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To

The Dean (Academics)

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Sub: Submission of DM (Endocrinology) Thesis

Respected Sir

I, Dr Parul Gupta, hereby submit 5 copies of my DM thesis, titled **"Effect of WhatsApp based diabetes education and instructions on glycemic status, knowledge, quality of life and coping skills in patients of Type 1 Diabetes Mellitus: A Randomized Controlled Trial"**. This thesis was done under the guidance of Dr Ravindra Shukla (Guide) and Co-guides, Dr M.K.Garg, Dr. Madhukar Mittal, and Dr Varuna Vyas.

I hereby request you to kindly accept five copies of my thesis and do the needful. I shall be highly obliged.

Thanking You

Yours Sincerely

Dr Parul Gupta

Senior Resident

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R-ec & fwd

14|2

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EFFECT OF WHATSAPP BASED DIABETES EDUCATION AND INSTRUCTIONS ON GLYCEMIC STATUS, KNOWLEDGE, QUALITY OF LIFE AND COPING SKILLS IN PATIENTS OF TYPE 1 DIABETES MELLITUS: A RANDOMIZED CONTROLLED TRIAL

THESIS

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfilment of the requirement for the degree of

DOCTORATE OF MEDICINE (DM)

(ENDOCRINOLOGY)

BATCH : JULY, 2019   **DR. PARUL GUPTA**

AIIMS, JODHPUR

All India Institute of Medical Sciences, Jodhpur

<u>DECLARATION</u>

I hereby declare that the thesis titled **"Effect of WhatsApp based diabetes education and instructions on glycemic status, knowledge, quality of life and coping skills in patients of Type 1 Diabetes Mellitus: A Randomized Controlled Trial"** embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled **"Effect of WhatsApp based diabetes education and instructions on glycemic status, knowledge, quality of life and coping skills in patients of Type 1 Diabetes Mellitus: A Randomized Controlled Trial"** is the bonafide work of **Dr Parul Gupta** carried out under our guidance and supervision, in the Department of Endocrinology, All India Institute of Medical Sciences, Jodhpur.

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The completion of this Thesis has been a journey of mettle and patience and it is with immense humility that I extend my gratitude to the people who aided me in this journey.

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and my in laws who took care of my child in my absence. I cannot express in words the sacrifices they made for me.

I would like to thank "WhatsApp" application for this wonderful and easy to use application for interaction between the doctors and the patients.

Last but by far not the least, I express thanks to all my patients without whom this milestone was not possible. Listening to them and understanding the problems they face daily, gave me the true insight about the management of Type 1 diabetes. They made me realize the power of social media and support groups. Moreover, I learnt so many new things including Hindi typing.

I would like to end with the saying that nothing worth achieving has ever been achieved without the guidance of our teachers and the support of family and friends and patients.

"Alone we can do so little; together we can do so much"

DR. PARUL GUPTA

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LIST OF ABBREVIATIONS

ADA   American Diabetes Association

CDE   Certified Diabetes Educators

CODI   Coping with disease

COVID   Coronavirus Disease

CDiC   Changing Diabetes in Children

CSDS   Centre for the Study of Developing Societies

DKA   Diabetic ketoacidosis

DMSES   Diabetes Management Self Efficacy Scale

DQOL   Diabetes Quality of Life

DKT   Diabetes Knowledge test

DSME   Diabetes Self-Management Education

MOTN   Moods of the Nation Survey

MMRM   Mixed Model Repeated Measures

NDEP   National Diabetes Educator Program

HPLC   High performance liquid chromatography

IV   Intra venous

IDF   International Diabetes Federation

ISPAD   International society of pediatric and adolescent diabetes

RT PCR   Reverse Transcriptase Polymerase chain reaction

RCT   Randomized Controlled Trial

SD   Standard Deviation

SMS   Short Message Services

WHO   World Health Organization

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SUMMARY

BACKGROUND: Diabetes Self-Management Education (DSME) is the keystone in management of Type 1 Diabetes. WhatsApp is a free to use mobile application which is popularly used for personal communication in India but there is no literature on its use in DSME of Type 1 Diabetes Mellitus patients.

OBJECTIVES: To study the effect of WhatsApp based DSME on glycemic status, knowledge, quality of life and coping skills of Type 1 Diabetes patients at 16 weeks and 28 weeks.

STUDY DESIGN: Single center, open label Randomized Controlled Trial with 28 weeks follow up conducted from June 2020 to September 2021.

METHODOLOGY: Fifty-Six Type 1 Diabetes patients (15-40 years) with WhatsApp were randomized into two groups "Intervention" (n=28) who received weekly educational WhatsApp messages and "Sham" (n=28) who received weekly greeting messages. In addition, patients without access to WhatsApp formed "Control" group (n=10). HbA1c, Diabetes Knowledge Test (DKT), Diabetes Quality of life (DQOL) and Coping with disease (CODI) questionnaires were administered at baseline, 16 and 28 weeks. Structured offline diabetes education was given prior to enrollment and continued at 4, 16, 28 weeks in all patients.

RESULTS: The mean baseline HbA1c was 10.69±2.74%. At 28 weeks, there was a significant reduction in HbA1c in the WhatsApp trial group (Intervention plus Sham) compared to the Control group (mean ± SE 9.144 ± 0.27% versus 11.66 ± 0.731%, p value 0.003). There was an improvement in knowledge score and coping skills and quality of life in the WhatsApp trial group as compared to Control group. Amongst

the two WhatsApp groups, there was a significant increase in the knowledge score with WhatsApp based DSME (p value 0.001) in the Intervention group. The mean HbA1c decreased in both Intervention and Sham WhatsApp group but the difference between them was not significant. There was no significant difference in the quality of life and coping skills in the Intervention versus Sham WhatsApp group.

CONCLUSION: WhatsApp group formation led to improvement in glycemic control, coping skills and quality of life if the treating team stayed in touch with the patients through a patient WhatsApp group, irrespective of whether WhatsApp based DSME was provided in the group or not. WhatsApp based DSME however did improve the knowledge score in the Intervention group. Hence, patient engagement through formation of WhatsApp groups with treating doctor can empower patients for self- management and provide a more interactive and cost-effective platform for managing Type 1 diabetes patients in resource limited settings and can be especially rewarding in this pandemic situation.

<u>INTRODUCTION</u>

Diabetes is a major public health problem throughout the world. The prevalence and incidence of diabetes is increasing at an alarming rate. As per the latest data by International Diabetes Federation (IDF) atlas 10th edition, there are total 537 million people with diabetes throughout the world accounting for 1 in 10 of the total population (1). This number is predicted to rise to 643 million by 2030 and to 784 million by 2045.   Diabetes itself has led to 6.7 million deaths in year 2021 alone thus amounting to approximately 1 death in every 5 seconds. Diabetes has caused 966 billion dollars health expenditure which has shown an increase of 316 % increase over the last 15 years (1). Four of these 5 people with diabetes live in low- and middle-income countries. It is even more alarming that in South East Asia, 1 in 2 diabetes patients remains undiagnosed (1).

India has a huge burden of diabetes. As per the latest data by IDF atlas, in the year 2021, India alone had 74194 thousand people with diabetes in the age group of 20 to 79 years which means a 2.27 times increase since the year 2000 (2). But the fact that the numbers are expected to increase exponentially over the next few decades is a matter of concern. Moreover, as per the IDF data, 53.1 percent population still remains undiagnosed in India (2) .

It is important to note that the IDF data includes patients with both Type 1 and Type 2 diabetes. The segregation or subcategorization is based on age of the patients rather than whether patient has Type 1 or Type 2 Diabetes. Thus, the age group 20-79 years mentioned as adults in IDF data includes both Type 2 Diabetes as well as Type 1 Diabetes. Thus, the exact data on worldwide as well as country wise prevalence, new onset or incident Type 1 Diabetes and complications and mortality data of Type 1

diabetes specifically is obscure. But still, if we consider the IDF data of patients with diabetes aged less than 19 years, as this is the age group in which 80-90 percent of all diabetes cases are due to Type 1 Diabetes, a rough estimate of the prevalence and incidence can be made. As per IDF atlas 2021, there are total 2,29,400 patients of diabetes in India in the age group 0-19 years and there were 24000 new cases of diabetes diagnosed in this age group in year 2021 itself (2). These numbers are alarming as the total number of children and adolescents with diabetes have increased by 1.85 times over last 2 decades (Year 2000 to 2021). The number of new cases diagnosed per year has also increased by 1100 patients over these 20 years. Although, we don't have the prediction over the next few decades for children and adolescents, seeing the secular trend over the past decades, it is evident that the numbers of children with Type 1 diabetes will increase exponentially over the next decades.

The prevalence of diabetes in India is variable across various states and multiple registries have quoted variable data. It is estimated to be 17.93 cases/100,000 children in Karnataka, 3.2 cases/100,000 children in Chennai, and 10.2 cases/100,000 children in Karnal (Haryana) (3) . Thus, considering this high prevalence, there is an unmet need for optimizing the management of these children with Type 1 diabetes.

Education is the keystone in the management of Type 1 diabetes. The International society of pediatric and adolescent diabetes (ISPAD) has emphasized on the importance of education and has laid down principles for education and the importance of structured education in these children (4). Diabetes education is defined as "an interactive process that facilitates and supports the individual and/or their families, those who provide care or significant social contacts to acquire and apply the knowledge, confidence, and practical, problem solving and coping skills,

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needed to manage their life with diabetes in order to achieve the best possible outcomes within their own unique circumstances" (4). Providing structured diabetes education helps in maximizing the effectiveness of diabetes treatment and has been shown to have beneficial effect on glycemic control and psychosocial outcomes (4). Various studies have shown diabetes education to be a cost effective intervention by decreasing the frequency of hospital admissions and presentation to emergency (4) . Also, it has been observed that patients who do not receive education are more likely to suffer from diabetes related complications (5,6).

In India, education to Type 1 diabetes patients is a huge challenge. National Diabetes Educator Program (NDEP) has been operational in India since 2011 with an aim to provide structured module based training to educators so that Certified Diabetes Educators (CDE) are available throughout the country for providing Diabetes self-management Education (DSME) (7). Changing Diabetes in Children (CDiC) program which works towards education of these patients in India reported in 2014 that there are currently 70000-75000 children with Type 1 diabetes but structured education is being provided to only 4000 of them (8).

Thus, face to face diabetes education is unable to cater to the huge burden of Type 1 diabetes in our country. With the current advancement in digital technologies, it is an unmet need to develop or innovate or link this digital technology based education system to provide diabetes education to Type 1 Diabetes patients.

REVIEW OF LITERATURE

India has a population of 1.38 billion (9) and as per a recent survey by Economic Times, India alone has 1.18 billion mobile connections, 700 million Internet users, and 600 million smartphones and the numbers are increasing by approximately 25 million per quarter (10).

With the easy availability of internet at a low cost, various messaging applications are now being increasingly used in India. Instant messaging is a type of online chat which offers real-time text transmission via internet. These newer applications have replaced SMS (short messages services) which used operator dependent transmission of messages. Graph 1 shows the most popular global mobile messenger apps as of October 2021, based on number of monthly active users in millions (11). WhatsApp, Facebook messenger, We chat, QQ, Telegram and snapchat are the commonly used instant messaging applications popular throughout the world. WhatsApp is a smartphone application which uses internet to send or receive messages/images/ audios/ videos/documents and thus allows bidirectional communication Globally, WhatsApp is the most commonly used instant messaging application with approximately 2000 million users all over the world. In India alone, there are over 487 million WhatsApp users, and thus India is the leading country in terms of WhatsApp usage (12). India is followed by Brazil which is ranked second with 118.5 million WhatsApp messenger users (12).

The number of WhatsApp users are rising all over the world and the number of WhatsApp users have progressively increased over the last decade as shown in graph 2 (13) . The number of smart phone users in India similarly has shown an exponential trend over the last decade (graph 3) and it is predicted that these numbers were will

continue to increase and thus further popularizing the use of WhatsApp in our country as shown in graph 4 (14).

A survey was conducted in 2017 by "Lokniti" which is a research programme at the Delhi-based Centre for the Study of Developing Societies (CSDS) and was named "Mood of the Nation" survey. It showed that in 2018, 45% of the Indian population had a mobile phone, 31% had mobile phone with internet access and only 24% of Indian population doesn't have mobile phone (15). As shown in Graph 5, average time spent per month on WhatsApp per user is approximately 21.3 hours which is far more than that spent on other social networking or instant messaging applications. As shown in Graph 3 & 4, the numbers of smart phone users are rising exponentially and thus the numbers of WhatsApp users are expected to be much more than that of the MOTN survey of 2018.
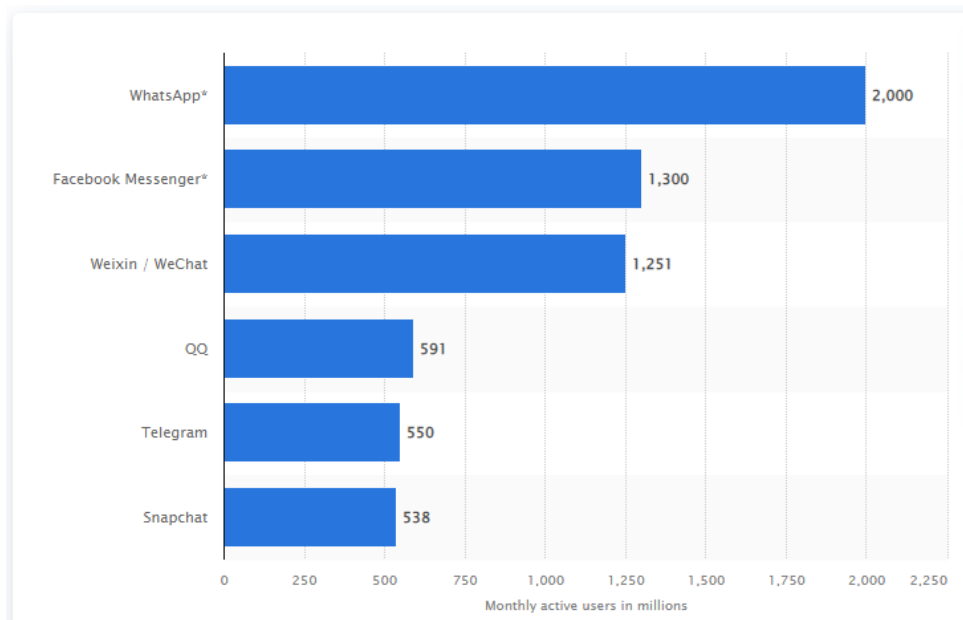
Graph 1: Most popular global mobile messenger apps as of October 2021, based on number of monthly active users (in millions)
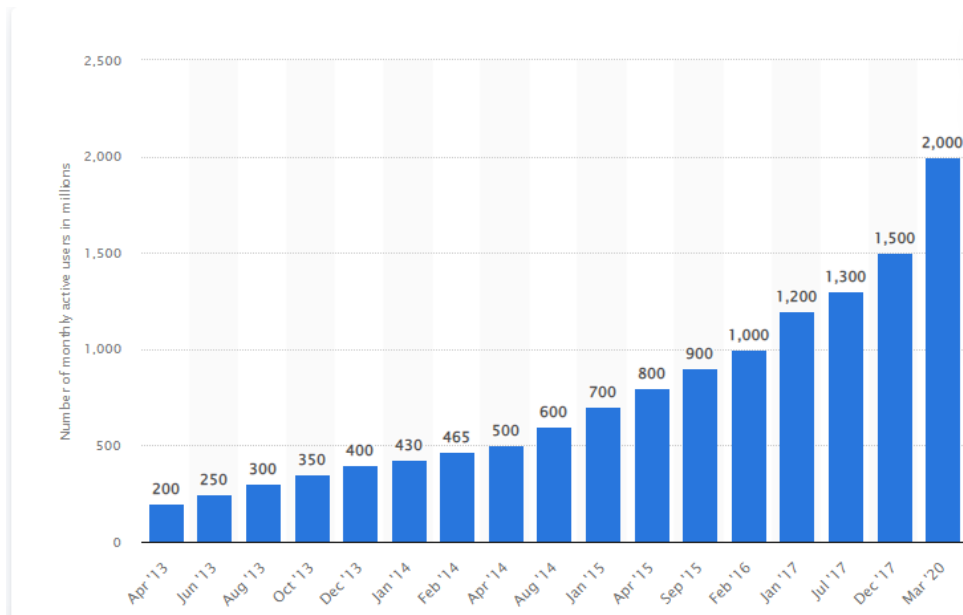
Graph 2: Number of monthly active WhatsApp users worldwide from April 2013 to March 2020 (in millions)
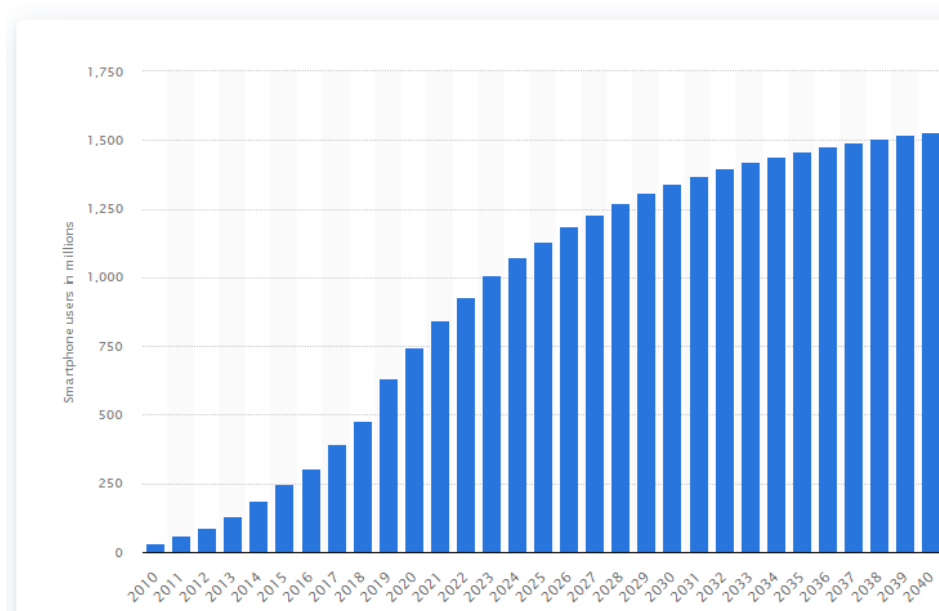
Graph 3: Number of smartphone users in India in 2010 to 2020, with estimates until 2040: in millions.

WhatsApp Extraordinary Growth in Users

First Four Years Growth after Launch
Monthly Active User Accounts of Selected Services that are 4+Years Old, in Millions

WhatsApp 419MM
Facebook 145MM
Gmail 123MM[1]
Twittter 54MM[2]
Skype 52MM[3]
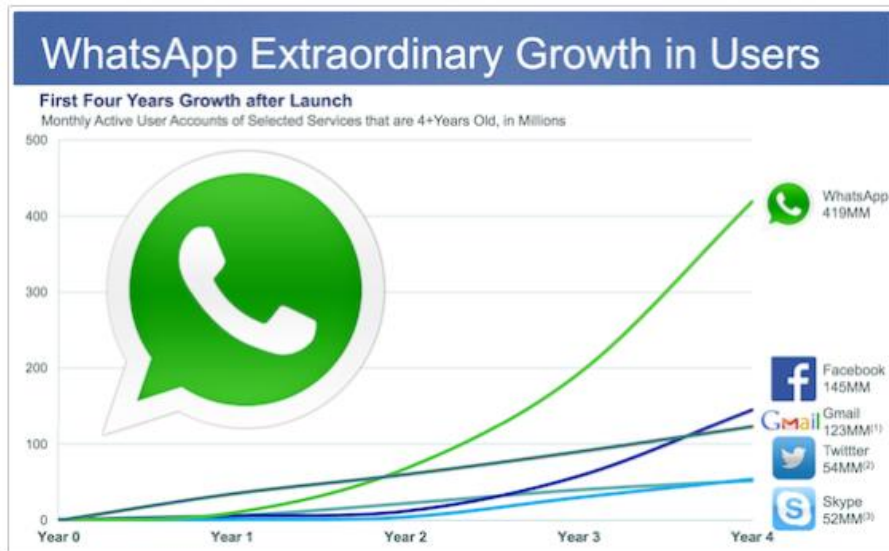
Exponential growth of WhatsApp users from 2009 to 2013

Graph 4: Exponential growth of WhatsApp over years

Average Monthly Time Spent Per User Among Top Social Networking Apps by Hours Spent in 2020

India

2020: 21.3 Average Hours Per Month
#1 WhatsApp Messenger

#1 WhatsApp Messeng...   #2 Facebook   #3 Instagram   #4 Truecaller   #5 TikTok
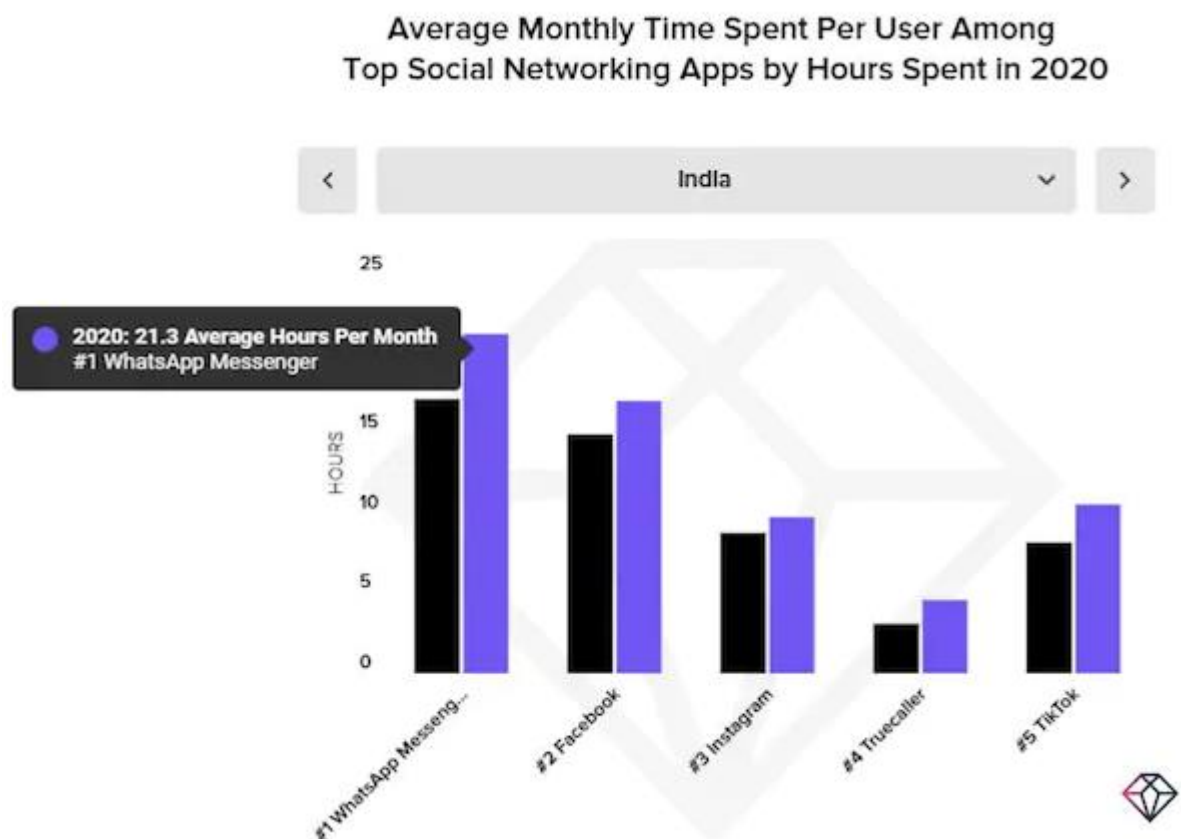
The penetration of mobile internet has increased sharply over the past year

Access to mobile/internet (% respondents)

2017 2018

Mobile phone with internet access

31%
21%

Mobile phone but no internet access

53% 45%

Don't have mobile phone

26% 24%
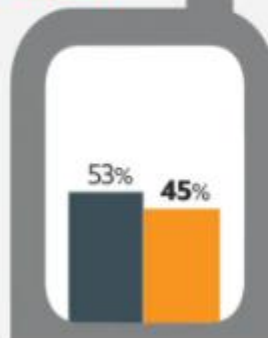
Source: Lokniti-CSDS MOTN surveys

Chart 1

Higher usage in urban India but rising coverage in rural India

Share of active WhatsApp users (% respondents)

2017 2018

Source: Lokniti CSDS MOTN surveys

Rural

10 20

Urban

22 38
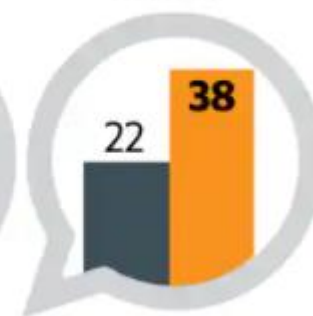
Chart 2

The reach of WhatsApp extends beyond the rich

Share of active WhatsApp users (in %)

Poor
8
14

Lower income class
6
24

Middle class
15
34

Upper middle class and rich
29
45
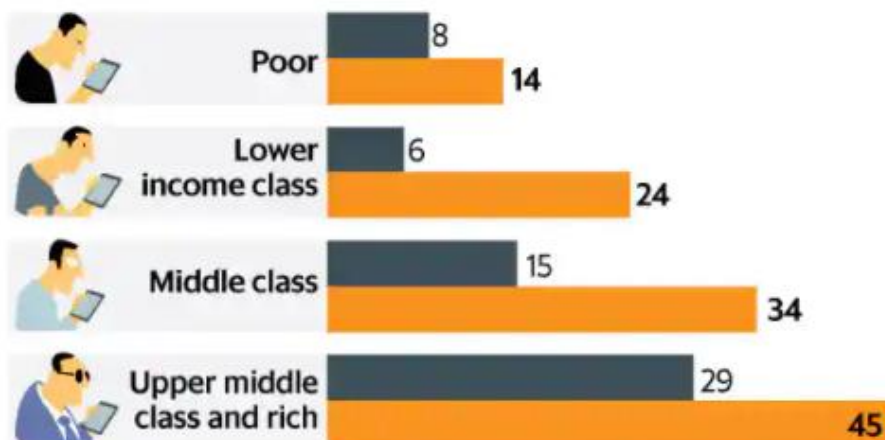
Source: Lokniti-CSDS MOTN surveys

Chart 3
The youth are the biggest constituency for WhatsApp

Share of active WhatsApp users (in %)

Age group		
18-25 years	30	49
26-35 years	21	35
36-55 years	10	17
56 years and above	3	7
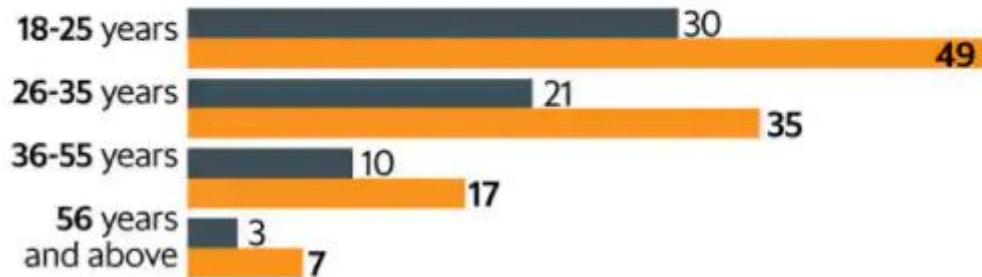
The rise in internet usage and WhatsApp usage has higher in urban India than in rural India. In 2017, 20% of the rural population used WhatsApp as compared to 38% urban population but over a period of 1 year, the usage of WhatsApp doubled in rural India as shown in Chart 1. WhatsApp use continues to be still more in upper middle class and rich probably because of the easy availability of internet (chart 2). As expected, amongst various age groups, people aged 18-25 years use WhatsApp the maximum as shown in Chart 3 (15).

