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Short Message Service as a Tool for Health Education in Families of Children with Type 1 Diabetes in Pakistan: A Randomized Control Trial

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ABSTRACT

Objective: To determine the efficacy of short message service (SMS) for educating families of children with Type 1 Diabetes (T1D).

Study Design: Single-masked randomized control trial (IRCT: 54713).

Place and Duration of Study: Tertiary care hospitals of Rawalpindi and Islamabad Pakistan, from Mar to Jul 2021.

Methodology: Twenty-nine T1D patients aged 1 to 18 years were randomly allotted to two groups: 15 to intervention or Group-A (receiving 5 SMS per week) and 14 to Control or Group-B (receiving disease education during hospital visits). Patients were followed up and their blood sugar levels (BSLs), HbA1c levels, journal maintenance, number of ER visits, number of Self-Monitored Blood Glucose (SMBG) levels, and hypoglycemic episodes compared at baseline and after intervention.

Results: HbA1c had a mean decrease of 2.13±1.89% in Group-A and a mean increase of 0.18±0.84% in Group-B (p-value <0.001). Similarly, the decrease in BSLs post-intervention was significantly greater in Group-A (p-value=0.001). Trends in secondary outcomes: journal maintenance, number of self-monitoring blood glucose levels, admissions in ER, and hypoglycemic episodes in the past three months showed improving trends in both groups. However, the p-value was significant post-intervention only for hypoglycemia incidence (p-value=0.021) and diary maintenance (p-value=0.005).

Conclusion: SMS is an efficient tool for delivering education to T1D patients that significantly improves metabolic control. In light of these results, current routine practice is not sufficient to achieve therapeutic goals.

Keywords: Blood sugar levels (BSL), education, HbA1c, Self-monitoring blood glucose, Type 1 diabetes.

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INTRODUCTION

Type 1 Diabetes (T1D) previously called Insulin Dependent Diabetes Mellitus, is primarily due to beta-cell dysfunction that leads to insulinopenia. Worldwide, 15 million people are affected by T1D, which continues to increase. Incidence, however, varies among countries, being much higher in developed countries than in developing countries.[1] Earlier research mostly focused on genetic causes. However, recent trends have pointed towards environmental factors. Studies by The Environmental Determinants of Diabetes in the Young (TEDDY) have extended the environmental influencers by suggesting a contributing role of vitamin C, D, E and Zinc deficiencies.[2,3]

The International Society of Paediatric and Adolescent Diabetes (ISPAD) guidelines regarding diabetic technologies mention Continuous Glucose Monitoring (CGM) systems and Closed-Loop Systems (CLS), which may not be feasible in low or low-middle income countries because of their unavailability and also because of their unaffordability. Those guidelines also mentioned telemedicine as a vital management aspect in resource-limited settings.[4] In 2022, ISPAD introduced a new chapter pertaining to diabetes management in low-resource settings, which mentions WhatsApp groups as a mode of education.[5] Telemedicine has become all the more relevant in this post-COVID era. As of February 2023, Pakistan has over 194 million cellular subscribers in a population of 216 million. These figures have continued to increase against all odds, and the Pakistan Telecommunication Authority claims cellular phone penetration of 86.53%.[6] Newzoo 2020 Global Mobile market report ranks Pakistan 20th with smartphone penetration of 18.4%.[7] Telemedicine provides us an excellent opportunity to harness this resource to bridge the gap in healthcare services.

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Diabetes management hinges on glycemic control but is not limited to it. A holistic approach to diabetes management was highlighted by Duckworth *et al*. in an RCT in 2009.[8] Behavioural modification with education as an intervention has been explored amongst Type 2 Diabetes patients for a long.[9,10] It has been suggested that the patient and family's knowledge regarding the disease is the primary determinant of the patient's well-being rather than the treating physician's knowledge.[9] This study aims to determine the efficacy of SMS as a tool for educating caregivers of children with type I diabetes and to assess its effect on HbA1c and patient's quality of life.

METHODOLOGY

The single-masked randomized control trial was conducted at Tertiary Care Hospitals of Rawalpindi and Islamabad from March to July 2021, after approval from Institutional Review Board (letter number A/28/EC/249/2021 dated 26th January 2021). The trial was registered in the Iranian Registry of Clinical Trials under trial ID 54713. The sample size was calculated using the OpenEpi calculator keeping the incidence of Type 1 Diabetes to be 0.7 per 100000 per year.[2]

Inclusion Criteria: Type 1 diabetes mellitus patients of either gender, aged 1 to 18 years who possess mobile phones, were included.

