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Original Article

Mobile phone messaging system for reporting of laboratory results among patients with type-2 Diabetes Mellitus in Himachal Pradesh, India

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Abstract:

Introduction: Mobile phone messaging system has considered as a useful mechanism to improve the treatment adherence for type-2 Diabetes Mellitus (DM) patients. With the limited available literature with valid study designs the present study report the early experiences of a randomized control trail (RCT) to assess the effectiveness of software assisted mobile phone messaging system for improving treatment adherence. **Methodology**: Descriptive study to report early experiences of a RCT. **Results**: The online software with a variable enabled decision support system was developed based on national guidelines for treatment of DM. Total 475 patients were randomized for intervention and 481 kept as a control. The baseline variables of both the groups showed no statistically significant difference like for age, gender, socio-economic status, alcohol and tobacco use, dietary preferences, salt use, physical activity, body mass index, fasting blood glucose, and lipid profile. **Conclusion**: The mobile phone messaging system over a significant duration of period is a feasible method in rural settings and has the potential to serve as an additional behavior change strategy for improving treatment compliance.

Key Words: SMS, Diabetes Mellitus, Mobile Phone

Introduction:

Secondary prevention for chronic diseases like type-2 diabetes mellitus (DM) requires life course approach for patient specific management. It includes effective measures like physical activity, diet control, alcohol and tobacco abstinence, and regular intake of recommended medications.[1] Patient act as a central player and its inclusion for disease management plays an important role. Disease specific health education has a goal to support patient efforts with an understanding of disease nature and treatment. Physicians often provide education but require sustained coordinated efforts to ensure adherence for disease management. For chronic diseases, it often found to be difficult due to various reasons like engagement in daily work, forgetfulness for medicines, differential value for disease, declining motivation, etc., which could lead to poor compliance in a subset of patients. This has lead to search of innovative patient oriented educational interventions for treatment adherence.

Efforts like computerized, telephonic, mailing, electronic medical records system etc. assisted

Short Message Service (SMS) reminder system have developed and tested for prompting both patients and physicians.[1] SMS had viewed as a behavioral rather than just an educational intervention for a desired change.[2] A narrative review suggested improved outcomes like treatment and appointment adherence, decrease number of missed doses with positive attitude towards medication, and reduced irregular treatment with SMS intervention.[3-5] In a systematic review, SMS has been identified as a common tool for improving adherence to manage chronic diseases.[6] Messaging even for short duration (3 to 5 months) period have proved beneficial for improving treatment adherence and glycemic control.[7-9] Though, reviews suggested that more robust evidence like randomized control trial (RCT) needs to be systematically generated to assess the SMS effectiveness for management of chronic diseases.[4,6] To enrich the current literature, the current clinic based RCT was planned among diabetic patients to assess its effectiveness in terms of reduction in mean fasting blood glucose (FBG) after log duration (one year) of SMS intervention. As an interim analysis we wish to report the baseline characteristics of the patients and methods for development of patient tailored SMS based intervention.

Materials and Methods:

A double-blind randomized control trail (RCT) was conducted among 956 known cases of DM. The outpatient departments of total five health facilities were involved in patient recruitment; two secondary; two primary, and one private. Himachal Pradesh is northern state of country with the population of about 7 million and 12 district administrative units. As per 2011 census state has 90.0% population residing in rural, 4.0% in tribal and rest aggregated in its urban areas. The total number of patients was recruited against the calculated sample size of sample 786 (393+393) with 80.0% study power and 5.0% level of significance with the prior hypothesis to detect reduction in blood glucose with the mean difference of 10.0 g/dl in intervention and control group from baseline to end line.[10] All patients were arranged in sequence, as and when recruited, from the health facilities with the inclusion criteria; known case of DM with mobile phone and informed consent to participate. Patients with end organ damage requiring admission for critical care were excluded from the study. Based on place of residence the patients were stratified into urban, rural and tribal area during the recruitment period of six months (01/01/2015 to 30/06/2015). Calculated sample size was distributed proportionally to the population for geographical representativeness and was not derived stratum specific. For each stratum an independent random numbers were generated from one digit to three digits using a computer by a statistician unaware about study methodology. First random number was considered for intervention or control was decided by tossing of coin for each stratum urban, rural and tribal area. Then, every alternative random number (coinciding with patient serial number) was allocated to intervention or control. In such a way, of all recruited patients 78 and 93 from urban, 367 and 357 from rural area, and 30 and 31 from tribal area were allocated to intervention and control group respectively. The intervention was SMS text information for reporting patient specific values for FBG, BP and weight and suggested preventive measures. The intervention period was kept for one year i.e, 01/07/2015 to 30/06/2016.