With the widespread and easy availability of internet, the use of internet in providing information to patients with chronic illnesses has been explored in recent years. In 2017, Brady et al used semi structured interviews in 21 patients of diabetes and reported the advantage of online forums in diabetes management by empowering patients and motivating them (16).

Diabetes education is the key to Type 1 diabetes management. Providing structured diabetes education helps in maximizing the effectiveness of diabetes treatment and has been shown to have beneficial effect on glycemic control and psychosocial outcomes (4). Various studies have shown diabetes education to be a cost effective intervention by decreasing the frequency of hospital admissions and presentation to

emergency (4) . Also, it has been observed that patients who do not receive education are more likely to suffer from diabetes related complications (5,6).

Mobile health or "m-health" is the use of mobile phones for health and chronic disease management. It includes social media to connect to health care professionals and/or to other patients and /or community as well as includes smart phone applications example those for keeping a log of blood glucose values or those that give a graphical analysis of glucose or insulin dose calculator or carbohydrate counting (17,18).

Telemedicine term was coined in 1970's and literally means "healing at a distance". World Health Organization (WHO) in 2010 convention has defined Telemedicine as "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"(19).

The management of Type 1 diabetes requires close monitoring and insulin dose adjustment to ensure optimal glycemic control. The need for connecting patients and health care providers through telemedicine has become even more necessary during the Corona Virus Disease (COVID) pandemic. Due to the use of mobile phone and internet services by both patients and their caregivers for school and college online classes has made them well versed with its usage and thus it has made WhatsApp a very convenient platform to use. It has helped to avoid the cost and time spent in

traveling and waiting   in OPD and thus enabling more time available for studies and school work for students and less absenteeism from work.

In 2019, Fischer et al from Johannesburg evaluated various information delivery platforms, to increase diabetes awareness including television, radio, newspaper, SMS, WhatsApp, emails, mobile applications, and social media. They reported that patients were most receptive to television and WhatsApp followed by SMS, newspaper, radio and social media (20).

In 2014, Saboo et al conducted a study to evaluate the role of social media in management of Type 1 diabetes. 79 patients of Type 1 diabetes aged > 18 years were connected to the diabetes care team via Facebook, email and WhatsApp. In addition, patient support groups were created on WhatsApp and Facebook. HbA1c and Quality of life were assessed 3 monthly for a period of 2 years. The authors reported that the use of social media enabled the patients to share their glucose charting, discuss day to day issues and to share their experiences. In addition, the doctor and patient interaction via these social media platforms enabled the patient to contact the treating doctors during emergency situations like hypoglycemia and hyperglycemias and also gave the opportunity to the doctors to remind the patients for regular follow ups and monitoring of Hba1c. The quality of life score decreased from 65.79 ± 2.41 to 59.84 ± 1.89; p< 0.01 suggesting an improvement in quality of life. The HbA1c decreased from 9.21 ± 1.76 to 8.49 ± 0.89 (p< 0.01) (21). The authors concluded that the use of social media not only improved the quality of life but also decreased the impact of diabetes on Type 1 diabetes patients.

The same authors, Saboo et al in 2020 also evaluated the utility of social media during the COVID pandemic for educating Type 1 diabetes patients. They observed that the

use of social media for Diabetes self-management education (DSME) was especially rewarding during the COVID pandemic. The pandemic itself especially the COVID lockdown created a lot of problems related to affordability and accessibility to health care services. Saboo et al also reported that they faced various challenges while managing Type 1 diabetes during the pandemic. They used video calls for managing Type 1 diabetes patients. They tried to teach insulin techniques and the use of blood glucose monitors through video calls. Authors connected the families of children with Type 1 diabetes living in the same region in order to offer support and promote confidence and they made one patient with type 1 diabetes as a peer educator to act as an inspiration to others. The authors concluded that advancement in technology and telemedicine proved to be very effective in managing patients and the use of telemedicine proved both time and cost-saving and resulted in high appointment adherence with minimum difficulties. As per the authors, the telemedicine approach was well-received by people living with diabetes and their families and they concluded that in the aftermath of COVID-19, telemedicine can provide a promising solution for patients for delivering diabetes related care (22).

In another study from India conducted by Muthukrishnan et al over a period of 1 year during COVID lock down, 46 Type 1 diabetes patients (including 10 on insulin pump) were followed via a telephonic consultation. They were counselled fortnightly via web-based education session. The authors concluded that teleconsultation via video conferencing ensures optimal delivery of health care services and can even be continued after the pandemic was over to reduce the OPD burden and increase convenience to patients (23). In this study of 46 patients, the mean age was 19.1 years, the duration was 4.88 years and mean HbA1c was8.2. There was improvement in HbA1c in 62.5% patients over a period of 1 year after teleconsultation.

The concept is not new but it is largely unexplored. In 2012, in Norway a pilot study on 12 patients evaluated the use of mobile phones in facilitating visual learning in Type 1 diabetes using mobile phones using SMS and application using picture based diary. The authors did not find a statistically significant difference in HbA1c or in knowledge score after 3 month of intervention. Although the sample size was very small, the authors reported that the patients appreciated the picture based diary more than the SMS as the visual impression facilitated the link between theoretical knowledge and executive functions and thus suited more to the adolescent brain (24).

A study in 2019 conducted by Sap et al from Cameroon studied the impact of patient education through WhatsApp on knowledge and glycemic control of Type 1 diabetes patients. They enrolled patients between 13-26 years as this age group uses social networking applications the maximum. It was a non-randomized 2 arm trial enrolling total 54 patients (25 in the intervention group and 29 in the control group). The intervention group received weekly sessions of 60-90 minutes in the form of focus WhatsApp group for 4 weeks. HbA1c was repeated after 12 weeks. Modified Revised Brief Diabetes Knowledge Test was used for evaluating knowledge. They reported that there was significant improvement in knowledge score from 13/20 to 16/20 in the intervention arm (p value <0.01) while there was a decrease in knowledge score in control arm 11.6 to 11.3 but there was no improvement in HbA1c in both the groups. There was non-significant decrease in acute complications in the intervention group. The authors concluded that patient education through social network over a period of 2 months helped to improve knowledge and acute complications but without an improvement in glycemic control. It was a non-randomized trial and the authors also highlighted the need for further studies to study the long term effect on glycemic control (25).

In 2016, Blackstock et al evaluated the use of WhatsApp in Type 1 diabetes adolescents in West London. They used WhatsApp "Broadcast" rather than an open WhatsApp group to ensure quality control in the messages sent by the patient and the research team reviewed and approved all the messages sent by the patient before it was disseminated to other members. They enrolled only 24 patients and reported that the mean HbA1c changed from 9.7 to 9% while the median HbA1c decreased from 9.8 to 7.9%. Another observation which the authors reported that the 2 patients who did not report for clinic visits were amongst the highest WhatsApp users and one of them had significant improvement in HbA1c. Thus, they hypothesized that WhatsApp could be useful in targeting even the difficult diabetic patients who don't come for follow up visits. They concluded that this innovative use of technology for Type 1 diabetes management provides easy access of information as well as improves patient's engagement in diabetes self-management (26).

In 2017, Goyal et al from Canada tried the use of mobile application "*bant*" for diabetes self-management education in adolescents. They designed a RCT to compare the application "*bant*" with usual care over 12 months. The application had features of wireless blood glucose monitoring transfer with out-of-range glucose alert with causation and fixation alert. The primary objective was change in Hba1c while secondary objective was SMBG frequency, quality of life, and satisfaction and usage rates of "*bant*" application. They enrolled 96 patients and the mean duration of diabetes was 7.1 years and the mean baseline HbA1c was 8.96 %. With 12 months intervention, there was no significant difference in the HbA1c in the intervention versus the control group. Both the group showed an initial decline of HbA1c which then returned to pretreatment value at the end of 12-month study. There was no change in the secondary outcome including the quality of life and satisfaction score.

The authors also reported that the use of the application declined over time and 37% patients had very low usage of application (less than once per 2 weeks) , 28 % had low usage (less than once per week) and 26% moderate usage (1-3 times per week) and only 9% patients used the application more than 3 times per week (27).

American Diabetes Association (ADA) has suggested the 5A's model approach to promote behavior change i.e. Ask, Advise, Assess, Assist and Arrange. For the emotional support to the patients, the BATHE approach has been suggested i.e. Background, Affect, Trouble, Handling, and Empathy. Previous studies have shown that the 2 major coping issues in patients of diabetes include: problem focused coping (i.e. strategies to resolve and to prevent problems) and emotion focused coping (i.e. strategies to deal with negative emotions) (28). Very few studies have evaluated the effect of mobile based Diabetes education on Quality of life and coping skills of Type 1 diabetes patients. These studies are enumerated in the Reference Table 1.

In 2018, Klee et al conducted a RCT in Geneva Switzerland and 33 patients were enrolled. There was a 0.33% reduction in Hba1c (p value 0.04) in patient using a Webdia "Do it Yourself" application with respect to the standard care group. No difference in quality of life score. (29)

In a study in 2020 by Nachimuthu et al in Chennai, an online survey "Survey Monkey" was conducted in patients who did not come for physical OPD follow up during the COVID lockdown. This survey had questions regarding SMBG, compliance to diet and exercise and patients' anxiety regarding COVID. Their cohort of 100 patients had 92 Type 2 diabetes and 8 Type 1 diabetes patients.   They reported that 80% of the people were compliant with diet and exercise but only 28 % did

regular (at least once a day) monitoring of blood glucose and 40% patients were anxious about COVID infection and its after effects (30).

Sun et al in 2019 published a systematic review on various available mobile applications for improving glycemic control in Type 1 diabetes patients (31). The review evaluated 14 studies, 9 on standalone mobile apps while 5 on mobile apps with text messaging or feedback system. Reference table 1 summarizes the results of the 5 studies with involvement of health care professionals along with application for providing feedback and management advice.

Thus, many studies have been conducted to evaluate use of mobile phone SMS (Short messages service) and various other mobile applications for diabetes self-management education (DSME) in Type 2 Diabetes and very limited studies on Type 1 Diabetes. They have shown varied results on glycemic control. There are very few studies which have evaluated the role of mobile phone SMS and emails and other social networking media like Facebook to bring a change in quality of life and coping skills in Type 1 diabetes patients.

The number of WhatsApp users in India has increased in the last 4 years and to the best of our knowledge, there is only one study conducted by Sap et al in 2019 (25) on evaluating glycemic control and knowledge in Type 1 diabetes patients. This was a non-randomized study with a sample size of 54 patients with 2 months follow up period. There is no study specifically to evaluate the use of WhatsApp for improving quality of life and coping skills in Type 1 diabetes patients.

We hypothesize that WhatsApp will provide an opportunity to patients to discuss their fears and experiences with doctors and also to gain knowledge about diabetes self-management. Patients can also learn from other patient's experiences. So, we

designed a randomized trial to evaluate the use of WhatsApp in providing DSME and its effect on glycemic control, knowledge, quality of life and coping skills.

Using modern communication technology and smart phone-based application in a developing country to enable behavior change and self-empowerment in diabetes management can reduce economic burden on patients by reducing the need for frequent follow ups.

This study can help provide policy makers in India to design strategies using WhatsApp to provide diabetes education to masses and thus reduce morbidity & mortality due to diabetes and its complications.

REFERENCE TABLE 1

Author (Reference)	Year/ country	Study design	Duration months	Number of patients	Mobile app used	Results: Primary: HbA1c decrease	Results Secondary
Rossi et al (32)	2009 Italy	Pre/post	9	41	Diabetes interactive diary	-0.37% Non significant	FPG, PPG : Non significant
Froisland et al (24)	2012 Norway	Pre/post	3	12	Diamob	-0.2% Non significant (P 0.38)	Knowledge change : Non significant (P 0.82)
Kirwan et al (33)	2013 Australia	RCT (compared to usual care)	6	72	Glucose Buddy	-1.28% Significant	change in self-efficacy, self-care activities, and quality of life. : Non significant
Rossi et al (34)	2013 Italy	RCT (compared to usual care)	6	127	Diabetes interactive diary	-0.49 % Non significant (p 0.73)	Reduction in hypoglycemia
Ryan et al (35)	2017 Canada	Pre/post	5	18	Intelligent diabetes management	-0.3% Significant (p 0.001)	-
Zhang et al (36)	2019 China	RCT (A:B:C) Control, app self management, app interactive	6	234 (21 Type 1 , 213 Type 2)	Welltang app + daily guidance based on app data by health manager in group C	A1c reduction in all 3 groups. Group C lower A1c as compared to Group B. No difference between A and B.	App self management not enough for achieving a good control but combining with interactive management achieves control.

AIMS & OBJECTIVES

AIM: To evaluate the effect of WhatsApp based diabetes education and instructions on diabetes management.

PRIMARY OBJECTIVE: To study the effect of WhatsApp based diabetes education and instructions on glycemic status of patients of Type 1 Diabetes Mellitus.

SECONDARY OBJECTIVE: To study the effect of WhatsApp based diabetes education and instructions on knowledge, quality of life and coping skills in patients of Type 1 Diabetes Mellitus.

MATERIAL & METHODS

STUDY SETTING

It was conducted in Department of Endocrinology & Metabolism, AIIMS Jodhpur.

STUDY DESIGN

Randomized Controlled Trial

STUDY DURATION

22nd June 2020 to 7th September 2021

STUDY PARTICIPANTS

Patients with Type 1 diabetes presenting to Endocrinology and Metabolism OPD at AIIMS Jodhpur.

PATIENT ENROLLMENT

Inclusion criteria:

- Diagnosed as Type 1 diabetes as per WHO criteria and age 15 to 40 years

- Provided Written informed consent (or Parental consent & assent if age <18 years)

- Agreed for offline follow up (Endocrine OPD visits) at 4, 16, 28 weeks.

- Had attended at least 2 sessions of diabetes education in our center.

- Patient who had a personal mobile phone with internet access

- Patient who knew how to read messages on a mobile phone (Hindi or Hindi with English alphabets or English)

- Patient who gave willingness to receive WhatsApp messages for 28 weeks

Exclusion criteria:

- Patient with other chronic illness that could have interfered with study results e.g. mental illness

- Patient with conditions that might have altered HbA1c values e.g. Sickle cell disease

RANDOMIZATION

We used a computer generated randomization list to enroll the patients who had WhatsApp in the two groups, Intervention and Sham. The patients who satisfied our inclusion and exclusion criteria were explained in detail about the trial and were asked to sign the consent. Written informed consent was taken from all the patients above > 18 years and assent was taken from patients aged 15-18 years. On days when >1 patient was enrolled, the order of signing consent was used to decide who will be enrolled first and thus randomization list. This was done to ensure that there was no bias while randomization in the 2 groups.

All those patients who did not have a personal mobile phone or those who had a mobile phone but no internet connection or WhatsApp or those who did not know how to read or write messages on WhatsApp were put in the control group. Patient information sheet (in English as well as Hindi language) with details regarding the trial was given to all patients.

DATA COLLECTION:

After enrollment, baseline demographic data was collected in the case record form. Patient's clinical information including age, sex, and duration of diabetes, family

history, per capita income, education, insulin requirements, diabetes complications and past history including number of episodes of hypoglycemia and number of admissions in last 1 year were recorded. In all the patients, HbA1c, Fasting plasma glucose, Post prandial plasma glucose, serum creatinine and lipid profile were done at baseline.

QUESTIONAIRRES

Three questionnaires (Details in annexure) were administered at baseline:

- Diabetes knowledge test (37)
- CODI (coping with a disease) questionnaire (38)
- Diabetes quality of life questionnaire (39)

Diabetes Knowledge Test (DKT) questionnaire consisted of total 34 questions with maximum marks of 100. The questions were in both Hindi and English languages and related to these 9 aspects of diabetes management:

- Knowledge regarding Insulin Types and insulin administration (15marks): Question1-4, 19
- Knowledge regarding Nutrition (20 marks): Question 5-11
- Knowledge regarding Hypoglycemia (19 marks): Question 12-18
- Knowledge about Self-monitoring of blood glucose (SMBG) & glycemic targets (9 marks): Question 21, 22, 27
- Knowledge regarding Exercise (11 marks): Question 20, 23-26
- Knowledge regarding Sick day management (12 marks): Question 28, 29, 33
- Knowledge regarding Complications (4 marks): Question 30
- Knowledge regarding Travel precautions (6 marks): Question 31, 32

- Knowledge regarding insulin dose adjustment (4 marks): Question 34

CODI (Coping with disease) questionnaire consisted of questions related to 6 domains namely:

- Acceptance: 6 questions

- Avoidance: 4 questions

- Cognitive Palliative: 5 questions

- Distance: 4 questions

- Emotional reaction: 6 questions

- Wishful thinking: 3 questions

Patients were asked to mark their response on a 5-point Likert scale ranging from never to always i.e. Never/ Seldom/Sometimes/ Often/ Always.

DQOL (Diabetes Quality of Life) questionnaire consisted of total 46 questions on the following domains:

- Satisfaction: 15 questions

- Impact: 20 questions

- Worry: Social/ Vocational: 7 questions

- Worry: Diabetes related: 4 questions

Patients were asked to mark their responses on a 5-point Likert scale. Satisfaction was rated from 1 (very satisfied) to 5 (very dissatisfied). Impact and worry scales are rated from 1 (no impact and never worried) to 5 (always impacted and always worried).

OFFLINE DIABETES EDUCATION

All the patients who were enrolled in our study were given structured diabetes education after filling of the baseline questionnaires. This offline education session which was conducted in our Endocrine OPD for each patient took approximately 45 minutes. If more than 1 patient was enrolled on a given day, then the offline education session for all the patients on a single day were taken simultaneously and it was ensured that all the personal queries of each patient were appropriately answered. Not more than 3 enrollments were done in 1 day, so as to ensure appropriate time is given to each patient. All efforts were made to make this offline session interactive, encouraging patients to ask their questions and doubts and build rapport with the patient. All these sessions were taken by the same doctor (me) and were supervised by my guide, the principal investigator. To ensure uniformity, a structured PowerPoint presentation was used for diabetes education and patients were asked to interrupt in between and interact. The PowerPoint presentation was written in Hindi language and was presented in Hindi. It included information regarding:

1. What is diabetes and the various type of diabetes and the difference of Type 1 diabetes from Type 2 and gestational diabetes.

2. Insulin:

   - Normal physiology of insulin secretion and need for bolus and basal component

   - Types of bolus and basal insulin available

   - Regimens of insulin: Basal bolus/ split mix/ premix

   - Insulin injection sites, technique, storage, needle change & sharp disposal

- Insulin delivery devices: syringes, pen and pumps and the advantages of each

3. Glucose monitoring

    - What is HbA1c and its advantage

    - Timing of self-monitoring of glucose

    - Travel and sick day precautions

4. Acute complications

    - Hypoglycemia : symptoms and its management

    - Ketoacidosis and its early recognition

5. Chronic complications: via pictorial representation of all the organs which could be affected by diabetes and their basics about screening for them

6. Diet in diabetes: introduction to the concept of glycemic index and calorie counting and the common household food items and their classification into low, medium and high glycemic index

7. Importance of regular exercise

The information in the PowerPoint presentation while being presented were modulated as per the patient's current understanding of diabetes and focusing more on problem areas. For example if the patient had basic knowledge about insulin types and injection technique, then more stress was given on telling him about complications, diet and glycemic index and dose adjustment. But if while interaction with the patient, it was realized that patient has very minimal knowledge about diabetes management, then emphasis was laid on teaching him the basics and encouraging him for frequent follow up so that further detailed education could be given on subsequent follow ups. Offline diabetes education was stressed upon because we aimed to provide diabetes

education to improve glycemic control and empower patient regarding diabetes self-management irrespective of the trial arm to which the patient belonged.

At the end of each offline diabetes education session, the home based self-monitored glucose charting was reviewed and insulin doses adjusted accordingly and patients were told the basics of insulin dose adjustment and how they could make minor adjustments in their insulin doses on their own as per their home-based monitoring. The patients were encouraged to maintain a diary with home-based glucose monitoring and to come to Endocrine OPD at 4, 16 and 28 weeks after enrollment for follow up for the trial.

EDUCATION THROUGH WHATSAPP:

After enrollment, the patients were given the mobile number of both the resident doctor and the principal investigator who they can contact by a phone call at any time during the 28 weeks follow up period. The patients with WhatsApp were added to either WhatsApp "Intervention" or "Sham" group as per the randomization list. The Intervention WhatsApp group was named "Type 1 diabetes I" and Sham group was named "Type 1 diabetes S". No other person apart from the patient and investigating doctor was made the part of the WhatsApp group. To ensure that the sanctity of the group is maintained, it was decided in the protocol that the patient who will send inappropriate messages on the WhatsApp group will be removed from the group.

All the patients (both intervention and sham WhatsApp group patients) were asked to be online every Sunday between 5 pm to 6pm and were encouraged to participate actively in the group discussion on WhatsApp group. The patients were reminded to

participate in the group discussion a day prior as well as 4 hours prior to the group discussion time.

Every Sunday at 5pm, a greeting message was sent to both the WhatsApp groups "Type 1 diabetes I" and "Type 1 diabetes S" asking them about their general well-being and participation by the group members were encouraged. Few examples of the messages being:

- नमस्ते, कैसे है आप सबः
- मुझे आशा है की आप सब अपना ध्यान रख रहे हैं और इंसुलिन टाइम पर ले रहे हैं ।
- ये ग्रुप आप सब के लिए है, तो आप सब एक दूसरे से बात कर सकते हैं।

These greeting messages were sent to both the WhatsApp groups: Intervention and Sham. So, from the enrollment till this greeting on WhatsApp, both intervention and sham WhatsApp group patients were interacted with in a similar manner. It was after this greeting step that the "intervention" was begun in the Intervention group while in the Sham group, if there were any questions asked specifically to the doctor, they were answered, and otherwise patients were left to interact on their own with no extra effort made after the initial greeting messages to encourage interaction.

In the "Intervention" group, patients were encouraged to interact as much as possible with the doctor as well as with the other members of the group. They were encouraged to ask questions and doubts regarding diabetes and discuss the difficulties they face with diabetes and share their experiences. The focus of the discussions was to discuss one topic each week. The topic to be discussed was usually decided by the questions asked by the members. For example, if a patient asked that "डॉक्टर कल मेरा शुगर 50 तक कम हो गया था और मैंने चॉकलेट खाई, क्या यह सही था?" So, in that day's

discussion, hypoglycemia was discussed for example covering the following headings:

- शुगर कम होने को हाइपोग्लाइसीमिया कहते हैं
- आप में से कोई बताएगा की कितनी शुगर कम को हाइपो कहेंगे?
- आप में से कितने लोगों की शुगर कम हुई है?
- शुगर कम होने की क्या कारण होते हैं?
- शुगर कम होने के आपको क्या लक्षण आए थे?
- अगर आपकी शुगर कभी 70 से कम हो जाए तो आपको क्या करना चाहिए?
- अगर आप शुगर कम होने से बेहोश हो गए तो क्या करना चाहिए?

(English Translation: Glucose Can anyone tell below what glucose level will we label as hypoglycemia? How many of you have had low glucose readings? What are the reasons of low glucose readings? What symptoms did you have when you had low glucose readings? What should you do when your glucose level falls less than 70? What will you do if you get unconscious due to hypoglycemia?)