Exclusion Criteria: Patients with co-morbidities, associated illnesses, or syndromic causes of diabetes; patients using oral hypoglycemic drugs; and those with advanced diabetic complications. Those with severe visual impairment that rendered them incapable of reading SMS and those unwilling to participate were also excluded from the study.

Patients were recruited from tertiary care hospitals of Rawalpindi and Islamabad. Informed consent was obtained after the parents had provided the information. Thirty-six subjects were enrolled, and 30 were randomized into two groups. Patients and their families were assigned to the intervention or control group randomly. Written informed consent was taken from all patients/families. Education was defined as Primary school, and Urdu was used as the instruction language for verbal and written communication. Demographic data and information regarding primary and secondary outcome variables were collected from both groups at baseline. However, the Control Group was asked to follow up monthly in the outpatient clinic, receiving the usual standard of care that included counselling and education regarding diabetes management at each hospital visit. Each patient had six educational visits at baseline and the end of each month. Post-intervention data was collected at the end of the study period. At the end of the trial, one patient from the control group was lost to follow-up. Hence, 15 patients underwent intervention in Group-A and 14 in the Control Group (Group-B).

The Intervention Group received messages on their mobile phones five times weekly (Figure-1).

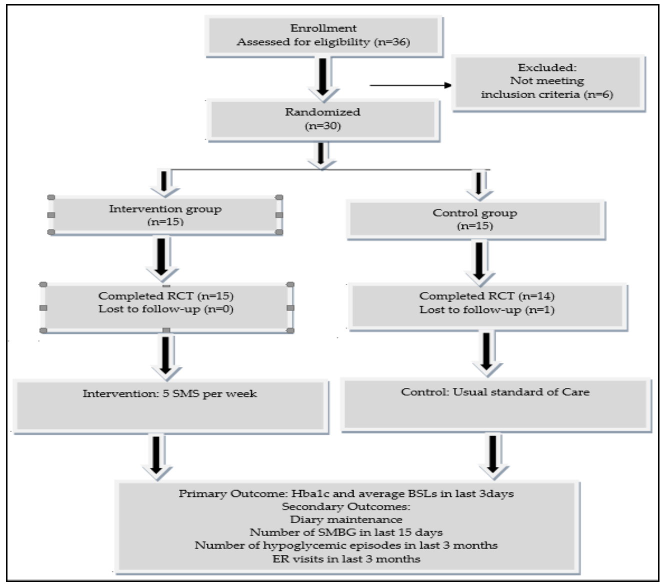

Figure-1: Patient Flow Diagram of the Trial

These messages consisted of reminders on the importance of maintaining a journal of SMBG levels; insulin administration, storage, transport and site rotation; dietary management; information regarding symptoms and management of hypoglycemia; and sick-day management. They also included pictures of low glycemic index foods and videos of insulin administration techniques both by pen and syringe. The control group was sent placebo messages as reminders to keep up with the monthly hospital appointments. All communication was in the Urdu language.

The primary outcome measures were a change in HbA1clevels and average BSLs in the last three days measured at baseline and after intervention. Secondary outcome measures were recorded as categorical variables: maintenance of a record journal; SMBG levels done in the last 15 days; hypoglycemic experienced in the last three months; ER visits in the last three months. SMBG levels were categorized as none, less than 15, 15-30, or more than 30.

Statistical analysis was performed with Statistical Package for the Social Sciences (SPSS) version 23:00. Frequencies and percentages were used for categorical variables. Quantitative data was analyzed by Mean±SD and median (inter-quartile range) where applicable. Independent t-test and Fisher's exact test were used to evaluate the quantitative and qualitative data. The chi-square test was used to analyze the number of SMBG values in the past 15 days. The *p*-value of ≤0.05 was considered significant.

RESULTS

Thirty patients were recruited for the study, but one patient from the control group could not follow up. Hence, the final data analysis was done on 29 patients. Group-A or the Intervention Group had a mean age of 8.06±4.90 years and Group-B, the control group, had a mean age of 8.85±4.94 years (*p*-value= 0.669) (Table-I).

Table-I: Comparison of Demographic Variables between Study Groups prior to Intervention (n=29)

Variables	Intervention or Group-A(n=15)	Control or Group-B (n=14)	*p*-value
Age (Years) Mean±SD	8.06±4.90	8.85±4.94	0.669
Weight (Kg) Mean±SD	23.40±14.76	24.21±13.23	0.877
Gender (Male) Mean±SD	7(46.7%)	4(28.6%)	0.450
Education (Yes) n%	15(100.0%)	13(92.9%)	0.483
Urdu (Yes) n%	15(100.0%)	13(92.9%)	0.483

Pre and post-intervention analyses for both groups revealed a significant difference in falls in HbA1c and an average change in BSLs in the intervention group. However, the change was non-significant for the Control Group. Group-A had a mean HbA1cof 12.83±2.11% and 10.70±1.89% at the beginning and end of the trial respectively with a *p*-value of 0.007 (Table-II).