An interview schedule was prepared for collection of information related to age gender, socio-economic status (SES), substance (alcohol and tobacco) use, diet, and physical activity. Dietary assessment was done for preference of food (vegetarian and non-vegetarian), intake of fruits (season and offseason), vegetables, salt use while cooking, extra-salt use, and butter/ghee use while eating. In addition, energy (Kilocalories) consumption based on 24 dietary recall method was also done. Extent of physical activity carried out by the patient was also asked like for vigorous (causing large increase in breathing, heart rate, and sweating) and moderate (causing small increase in breathing,

heart rate, and sweating). Anthropometry assessment was made for height (in meters), weight (in Kilogram), body and visceral fat (Tanita), along with blood pressure (mm of Hg). Biochemical assessment was made for Fasting Blood Glucose (FBG), Total Cholesterol (TC), corrected-High Density Lipoprotein (c-HDL), corrected-Low Density Lipoprotein (c-LDL), and Triglycerides (TGs).

For decision support value only selected variables for patients randomized for intervention group was entered into software. The values were for age (exact), gender (1=Male; 2=Female), mobile phone number (10 digits), height, weight, Blood Pressure, FBG, TC, LDL, HDL, and TGs. Values for variables like height, weight, and automated calculated BMI (in Kg/m^2) were up to one decimal point. The content of the SMS was designed according to above mentioned variables. The variable specific information was designed in sentences by group of investigator in simple English language. (Table: 1) The message was delivered once the repeat values for FBG, TC and weight are entered in the software. The focus of the message is to communicate the next due date for FBG assessment and dietary advices. The message is being delivered two days prior to the due date of FBG as a reminder. In a case patient is unable to report the values due to any reason then the next date of FBG assessment is calculated based on the "last value". The "variable specific sentence" depending on the previous value as entered in the software was picked up automatically by the software as the content of the message.

Due to cost constraints a feedback mechanism to assess the follow-up values for the set of variables was assessed telephonically both form intervention and control group. People asking for the feedback were unaware about the study design and asked to enquire about the variable specific values. Independently, the values are entered into the software by the data entry operator, who himself is blinded about the study design. At this stage, the patients, treating physicians of respective health facilities and group of investigators are unaware about, which patient is getting the SMS or which one does not. So, patients in the intervention group are receiving the SMS plus their usual care from the registered facility and the control group getting their routine care from the registered facility. So, far on the telephonic feedback none of the patient from control group has complaint about non-receiving of the SMS. In addition, three investigators have enrolled themselves into the software to check the quality of message delivery mechanism, and are not included in the analysis. The data entry operator and investigator have different login identification for the software, and the data editing right is inherent with the software designer only. The data has been entered into Microsoft excel 2007 and analyzed using Epiinfo software, chi-square and unpaired student "t" statistical tests are used to compare proportions and means respectively and exact p values are reported.

Results:

The online software with a variable enabled decision support system was developed. The decision support system was based on the standard national treatment guidelines by the Indian Council of Medical Research (ICMR). Software was programmed for communicating the latest exact RBG value along with the next scheduled visit for the blood glucose assessment. The next visit was kept after one week if RBG $\geq$ 180 mg/dl and after one month if it is $\geq$ 130 mg/dl; criteria decided by the experts during an intervention planning workshop. Along with RBG, exact value for the blood pressure, information related for estimated body weight on the BMI, and total cholesterol was communicated by the SMS to the patient. (Table: 1) An input model was prepared in the planning workshop based on values of RBG, BMI, sedentary lifestyle, blood pressure and TC. (Table: 2) For the variables and their patient specific values an input model functions in a program manner and automated message was constructed and communicated. So, the content of the message

differed for patient to patient and was individualized. The message was delivered one day before and one day after the scheduled date for RBG assessment as a reminder. Updated information during the follow up period for variables like RBG, BP, and TC was gathered telephonically from both the intervention and control group. This method was adopted due to logistic constraints as patients did not communicate their results on their own. Ideal option would be to gather the values form the laboratory itself i.e., provider side and communicated in the form of SMS, but was not possible as there was no single source of laboratory from where patient was having the tests.