All efforts were made to provide maximum information to the patients and at the same time to make the discussion more interactive and patient centric. Practical aspects of diabetes management were stressed upon more.

Patients were also encouraged to do calorie and carbohydrate counting. For example: आप सबने कल जो खाना खाया उसे में चेक किया की कितना कार्बोहाइड्रेट/ कैलोरी है? (Did you check the carbohydrates and calories of the food you ate today?)

So, with patients queries and their day to day difficulties in mind, the group discussions were conducted over a period of 1 hour (every Sunday 5 to 6 pm) trying to deal with one problem area each week encouraging maximum patient participation.

Thus, the topics discussed during this weekly 1 hour group discussion cum education session of the intervention group included:

1. INTRODUCTION TO DIABETES
   a. What is diabetes?
   b. Types of Diabetes?
   c. Symptoms of diabetes/ poor glycemic control?
   d. Treatment of diabetes :
      - Type 1 DM: insulin
      - Type 2 DM: Life style, Oral agents , Insulin
      - GDM: Life style, insulin, oral
   e. Importance of support groups in diabetes
2. INSULIN
   a. Types of insulin available
      - Concept of Basal & bolus insulin
      - Rapid, short, intermediate, long acting: with examples & common brand names
      - Onset & duration of action
      - Premix insulin vs Basal bolus: Advantages & disadvantages
   b. Insulin delivery devices:
      - Syringe/ pen/ Pump: with demonstration
      - Advantages & disadvantage & precaution with each delivery device
      - Mixing of insulin
   c. Sites of insulin injection & technique demonstration
   d. Insulin storage
   e. Needle change & Cartridge (pen) change demonstration with priming for 1st inj.
3. DIET & DIABETES:
   a. Components of diet & examples
      - Carbohydrate/protein/fat/fiber
   b. Concept of glycemic index & glycemic load
      - Examples of low, medium & high GI foods

  c. Carbohydrate counting

    • Food exchange list

    • Insulin carbohydrate ratio (ICR)

  d. Plate method

4. HYPOGLYCEMIA:

  a. Definition

  b. What are the causes of hypoglycemia?

  c. Symptoms: initial & subsequent?

  d. Treatment & immediate monitoring

    • Oral glucose/ Glucagon

    • When to visit doctor?

    • What to do if found unconscious?

  e. Prevention

  f. HypoKIT & diabetes identification card

5. MONITORING IN DIABETES:

  a. SMBG (Self-monitoring of blood glucose)

    • Timings

    • Where to prick & why?

    • Concept of after dinner & 3am monitoring

    • While purchasing Glucometer/ strips: Cost of strips vs glucometer, technology, memory, desiccant

  b. Role of HbA1c

  c. Glycemic targets

  d. Continuous glucose monitoring

    • Types & cost

    • Advantages

    • Concept of Artificial pancreas

6. EXERCISE & TRAVEL

  a. What exercises: aerobic vs anaerobic with examples

  b. Timing & duration of exercise

  c. Effect of exercise on glucose & risk of delayed hypoglycemia

  d. Precautions while exercise:

- When not to exercise: SMBG/ ketone / sick day

- Insulin injection site

- Guidance on carbohydrate intake before/during/after exercise as per SMBG

    e. Travel:

- Things to be carried while travelling: kit

- Precautions while long distance travelling: cold chain

- Air travel

7. SICK DAY GUIDELINES

    a. Precaution to be followed during sick day

- Extra insulin & dose

- Monitoring: SMBG frequency

- Diet/ fluid/ rest/ medications

    b. Ketones

- When to check: causes & Symptoms of DKA?

- Home based ketone monitoring: Urine/ serum: How to check?

- Home based management

    c. When to go to hospital?

8. COMPLICATIONS OF DIABETES

    a. Basic symptoms, prevention, screening and management of complications of:

- Eyes

- Kidney

- Nervous system

- Blood circulation

- Foot

- Wound care/infection

The details of the various aspects and modules of diabetes education discussed during WhatsApp diabetes education session of the intervention group is given in Annexure 5.

FOLLOW UP

So, for all the patients in the Intervention WhatsApp group, this WhatsApp diabetes education session was conducted for a minimum of 28 weeks. The patients who completed their 28 weeks (as per their date of enrollment) follow up continued to be a part of the WhatsApp group till the last enrolled patient completed the 28 weeks follow up i.e. till 7th September 2021.

Patients were called for follow up at 4, 16 and 28 weeks after enrollment. 4 weeks follow up was just a routine OPD visit to ensure compliance and it was made optional during the peak COVID pandemic and telemedicine consultation was done for those patients who could not come for physical OPD follow up. At 16 week and 28 weeks, HbA1c was done and patients were asked to fill the questionnaires regarding the knowledge, coping skills and quality of life. To ensure uniformity, and to ensure that the sham and control group are not deprived of diabetes education, we conducted offline diabetes education after the questionnaires were filled at 16 and 28 weeks also. The offline education during the follow up like the baseline session was through a structured power point presentation with no discrimination between the 3 groups during the offline sessions. The following patients were excluded from analysis:

- Patients who remained inactive on WhatsApp group for > 4weeks in continuation
- Patients who were absent on >1 offline visit
- Patients with > 1 hospitalization in study period due to diabetic ketoacidosis
- Patients removed from the WhatsApp group in view of sending inappropriate message on WhatsApp group

SAMPLE SIZE

While planning the study protocol, we could not calculate the exact sample size as we did not have any other similar randomized trial to provide us the required data for sample size calculation. We had planned to enroll at least 90 patients as we had approximately 140 Type 1 diabetes patients under our OPD follow up and thus we had expected to enroll 2/3rd of them. We had planned to enroll 30 patients in each group i.e. WhatsApp intervention, WhatsApp Sham and control group without WhatsApp but finally we could enroll 66 patients (28 each in WhatsApp Intervention and Sham group and 10 in the control group).

LAB ANALYSIS

HbA1c determination was done with the Bio-Rad VARIANT II Hemoglobin A1c program using ion exchange high performance liquid chromatography (HPLC) by measuring change in absorbance at 415 nm followed by an additional filter at 690 nm for correction for background absorbance. The results were traceable to the reference methods of both the NGSP and IFCC, with the reportable range for HbA1c for the assay being 3.1-18.5%. Precision parameters provided by the manufacturer in a normal patient included a within-run, between-run and between-day CV of 0.9%, 0.64% and 1.15% respectively. Similarly, in diabetic patients, the parameters were 0.59%, 0.46% and 1.15% respectively.

STATISTICAL ANALYSIS:

Mixed Model Repeated Measures (MMRM) was used for analysis of primary and secondary end points. Wilcoxon Sign rank test was used for parameters not included in primary and secondary end points.

RESULTS

The study was conducted in Department of Endocrinology, AIIMS Jodhpur. Total 103 patients were screened for enrollment into the trial. The study flow is shown in figure 1. The month wise distribution of patient enrollment is shown in Table 1. The reason for exclusion of 37 patients in enumerated in Table 2.

STUDY ENROLLMENT:

The study received ethical approval on 1st Jan 2020 and we started our enrollment on 22nd June 2020 and the last patient enrolled was on 10th February 2021. We had to stop our enrollment on 10th February 2021 as we had to do a 28 week follow up and since it was a time bound study and had to be submitted before 31st December 2021, we wanted our follow up to be complete on 10th September 2021 ±7 days, so that the analysis and thesis writing could be completed on time. So, we enrolled the patients over this period of approximately 7.5 months (22nd June 2020 to 10th Feb 2021) who satisfied our enrollment criteria (consent, inclusion and exclusion criteria). We were planning to enroll 90 patients (30 each in WhatsApp Intervention, WhatsApp Sham and Control group), but the numbers of patients enrolled were less than expectation as because of the COVID peak during the enrollment period, the OPD visits were limited. So, finally we could enroll 28 patients each in WhatsApp intervention and WhatsApp sham group and 10 patients in the control group, thus enrolling only 66 patients. The number of patients in the control group was less as mobile phone use has become so common in our country and because of the reduced cost of smartphones and easy availability of internet facilities; most of the Type 1 diabetic patients had their personal mobile phones with WhatsApp. So, only 10 Type 1 diabetes patients who did not have a personal mobile phone with internet and WhatsApp could be included in the control group.

Figure 1: STUDY FLOW CHART

TOTAL TYPE 1 DIABETES SCREENED
(n=103)

INCLUSION CRITERIA
- Age 15 to 40 years
- Personal mobile phone with internet access & knows how to read messages

CONTROL GROUP (n=10)
- AGE 15-40 Years
- Without a smart phone /does not know how to use WhatsApp

EXCLUSION CRITERIA
- LADA (n=18)
- Not willing for follow up (n= 7)
- Pregnancy (n=5)
- Mental illness (n=2)
- Refused consent (n=2)
- Visual impairment (n=1)
- 1st or 2nd degree relative already included in same trial (n=1)

TOTAL RANDOMIZED
(n=56)

WHATSAPP INTERVENTION GROUP
Educational messages weekly
(n= 28)

WHATSAPP SHAM GROUP
Greeting messages week.
(n=28)

WEEK 0
Baseline investigations including HbA1c
Questionnaires (knowledge test, CODI, DQOL)

WEEK 4
Routine OPD visit

WEEK 16 & WEEK 28
HbA1c
Questionnaires (knowledge test, CODI, DQOL)

LOST TO FOLLOW UP (N=2)

LOST TO FOLLOW UP (N=7)

LOST TO FOLLOW UP (N=5)
EXPIRY (N=1)

FINAL ANALYZED CONTROL GROUP (n=8)

FINAL ANALYZED WHATSAPP INTERVENTION GROUP (n=21)

FINAL ANALYZED SHAM WHATSAPP GROUP (n=22)

37

Table 1: Number of patients enrolled month wise:

MONTH OF ENROLLMENT	NUMBER OF PATIENTS ENROLLED
June 2020	5
July 2020	13
August 2020	13
September 2020	6
October 2020	3
November 2020	2
December 2020	`12
January 2021	5
February 2021	7

Table 2: Reason for exclusion

REASON FOR EXCLUSION	NUMBER OF PATIENTS (N=37)
Suspected LADA	18
Not willing for follow up (Residence > 200 km away)	7
Pregnancy	5
Mental illness	2
1st or 2nd degree relative already included in same trial	2
Refused consent	2
Visual impairment	1

WHATSAPP INTERVENTION:

While enrolling the patients, they were asked regarding their preferred language for interaction in the WhatsApp group. 54 out of 56 patients preferred Hindi and knew how to read messages written in Hindi language. Six out of the 54 patients who preferred Hindi language (Three each in WhatsApp Intervention and Sham group) although could read messages typed in Hindi but were not well versed in typing either Hindi or Hindi with English alphabets. So, they preferred sending voice messages for asking their queries or for responding to the group. Two out of the 56 patients in the WhatsApp group preferred English. One of these two patients who preferred English, was well versed with both Hindi and English and could read and write both Hindi and English. The other patient who preferred English (in the Intervention group) could understand and read Hindi but was not comfortable in typing either Hindi or Hindi

with English alphabets. So, he sent messages in English to the group which were converted by the investigators to Hindi for the better understanding of the other group members and replies were sent to him in both English and Hindi (so that the other group members could also benefit from the conversation). So, all the messages were typed in Hindi during the 1 hour group discussion.

FOLLOW UP:

Out of total 66 enrolled patients, only 30 patients (45 %) could visit our hospital for follow up at 16 week after enrollment and only 44 patients (66 %) at 28 weeks. So, we have the follow up questionnaires of CODI and DQOL only for these patients. Since, our primary objective was to see change in HbA1c which was used as a marker of glycemic control, at 16 and 28 weeks, for those patients who were not able to visit our hospital due to COVID related reasons, we asked to get the HbA1c tested from a lab near to their residence. So, finally we have HbA1c data of 50 out of 66 enrolled patients (75.7%) at 28 weeks and 31 patients at 16 weeks. The most common reason for inability to come for follow up visit was travel restrictions due to COVID lockdown. COVID led to restriction of patient movement and unavailability of public transport during the lock down. Thus out of 36 patients who could not come for follow up at 16 week, 24 patients were actually willing to come for follow up but could not due to the travel restrictions. Similarly, 14 out of 22 patients were willing to come at 28 weeks follow up but could not. Moreover, five patients did not visit the nearby lab for getting their Hba1c checked and neither called the lab personnel for home collection due to the fear of contacting COVID by visiting the lab or through lab personnel. The other reasons for lost to follow up include:

- Two patients shifted to alternate medications (Naturopathy and Ayurveda) and stopped insulin and thus refused to come for follow up.

- One patient had a dispute with her husband who refused to bring the patient to hospital for follow up and one patient's husband got transferred to Chandigarh (approx 800 km away)

- One patient was fearful of blood sampling and felt that too many tests are being done in the hospital, and he doesn't want to give his blood sample and thus preferred treatment from the local doctor.

- Two patients shifted to their village almost 300km away due to lack of employment in Jodhpur and thus refused to come for follow up visit.

- Two patients of the Intervention group said that they don't want to come for OPD follow up and if they will need an advice or dose adjustment, they will discuss the same on WhatsApp group only.

- One patient due to unknown reasons after enrollment into WhatsApp group remained inactive for 3 weeks, did not answer any phone calls and then exited from the group.

To ensure that the sanctity of the group is maintained, it was decided in the protocol that the patient who will send inappropriate messages on the WhatsApp group will be removed from the group. But, none of the patients had to be removed from the group because of the above reason. One patient in the Intervention group exited from the WhatsApp group on own after 3rd discussion week. He came for OPD follow up 2 days after exiting the group and told that he impulsively exited from the group due to stress when he came to know the possible complications which can occur in Type 1

diabetes. He was counselled and even a formal psychiatric consultation was sought.

He himself requested for re-addition to the group after 2 days.

BASELINE CHARACTERISTICS:

The baseline characteristics of the total 66 patients are shown in Table 3 and in

figures 2 to 8.

Table 3: CHARACTERISTICS OF THE STUDY SUBJECTS

PARAMETER	MEAN ±SD (Range) (N=66)
Age (Years)	24.5 ± 7.1 (15 – 40 years)
Gender: Male/Female	41 (62.1%)/25 (37.9%)
Age Of Onset (Years)	16.8 ± 6.1 (6 – 33)
Duration Of Diabetes (Years)	7.68 ± 5.89
C-Peptide (ng/ml)	0.11 ± 0.18 (0.01 - 0.90)
Marital Status : Married	33 (50.0%)
Weight (kg)	52.58 ± 11.09 (24 - 81.60)
Height (cm)	161.14 ± 9.69 (140.00 – 182)
BMI (Kg/m²)	20.16 ± 3.53 (12.24 - 31.33)
Years Of WhatsApp Use	2.46 ± 1.90 (0- 8)
Insulin Storage: Fridge	61 (92.4%)
Insulin Storage: Others	5 (7.6%)
Monthly Income Per Capita (Rupees)	9060.61 ± 6385.40 (1500 – 35000)
Complications	
Retinopathy	17 (26.6%)
Neuropathy	24 (36.4%)
Nephropathy	10 (15.2%)
Infection	8 (12.1%)
Hypertension	12 (18.2%)
Hypothyroidism	10 (15.2%)
Vitamin D Deficiency	22 (33.3%)
Insulin Dose Total (units)	42.74 ± 14.20 (16 – 76)
Insulin Dose (units Per Kg)	0.84 ± 0.29 (0.30 - 1.54)

Distribution of Age

Legend:
- ≤20 Years
- 21-30 Years
- 31-40 Years

21%

36%

42%
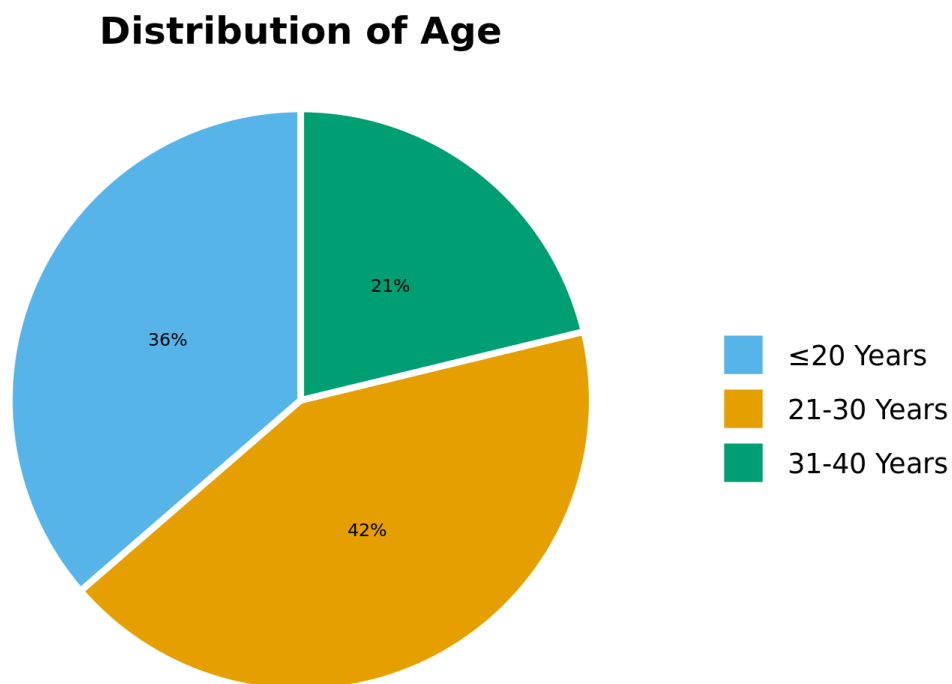
Distribution of Highest Education

Legend:
- Primary
- Tenth
- Twelfth
- Graduate
- Postgraduate

11%

33%

17%

15%

24%
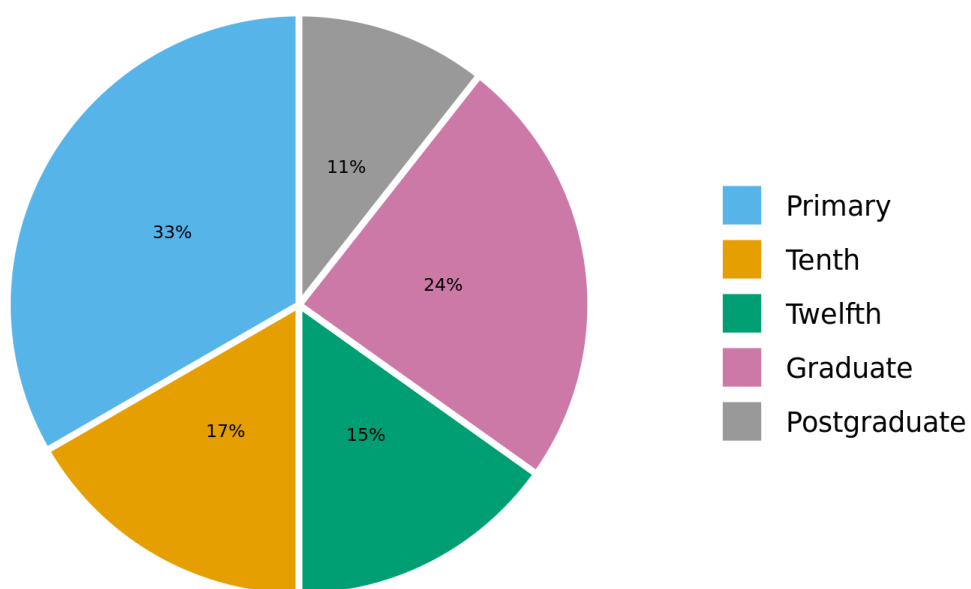
Figure 4:

Distribution of Occupation

- None
- Student
- Working

36%
35%
29%
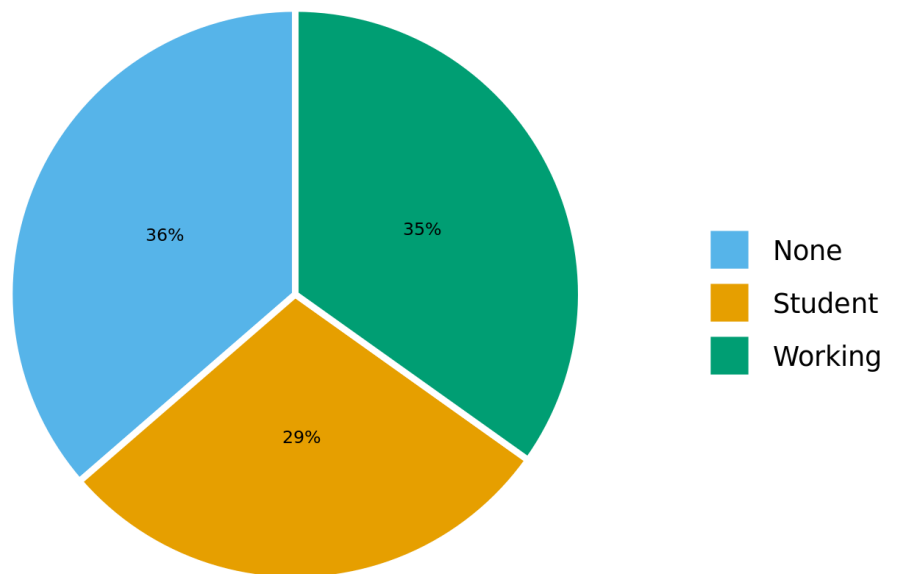
Figure 5:

Distribution of Duration Of Diabetes

- <1 Year
- 1-5 Years
- 6-10 Years
- >10 Years

12%
29%
33%
26%
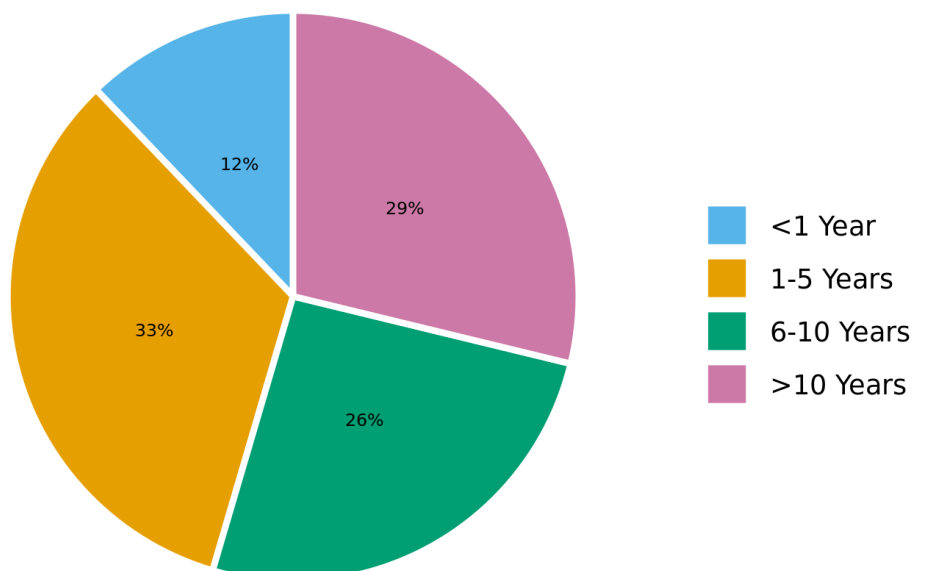
Figure 6:

Distribution of BMI

Legend:
- <18.5 Kg/m2
- 18.5-22.9 Kg/m2
- 23.0-24.9 Kg/m2
- 25.0-29.9 Kg/m2
- 30.0-34.9 Kg/m2

Values: 2%, 9%, 38%, 8%, 44%
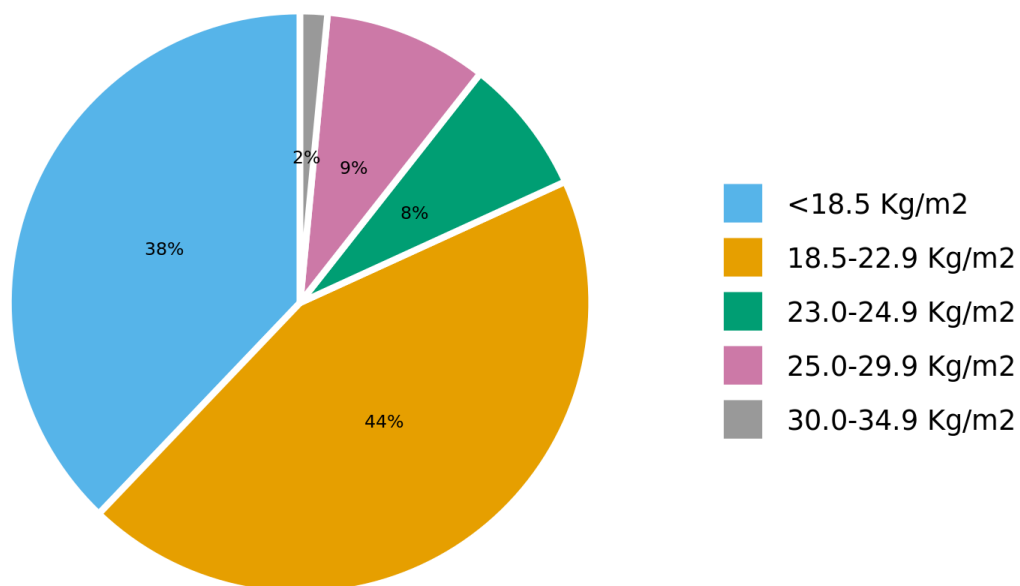
Figure 7:

Distribution of Insulin Regimen

Legend:
- Basal Bolus
- Premix
- Split Mix

Values: 11%, 22%, 68%

Figure 8:

