 7.8, 62 mmol/mol ± 1.5% $p = 0.044$).

In the two study groups, the glycaemic parameters showed significant reductions ($p < 0.0001$) at 3 months and the improvement persisted at each review visit (Table 2). The per protocol analysis also showed similar results (Supplementary Table).

Among the secondary outcomes, the intervention group achieved significantly lower fasting plasma glucose and systolic blood pressure ($p = 0.007$) in comparison to the control group. The post prandial glucose value did not differ between the groups (Table 1).

When compared with the baseline value, at 24 months, the participants on the intervention showed lower SBP ($p < 0.0001$), DBP ($p = 0.048$), LDLc ($p = 0.029$) and glycaemic levels; FPG, 2hPG and HbA1c ($p < 0.0001$). The control group had significantly lower SBP ($p = 0.004$), DBP ($p = 0.017$) and FPG, 2hPG and HbA1c ($p < 0.0001$ for all parameters) at 24 months.

Table 3 shows the outcome of other secondary variables: dietary intake, quality of life and physical activity. There was significant reduction at 24 months in the intake of total calories and fat in the control group and in the intervention group. The fibre intake improved significantly in both groups (control, $p = 0.02$, intervention, $p = 0.001$). However, there was no intergroup difference in the value at 24 months.

The drugs received by the participants in the two groups were similar at randomisation. During the study period, 78.6% of the participants in the control group and 86.1% in the intervention group continued to use the same drug and dosages ($\chi^2 = 0.87$, $p = 0.35$).

The multivariate analysis showed that significant reduction in HbA1c at 24 months was associated with the intervention alone (Odds Ratio (95%CI) 1.79 (1.07–3.01, $p = 0.028$)). None of the other variables had independently contributed to the beneficial effect.

4. Discussion

In the last decade mobile phone SMS has been increasingly used in many countries as a tool for education and reinforcement among patients with a variety of disorders [14]. Many studies have used this technology in a clinical setting to improve patients' behavior and health outcomes particularly in the case of chronic disorders such as diabetes [15–18].

Table 3 – Characteristics of diet intake, quality of life (EQ5D), physical activity and occupation at baseline and 24 months follow up.

					Inter Group		Intra Group	
	Baseline		24 months follow up		Baseline	Follow up	Control	Intervention
Variables	Control	Intervention	Control	Intervention	P value	P value		
n	122	126	122	126				
Dietary intake per day	Mean ± SD		Mean ± SD					
Total Calories (kcal)	1641 ± 310	1642 ± 324	1558 ± 213	1591 ± 256	0.973	0.269	**0.002**	**0.043**
Carbohydrates (gm)	234.8 ± 46.9	238.3 ± 59.1	233.1 ± 35.8	240.4 ± 46.5	0.599	0.172	0.732	0.668
Protein (gm)	64.0 ± 19.9	61.5 ± 16.1	59.9 ± 16.9	60.0 ± 13.6	0.285	0.933	**0.002**	0.331
Fat (gm)	48.5 ± 17.3	48.4 ± 13.9	43.8 ± 14.5	44.2 ± 12.1	0.962	0.833	**0.001**	**0.002**
Fiber(gm)	23.5 ± 7.5	22.7 ± 7.6	25.2 ± 6.6	25.6 ± 6.8	0.438	0.619	**0.020**	**0.001**
EQ5D summary measure	0.99 ± 0.03	0.99 ± 0.02	0.99 ± 0.03	0.99 ± 0.03	0.461	0.726	0.223	0.228
PAEE (kJ/kg/day) measured by RPAQ	Median(IQR)		Median(IQR)		P value	P value	P value	P value
Total	10.0 (4.2–16.8)	8.1 (4.1–16.6)	10.1 (4.2–17.2)	10.2 (5.7–20.2)	0.535	0.459	0.684	0.276
Home	0.5 (0.3–0.7)	0.5 (0.3–0.6)	0.5 (0.3–1.2)	0.5 (0.46–0.54)	0.275	0.062	1.000	0.063
Work	3.7 (3.7–9.5)	3.7 (3.7–9.5)	3.7(3.6–9.5)	3.7(3.7–9.5)	0.926	0.808	1.000	0.317
Commuting	0.4 (0.2–1.1)	0.4 (0.2–1.1)	0.3(0.1–1.0)	0.3(0.2–1.1)	0.706	0.790	0.813	0.163
Leisure	8.0 (5.3–16.0)	8.5 (2.2– 16.0)	10.7(5.3–10.9)	8.0(5.3–13.5)	0.766	0.623	0.225	0.655

PAEE: Physical Activity Energy Expenditure, RPAQ: Recent Physical Activity Questionnaire.
P values <0.05 are considered statistically significant and are highlighted in bold.