Table 1: Message input model for software assisted mobile phone messaging system for reporting of laboratory results among patients with type-2 diabetes mellitus

Possible Scenarios	Sedentary	BMI	BP	TC >180
Sedentary	1,2,3,7	1,2,3,4,7	1,2,3,5,7	1,2,3,6,7
BMI	1,2,3,4,7	1,2,4,7	1,2,5,7	1,2,6,7
BP	1,2,3,5,7	1,2,4,5,7	1,2,5,7	1,2,5,6,7
TC >180	1,2,3,6,7	1,2,4,6,7	1,2,5,6,7	1,2,6,7

Digits referred to message lines (Refer Table: 2)

Total 475 patients were randomized for intervention and 481 kept as a control. Patients from both the groups were receiving the usual care from practitioners and automated messages only among patients of intervention group. In both the groups the patients had insignificant difference and comparable for basic set of characteristics. Fraction of males was low as it was 37.9 and 31.4 percent in intervention and control group respectively. Majority of patients were of 41-60 years of age in both intervention (53.6%) and control (54.6%) group (p=0.741) with no statistically significant (p=0.913) difference in their mean age (intervention: 57.1; control: 57.0). The average SES score was 28.2 and 20.0; and 84.5 and 83.7

Table 2: Message content based on scenario specific lines for software assisted mobile phone messaging system for reporting of laboratory results among patients with type-2 diabetes mellitus

Message Header: RPGMC

Message Lines	Contents
1	Name of Patient
2	Your Sugar Value is ___, Next Date for Test is _____.* Do Not have sugar in tea, Sweets, Potato, Potato, Sweet Potato as they increases the blood sugar.
3	You Should walk FAST for 30-60 minutes every day
4	Your Weight is ___ Kg and should be ___ Kg.
5	You have high blood pressure ____/__, Eat Salt less than 6 gram in day.
6	Your Cholesterol is high, Do not Eat PARATHA, PAKODA, SAMOSA, BUTTER, DESI GHEE.
7	Please go to your doctor regularly

*Based on recent date of laboratory test, if FBG is > 130 mg/dl and postprandial blood glucose is more than 180 mg/dl, then the next date of visit (DD/MM/YY) is automatically calculated for next seventh day, otherwise it is calculated for next 30th day

percent of patients were of middle SES class for intervention and control group respectively. Dietary assessment revealed that the average daily consumption of calories were 1221.7 (± 376.1) in intervention and 1257.5 (± 374.8) group (p=0.185). Respectively for intervention and control group the fraction of patients with substance abuse was 8.4 and 6.6 percent for current smoking (p=0.313), and 10.6 and 9.7 percent for current alcohol use (p=0.660). Patients were drinking alcohol were consuming 114.7 (± 53.0) and 114.2 (± 66.5) ml/day (p=0.964), and 92.3 (± 38.4) and 104.9 (± 60.9) ml/sitting (p=0.239) of intervention and control group respectively. (Table: 3)

Table 3: Demographic, socio-economic, and substance abuse distribution among patients with type-2 diabetes mellitus for software assisted mobile phone messaging system for reporting of laboratory results

Variable	Intervention (475)	Control (481)	p value
Male (%)	37.9	31.4	0.108
Mean age in years (± SD)	57.1 (10.9)	57.0 (10.8)	0.913
20-40	7.3	7.8	0.792
41-60	53.6	54.6	0.741
61-80	38.1	36.6	0.627
>80	1.0	1.1	0.755
Mean SES Score (± SD)	28.2 (3.2)	28.0 (4.6)	0.534
SES Category (%)			
Upper class (>45)	0	0.2	NC
Upper-middle class (33-42)	2.6	3.7	0.373
Middle class (24-32)	84.5	83.7	0.748
Lower-middle class (13-23)	12.9	12.0	0.664
Lower class (< 13)	0.0	0.5	NC
Mean Kcal in 24 hours (± SD)	1221.7 (376.1)	1257.5 (374.8)	0.185
Mean duration of tobacco smoke (± SD)	93.4 (20.3)	94.9 (16.8)	0.130
Current Smoker (%)	8.4	6.6	0.313
Current drinker (%)	10.6	9.7	0.660
Mean alcohol consumption in a day (± SD)	114.7 (53.0)	114.2 (66.5)	0.964
Mean alcohol consumption in sitting (± SD)	92.3 (38.4)	104.9 (60.9)	0.239