Distribution of Hypoglycemia Episodes In Last 1 Year Prior To Enrollment
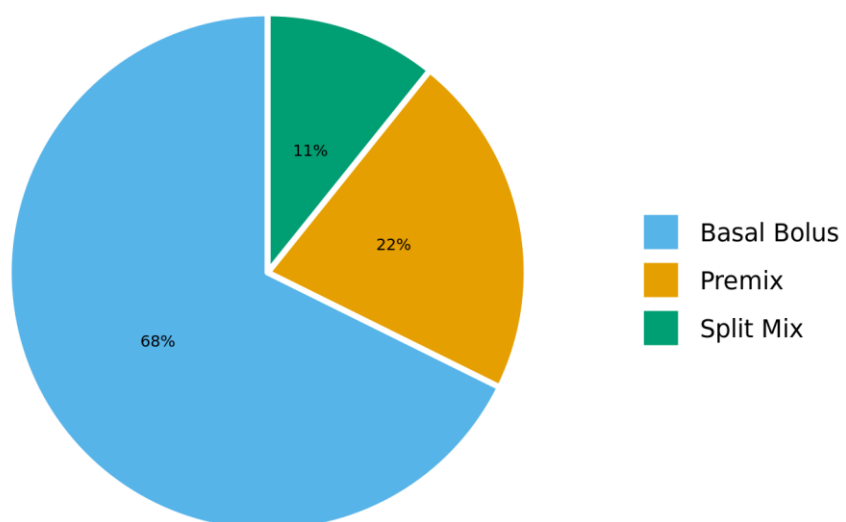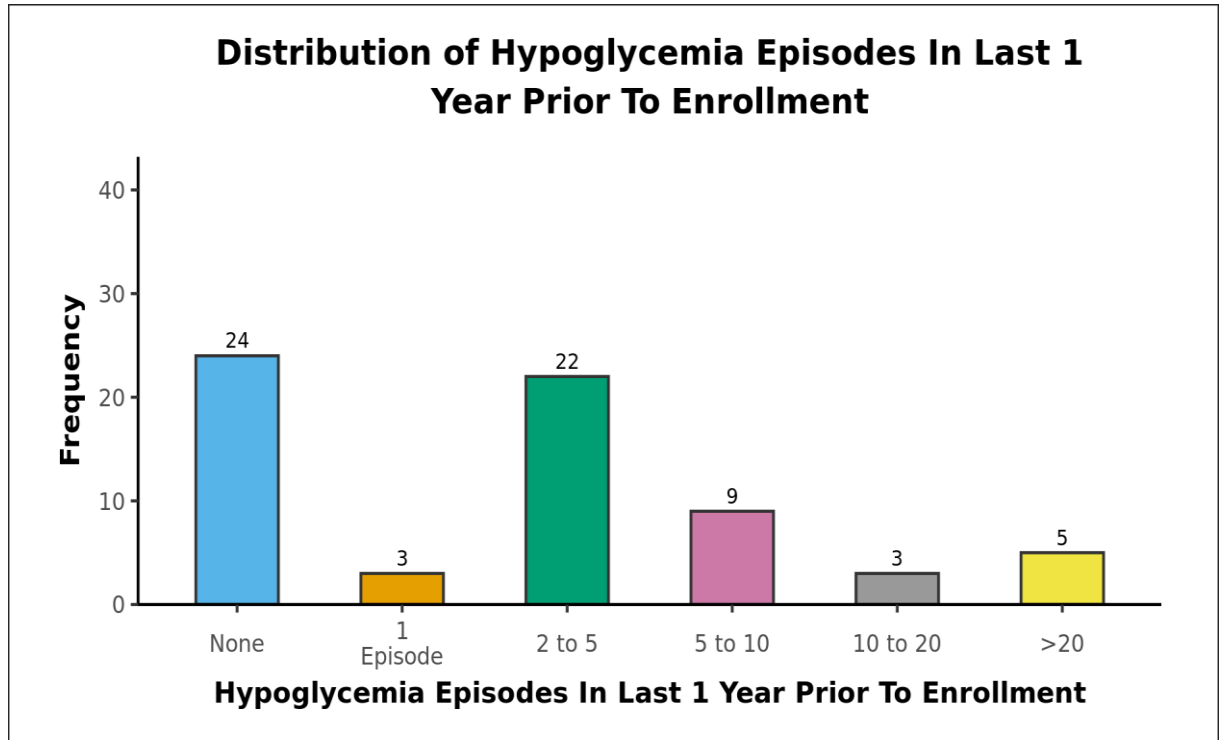
Table 4: BASELINE CHARACTERISTICS OF INTERVENTION VERSUS SHAM WHATSAPP GROUP

PARAMETER	INTERVENTION N=28 MEAN ±SD	SHAM N=28 MEAN ±SD
Age (Years)	24.75 ± 7.49	23.86 ± 6.35
Age		
≤20 Years	10 (35.7%)	11 (39.3%)
21-30 Years	13 (46.4%)	12 (42.9%)
31-40 Years	5 (17.9%)	5 (17.9%)
Gender		
Male	17 (60.7%)	19 (67.9%)
Female	11 (39.3%)	9 (32.1%)
Age Of Onset (Years)	16.91 ± 6.21	15.14 ± 4.87
Duration Of Diabetes (Years)	7.74 ± 6.39	8.69 ± 5.51
Duration Of Diabetes		
<1 Year	4 (14.3%)	1 (3.6%)
1-5 Years	9 (32.1%)	9 (32.1%)
6-10 Years	6 (21.4%)	9 (32.1%)
>10 Years	9 (32.1%)	9 (32.1%)
C-Peptide	0.11 ± 0.17	0.10 ± 0.20
Occupation		
None	10 (35.7%)	9 (32.1%)
Student	10 (35.7%)	8 (28.6%)
Working	8 (28.6%)	11 (39.3%)
Marital Status (Yes)	13 (46.4%)	12 (42.9%)
Highest Education		
Primary	4 (14.3%)	9 (32.1%)
Tenth	4 (14.3%)	6 (21.4%)
Twelfth	5 (17.9%)	5 (17.9%)
Graduate	10 (35.7%)	6 (21.4%)
Postgraduate	5 (17.9%)	2 (7.1%)
Weight (kg)	52.60 ± 10.43	53.81 ± 12.09
Height (cm)	159.42 ± 8.97	163.40 ± 9.61
BMI (Kg/m²)	20.70 ± 3.93	19.96 ± 3.04
BMI		
<18.5 Kg/m2	10 (35.7%)	11 (39.3%)
18.5-22.9 Kg/m2	12 (42.9%)	12 (42.9%)
23.0-24.9 Kg/m2	1 (3.6%)	3 (10.7%)
25.0-29.9 Kg/m2	4 (14.3%)	2 (7.1%)
30.0-34.9 Kg/m2	1 (3.6%)	0 (0.0%)

PARAMETER	INTERVENTION N=28 MEAN ±SD	SHAM N=28 MEAN ±SD
Years Of WhatsApp Use	2.84 ± 1.70	2.96 ± 1.78
Hypoglycemia Episodes In Last 1 Year		
None	10 (35.7%)	9 (32.1%)
<5	11 (39.3%)	10 (35.7%)
>5	7 (25.0%)	9 (32.1%)
Insulin Storage		
Fridge	26 (92.9%)	28 (100.0%)
Others	2 (7.1%)	0 (0.0%)
Monthly Income Per Capita	10432.14 ± 6578.60	9175.00 ± 6668.65
Retinopathy	8 (30.8%)	7 (25.0%)
Neuropathy	13 (46.4%)	9 (32.1%)
Nephropathy	3 (10.7%)	5 (17.9%)
Infection	2 (7.1%)	4 (14.3%)
Hypertension	6 (21.4%)	5 (17.9%)
Hypothyroidism	6 (21.4%)	4 (14.3%)
Vitamin D Deficiency	8 (28.6%)	10 (35.7%)
Insulin Regimen		
Basal Bolus	21 (75.0%)	16 (59.3%)
Premix	5 (17.9%)	8 (29.6%)
Split Mix	2 (7.1%)	3 (11.1%)
Insulin Dose Total	40.18 ± 13.49	44.61 ± 14.29
Insulin Dose Per Kg	0.77 ± 0.23	0.87 ± 0.35

Table 5: BASELINE CHARACTERISTICS OF TRIAL WHATSAPP GROUP

(INTERVENTION plus SHAM) versus CONTROL group

PARAMETER	TRIAL GROUP N=56 MEAN ±SD	CONTROL GROUP N=10 MEAN ±SD
Age (Years)	24.30 ± 6.89	25.60 ± 8.33
Age		
≤20 Years	21 (37.5%)	3 (30.0%)
21-30 Years	25 (44.6%)	3 (30.0%)
31-40 Years	10 (17.9%)	4 (40.0%)
Gender		
Male	36 (64.3%)	5 (50.0%)
Female	20 (35.7%)	5 (50.0%)
Age Of Onset (Years)	16.03 ± 5.60	20.85 ± 7.33
Duration Of Diabetes (Years)	8.22 ± 5.93	4.68 ± 4.86
Duration Of Diabetes		
<1 Year	5 (8.9%)	3 (30.0%)
1-5 Years	18 (32.1%)	4 (40.0%)
6-10 Years	15 (26.8%)	2 (20.0%)
>10 Years	18 (32.1%)	1 (10.0%)
C-Peptide	0.11 ± 0.19	0.13 ± 0.15
Occupation		
None	19 (33.9%)	5 (50.0%)
Student	18 (32.1%)	1 (10.0%)
Working	19 (33.9%)	4 (40.0%)
Marital Status (Yes)	25 (44.6%)	8 (80.0%)
Highest Education		
Primary	13 (23.2%)	9 (90.0%)
Tenth	10 (17.9%)	1 (10.0%)
Twelfth	10 (17.9%)	0 (0.0%)
Graduate	16 (28.6%)	0 (0.0%)
Postgraduate	7 (12.5%)	0 (0.0%)
Weight (kg)	53.20 ± 11.20	49.08 ± 10.26
Height (cm)	161.41 ± 9.43	159.67 ± 11.51
BMI (Kg/m²)	20.33 ± 3.50	19.18 ± 3.67
BMI		
<18.5 Kg/m2	21 (37.5%)	4 (40.0%)
18.5-22.9 Kg/m2	24 (42.9%)	5 (50.0%)
23.0-24.9 Kg/m2	4 (7.1%)	1 (10.0%)
25.0-29.9 Kg/m2	6 (10.7%)	0 (0.0%)
30.0-34.9 Kg/m2	1 (1.8%)	0 (0.0%)

PARAMETER	TRIAL GROUP N=56 MEAN ±SD	CONTROL GROUP N=10 MEAN ±SD
Insulin Storage		
Fridge	54 (96.4%)	7 (70.0%)
Others	2 (3.6%)	3 (30.0%)
Monthly Income Per Capita	9803.57 ± 6593.86	4900.00 ± 2469.82
Retinopathy	15 (27.8%)	2 (20.0%)
Neuropathy	22 (39.3%)	2 (20.0%)
Nephropathy	8 (14.3%)	2 (20.0%)
Infection	6 (10.7%)	2 (20.0%)
Hypertension	11 (19.6%)	1 (10.0%)
Hypothyroidism	10 (17.9%)	0 (0.0%)
Vitamin D Deficiency	18 (32.1%)	4 (40.0%)
Insulin Regimen		
Basal Bolus	37 (67.3%)	7 (70.0%)
Premix	13 (23.6%)	1 (10.0%)
Split Mix	5 (9.1%)	2 (20.0%)
Insulin Dose Total	42.39 ± 13.95	44.70 ± 16.19
Insulin Dose Per Kg	0.82 ± 0.30	0.90 ± 0.24

PRIMARY OBJECTIVE: HbA1c CHANGE

The primary objective of our study was the effect of WhatsApp based diabetes education and instructions on glycemic status of patients of Type 1 Diabetes Mellitus patients. HbA1c was used as a marker of glycemic control in our study which was done at baseline, 16 weeks and 28 weeks.

Intervention WhatsApp group versus Sham WhatsApp group:

As shown in Table 6, there was a decline in HbA1c from the baseline in both the Intervention and Sham WhatsApp group both at 16 week (9.11 ± 1.82 vs 9.13 ± 2.53, p 0.695) and 28 weeks (9.60 ± 1.5 vs 8.91 ± 1.70, p 0.262). After adjustment for baseline HbA1c also, the covariates were evaluated at HbA1c 9.60 (figure 9) and there was no significant difference between the groups in terms of HbA1c % at both 16 Weeks and 28 weeks as shown in figure 9. Thus, the difference between the 2 groups was not significant at both the time points. Actually, the HbA1c initially decreased to nadir 9.11% in the intervention group at 16 week but then again increased to 9.60 at 28 weeks while the Sham group showed a progressive decline from the baseline.

Table 6: Change in HbA1c in intervention WhatsApp group versus Sham WhatsApp group.

HbA1c	INTERVENTION MEAN ±SD	SHAM MEAN ±SD
Baseline	11.21 ± 2.49	9.54 ± 2.42
16 Weeks	9.11 ± 1.82	9.13 ± 2.53
28 Weeks	9.60 ± 1.50	8.91 ± 1.70

Figure 9:
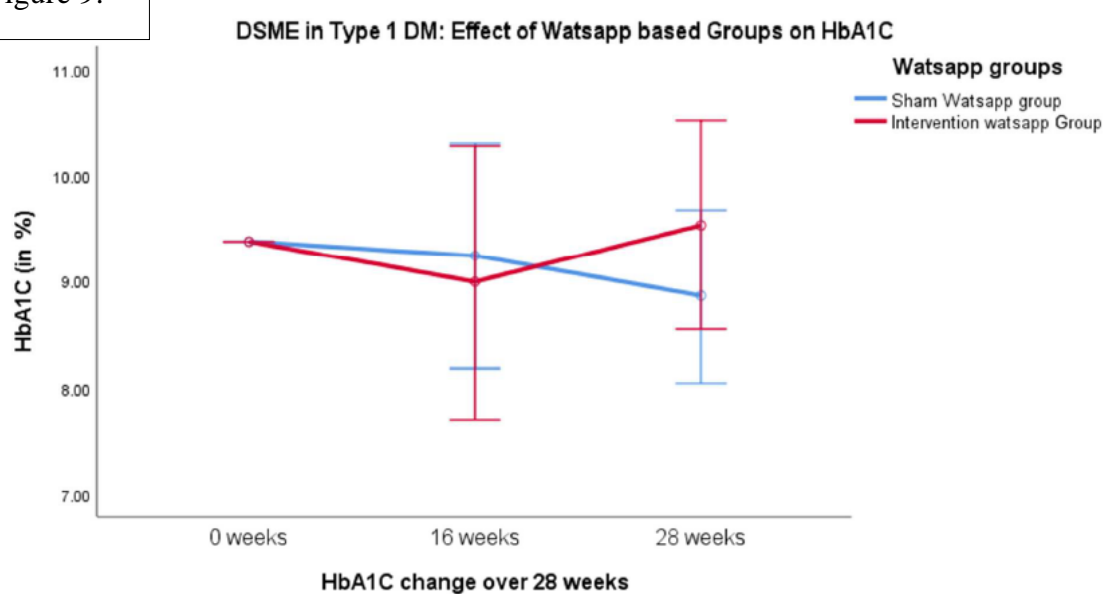
Trial WhatsApp (Intervention plus Sham) group versus Control group:

As shown in Table 7, there was a significant decrease in HbA1c from baseline in trial group as compared to Control group without WhatsApp at 16 week (9.12 ± 2.19 vs 11.40 ± 1.04, p value 0.035) and at 28 weeks (9.24±1.63 vs 11.59±2.36, p 0.007). Thus, those in Trial had statistically significant improvement in HbA1c as compared to controls.

Table 7: HbA1c in Trial WhatsApp (Intervention plus Sham) group versus Control group:

HbA1c	Trial WhatsApp group MEAN ±SD	Control group MEAN ±SD
Baseline	10.38 ± 2.57	12.42 ± 3.10
16 Weeks	9.12 ± 2.19	11.40 ± 1.04
28 Weeks	9.24 ± 1.63	11.59 ± 2.36

As shown in figure 10, to adjust for the baseline HbA1c, the covariates were evaluated at the HbA1c baseline of 10.24. The trial group showed a significant decline in HbA1c as compared to control group even after adjustment for baseline HbA1c. The Mean ±SE of trial vs control group at 28 weeks was 9.144±0.276 vs 11.668±0.731 with mean square 1.453, p value 0.003. The control group was not analyzed at 16 weeks because only 3 out of 10 patients followed up at 16 week in the control group.

Figure 10:

HbA1C comparison between trial and control subjects

Change in HbA1c (%) Over Time

53
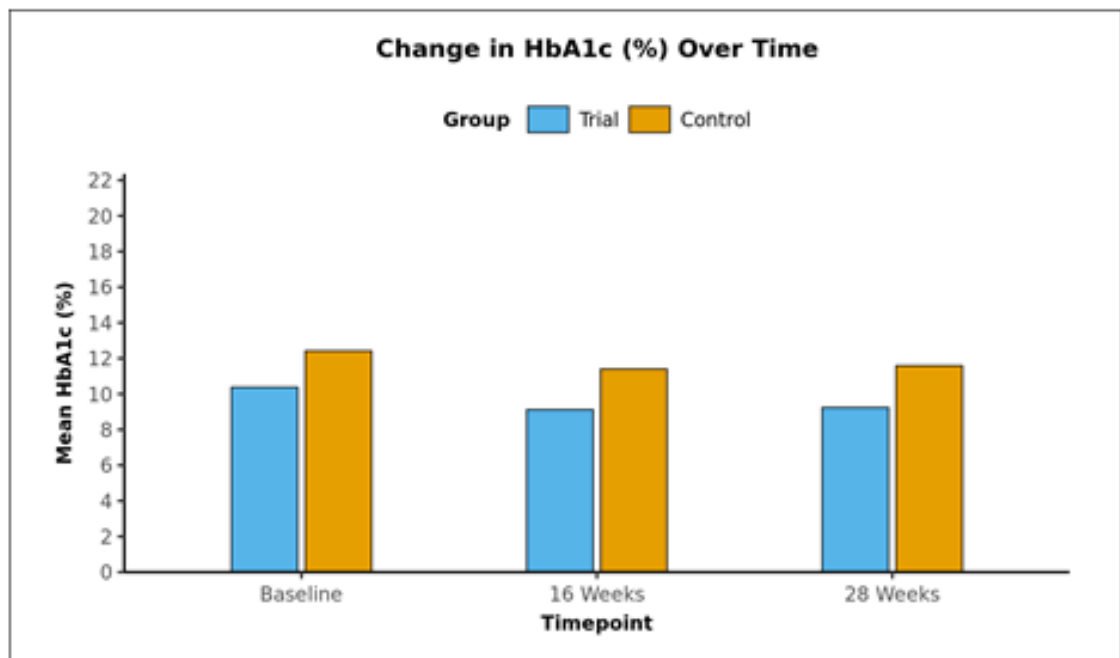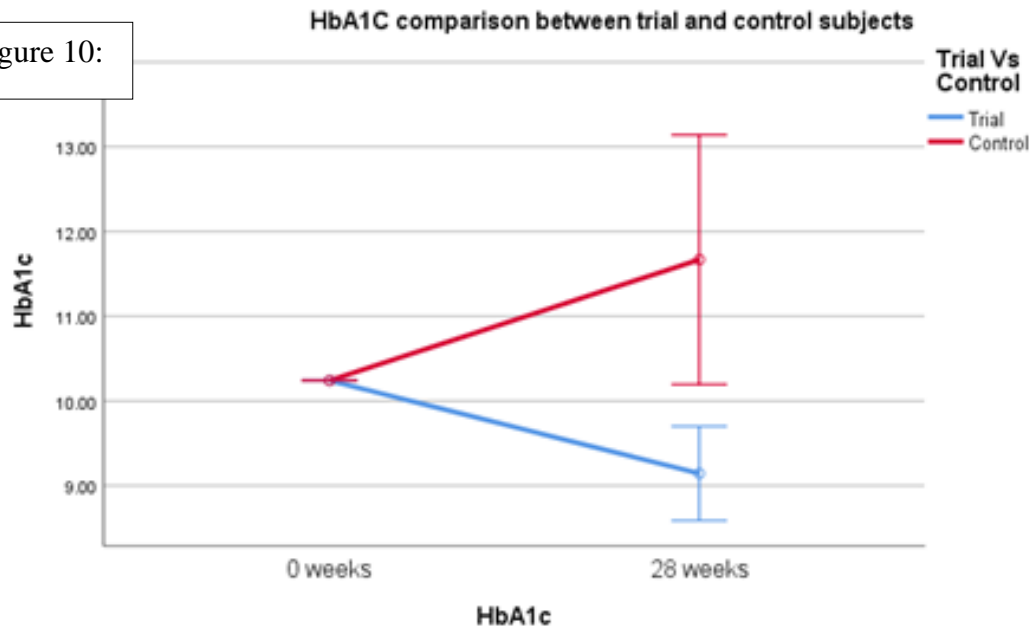
SECONDARY OBJECTIVE: CHANGE IN KNOWLEDGE:

Intervention WhatsApp group versus Sham WhatsApp group:

The knowledge of the patients was assessed in terms of 9 parameters via the Diabetes Knowledge Test questionnaire (DKT). The total maximum score was 100. Over the 28 weeks follow up period, in both the WhatsApp groups, Intervention and Sham, the total Knowledge score improved from baseline to 16 Weeks and 28 Weeks. The maximum percent change from the baseline was observed at the 28 Weeks (Table 8, Figure 11). There was a significant improvement in Intervention group in Knowledge Total score at both 16 week (68.38 ± 11.74 vs 50.67 ± 16.36, p value 0.003) and 28 weeks (68.63 ± 16.15 vs 59.28 ± 12.15 , p value 0.05) with respect to Sham group as shown.

Figure 11: Change in total knowledge in the 2 WhatsApp groups
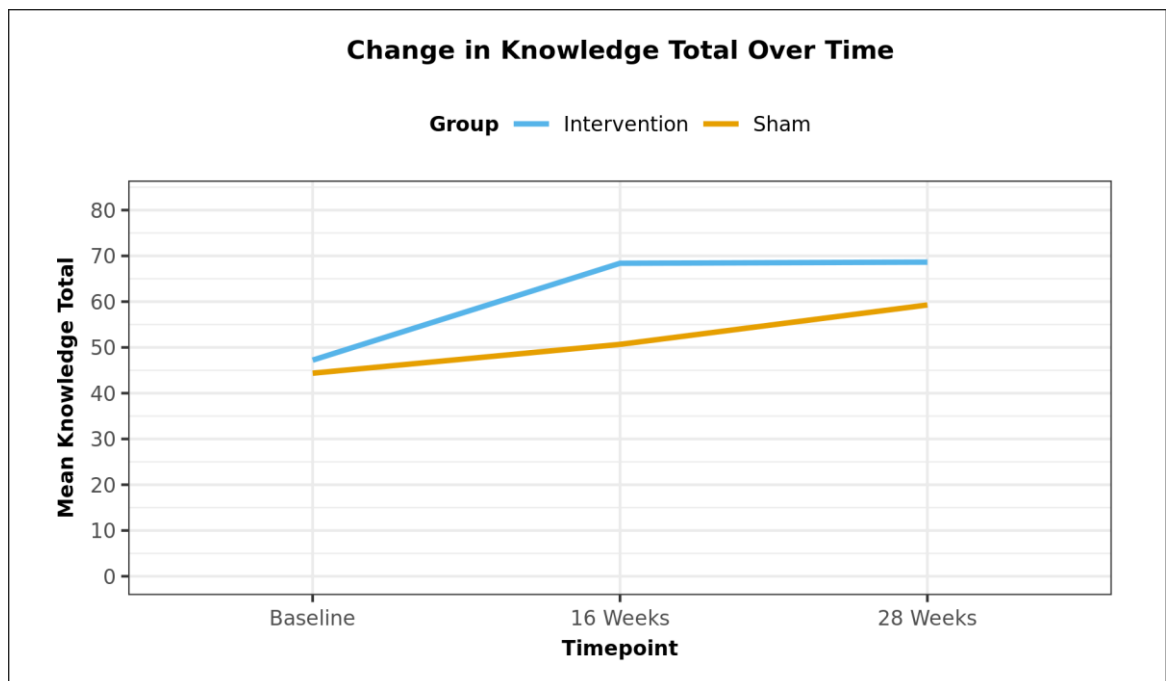
After adjusting for the baseline, the covariates were re-evaluated at baseline knowledge 49.2917 and there was a significant difference (p value 0.003) in the knowledge in the intervention group as compared to Sham WhatsApp group (Figure 12).