Inter-group data analysis showed that HbA1c had a mean decrease of 2.13±0.46% in Group-A and a mean increase of 0.18±0.84% in Group-B (*p*-value <0.001). The mean blood sugar levels (BSL) in the intervention group were 336.53±61.30mg/dl and 290.14±70.82 mg/dl in the Control group at the beginning of the trial (*p*-value= 0.070). The mean BSL in Group-A were 262.73±54.29 mg/dl, and Group-B had 283.42±46.74 mg/dl after the intervention (*p*-value=0.283). However, the change in BSLs between the two groups was significant. Group-A had a fall of

Table-II: Pre-intervention and post-intervention comparison of primary outcomes among cases and controls (n=29)

Primary Outcomes	Pre-intervention (n=29)	Post-intervention (n=29)	*p*-value
	Mean±Standard Deviation	Mean±Standard Deviation	
HbA1c(%) Intervention Group/Cases	12.83±2.11	10.70±1.89	0.007
HbA1c(%) Control Group	11.28±2.12	11.46±1.89	0.814
BSL (g/dl) Intervention Group/Cases	336.53±61.30	262.73±54.29	0.002
BSL (g/dl) Control Group	290.14±70.82	283.42±46.74	0.769

73.80±32.97mg/dL while Group-B had a fall of only 6.71±38.45 mg/dL. (*p*-value<0.001)

Among the secondary outcomes, the increase in diary maintenance and the decrease in hypoglycemic episodes experienced in the past three months showed a significant difference between the two groups after intervention (Figure-2).

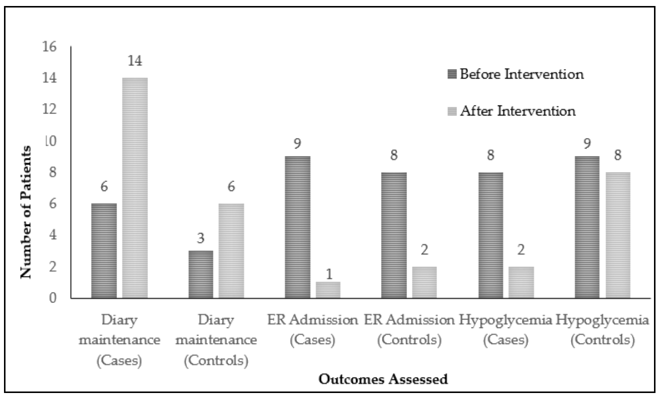

Figure-2: Secondary Outcomes (Diary Maintenance, ER Admissions and Hypoglycemia) Before (Blue bars) and after (Red Bars) Intervention Amongst Cases and Controls. The x-Axis Features the Outcome Assessed and y-axis is Featuring the Number of Patients (n=29)

Nine patients (60%) from Group-A, and eight patients (57.1%) from Group-B had an ER admission in the last three months at the beginning of the trial (*p*-value=1.000). While at the end of the trial, only one patient (6.7%) from group-A and two patients (14.3%) from Group-B had an ER admission in the last three months. Though the results showed improvement, the difference between the groups was statistically non-significant (*p*-value=0.598). The number of self-monitored blood glucose (SMBG) values in the last 15 days remained low in both groups, and the difference between the two after intervention remained non-significant (*p*-value=0.195) (Table-III).

Education as an intervention to modify behavioural change has been explored in various studies.[16-18] A systemic review covering 12 clinical areas and comprising more than 38 thousand patients, both adult and paediatric, showed significant improvement in aspects of behavioural modification, symptoms, and biochemical parameters after text messaging as an intervention.[16] Similarly, a meta-analysis of 43 studies of 6529 patients with T2D showed that all educational interventions produced statistically significant results in all health outcomes, but the results are most pronounced for HbA1c.[19] The 2014 position statement by the American Diabetes Association laid particular emphasis on Diabetes self-management education (DSME) and support (DSMS) as vital components of optimizing management in children and adolescents with diabetes.[20]

Table-III: Comparison Primary and Secondary Outcomes Between Study Groups Before and after Intervention (n=29)