There are few pilot studies from developing countries [19–24] which have shown the utility of using SMS for motivation of the patients to adhere to medical prescriptions. However these studies were of short duration done in small numbers of known cases of patients with diabetes. A meta analysis of 12 trials showed that mobile phone based intervention helped in reducing HbA1c, the duration of intervention ranging from 1 to 12 months [25]. Another meta analysis of 15 trials showed that interventions conducted in low and middle income countries showed greater impact of SMS than those conducted in high income countries [26] All the above mentioned studies were done in known cases of diabetes. We had noted that SMS could be used effectively in preventing conversion of prediabetes to T2D over a period of 2 years [5]. According to a systematic review of 15 studies conducted in 13 developing countries in Europe, Africa, Latin America and South America among adults who were healthy, but had risk of diabetes or hypertension, e and m-health intervention were effective in promoting physical activity and healthy diet [27].

In the present RCTwe aimed at assessing the utility of education and motivation through SMS, among persons with newly diagnosed T2D in controlling glycaemic and other metabolic parameters. There is sparse data on the use of m-health in newly diagnosed patients with T2D particularly assessing its long term impact. This multi centric study showed improvement in the glycaemic parameters in the persons receiving standard care and also among those who received motivating text messages at regular intervals. The improvement persisted during the 24 month study period in both the groups. It was noted that the primary outcome, namely reduction in the HbA1c at the end of 24 months was significantly better among those who received SMS intervention. There were significant improvements in FPG and SBP also in this group, but no significant improvement in the anthropometric characteristics and physical activity were observed. Weight gain was seen only in the control group. Considerable improvement occurred in the dietary parameters in both the groups which included a reduction in total fat and calorie consumption and increase in food fibre intake. A multivariate analysis showed that there was a significantly better improvement in the HbA1c value among the intervention group, but none of the other tested variables were independently associated with the beneficial effect. In our previous study among persons with prediabetes, the intervention with SMS resulted in beneficial changes in dietary habits. This was associated with improved insulin sensitivity whereby the conversion to diabetes was prevented [5,28].

It is a limitation that we could not make an assessment of drug adherence in this study. Although HbA1c is not a measure of adherence to treatment but for the follow-up data it is more useful as an index of glycaemic changes over a period of time. Fasting and post prandial glucose reflect acute changes in glycaemia.

It is noteworthy that in this study among newly detected persons with diabetes, we found the effectiveness of SMS intervention persisted for two years. Further research is required in a larger number of subjects with analysis of the different components of therapy to know the effectiveness of SMS based intervention in diabetes care.

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Author contributions

AR is the Principal Investigator; VR, AR, CS, AN, Arun R, KS contributed to the study design, developing the protocol, supervising study progress and drafting the manuscript or revising it with critical input. VR, AR, CS, KS contributed to data preparation and analysis. KS and PS participated and coordinated the field work and data collection. All authors have read and approved the final draft.

Declaration of Competing Interest

All authors have no conflict of interest to declare.

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Appendix A. Panel: Sample text messages sent to the participants

Category: Diet

- Persons with diabetes should avoid sweets, sugar, honey, jaggery and chocolates.
- Taking 3 heavy meals a day is not advisable, taking 3 light meals and snack in between is good for control of blood glucose.
- Two to three pieces of pineapple, watermelon, papaya (big fruit) can be taken every day if your blood glucose is under control.

Category: Physical activity

- Finish your exercise in a slow pace, do not stop abruptly.
- Do not walk bare foot, wear a comfortable pair of shoes, check your shoes for foreign bodies before you wear.
- Brisk walking is more beneficial for burning calories than slow or relaxed walking.

Category: Diabetes awareness

- Diabetes is self management - manage with regular use of drugs, healthy diet and exercise.
- Do not miss the medicines, be regular with exercise and healthy diet.

- Food habits, physical activity level, stress, sleep disorders can influence blood glucose level.

Category: Awareness of complications

- Good control of diabetes prevents complications.
- Uncontrolled diabetes affects: eyes, heart, kidney, foot, nerves and tooth.
- Periodic diabetes check up prevents complications.

Category: Medication adherence

- Take medicines regularly for good control of diabetes.
- Don't skip medicines; it affects blood glucose control.
- Persons with diabetes should not stop, reduce or increase tablets or insulin dose without doctor's advice.

Appendix B. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.107919.

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