Figure 12:

Knowledge about DSME over the study period

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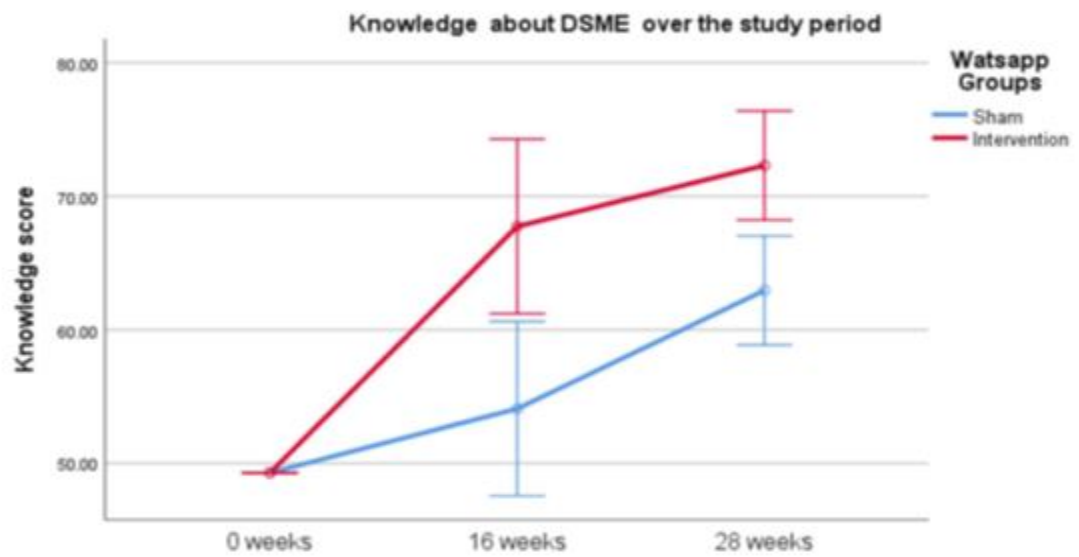
Table 8: Change in total knowledge in the 2 WhatsApp trial groups:

PARAMETER Knowledge Total (Max marks 100)	INTERVENTION MEAN ±SD	SHAM MEAN ±SD
Baseline	47.22 ± 20.66	44.37 ± 16.23
16 Weeks	68.38 ± 11.74	50.67 ± 16.36
28 Weeks	68.63 ± 16.15	59.28 ± 12.15

The knowledge of the patients was assessed in terms of 9 parameters via the Diabetes Knowledge Test questionnaire (DKT). The total maximum score was 100. The parameters assessed (with their maximum marks) were namely:

1. Knowledge regarding Insulin Type (15 marks)

2. Knowledge regarding Nutrition (20 marks)

3. Knowledge regarding Hypoglycemia (19 marks)

4. Knowledge about Self-monitoring of blood glucose (SMBG) (9 marks)

5. Knowledge regarding Exercise (11 marks)

6. Knowledge regarding Sick day management (12 marks)

7. Knowledge regarding Complications (4 marks)

8. Knowledge regarding Travel precautions (6 marks)

9. Knowledge regarding insulin dose adjustment (4 marks)

The trend in change in knowledge of all the 9 parameters are shown in figure 13.

Analysis beyond secondary objective will be considered as post hoc subgroup analysis which is not possible with this sample size. Hence, we present a graphical pattern to look at the trend but without any inferences.

Figure 13: Change in Knowledge Regarding Insulin Type Over Time
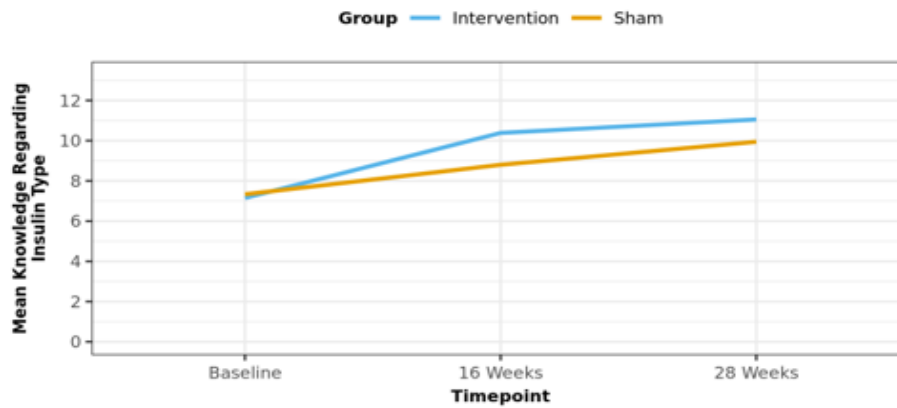
Change in Knowledge Regarding Nutrition Over Time
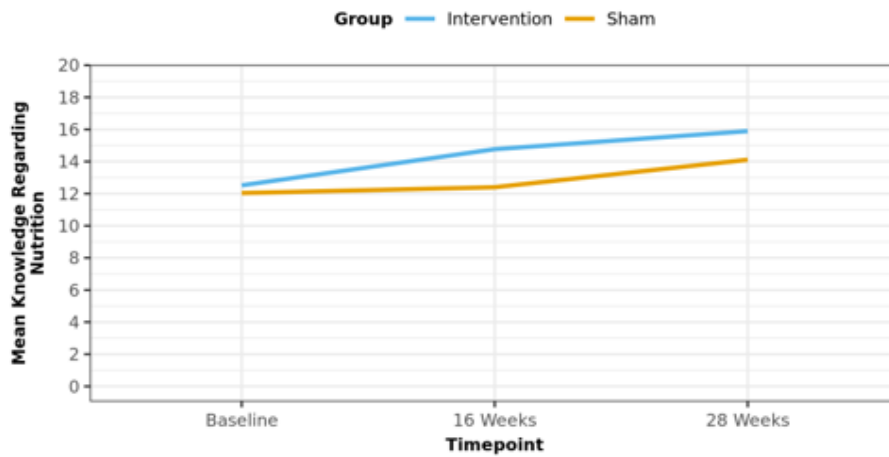
Change in Knowledge About Hypoglycemia Over Time

57

Change in Knowledge About SMBG Over Time

Change in Knowledge About Exercise Over Time

Change in Knowledge About Sick Day Over Time

Change in Knowledge Regarding Complications Over Time

Change in Knowledge Regarding Insulin Dose Adjustment Over Time

59
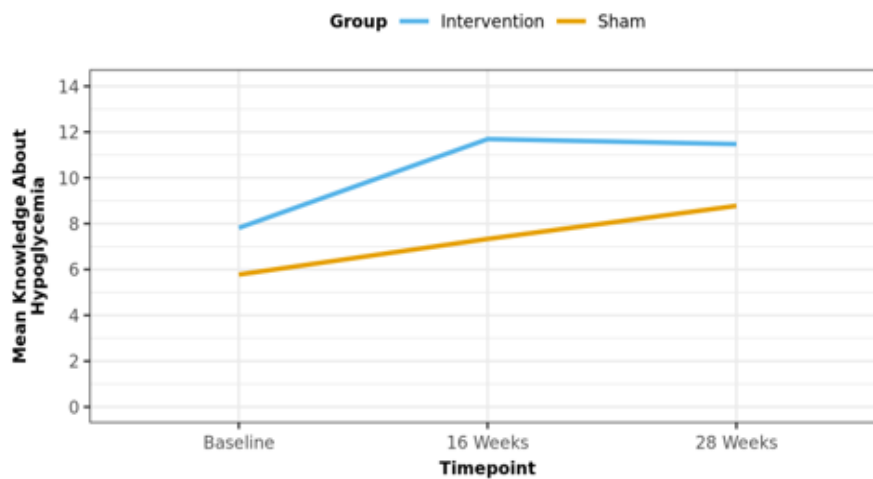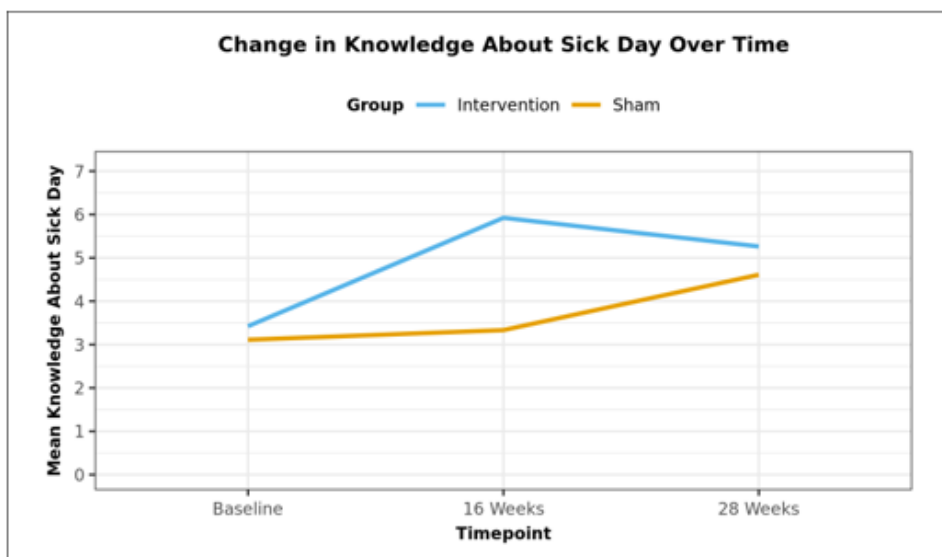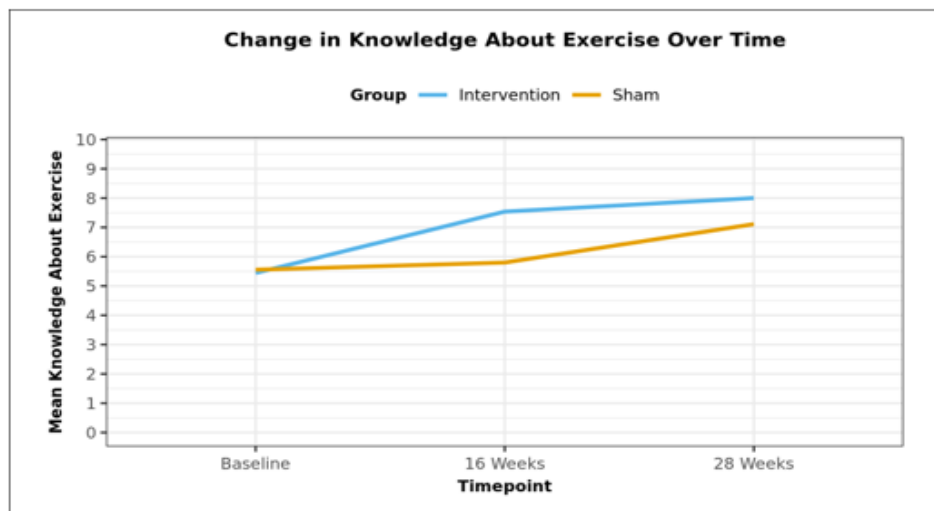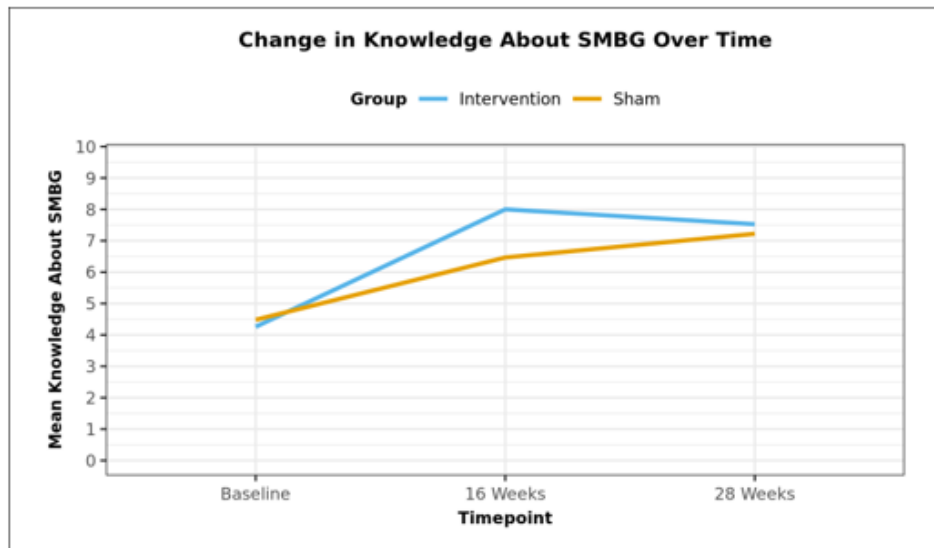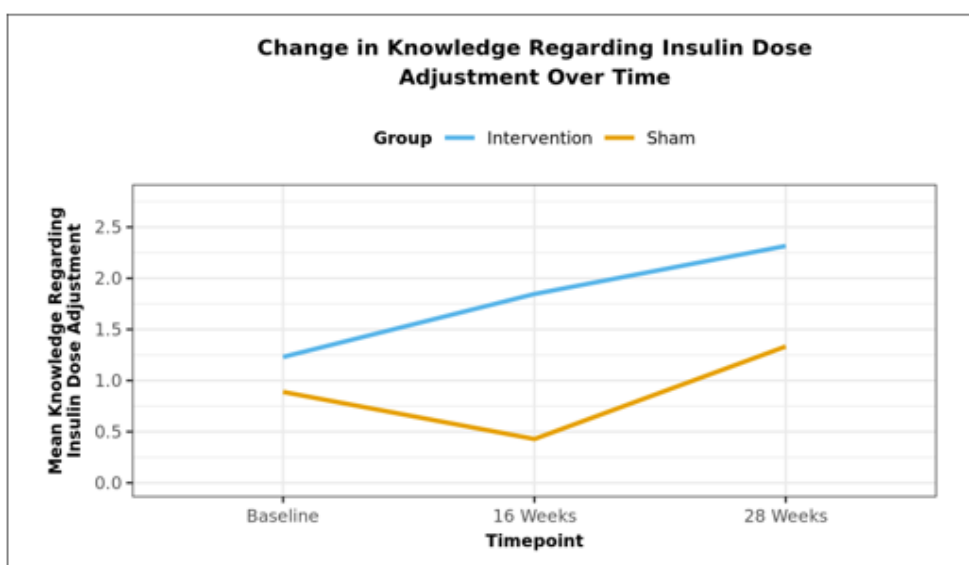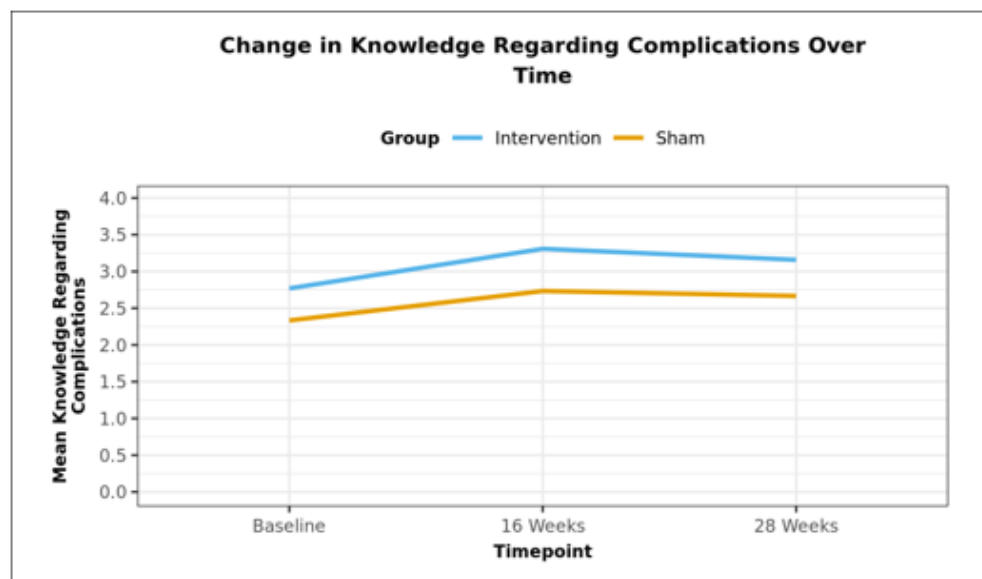
SECONDARY OBJECTIVE: Change in knowledge: Trial versus Control

The comparison of Trial group (WhatsApp intervention and Sham group) versus Control group showed that there was improvement on total knowledge in the trial group as compared to the control group at 28 weeks as shown in Table 9 and figure 14. But since the number of patients in the control group was small, the inference of the significance of difference between the two cannot be made.

Figure 14:
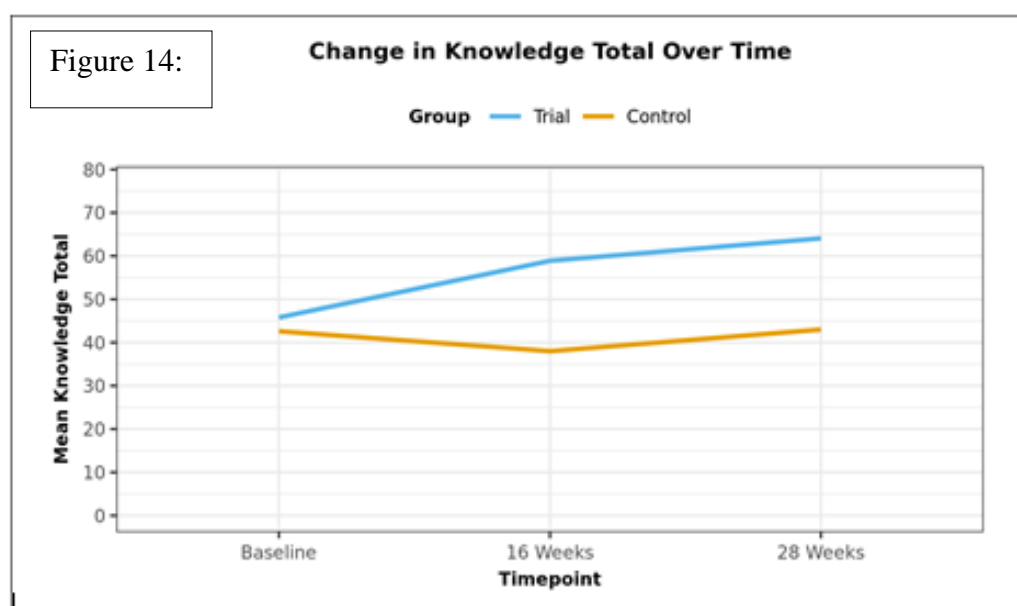
Table 9: Knowledge score of Trial group versus Control group

PARAMETER	TRIAL MEAN ±SD	CONTROL MEAN ±SD
Knowledge Total (Baseline)	45.80 ± 18.46	42.60 ± 23.45
Knowledge Total (16 Weeks)	58.89 ± 16.76	38.00 ± 5.66
Knowledge Total (28 Weeks)	64.08 ± 14.92	43.00 ± 14.13

After adjustment for baseline, covariates analysis could not be done due to inadequate sample size in the Control group.

SECONDARY OBJECTIVE: CHANGE IN COPING SKILLS:

Intervention WhatsApp versus Sham WhatsApp group:

Coping with disease (CODI) questionnaire was used for assessment of change in coping skills at 16 week and 28 weeks. There was no significant change in the coping skills between the intervention and Sham group at both time point 16 week and 28 weeks. The Coping skills score actually decreased at 16 week as compared to baseline and then improved at 28 weeks but the difference was not significant.

Table 10: CODI score in Intervention WhatsApp versus Sham WhatsApp group:

	INTERVENTION Mean	SHAM	P value
CODI Total (Baseline)	19.14 ± 4.51	18.71 ± 4.65	0.509
CODI Total (16 Weeks)	10.74 ± 9.80	12.64 ± 10.84	0.318
CODI Total (28 Weeks)	19.00 ± 2.87	20.94 ± 3.62	0.080

After adjusting for baseline, Covariates evaluated at CODI = 18.29, as shown in figure 15, and there was no significant difference between the 2 groups (p value 0.482).

Figure 15:

Change in Coping Skills in the RCT

Covariates appearing in the model are evaluated at the following values: CODI 0 = 18.29

Error bars: 95% CI

The CODI questionnaire consisted of questions related to 6 domains and patients were asked to mark their response on a 5 point Likert scale ranging from never to always i.e. Never/ Seldom/Sometimes/ Often/ Always.

- Acceptance: 6 questions

- Avoidance: 4 questions

- Cognitive Palliative: 5 questions

- Distance: 4 questions

- Emotional reaction: 6 questions

- Wishful thinking: 3 questions

Analysis beyond secondary objective will be considered as post hoc subgroup analysis which is not possible with this sample size. Hence, we present a graphical pattern to look at the trend but without any inferences in Figure 16.

Figure 16:

Change in CODI: Acceptance Over Time

Group ── Intervention ── Sham

Mean CODI: Acceptance vs Timepoint (Baseline, 16 Weeks, 28 Weeks)
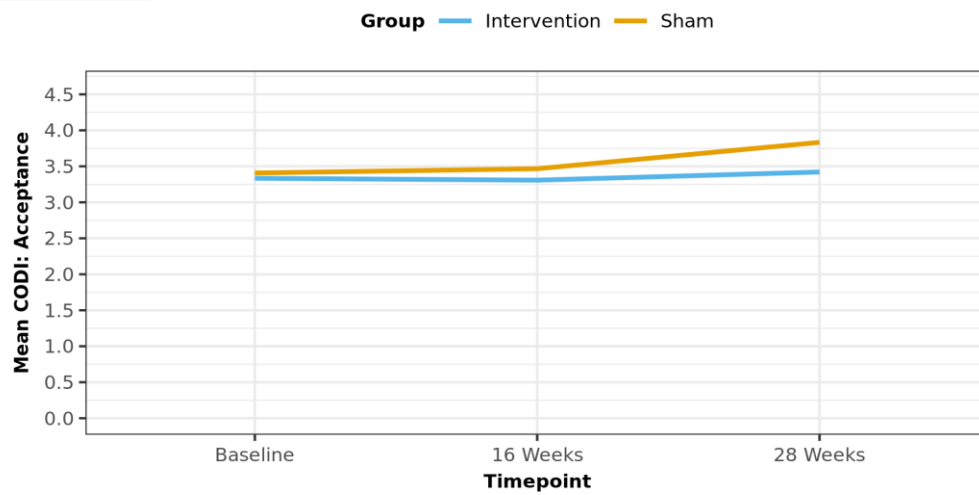
Change in CODI: Avoidance Over Time

Group ── Intervention ── Sham

Mean CODI: Avoidance vs Timepoint (Baseline, 16 Weeks, 28 Weeks)

Change in CODI: Cognitive Over Time

Group ── Intervention ── Sham

Mean CODI: Cognitive vs Timepoint (Baseline, 16 Weeks, 28 Weeks)