Secondary Outcomes		Intervention or Group-A(n=15)	Control or Group-B (n=14)	*p*-value
		Mean±Standard Deviation, Number (Percentage)	Mean±Standard Deviation, Number (Percentage)	
HBA1C (Percentage) before intervention		12.83±2.11	11.28±2.12	0.060
HBA1C (Percentage) after intervention		10.70±1.89	11.46±1.89	0.287
Change in HBA1C after intervention		2.13±0.46	-0.18±0.84	<0.001
BSL (mg/dl) before intervention		336.53±61.30	290.14±70.82	0.070
BSL (mg/dl) after intervention		262.73±54.29	283.42±46.74	0.283
Change in BSL (mg/dl) after intervention		73.80±32.97	6.71±38.45	<0.001
Diary Maintenance before intervention		6(40.0%)	3(21.4%)	0.294
Diary Maintenance after intervention		14(93.3%)	6(42.9%)	0.005
Admission in ER before intervention		9(60.0%)	8(57.1%)	1.000
Admission in ER after intervention		1(6.7%)	2(14.3%)	0.598
Hypoglycemic Episodes before intervention		8(53.3%)	9(64.3%)	0.710
Hypoglycemic Episodes after intervention		2(13.3%)	8(57.1%)	0.021
Number of Blood Sugar Recordings In past 15 days (before intervention)	None	2(13.3%)	2(14.3%)	0.452
	1-14	2(13.3%)	5(35.7%)	
	15-29	6(40.0%)	5(35.7%)	
	>30	5(33.3%)	2(14.3%)	
Number of Blood Sugar Recordings In past 15 days (after intervention)	None	0(0.0%)	2(14.3%)	0.195
	1-14	3(20.0%)	3(21.4%)	
	15-29	7(46.7%)	8(57.1%)	
	>30	5(33.3%)	1(7.1%)	

DISCUSSION

Diabetes was identified as the most common co-morbidity in COVID-19 patients. However, research regarding patients less than 18 years of age shows otherwise. One US study of 2572 COVID-19 patients under the age of 18 did not mention diabetes as a co-morbidity.[11]

The use of technology in Paediatric Diabetes dates back to 1970 when the first insulin pumps were introduced. Worldwide, continuous subcutaneous insulin infusion (CSII) has become the standard of care.[12] Doctors managing children with diabetes rely more on time-in-range from continuous glucose monitoring (CGM) devices than HbA1c.[13] However, CSII is unheard of in the developing world, and CGM devices, though recently made available, still need to be made affordable for most patients with T1D. Though paediatrics is ahead of adult medicine when it comes to technology for managing diabetes, the use of SMS and telephone to improve the managerial skills of patients with diabetes was probably explored first in adult medicine.[14,15].

Busy OPDs with a lack of sub-speciality clinics mean many children with diabetes are unable to get sufficient attention required for managing a disease as complex as T1D. A study conducted by Kim H-S and Oh J-A14 over 12 weeks showed similar results. However, their study adopted telephonic calls to T2D patients by Nurses as an intervention. Only one study has evaluated the effect of SMS on glycemic control in children in Pakistan. Khan WI et al. observed that HbA1c decreased by 1% over a period of 3 months after intervention.[21] However, it was a single-group pre-and post-intervention study, so no comparison to routine practice could be established. In addition, whether the SMS brought about this difference or the insulin treatment itself needs to be clarified.

It is important to consider that though most studies show improvement in management with SMS as an intervention, some also advise caution. Van Olmen [et al]. conducted a randomized trial in three low-income countries that did not establish a statistically significant difference between the intervention and control group.[22] In 1995, Marero *et al*. evaluated various biochemical, patient, and HCW-related outcomes in the Computer-linked Outpatient Clinic (CLOC) study.[23] Although there was no significant difference in metabolic control, quality of life, or ER visits, a significant decrease in the time required for consultation was observed. However, in this study, the experimental group was managed by nurses, while physicians managed the control group.

LIMITATION OF STUDY

The authors recognize that no study is without its limitations. Our patients were receiving multiple types of Insulin. The regimens included twice and thrice daily injections by an insulin syringe and basal-bolus regimen with pens. It is safe to propose that SMS is an effective tool for health education, irrespective of the insulin type or regimen. The number of SMBG values showed little improvement. One of the contributing factors that could explain it is the high cost and unaffordability of blood sugar strips for most patients. It is, hence, postulated that diabetic control is expected to improve further as CGM devices become more readily available and affordable in the developing world.

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CONCLUSION

This RCT establishes the efficacy of SMS as an adjunct to therapeutics in a low-middle-income country, just like the developed world. The authors of this study recommend complementing routine medical care with telemedicine to help bridge the gap in healthcare services and enhance clinical outcomes in resource-limited settings for children and adolescents with T1D. It is recognized that future studies with a longer follow-up period and a higher number of patients may provide more reproducible results. This study adds valuable results to the existing literature that will drive further research and is expected to alter clinical practices and improve patient outcomes.

Conflict of Interest: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AR & AR: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

MSK & NN: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SN & SA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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