NC: Not Computed

Dietary assessment showed that relatively the patients with vegetarian food preference were more in control (44.1%; p=0.060) and non-vegetarian in intervention group (38.1%; p=0.041). Among non vegetarian most of the patients in both the groups were consuming mutton the most. In both the groups during the season on average patients were consuming fruits 5 times in a week (p=0.394) and about 1.3 (p=0.339) times in a day. The frequency reduces in off season where the average consumption decreased to 3 times in a week (p=0.553) and 1 times in a day (p=0.600). As for fruits the average vegetable consumption was also observed statistically not significantly different between the groups where it was almost every day in a week (intervention: 6.6; Control: 6.4, p=0.229) and at least one time in a day (intervention: 1.3; Control: 1.4, p=0.099). In the family of patients an average

consumption for cooking oil was 12.1 and 12.0 ml/day (p=0.229), 0.7 and 0.7 grams/day (p=0.993) of butter/ghee, and 5.0 and 5.2 grams/day of salt while cooking (p=0.403) in intervention and control group respectively. Use of extra salt while eating was very less in both the groups. Extent of physical activity was assessed for its severity and observed that 21.3 and 17.4 percent (p=0.137) were carrying out vigorous, and 72.6 and 68.6 percent (p=0.172) had moderate level of physical activity in respective intervention and control group. Vigorous level of activities were carried out on average 3.4 and 3.5 days (p=0.508), and 4.8 and 4.6 days (p=0.315) for moderate level in intervention and control group respectively. The activities were categorized related to the level of their day to day activities and none of the patient was specifically engaged in the form of exercise. Significantly more number of patients in intervention group were using bicycle/walking (9.5% vs. 3.3%) to reach at their workplace and carrying out brisk walk (11.3% vs. 1.8%) as an exercise. (Table: 4)

Tanita assessment was made for both groups and metabolic age was assessed similar as 58.9 and 59.2 years in respective intervention and control groups (p=0.900). Mean BMI was high in control (27.9) as compare to intervention (24.3) group (p=0.021). Average body and visceral fat was observed statistically similar in both the groups. Body fat was 27.0 and 26.4, and visceral fat was 11.7 and 14.7 in intervention and control group respectively. Biochemical assessment for FBG, TC, HDL, LDL and TG showed that their average levels were similar in both the groups. Assessment for high risk categories observed that based on BMI 43.2 and 49.8 percent (p=0.276) were overweight and 17.0 and 15.7 percent (p=0.667) were obese in intervention and control group respectively. Based on FBG among diabetics it was found that majority (intervention: 68.7%; control: 64.9%, p=0.216) were having poor glucose control. High level of TC was observed among 14.0 and 15.1 percent (p=0.772); LDL was observed high in 3.3 and 7.5 (p=0.168) whereas, very high in 2.3 and 3.3 percent (p=0.936); low HDL in 23.3 and 20.7 percent (p=0.616); and high level of TG in 30.2 and 37.0 (p=p0.248) whereas, very high in 2.8 to 2.2 percent (p=0.936), in intervention and control group respectively. (Table: 4)

Table 4: Anthropometric and biochemical level distribution among patients with type-2 diabetes mellitus for software assisted mobile phone messaging system for reporting of laboratory results

Variable	Intervention (215)	Control (92)	p value
Mean (± SD) metabolic age (years)	58.9 (11.9)	59.2 (15.9)	0.900
Mean (± SD) BMI (Kg/m^2)	24.3 (4.1)	27.9 (3.9)	0.021
Mean (± SD) body fat (%)	27.0 (6.7)	26.4 (5.2)	0.339
Mean (± SD) Visceral fat rating	11.7 (17.0)	14.7 (189.7)	0.108
Mean (± SD) FBG (mg/dl)	166.2 (68.0)	163.0 (74.4)	0.602
Mean (± SD) TC (mg/dl)	186.6 (52.2)	191.5 (49.8)	0.438
Mean (± SD) HDL (mg/dl)	51.2 (20.8)	48.5 (10.1)	0.251
Mean (± SD) LDL (mg/dl)	96.3 (39.7)	103.0 (44.4)	0.159
Mean (± SD) TG (mg/dl)	194.6 (115.5)	196.0 (90.6)	0.918
Asian criteria BMI (Kg/m^2)			
Undernourished (<18.5)	5.9	1.7	0.248*
Normal (18.5-22.9)	34.0	32.8	0.819
Overweight (23.0-27.5)	43.2	49.8	0.276
Obese (>27.5)	17.0	15.7	0.667
FBG control in mg/dl (%)			
Ideal (80-110)	14.1	22.7	0.000
Satisfactory (111-125)	17.2	12.3	0.113
Poor (≥ 126)	68.7	64.9	0.216