Change in CODI: Distance Over Time

Change in CODI: Emotional Reaction Over Time

Change in CODI: Wishful Thinking Over Time
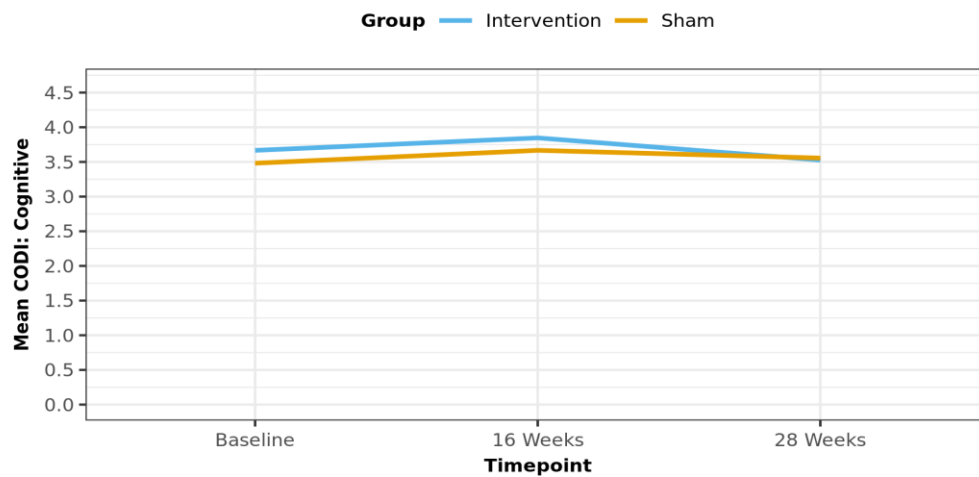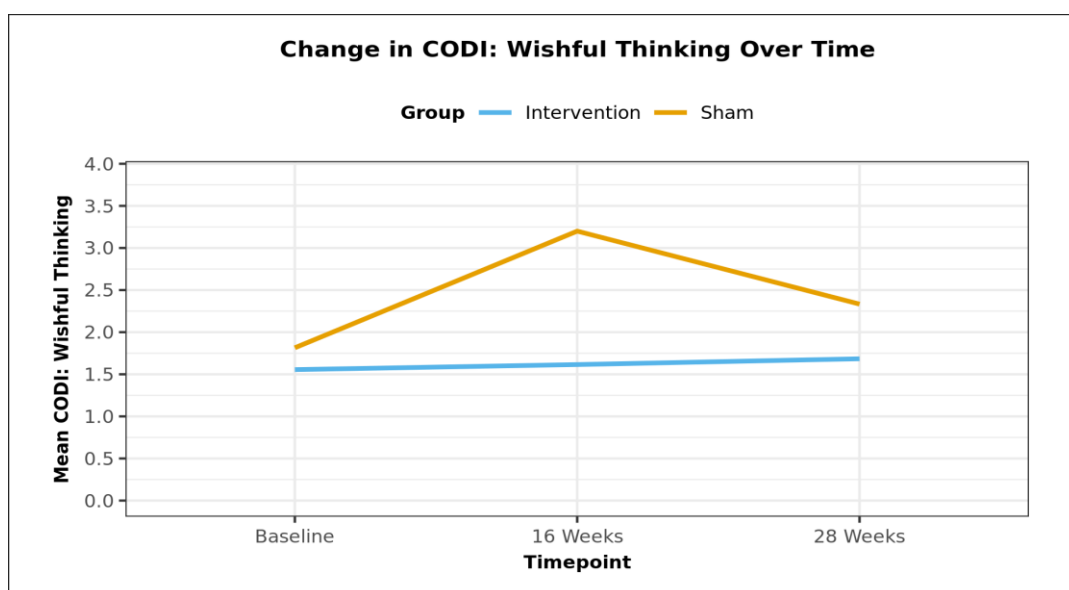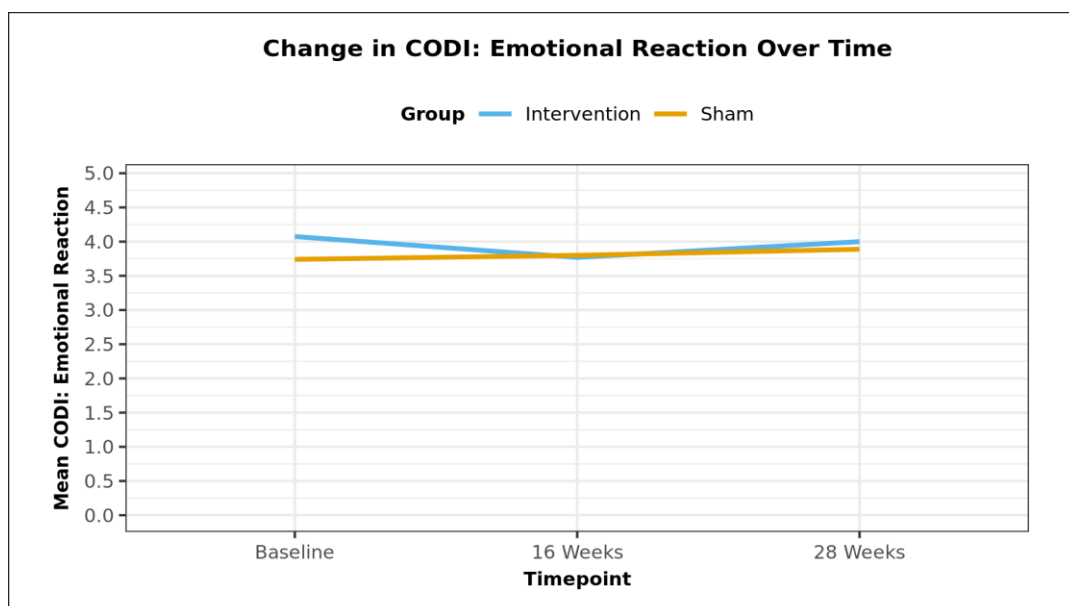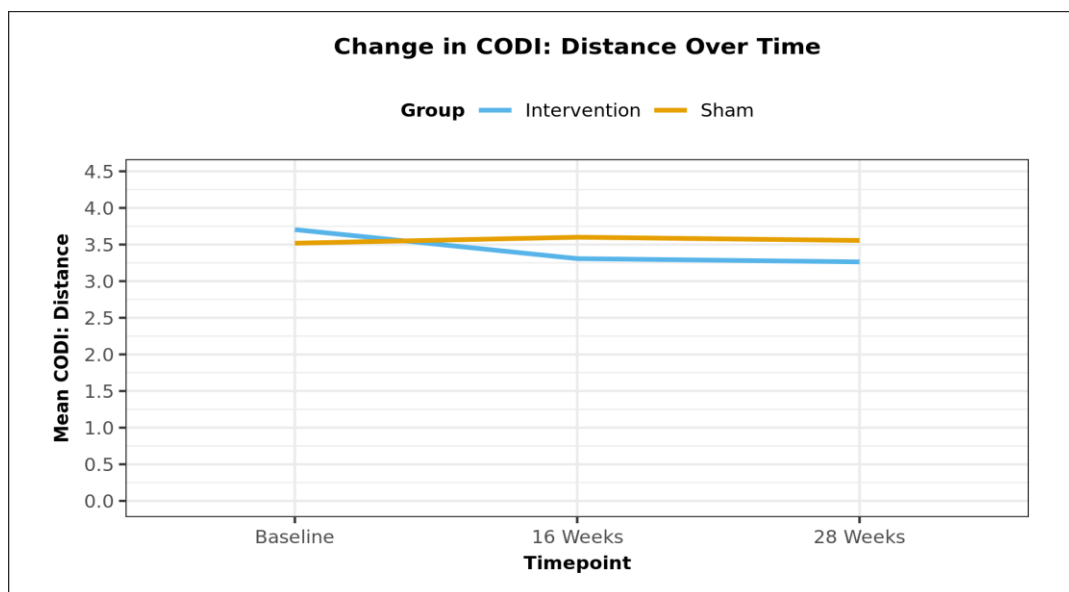
SECONDARY OBJECTIVE: Change in Coping Skills: Trial versus Control

There was improvement in the coping skills in the Trial group (Intervention plus Sham) as compared to the control group but since the number of patients in the control group was small, the inference of the significance of difference between the two cannot be made.

Table 11: CODI score in Trial (Intervention plus Sham) versus Control group

	TRIAL **MEAN ±SD**	CONTROL **MEAN ±SD**
CODI Total (Baseline)	18.93 ± 4.54	18.30 ± 3.02
CODI Total (16 Weeks)	11.73 ± 10.29	17.00 ± 0.00
CODI Total (28 Weeks)	19.95 ± 3.36	14.89 ± 8.70

After adjustment for baseline, covariates analysis could not be done due to inadequate sample size in the Control group.

SECONDARY OBJECTIVE: CHANGE IN QUALITY OF LIFE

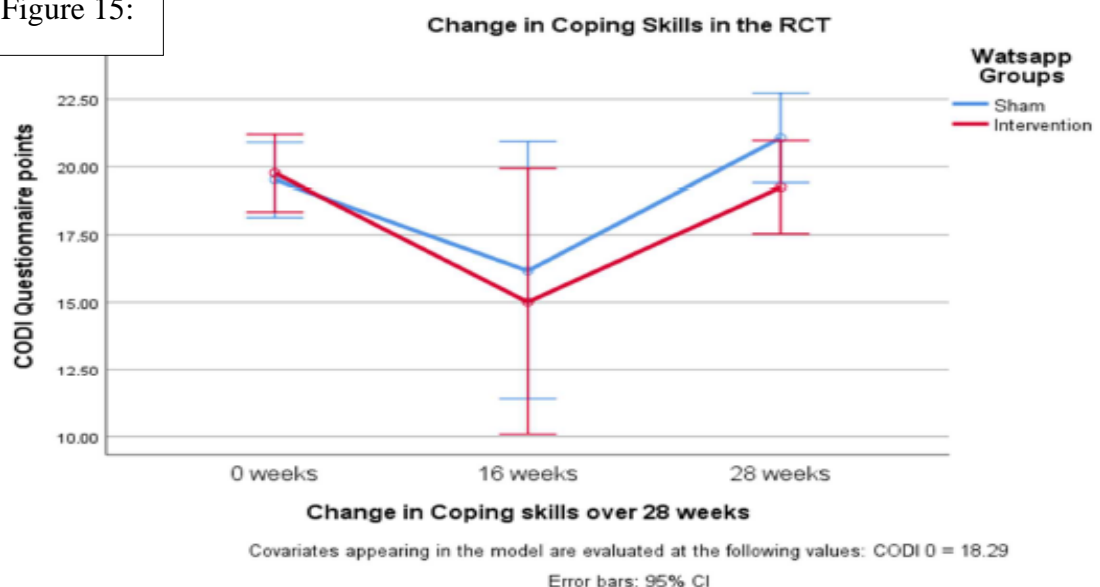### Intervention WhatsApp versus sham WhatsApp group:

Quality of life was assessed by DQOL (Diabetes quality of life questionnaire) which assessed the Satisfaction, Impact and Worry - social and diabetes related. The lower DQOL score indicates improvement in the quality of life. There was no difference in the quality of life between the Intervention and Sham WhatsApp group as shown in Table 12.

Table 12: DQOL in Intervention versus Sham WhatsApp group

DQOL Total	INTERVENTION Mean ±SD	SHAM Mean ±SD	P value
Baseline	7.81 ± 2.53	8.22 ± 2.68	0.588
16 Weeks	6.50 ± 2.71	8.44 ± 3.92	0.123
28 Weeks	6.29 ± 4.13	6.77 ± 3.94	0.688

The trend in DQOL after adjustment for baseline and evaluation of covariates at DQOL 7.88 is shown in figure 17. There was no significant difference between the 2 groups (p value 0.495).

Figure 17:
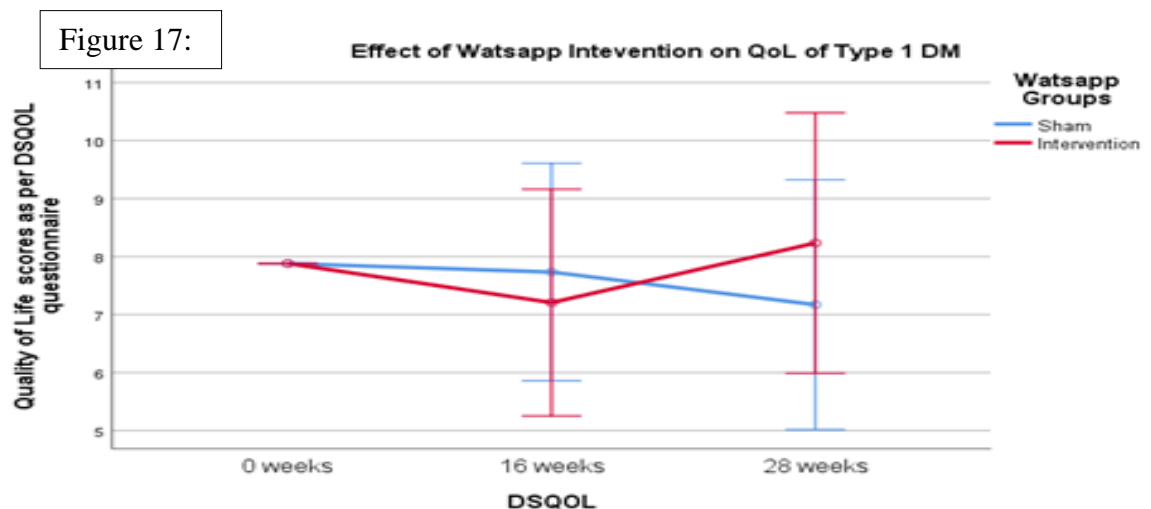
DQOL was assessed by likert scale in terms of

- Satisfaction (15 questions): 1 point if completely satisfied, 5 points if dissatisfied

- Impact: 20 questions: 1 point if never impacted, 5 if always impacted

- Worry: social: 7 questions: 1 point if never worried, 5 if always worried

- Worry : diabetes related: 4 questions: 1 point if never worried, 5 if always worried

Analysis beyond secondary objective will be considered as post hoc subgroup analysis which is not possible with this sample size. Hence, we present a graphical pattern to look at the trend but without any inferences in Figure 18.

Figure 18:

Change in DQOL: Impact Over Time

Change in DQOL: Worry - Social Over Time

Change in DQOL: Worry - Diabetes Over Time
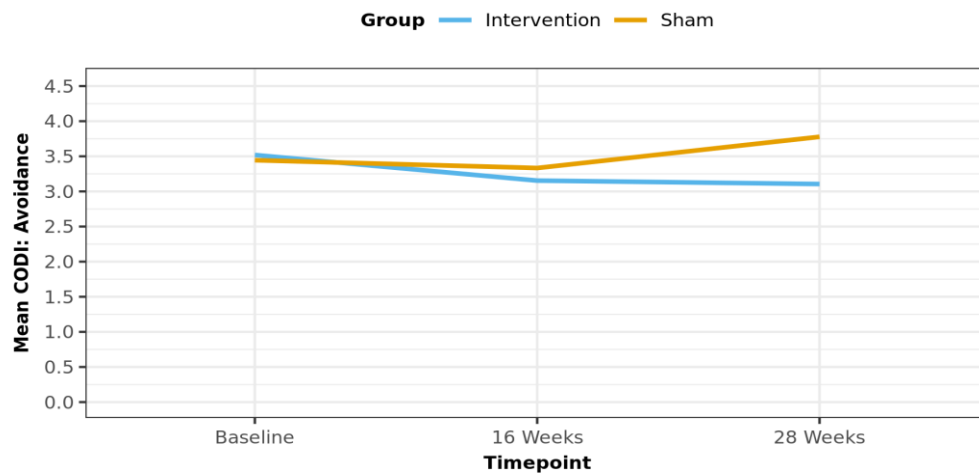
68
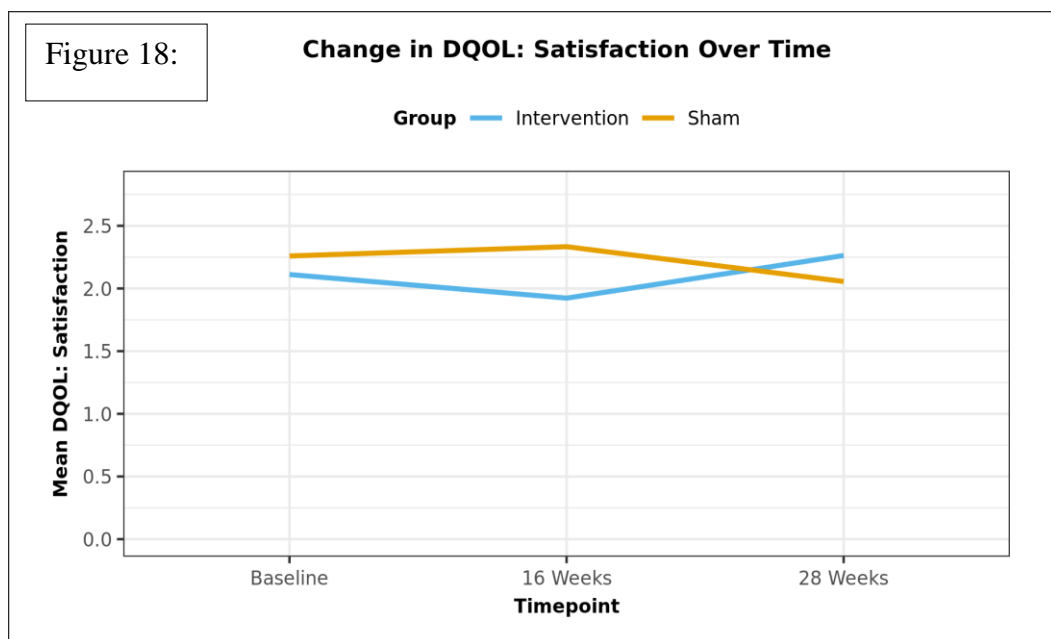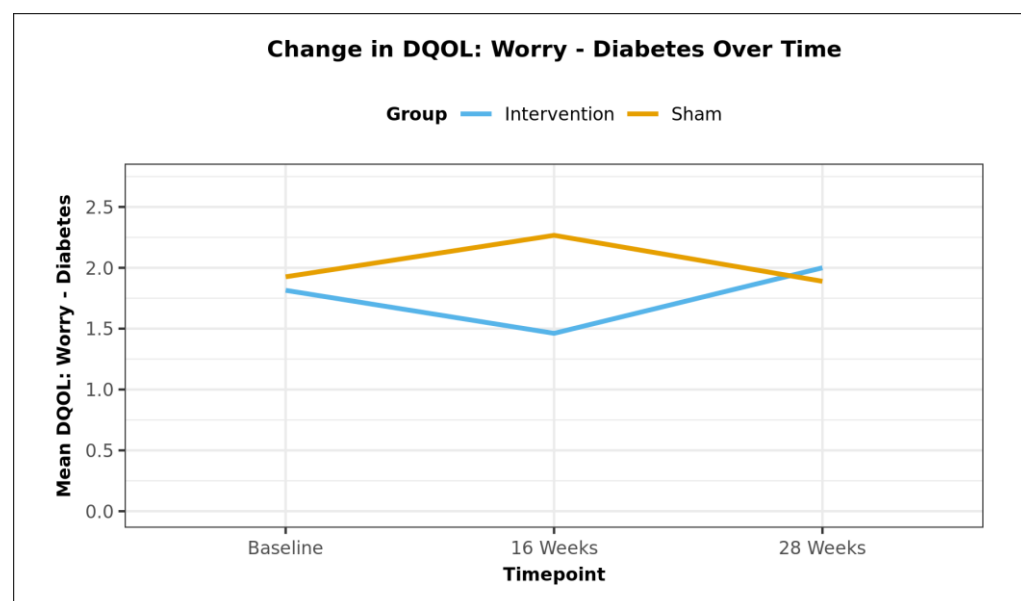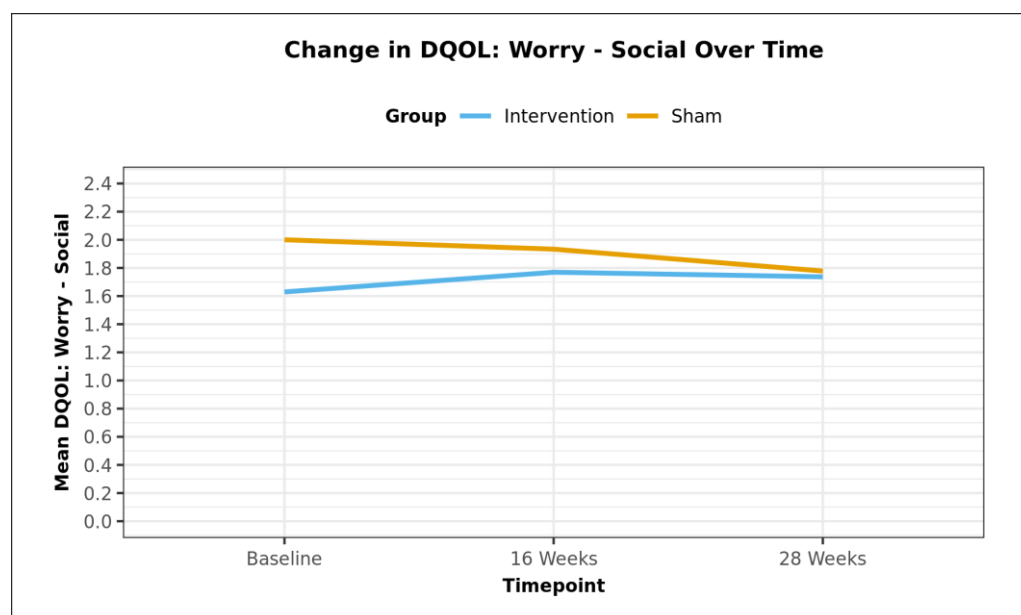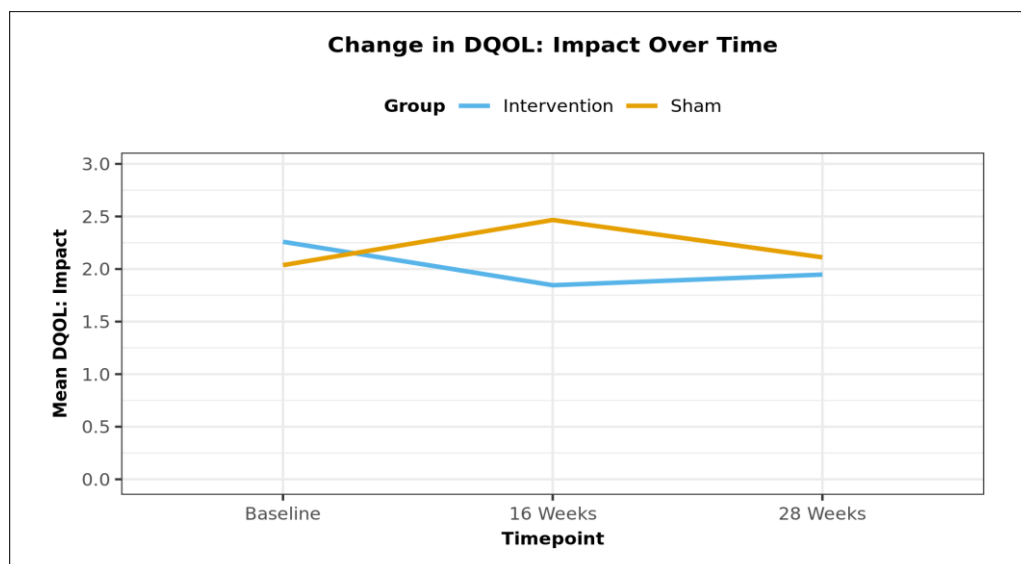
SECONDARY OBJECTIVE: Change in DQOL: Trial versus Control

There was improvement in the coping skills (lower DQOL score) in the Trial group (Intervention plus Sham) as compared to the control group but since the number of patients in the control group was small, the inference of the significance of difference between the two cannot be made.

Table 13: DQOL in Trial (Intervention plus Sham) versus Control group

	TRIAL	CONTROL
DQOL Total (Baseline)	8.02 ± 2.59	8.50 ± 2.76
DQOL Total (16 Weeks)	7.53 ± 3.49	10.50 ± 0.71
DQOL Total (28 Weeks)	6.52 ± 4.00	8.57 ± 2.70

After adjustment for baseline, covariates analysis could not be done due to inadequate sample size in the Control group.

OTHER OBSERVATIONS DURING THE STUDY:

1. HYPOGLYCEMIC EPISODES DURING THE STUDY:

Most of the patients did not do a regular SMBG charting and did not maintain a record of the exact days and number of hypoglycemic episodes they had and whether they were symptomatic or not during the episode. The following data is mostly on the recall basis by the patients during OPD visits. Our data below includes both documented Hypoglycemic episode (SMBG glucose was < 70 mg/dl with or without symptoms) and Patient perceived hypoglycemic episodes (symptoms attributable to hypoglycemia relieved on taking oral glucose but without documentation of glucose value during the episode). Three patients in the Sham group and one patient in Intervention group had multiple hypoglycemic episodes (approximately 4-5 episodes per month or > 20 over 28 weeks) most of which were symptomatic, undocumented but were relieved with oral glucose intake. The Intervention group had lower number of hypoglycemic episodes as compared to Sham group, the difference between them was significant (p value 0.037).

Only 2 patients (1 each in Intervention and Sham group) had severe symptomatic hypoglycemia requiring assistance during the 28 week follow up. The patient in the intervention group was 26 year female on basal bolus regimen and used to take regular insulin (40 unit/ml) by syringe and mistakenly took the same dose of insulin from the 100 unit per ml insulin cartridge with 40 unit syringe (she got the cartridge free of cost from an outside government hospital supply). The patient had loss of consciousness approximately half hour after insulin injection (RBS 34 mg/dl) and was informed to the treating doctor on phone by the parents and appropriate management was told and counselling done. This patient was irregular on follow ups and mostly

remained inactive on WhatsApp group.   The patient in the Sham group was a 22 year female, known case of Type 1 diabetes since last 12 years with poor glycemic control with Diabetic Nephropathy. She had taken her usual dose of insulin and missed her meal and was admitted in emergency with RBS 27 mg/dl.

Table 14: Number of patients with Hypoglycemic episodes during the 28 week follow up:

Hypoglycemia Episodes During Study (28 week follow up)	INTERVENTION (N=21)	SHAM (N=24)
None	13 (61.9%)	9 (37.5%)
1 Episode	0 (0.0%)	6 (25.0%)
2 to 5	6 (28.6%)	3 (12.5%)
5 to 10	1 (4.8%)	3 (12.5%)
10 to 20	0 (0.0%)	0 (0.0%)
>20	1 (4.8%)	3 (12.5%)
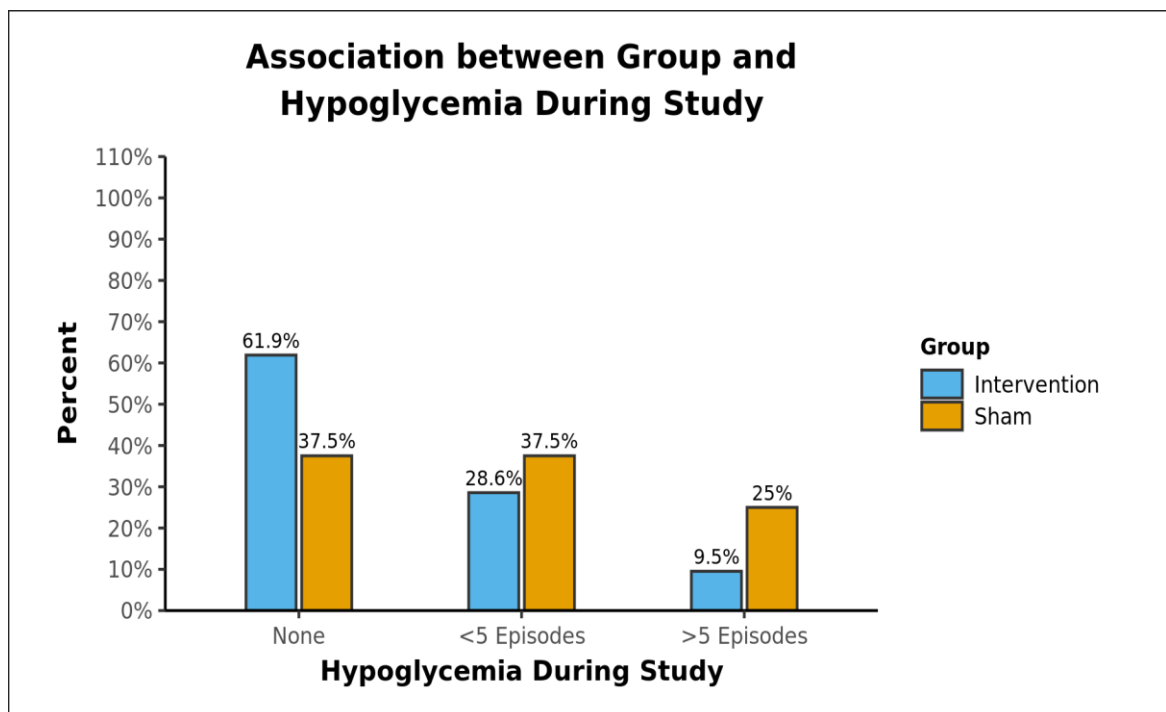
There was no significant difference in the number of Hypoglycemic episodes during study between the Trial (Intervention plus Sham WhatsApp) group as compared to the control (p value 0.21) as shown in Table 15.

Table 15: Number of patients with hypoglycemic episodes during the 28 week follow up:

Hypoglycemia Episodes During Study	TRIAL N=45	CONTROL N=8
None	22 (48.9%)	3 (37.5%)
1 Episode	6 (13.3%)	0 (0.0%)
2 to 5	9 (20.0%)	3 (37.5%)
5 to 10	4 (8.9%)	1 (12.5%)
10 to 20	0 (0.0%)	1 (12.5%)
>20	4 (8.9%)	0 (0.0%)
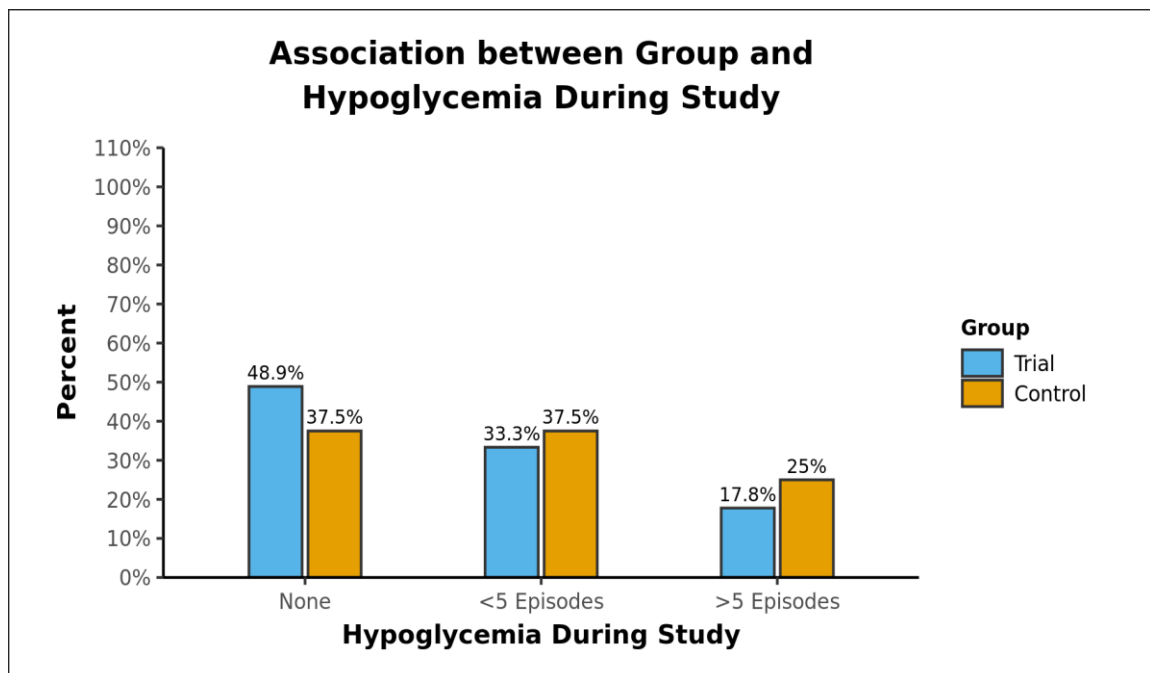
2. NUMBER OF ADMISSIONS DURING THE 28 WEEKS STUDY PERIOD:

There were total 12 admissions during the study duration of 28 weeks. The details of these are given in the table 16:

Table 16: Number of admissions during 28 weeks follow up

Group	Age/ sex	Duration of Diabetes	Indication of Admission
Intervention	15 years/M	6 years	Severe DKA (Precipitation: ? erratic meal/exercise/ insulin timings)
Intervention	26 years/ F	14 years	Acute gastroenteritis without DKA
Intervention	39 years/F	13 years	Mild DKA (Precipitation: Acute gastroenteritis)
Intervention	37 years/M	12 years	Mild to Moderate COVID: Admitted in Army Hospital for isolation. Managed with oral drugs
Sham	22 years/F	12 years	1 admission in Mild DKA (respiratory infection, COVID Negative) 1 admission for Hypoglycemia
Sham	15 years/F	8 years	2 admissions in view of DKA in outside government hospital. Cause? Missing insulin doses
Sham	24 years/M	17 years	Known case of Chronic liver disease Admitted in ILBS hospital Delhi for liver transplant. Succumbed in pre-operative period. Cause of death not known to parents. No documents available.
Control	20 years/F	8 years	Mild DKA (Cause ? missing insulin dose + UTI)
Control	37 years/M	8 years	2 admissions 1 month apart for Diabetic foot and glycemic management

3. COVID INFECTION DURING 28 WEEKS FOLLOW UP:

There were only four documented RT PCR positive COVID infection during our follow up. But the exact number cannot be predicted as approximately 10 other patients had cough, running nose, myalgia with or without fever but they did not go the nearby facility for RT PCR. But none of the patients had any complication or DKA or hypoglycemic episodes with these symptoms and only one of them required supplemental oxygen or intravenous fluids or drugs.

Table 17: COVID during 28 weeks follow up

Group	Age/ sex	Duration of Diabetes	Severity of COVID
Intervention	37 years/M	12 years	Mild to Moderate COVID: Admitted in Army Hospital for 14 days for isolation and managed with oral drugs. Oxygen not required
Intervention	21 years/M	14 years	Mild COVID: Managed at home
Sham	34 years/M	18 years	Mild COVID: Managed at home
Control	32 years/F	16 years	Admitted for 4 days. Managed with iv fluids and steroids

DISCUSSION

We designed a randomized Controlled trial as it provides level-1 evidence to answer any research question. The primary objective of our study was to study the effect of WhatsApp based diabetes education and instructions on glycemic status of patients of Type 1 diabetes mellitus. The secondary objective was to study the effect of WhatsApp based diabetes education and instructions on knowledge, quality of life and coping skills of Type 1 diabetes patients.

PATIENT ENROLLMENT:

Patients aged 15-40 years using WhatsApp and satisfying our inclusion criteria were randomized into 2 groups. The Intervention group received weekly educational messages via group discussion while Sham group received only greeting messages. All those patients who did not have a personal mobile phone or those who had a mobile phone but no internet connection or WhatsApp or those who did not know how to read or write messages on WhatsApp were put in the control group. Total 66 patients were enrolled: 56 in the Trial group (28 each in Intervention and Sham WhatsApp group) and 10 in the Control group. Two out of these ten did not have a mobile phone while eight had a phone but without WhatsApp. Amongst the WhatsApp users (n=56), the mean duration of WhatsApp use was 2.5 years with maximum duration of use being 8 years.

As per the survey by "Lokniti" or Study of Developing Societies (CSDS) named "Mood of the Nation" survey, in 2018, 45% of the Indian population had a mobile phone, 31% had mobile phone with internet access and only 24% of Indian population did not have mobile phone and the numbers were projected to increase

exponentially over years (15). As per the recent survey, of the 1.38 billion population in India, 1.18 billion have mobile connection and 600 million have smartphones (10). Of the total population who use WhatsApp, 84% belonged to age group 18 to 35 years (49% aged 18-25 years and 35% aged 26 to 35 years) (15). Since we had enrolled patients in the age group 15 to 40 years (the age group which uses WhatsApp the maximum), the WhatsApp usage in our enrolled cohort was as high as 85% (56/66 patients) which is very similar to the national data.

BASELINE CHARACTERISTICS:

In the total cohort of 66 patients, the mean age of our patients was 24.5 years with 42.4% patients of age 21 to 30 years. There were 62.1% males and 37.9% females. The mean age of onset was 16.76 years while the mean duration of diabetes was 7.68 years ranging from minimum 4 months to maximum 27 years duration. As per the report of India's Young Diabetes Registry by ICMR published in 2021 including 3545 Type 1 diabetes patients, the mean age of patient of Type 1 diabetes in India is 16.1 years, the mean age of onset is 12.9 years and mean duration of diabetes being 3.2 years with 48.3% females (40).

The mean age of patient and age of onset in our study was higher as compared to nation wise data because as per our inclusion criteria for WhatsApp group, patient should have a personal mobile phone with internet access, so we included only patients >15 years of age, and hence the higher age. There were higher percentage of males as compared to females probably because of the state's skewed gender distribution (41) and more medical attention being given to males as compared to females in our state Rajasthan (an observation).

One third of our cohort had received only primary education and only 10% patients had done a post-graduation. Our cohort had only 34.8% patients who were working and earning and thus the majority i.e. 65.2% patients were dependent on their family (28.8% students and 36.4% non-working) for their daily needs including buying their insulin, glucometer strips, blood tests, travelling expenditure, etc.

The mean baseline HbA1c of our patient was 10.69±2.74% with a median of 9.85 (Range 5.50 - 16.50). This is higher than HbA1c reported in previous studies. In a study from Lucknow in 2019, Sudhanshu et al reported the median HbA1c of 8.3% (range 5.1-15%) in a cohort of 257 patients (42). In 2016, Jevalikar et al reported in a series of 467 Type 1 diabetes patients, the mean HbA1c as 9.5±2.2% (43). The reason for higher baseline HbA1c in our population could be because of sociocultural reasons as this study was conducted in Rajasthan and most of our patients belonged to remote areas where availability of insulin and glucometer strips is difficult. Also, because of the dietary habits in Rajasthan with food high in carbohydrates and fat, achieving a good glycemic control is difficult. Lastly, as this study was conducted while COVID was at peak, various COVID related reasons as mentioned further would have worsened the HbA1c of our patients.

The prevalence of hypothyroidism in our study was 15% while Vitamin D deficiency was found in 33.3% patients and Celiac disease in 8.5% patients. Jevalikar et al in 2016 reported the prevalence of hypothyroidism as 11.6% and celiac as 9.7% (43,44) in their cohort of 467 Type 1 diabetes patients. 26.6% of our patients had retinopathy, 36.4% had neuropathy, 15.2% had nephropathy and 18.2% had hypertension. The study by Jevalikar et al in 2016 reported 10.1% retinopathy, 13.4% nephropathy, 6.2% neuropathy and 17% hypertension (43). The ICMR registry also reports that 11.1% patient had at least 1 complication of diabetes (40). The complications rate in

our study was higher as compared to national data due to the poorer glycemic control and longer duration of diabetes in our cohort.

As mentioned in the results section Table 3, the Trial WhatsApp group (Intervention plus Sham) was comparable to the Control group in all the baseline characteristics and the Intervention WhatsApp group was comparable to the Sham WhatsApp group.

PRIMARY OBJECTIVE: HbA1c CHANGE

TRIAL WHATSAPP (INTERVENTION PLUS SHAM) GROUP VERSUS CONTROL GROUP: There was a significant decrease in HbA1c from baseline in trial group as compared to Control group without WhatsApp both at 16 weeks (9.12±2.19 vs 11.40±1.04, p value 0.035) and at 28 weeks (9.24±1.63 vs 11.59±2.36, p value 0.007). Thus, our study highlights that formation of a WhatsApp group definitely leads to improvement in HbA1c or glycemic control in Type 1 diabetes patients.

Similar observation of improvement in glycemic control with creation of patient groups along with health care professional intervention were made by Saboo et al in 2014 who conducted a study to evaluate the role of social media in management of Type 1 diabetes (21). 79 patients of Type 1 diabetes aged > 18 years were connected to the diabetes care team via Facebook, email and WhatsApp. In addition, patient support groups were created on WhatsApp and Facebook. HbA1c and Quality of life were assessed 3 monthly for a period of 2 years. The authors reported that the use of social media enabled the patients to share their glucose charting, discuss day to day issues and to share their experiences. In addition, the doctor and patient interaction via these social media platforms enabled the patient to contact the treating doctors during emergency situations like hypoglycemia and hyperglycemias and also gave the opportunity to the doctors to remind the patients for regular follow ups and monitoring of HbA1c. The HbA1c decreased from 9.21 ± 1.76 to 8.49 ± 0.89 (p< 0.01) and quality of life significantly improved (21). The authors concluded that the use of social media not only improved the quality of life but also decreased the impact of diabetes on Type 1 diabetes patients.

Blackstock et al in 2016 evaluated the use of WhatsApp in Type 1 diabetes adolescents in West London. They used WhatsApp "Broadcast" rather than an open WhatsApp group to ensure quality control in the messages sent by the patient and the research team reviewed and approved all the messages sent by the patient before it was disseminated to other members. They enrolled only 24 patients and reported that the mean HbA1c changed from 9.7 to 9% while the median HbA1c decreased from 9.8 to 7.9%. Another observation which the authors reported that the 2 patients who did not report for clinic visits were amongst the highest WhatsApp users and one of them had significant improvement in HbA1c. Thus, they hypothesized that WhatsApp could be useful in targeting even the difficult diabetic patients who don't come for follow up visits. They concluded that this innovative use of technology for Type 1 diabetes management provides easy access of information as well as improves patient's engagement in diabetes self-management (26).

INTERVENTION WHATSAPP GROUP VERSUS SHAM WHATSAPP GROUP: CHANGE IN HbA1C

There was a decline in HbA1c from the baseline in both the Intervention and Sham WhatsApp group both at 16 week (9.11 ± 1.82 vs 9.13 ± 2.53, p value 0.695) and 28 weeks (9.60 ± 1.5 vs 8.91 ± 1.70, p value 0.262), but the difference between the 2 groups was not significant at both the time points. Actually, the HbA1c initially decreased to nadir 9.11% in the intervention group at 16 weeks but then again increased to 9.60 at 28 weeks while the Sham group showed a progressive decline from the baseline.

Similar results were reported in a study conducted by Sap et al (2019) in Cameroon which studied the impact of patient education through WhatsApp on knowledge and

glycemic control of Type 1 diabetes patients (25). They enrolled patients between 13-26 years as this age group uses social networking applications the maximum. It was a non-randomized 2 arm trial enrolling total 54 patients (25 in the intervention group and 29 in the control group). The intervention group received weekly sessions of 60-90 minutes in the form of focus WhatsApp group for 4 weeks. HbA1c was repeated after 12 weeks. Modified Revised Brief Diabetes Knowledge Test was used for evaluating knowledge. They reported that there was significant improvement in knowledge score from 13/20 to 16/20 in the intervention arm (p value <0.01) while there was a decrease in knowledge score in control arm 11.6 to 11.3 but there was no improvement in HbA1c in both the groups. There was non-significant decrease in acute complications in the intervention group. The authors concluded that patient education through social network over a period of 2 months helped to improve knowledge and acute complications but without an improvement in glycemic control. The authors also highlighted the need for further studies to study the long term effect on glycemic control (25).

In 2017, Goyal et al from Canada tried the use of mobile application "*bant*" for diabetes self-management education in adolescents. They designed a RCT to compare the application "*bant*" with usual care over 12 months. The application had features of wireless blood glucose monitoring transfer with out of range glucose alert with causation and fixation alert. The primary objective was change in Hba1c while secondary objective was SMBG frequency, quality of life, satisfaction and usage rates of "*bant*" application. They enrolled 96 patients and the mean duration of diabetes was 7.1 years and the mean baseline HbA1c was 8.96 %. With 12 months intervention, there was no significant difference in the HbA1c in the intervention versus the control group. Both the group showed an initial decline of HbA1c which

then returned to pretreatment value at the end of 12-month study. There was no change in the secondary outcome including the quality of life and satisfaction score (27).

Reference Table 1 enlists the six studies which used a mobile application along with the involvement of health care provider in providing information/feedback to the patients. Of these six studies, there were three randomized controlled trials (RCTs). For Type 1 diabetes, the RCT by Kirwan et al in 2013 enrolling 72 patients (33) and a non-randomized study by Ryan et al (35) enrolling only 18 patients showed a significant reduction in HbA1c. The other RCT by Rossi et al in 2013 (34) as well the non-randomized trials by Rossi et al in 2009 and Froisland in 2012 (32,24) showed a non-significant reduction in HbA1c despite the healthcare provider involvement in diabetes management along with the smart phone application. Another RCT involving primarily Type 2 diabetes patients conducted by Zhang et al in 2019 (36) showed that only the self-management application does not achieve a good glycemic control but combining interactive management with the health care provider improves the control.

In our study, in the Intervention group (where weekly educational group discussions were done and an extra effort made to teach the patients), patients were less responsive and with time as weeks passed by, lesser number of patients were online during the time of discussion. Similar to our study, Goyal et al in 2017 also reported that there is decrease in patient's interests over time. The use of their application declined over time and 37% patients had very low usage of application (less than once per 2 weeks) , 28 % had low usage (less than once per week) and 26% moderate usage (1-3 times per week) and only 9% patients used the application more than 3 times per week (27).

Similar observations were made in the CARDS (Computerized Automated Reminder Diabetes System) study done by Hanauer et al in 2009 from Joslin diabetes center in Boston (45). The authors compared the use of SMS (short message service) reminders with email reminders for encouraging patients to do and share blood glucose monitoring. They observed that in the first month, the cell phone users i.e. SMS group submitted twice as many blood glucose monitoring charts as compared to the Email group but with time at 3 month follow up, the responses in both the groups decreased, more so in the SMS group. So, the authors concluded that although usage of cell phones text messaging for encouraging blood glucose monitoring is an acceptable option in Type 1 diabetes patients, but maintaining the interests of the patient for prolonged intervals remains a challenge (45).

SECONDARY END POINT: KNOWLEDGE

The knowledge score of the Trial WhatsApp group (Intervention and Sham) improved significantly as compared to the Control group without WhatsApp (p value 0.003 at 28 weeks) and this was reflected in the significant improvement in the glycemic control in terms of HbA1c as discussed earlier. Also, the knowledge of the patients in the Intervention group improved significantly as compared to the Sham WhatsApp group (p value 0.003 at 16 weeks and 0.05 at 28 weeks). But this improvement in knowledge, failed to translate into improvement in HbA1c.

A RCT conducted in 2016 in Saudi Arabia by Alanzi et al in 84 Type 2 diabetes patients evaluated the role of WhatsApp in improving knowledge and self-efficacy after 8 weeks of weekly WhatsApp messages in the intervention group as compared to the Control group. They used Diabetes knowledge test (DKT) questionnaire from Diabetes Education Study, USA which had 24 items with answers as Yes/No/I don't know while for self-efficacy assessment they used US-DMSES (Diabetes Management Self Efficacy Scale) with 20 self-management activities. They reported that the intervention group had significant improvement in the knowledge and self-efficacy. But the limitation of the study was that it was conducted over a period of 8 weeks only and glycemic change/ HbA1c was not studied. Moreover, since the control group was not enrolled in WhatsApp group and thus it cannot be ascertained whether the improvement in knowledge and self-efficacy was because of the educational messages on the group or just because of group interactions between patients and doctor (46)**.**

As mentioned earlier similar to our study, the study in 2019 by Sap et al (25) also showed an improvement in knowledge score after 2 months of education through WhatsApp but with no significant change in HbA1c.

SECONDARY END POINT: COPING SKILLS AND QUALITY OF LIFE:

TRIAL WHATSAPP GROUP (INTERVENTION PLUS SHAM) VERSUS CONTROL:

Coping skills refer to individual's competency to handle a situation. In our study, coping skills were assessed by CODI questionnaire in terms of acceptance, avoidance, cognitive palliative, distance, emotional reaction and wishful thinking. The higher CODI score indicates improvement in the coping skills. The CODI score was increased in the Trial WhatsApp group (Intervention plus Sham) while it decreased in the control group.

Quality of life was assessed by DQOL (Diabetes quality of life questionnaire) which assessed the Satisfaction, Impact and Worry - social and diabetes related. The lower DQOL score indicates improvement in the quality of life. The DQOL score was decreased i.e. quality of life improved in the Trial WhatsApp group (Intervention plus Sham) with respect to Control group. But since the number of patients in the control group was small, the inference of the significance of difference in coping skills or quality of life between the two groups cannot be made.

Similar improvement in self-efficacy was reported in a study in 2016 by Alanzi et al mentioned earlier in patients of Type 2 diabetes with weekly WhatsApp messages (46). In another review in 2019 by Verma et al on effect of social media in Type 2 diabetes studying the effect of online communities on diabetes management concluded that these support groups help in emotional support and confidence building to fight diabetes (47).

In 2015, Blackstock et al also quoted a patient's words that he finds easier to ask question on a WhatsApp group as compared to the clinic" (26,48). They also reported that 67% patients felt more motivated after joining the group.

INTERVENTION WHATSAPP GROUP VERSUS SHAM WHATSAPP GROUP:

There was no significant change in the Coping skills of Intervention and Sham WhatsApp group from baseline at both the time points16 weeks (p value 0.31) and 28 weeks (p value 0.08) and the difference between the 2 groups was also not significant.

There was no significant change in the Quality of life of Intervention and Sham WhatsApp group from baseline at both the time points16 weeks (p value 0.12) and 28 weeks (p value 0.68) and the difference between the 2 groups was also not significant.

Similar observation was made in the RCT conducted by Kirwan et al in Australia in 2013 over a period of 6 months where although a significant reduction in HbA1c was seen after using Mobile app Glucose Buddy along with physician's feedback, there was no change in self-efficacy, self-care activities and quality of life (33). Klee et al conducted a RCT in Geneva Switzerland in 2018 enrolling 33 patients and used Webdia "Do it yourself" application. They reported a 0.33% reduction in Hba1c (p value 0.04) in patient using the application with respect to the standard care group but there was no difference in quality of life score (29). But as mentioned earlier, the study conducted by Saboo et al in 2014 on 79 patients of Type 1 diabetes who were connected to the diabetes care team via Facebook, email and WhatsApp reported a significant improvement in quality of life of patients (The quality of life score decreased from 65.79 ± 2.41 to 59.84 ± 1.89; p< 0.01 suggesting an improvement in quality of life) (21). The authors used the brief clinical inventory of DQOL score

consisting of 15 items while we used the original DQOL consisting of 46 items graded on a likert scale.

In our study, the probable reason for no change in quality of life or coping skills of Intervention group as compared to the Sham group despite an improvement in their knowledge was because of the varied response of the patients.

For example, after a discussion on dose adjustment was done, most people were thankful that they learnt and will be able to do minor adjustments themselves and after a WhatsApp discussion on chronic complications and their screening was done, most of the patients responded that they now know how important it is to keep their glucose levels under control.

Few examples of patient's response include: "इस ग्रुप से मुझे पता चला की कितने सारे लोग इन्सुलिन ले रहे हैं। छोटे बच्चे भी इंसुलिन खुद लगा रहे हैं। पहले मुझे लगता था की बस मुझे ही डायबिटीज है। मैं अपने शुगर को नियंत्रण में रखने की कोशिश करूंगी । मैं हर साल आंखों के परदे के टेस्ट के लिए जरूर जाऊंगी । धनयवाद डॉक्टर हम ये ग्रुप बनाने के लिए और ये सब बताने के लिए।

(With this group, I came to know that there are so many others like me who are on insulin. Even kids younger than me are taking insulin. Earlier I used to think that only I have diabetes. I will try to keep my glucose values under control. I will go for retina check up yearly. Thank you doctor for making this group and giving us all this information).

But, there were instances where patients will write on group that they do not want to be educated and they are happier being ignorant. Most of the patients were thankful after the discussion but few will respond with such messages: "आपने इतना बता दिया, हमें लगा रहा है हम खुद डॉक्टर बन गए । हमें नहीं सीखना इंसुलिन की खुराक कैसे ऊपर नीचे करते हैं, आप तो बस बता दो कितनी इंसुलिन लेनी है ।" (Doctor, you have told me so much about diabetes, that I have started thinking that I am a doctor myself. I don't want to learn how to manage, just tell me how much insulin I should take). Similarly after the discussion on diabetes complications was done, a patient responded with message like "आपने इतना कुछ डायबिटीज के बारे में बता दिया, अब तो टेंशन होने लगी की आगे क्या होगा। इतनी सब परशानी होती है मधुमेह में, ये जब तक नहीं पता था, तब तक ही ठीक था। कभी कभी तो डिप्रेशन ही हो जाता है सोच कर की मुझे ही क्यों हुई है डायबिटीज।" (You have told so much about diabetes and its complications, that now I am actually stressed about the future. Sometimes, I feel depressed thinking, why did I develop diabetes). Similar observation was made by Verma et al in their review in 2019 on impact of social media on Type 2 diabetes management. They also reported that not all people share positive messages and few may share anxiety and fear regarding diabetes and complications (47).

Thus, we hypothesize that probably because the Intervention WhatsApp group had more knowledge regarding diabetes "complications" it increased their "worry" regarding diabetes and also due to various sociocultural and economic constraints of the patients and their inability to achieve a good glycemic control, patients were not satisfied with their own efforts regarding diabetes management. Hence, their Quality of life score (which assessed the satisfaction, impact and worry) could not improve.

EFFECT OF COVID PANDEMIC:

The COVID pandemic greatly affected our study and its results. Firstly, we could enroll lesser number of patients than we had expected in our study. Ours being a tertiary care hospital, a large number of our patients belong to remote areas of Rajasthan and our hospital caters to approximately 300 kilometer radius around Jodhpur. So, because of the unavailability of public transport facility from the remote areas to Jodhpur, the number of Type 1 diabetic patients visiting the OPD was reduced. Moreover, because of our hospital policy of a mandatory online OPD appointment during the COVID pandemic period, many of our patients who were unable to book an appointment were unable to visit, thus greatly reducing the OPD numbers In the Pre-COVID time, we had a daily total Endocrine OPD visit of approximately 130 to 150 patients, which reduced to only 10-20 patients daily during COVID peak. Hence, the total number of enrollments could be only 66 patients over a period of 7.5 months. Also, this study was conducted while COVID was at peak and patient's compliance to insulin was poor. The insulin availability issues further worsened during the lock down. Availability of basal insulin (glargine/degludec) was a major concern and many patients shifted to NPH or premix insulin intermittently during periods of short supply. Also, the glucose monitoring strips availability during lockdown was limited and the prices of the strips were hiked up by the local pharmacists and thus patients could not do frequent SMBG. During lockdown and travel restrictions, the maintenance of cold chain while supplying the insulin from manufacturer to the distributor was also questionable. There was lack of regular exercise especially outdoor sports/ gym due to COVID restrictions further worsening their control. COVID adversely affected various family members of the patients, and due to stress of ill health of family members, compliance to insulin & diet reduced.