TC (mg/dl)			
Desirable (<200)	65.1	63.4	0.728
Borderline High (200-239)	20.9	21.5	0.873
High (≥240)	14.0	15.1	0.772
LDL (mg/dl)			
Optimal (<100)	53.0	51.1	0.755
Near Optimal (100-129)	29.3	26.1	0.566
Borderline High (130-159)	12.1	12.0	0.973
High (160-189)	3.3	7.5	0.168*
Very High (≥190)	2.3	3.3	0.936*
HDL (mg/dl)			
Low (< 40)	23.3	20.7	0.616
40-59	57.2	62.0	0.439
High (≥ 60)	19.5	17.4	0.660
TG (mg/dl)			
Normal (<150)	42.3	30.4	0.050
Borderline High (150-199)	24.7	30.4	0.292
High (200-499)	30.2	37.0	0.248
Very High (≥500)	2.8	2.2	0.936*

*Yates corrected chi-square statistics

Discussion:

Non-adherence for medications is a common concern especially for chronic diseases and requires patient level motivation. Evidence synthesis have developed behavioral model which explored the extent of mobile phone based text messaging for management of DM. Messages found to be a tool to reduce denial and reinforce the importance of self management for DM.[11] Mobile phone based interventional program has been advocated as an opportunity to effectively use the technology. Significant penetration of mobile phones for interpersonal communication gave an idea to direct individual tailored messages for improving knowledge, raising concern, developing attitude and changing behavior. The potential use of phone has been used as a medium to improve the treatment compliance for management of DM.[12] Accumulating evidence for improving adherence for DM treatment is proving messaging system as a useful tool. Communicating the results for blood glucose, body weight and other relevant proves efficient, cost-effective, feasible, acceptable method for management of DM.[5,7,8,9,13,14] A cluster randomized trial has demonstrated the acceptance of type of primary care practices were found useful facilitated with the use of mobile phone based and internet assisted patient coaching system and provider clinical decision support system.[15]

Messaging system has been proved useful but often studies were conducted on small set of patients recommending requirement of more supportive evidence with use of valid study design.[4,5] Current evidence intend address the extent of use of messaging system for reduction of mean FBG with a randomized control trial (RCT) study design among a total of 1000 diabetic patients in rural settings of northern state of India. Randomized patients did not differ for their demographic, socio-economic status, dietary consumption (in Kcal), tobacco use, alcohol drinking, consumption of fruits and vegetable, salt use while cooking, level and extent of vigorous and moderate activity, along with mean level and at risk levels for FBG, TC, HDL, LDL, and TG. Fraction of patients with an ideal level of FBG (80-110 mg/dl) was observed significantly in control than in intervention group whereas; prevalence for satisfactory and poor levels of FBG was statistically insignificant in both the groups. Relatively, in Intervention group significantly (p=0.00) more fraction of patients reported with brisk walk

and use of cycle/walk for going to workplace. Though, the mean days of brisk walking and use of cycle/walk was statistically indifferent in both intervention and control group. For the present study purpose a less degree of bias is expected for study effect measure as the overall fraction of patients with brisk walk and cycle/walk is quite low of about 6 percent.

Communication rather than just exchange of information paves a way to bring desired behavior change. Health education by information dissemination intends to encourage community/individual participation to understand, achieve, and sustain health. The phone has visualized as a mass media or interpersonal channel to approach receiver, the patient, from the sender as a part of communication process. The desired outcome relies on the construct of message not ignoring its inherent qualities like specificity, clarity, simplicity, and relevance.[16] It would become more effective if message is action oriented understanding the literacy and comprehension of the target group. Theoretical models like medical, motivational and social intervention, approach, and content of health education for desired change should be conceptualized focusing the clearly stated research question.[16] Present study adopted motivational model with health education approach for patients with the use of mobile phone to create awareness, motivation and action for treatment compliance for DM. Current study has tried to adhere with the basic principles of health education like credibility, interesting, motivation, comprehension, and reinforcement while designing the content of message and its frequency of delivery to the patient.

Conflict of Interest: None

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