Our follow up was also greatly affected by COVID pandemic. Out of total 66 enrolled patients, only 30 patients (45 %) could visit our hospital for follow up at 16 week after enrollment and only 44 patients (66 %) at 28 weeks. So, we have the follow up questionnaires of CODI and DQOL only for these patients. Since, our primary objective was to see change in HbA1c which was used as a marker of glycemic Control, at 16 and 28 weeks, for those patients who were not able to visit our hospital due to COVID related reasons, we asked to get the HbA1c tested from a lab near to their residence. So, finally we have HbA1c data of 50 out of 66 enrolled patients (75.7%) at 28 weeks and 31 patients at 16 weeks. Thus, although we had expected a 10-15% loss to follow up but probably because of COVID and it's related after effects, 24.3 % patients were lost to follow up in our study thus further reducing the number of patients analyzed finally. The number of patients in the Control group was already very small and 2 patients out of these 10 patients were lost to follow up. The probable reasons for the lost to follow up include:

1. COVID led to restriction of patient movement and unavailability of public transport during the lock down. Thus, out of 36 patients who could not come for follow up at 16 week, 24 patients were actually willing to come for follow up but could not due to the travel restrictions. Similarly, 14 out of 22 patients were willing to come at 28 weeks follow up but could not.

2. Type 1 diabetes patients as well as their caregivers had a fear and a sense of panic that Type 1 diabetes patients are at higher risk of contracting COVID infection and moreover the COVID infection is more severe and fatal in these patients. This prevented the patients to visit the OPD for the follow up visits at 16 and 28 weeks. Moreover, 5 patients did not visit the nearby lab for getting their Hba1c checked and neither called the lab personnel for home collection

due to the fear of contacting COVID by visiting the lab or through lab personnel.

3. COVID affected the jobs/profession of many patients and their care givers. 3 patients lost their jobs in the Jodhpur city and thus resorted back to their village for farming and thus due to the lockdown could not come at 16 week follow up. Even when the travel restrictions were removed when these 3 patients were scheduled for 28 week follow up, due to the cost involved in travelling back to Jodhpur, they refused to come for physical OPD follow up.

4. COVID greatly affected the finances of the patients and the care givers. Thus, even when the lockdown was opened, the patients preferred their work over the hospital visit because some patients were the sole bread earners of their family and they were concerned about the finances. As quoted by one of the patients "अभी पैसे की बहुत समस्या है, अस्पताल आने में पूरा दिन लग जाएगा, एक दिन की तनख्वाह जाएगी। वैसा भी कोविड अभी खतम तो नहीं हुआ है। अस्पताल आने में संक्रमण का भी तो जोखिम है।"

5. 2nd wave of COVID had a high mortality and 1 patient could not come for follow up as her father expired due to COVID.

6. During the COVID pandemic, there was acute shortage of hospital beds. Thus investigators did not convince patients to a large extent for follow up because of the fear that if by chance, the patient contacts COVID during his follow up visits, it will be difficult to arrange for hospital beds.

7. During the latter part of pandemic, since our enrolled patients were aged 15-40 years and thus only 8 patients were vaccinated with both doses of COVID vaccine, 22 patients had not received even a single dose of vaccine while rest i.e. 36 patients had received only 1 dose of vaccine. Thus, the investigators were fearful to call patients for follow up to the hospital.

The other reasons for lost to follow up in our study as detailed in the results section include use of alternative medication, change of city, fear of blood sampling and preferring to use WhatsApp discussion to coming to physical OPD.

The problems faced by us in our study were also reported by other authors. In year 2020, Saboo et al also reported that the pandemic itself especially the COVID lockdown created a lot of problems related to affordability and accessibility to health care services and they faced various challenges while managing Type 1 diabetes during the pandemic. They thus evaluated the utility of social media during the COVID pandemic for educating Type 1 diabetes patients. They used video calls for managing Type 1 diabetes patients. They tried to teach insulin techniques and the use of blood glucose monitors through video calls. Authors connected the families of children with type 1 diabetes living in the same region in order to offer support and promote confidence and they made one patient with Type 1 diabetes as a peer educator to act as an inspiration to others. The authors concluded that advancement in technology and telemedicine proved to be very effective in managing patients and the use of telemedicine proved both time and cost-saving and resulted in high appointment adherence with minimum difficulties and that the use of social media for Diabetes self-management education (DSME) was especially rewarding during the COVID pandemic. As per the authors, the telemedicine approach was well-received by people living with diabetes and their families and they concluded that in the aftermath of COVID-19, telemedicine can provide a promising solution for patients for delivering diabetes related care (22).

In another study from India conducted in 2021, by Muthukrishnan et al over a period of 1 year during COVID lock down, 46 Type 1 diabetes patients (including 10 on insulin pump) were followed via a telephonic consultation. They were counselled

fortnightly via web based education session. The authors concluded that teleconsultation via video conferencing ensures optimal delivery of health care services and can even be continued after the pandemic was over to reduce the OPD burden and increase convenience to patients (23). In this study of 46 patients, the mean age was 19.1 years, the duration was 4.88 years and mean HbA1c was8.2. There was improvement in HbA1c in 62.5% patients over a period of 1 year after teleconsultation.

In a study by Nachimuthu et al in 2020 from Chennai, an online survey "Survey Monkey" was conducted in patients who did not come for physical OPD follow up during the COVID lockdown. This survey had questions regarding SMBG, compliance to diet and exercise and patient's anxiety regarding COVID. Their cohort of 100 patients had 92 Type 2 diabetes and 8 Type 1 diabetes patients. They reported that 80% of the people were compliant with diet and exercise but only 28 % did regular (at least once a day) monitoring of blood glucose and 40% patients were anxious about COVID infection and its after effects (30).

OUR EXPERIENCE:

We would like to share our experience and list certain advantages of use of WhatsApp for Type 1 diabetes patient education we observed in our study. Firstly, WhatsApp has the advantage over phone calls that if a patient is busy at a particular time, he can read the chat/ message at a time of his comfort. Another advantage of using a WhatsApp based education is that if these messages are available in patient's phone forever and he/she can refer to them whenever he wants to read them again. This is in contrast to a phone call in which unless the patient records the phone call, the information conveyed via a call cannot be retrieved if one wants to refer to it again.

Both SMS (short message service) and WhatsApp can be used to send message and thus convey information to the patient. But WhatsApp provided multiple benefits apart from just simple text message.

Firstly, through WhatsApp even images can be shared easily and we all know that pictures or images create a much greater impact on a patient's mind than just letters or words. Moreover, information gathered via a pictorial representation tends to stay in one's mind for a longer duration and thus has longer lasting effect. Pictures or images are easy to refer and can be easily accessed via the "media, links and docs" option in WhatsApp. So, for example with the help of WhatsApp, Type 1 diabetes patients shared their glucose monitoring (Self-monitoring of blood glucose SMBG) charts. If a patient shared his or her chart on the group during the group discussion time, then this chart was seen by both the doctor and the other patients. So, one advantage we felt that all the patients seeing the chart were encouraged to monitor their own glucose values. The other advantage was that the timing of glucose monitoring was indirectly reinforced. Thirdly, if there are hypoglycemic readings, the patients discussed regarding hypoglycemia amongst themselves and with the doctor in the group. Thus, various aspects of hypoglycemia like at what glucose level we call the patient to be hypoglycemic, what are the various symptoms which one experiences when one has hypoglycemia and how these symptoms are to be managed and what can be done in future to prevent them. Also, not all Type 1 diabetic patients have had a hypoglycemic episode. This is especially true for a newly diagnosed Type 1 diabetic who has not experienced hypoglycemia. So, a group discussion on hypoglycemia enabled him or her to recognize these symptoms at the earliest and take appropriate management steps and thus can prevent catastrophic complications. A glucose monitoring chart shared by one patient can had multiple other advantages to other patients as well to

the patient who has shared the chart. The one who had shared the chart through the discussion came to know how he/she can change the insulin doses to achieve a better glycemic control. If there are hypoglycemic readings, he or she was reinforced regarding hypoglycemia management while if there are very high blood glucose values, discussion was made regarding how to achieve a better control and possible causes of derangement of glycemic control were discussed. Also, pictures of food were shared highlighting their calorie and carbohydrate content. Patient shared photos of the labels of food items (ex. Peanut butter) and discussed their values.

The concept of picture-based education in Type 1 diabetes in not new but it is largely unexplored. In 2012, in Norway a pilot study on 12 patients evaluated the use of mobile phones in facilitating visual learning in Type 1 diabetes using mobile phones using SMS and application using picture-based diary. The authors did not find a statistically significant difference in HbA1c or in knowledge score after 3 months of intervention. Although the sample size was very small, the authors reported that the patients appreciated the picture based diary more than the SMS as the visual impression facilitated the link between theoretical knowledge and executive functions and thus suited more to the adolescent brain (24).

Blackstock et al in 2015 also reported similar experiences with the use of WhatsApp in the cohort of 16 patients in London. They used a broadcast group where messages were directed to diabetic team phone and not the whole group to maintain the patient's confidentiality and then were forwarded to the other group members. They reported that the overall feedback response was "overwhelmingly positive" and patients shared "snack advise" and "new pens usage" to motivate other Type 1 patients (48). In a follow up study, they enrolled 24 patients and reported that the mean HbA1c changed from 9.7 to 9% while the median HbA1c decreased from 9.8 to

7.9%. Another observation which the authors reported that the 2 patients who did not report for clinic visits were amongst the highest WhatsApp users and one of them had significant improvement in HbA1c. Thus they hypothesized that WhatsApp could be useful in targeting even the difficult diabetic patients who don't come for follow up visits (26).

Secondly, the patients who could not or did not want to type and send their reply during the discussion time, could record their voice and send on the group. This feature is not available with SMS. In our study, this feature of WhatsApp was utilized by 6 patients (3 each in intervention & Sham group) to give their opinion or ask their query as although they could read Hindi but they were not very comfortable writing Hindi or Hindi with English alphabets.

But still, despite all these advantages of WhatsApp use over 28 weeks follow up our mean HbA1c of the total cohort declined from baseline 10.69 ± 2.74 to 9.34 ± 2.21 at 16 week and 9.61 ± 1.94 at 28 week. Thus, our mean HbA1c was higher than expected after 28 weeks follow up period. Apart from the COVID related reasons enumerated above, it could be because of sociocultural reasons as this study was conducted in Rajasthan and most of our patients belonged to remote areas where availability of insulin is difficult especially due to unavailability of basal insulin, patients intermittently switch to premix NPH insulin instead of glargine and then due to frequent hypoglycemic episodes, they reduce the total insulin dose, leading to hyperglycemia and raised HbA1c. The glucometer strips of only selected companies are available in certain areas of Rajasthan which are too costly for patient to buy and to do frequent monitoring. Also, because of the dietary habits in Rajasthan with food high in carbohydrates and fat, achieving a good glycemic Control is difficult. And

lastly as discussed below, COVID greatly impacted our study and led to further worsening of glycemic control.

Overall, our experience of using WhatsApp for diabetes education was actually an eye opener. Through weekly discussions, Type 1 diabetes patients in the Intervention group were educated about insulin injections techniques, types of insulin, daily blood glucose monitoring, prevention and handling of acute complications, screening for and managing chronic complications and management of diabetes during sick days, while travelling and during and after exercises. But still the patient's response in the WhatsApp Intervention versus Sham group was contrary to our expectations. When this trial was being planned, we were hopeful of a positive result seeing the results of the previous trials using SMS for diabetes education i.e. we were expecting a significant decline in HbA1c in the WhatsApp Intervention group as compared to Sham group. The idea of creating a Sham group to which only greeting messages were sent was to eliminate the bias of internet use. But still Intervention group and Sham group showed a similar decline in HbA1c. So, although WhatsApp has multiple advantages, probably WhatsApp based education cannot replace completely the offline and clinic based one to one diabetes education but can be used to provide a ready reckoner through images. Secondly, patient support group and WhatsApp group of patients should be encouraged as patient learn better listening to experiences of other patients and learning from other patients' mistakes, rather than from a doctor teaching them what to do and what not to do. Thirdly, it is the availability of a contact number of doctor who is available for the patient 24 x 7 in case of an emergency need helps patient to cope up better and helps to improve his quality of life. Lastly, education given to a patient should be tailored to his or her background knowledge and interests and understandings and one prototype will not suit all. Whether this

education is given through WhatsApp or physical OPD visits, it should be patient centric. Frequent follow ups should be encouraged.

Intervention group did not achieve a better glycemic control despite efforts being made to educate them via WhatsApp. There could be various reasons for a non-significant decline in HbA1c in Intervention versus Sham group despite a significant improvement in knowledge. Firstly, our results are based on a total cohort of only 66 patients and thus the failure to reach statistical significance could be because of the small sample size of our study. But still it could be because of multiple other reasons including COVID related, patient specific enumerated earlier. Lastly, Failure to achieve statistically significant difference in the HbA1c between the Intervention versus Sham WhatsApp group could be because of investigators related reasons also. Probably the intervention done i.e. the information and education provided to the Intervention group via WhatsApp group discussions was not that effective. It could be because of investigators fatigue due to repeating the same information to patients. Also due to the decline in motivation of the investigators when appropriate response was not received from the patients as patients did not participate in the group discussions as expected, probably till the end of the trial, the investigators did not encourage patients enough regarding diabetes self-management

STUDY LIMITATIONS

As discussed earlier, we could enroll only 66 patients and thus because of the sample size, analysis beyond secondary objective will be considered as post hoc subgroup analysis which is not possible with this sample size. Hence, we presented a graphical pattern to look at the trend but without any inferences. Secondly, there were more than expected lost to follow up in our study due to the reasons enumerated above.

CONCLUSION

The management of Type 1 diabetes is especially difficult in developing country like India where the awareness about its management is very poor in the patients and caregivers of Type 1 diabetes. It is disheartening that the awareness amongst the health care professionals is also very minimal (8) and Type 1 diabetes management is sparingly included in the medical curriculum. Thus, there is an unmet need to increase this awareness. The traditional strategies which are used since years include conducting public awareness programs, workshops and structured training of diabetes educators throughout the country. The Changing Diabetes in Children (CdiC) program has been operational since 2009 as a public private partnership for educating doctors, nurses, dieticians and other health care professionals who manage diabetes patients. In year 2010, International Diabetes Federation (IDF) started an educational program named "Indian Diabetes Educator Program" targeting specifically diabetes educators. But this program too lacked specific education regarding Type 1 diabetes management (8). As reported in 2015, out of 75000 children with Type 1 diabetes, only 4000 were catered by these education programs. Considering the current burden of Type 1 Diabetes population of our country and the rising numbers and a huge gap in awareness, there is a need to develop novel ideas to reach these Type 1 diabetes patients with minimal available resources.

National diabetes education program is a training program for diabetes educators across the country targeting structured module based training. It's been training Diabetes educators since year 2011 all over the country (7). So, a decade earlier, there were no trained educators in our country.

Diabetes education is the key to Type 1 diabetes management. Providing structured diabetes education helps in maximizing the effectiveness of diabetes treatment and has been shown to have beneficial effect on glycemic control and psychosocial outcomes (4). Various studies have shown diabetes education to be a cost effective intervention by decreasing the frequency of hospital admissions and presentation to emergency (4) . Also, it has been observed that patients who do not receive education are more likely to suffer from diabetes related complications (5,6). Various platforms have been evaluated for education of Type1 Diabetes patients. Fischer et al in Johannesburg evaluated various information delivery platforms, to increase diabetes awareness including television, radio, newspaper, SMS, WhatsApp, emails, mobile applications, social media. They reported that patients were most receptive to television and WhatsApp followed by SMS, newspaper, radio and social media (20).

In 2019, Pramanik et al conducted a study in Vellore enrolling 28 patients and used the mobile app DMCare for providing 3 reminders per day regarding insulin, meal and exercise. Their primary objective i.e change in HbA1c showed a significant reduction (10.6 to 9.65%) over a period of 3 months and they concluded that mobile phone applications as motivational intervention is feasible in India (49).

In a review in 2015 by Das et al on overall insights of Type 1 Diabetes in India, the authors have highlighted the need for future studies on Type 1 diabetes evaluating the targets, treatment regimens and methods to prevent complications and promote education amongst patients (3).

India's diabetes population is growing exponentially and thus there is a lot of pressure on health care infrastructure. The use of innovative technology in diabetes management is thus the need of the hour. In a review in 2021 on digital health and

diabetes, Kesavadev et al also emphasized on adaptation of technology for diabetes management and implementation of policies to digitalize diabetes care in India (50).

The International Diabetes Federation also supports the use of mobile phone for diabetes management. As per IDF the use of technology or mobile phones is not a substitute to the care given by professionals but the use of mobile phones can play a supportive role and can have a significant impact on diabetes management (51).

In our study, WhatsApp group formation led to improvement in glycemic control, coping skills and quality of life if the treating team stayed in touch with the patients through a patient WhatsApp group, irrespective of whether WhatsApp based DSME was provided in the group or not. WhatsApp based DSME however did improve the knowledge score in the Intervention group. Hence, patient engagement through formation of WhatsApp groups with treating doctor can empower patients for self-management and provide a more interactive and cost-effective platform for managing Type 1 diabetes patients in resource limited settings and can be especially rewarding in this pandemic situation.

The management of Type 1 diabetes requires close monitoring and insulin dose adjustment to ensure optimal glycemic control. The need for connecting patients and health care providers through telemedicine has become even more necessary during the COVID pandemic. Due to the use of mobile phone and internet services by both patients and their caregivers for school and college online classes has made them well versed with its usage and thus it has made WhatsApp a very convenient platform to use. It has helped to avoid the cost and time spent in traveling and waiting   in OPD and thus enabling more time available for studies and school work for students and less absenteeism from work.

Further, the engagement of patients with various apps or social media platforms remains a concern in the long term. Although, there is data to show that smart phones and various applications have a role in DSME , their long term efficacy and effect on glycemic control needs further research (52). Certainly, technological advancements such as smartphone apps cannot replace diabetes team care neither they can they address all the risk factors for poor glycemic control in patients of Type 1 diabetes. With the challenges of access to healthcare services as well as issues with frequent clinic visits in our country, such interventions can play a supportive role in the long-term management. All of the solutions above are not mutually exclusive: in the best case they complement and reinforce one another. While they will not replace the care of a healthcare professional, they can support and relieve strained health system by reducing complications including hypo- or hyperglycemia as well as other serious complications resulting from inadequate monitoring or treatment.

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ANNEXURE 1

INSTITUTIONAL ETHICAL COMMITTEE CLEARANCE CERTIFICATE

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/2034   Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2019-20/986**

Project title: **"Effect of whatsApp based diabetes education and instructions on glycemic status, knowledge, quality of life and coping skills in patients of type 1 diabetes mellitus: A randomized controlled trial"**

Nature of Project:	**Research Project**
Submitted as:	**D.M. Dissertation**
Student Name:	**Dr.Parul Gupta**
Guide:	**Dr. Ravindra Shukla**
Co-Guide:	**Dr. M.K. Garg, Dr. Madhukar Mittal & Dr. Varuna Vyas**

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on **23-12-2019** and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:
- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma

Enclose:
1. Annexure 1

ANNEXURE 2

INFORMED CONSENT FORM

All India Institute of Medical Sciences Jodhpur, Rajasthan

Title of Thesis/Dissertation : EFFECT OF WHATSAPP BASED DIABETES EDUCATION AND INSTRUCTIONS ON GLYCEMIC STATUS, KNOWLEDGE, QUALITY OF LIFE AND COPING SKILLS IN PATIENTS OF TYPE1 DIABETES MELLITUS: A RANDOMIZED CONTROLLED TRIAL

Name of PG Student : Dr. PARUL GUPTA Mob No. 9654288685

Patient/Volunteer Identification No. :_____

I, _____S/o or D/o _____
R/o _____
give my full, free, voluntary consent to be a part of the study " Effect Of WhatsApp based diabetes education and instructions On Glycemic Status, Knowledge, Quality Of Life And Coping Skills In Patients Of Type1 Diabetes Mellitus: A Randomized Controlled Trial ", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and I am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from AIIMS Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____   _____
Place: _____   Signature/Left thumb impression
This to certify that the above consent has been obtained in my presence.
Date: _____   _____
Place: _____   Signature of PG Student

   1. Witness 1   2. Witness 2

     _____   _____
     Signature   Signature
     Name: _____   Name: _____
     Address: _____   Address: _____
     _____   _____

<div align="center">

<u>सूचित सहमति प्रपत्र</u>

</div>

प्रधान अन्वेषक: डॉ पारुल गुप्ता   **टेलीफोन नंबर:** 9654288685

रोगी / स्वयं सेवी पहचान संख्या: _____

मैं,_____पुत्र/पुत्री_____

_____निवासी_____फ़ोन_स्वयं को अध्ययन का

हिस्सा होने के लिए अपनी पूर्ण स्वैच्छिक सहमति देता हूँ। इस अध्ययन का शीर्षक है :

टाइप 1 मधुमेह के रोगियों में ग्लूकोज नियंत्रण ,ज्ञान,जीवन की गुणवत्ता और सामना करने की शक्ति पर व्हाट्सएप आधारित शिक्षा और निर्देश का प्रभाव: एक यादृच्छिक नियंत्रित परीक्षण

EFFECT OF WHATSAPP BASED DIABETES EDUCATION AND INSTRUCTIONS ON GLYCEMIC STATUS, KNOWLEDGE, QUALITY OF LIFE AND COPING SKILLS IN PATIENTS OF TYPE1 DIABETES MELLITUS: A RANDOMIZED CONTROLLED TRIAL.

मेरी पूर्ण संतुष्टि के लिए मेरी खुद की भाषा में मुझे समझाया गया है ।मैं इस बात की पुष्टि करता हूं कि मुझे सवाल पूछने का पूर्ण अवसर मिला है।

मैं यह समझता हूँ कि मेरी भागीदारी स्वैच्छिक है और बिना कोई कारण बताए किसी भी समय इस अध्ययन से स्वयं को वापस लेने के लिए मेरे अधिकार के बारे में मुझे पता है।

मैं यह समझता हूँ कि मेरे मेडिकल रिकॉर्ड की एकत्रित की गई जानकारी "अखिल भारतीय आयु विज्ञान संस्थान जोधपुर" या नियामक अधिकारियों द्वारा देखी जा सकती है ।मैं इन व्यक्तियों को मेरे रिकॉर्ड के उपयोग के लिए अनुमति देता हूँ।

दिनांक: हस्ताक्षर / वाम अंगूठे का निशान

स्थान:

यह प्रमाणित किया जाता कि इस संस्करण की सहमति मेरी उपस्थिति में प्राप्त की गयी है:

दिनांक: प्रमुख अन्वेषक के हस्ताक्षर

1. साक्षी1   2. साक्षी 2

हस्ताक्षर: _____   हस्ताक्षर:_____

PATIENT INFORMATION LEAFLET

You are being invited to willingly participate in the study entitled:

EFFECT OF WHATSAPP BASED DIABETES EDUCATION AND INSTRUCTIONS ON GLYCEMIC STATUS, KNOWLEDGE, QUALITY OF LIFE AND COPING SKILLS IN PATIENTS OF TYPE1 DIABETES: A RANDOMIZED CONTROLLED TRIAL.

Purpose of research

You are a type 1 diabetic patient and education plays an important role in your management. If you and your caregivers learn about multiple daily insulin injections, blood glucose monitoring, prevention and management of acute complications for example hypoglycemia and ketoacidosis, and importance of diet, then you can manage your diabetes on your own. We want to self-empower you so that you learn to manage your diabetes yourself and learn to adjust with diabetes.

Use of phone and WhatsApp has become very common in India. We hope that WhatsApp will help you so that you don't feel left out or isolated and can discuss your fears and experiences with us and can learn from other patients. Thus we hope that providing diabetes education through WhatsApp will not only improve the glucose control but will also help to improve your self-efficacy and coping skills and quality of life.

Study Design

Patients who have a mobile phone with internet and WhatsApp will be divided into 2 groups and discussion through WhatsApp messages will be done in both the groups weekly. You will be reminded of the time of start of discussion one day before and 4 hours prior to discussion. You are requested to participate actively in the discussions. We will test your 3 month average glucose values (HbA1c), knowledge, and ask you questions about your life, before and after16 and 28 weeks of WhatsApp discussions. We will compare with patients who don't have a mobile phone and WhatsApp. This

research will help to ascertain the importance of WhatsApp and whether it can be used for diabetes education on a large scale.

Confidentiality

Your medical records and identity will be treated as confidential documents. They will only be revealed to other doctors/scientists/monitors/auditors of the study if required. The results of the study may be published in a scientific journal but you will not be identified by name.

Ethics committee approval has been obtained for the study.

Your participation and rights

Your participation in the study is fully voluntary and you may withdraw from the study anytime without having to give reasons for the same. In any case, you will receive the appropriate treatment for your condition. You will not be paid any amount for the participation in the study. You will have to pay for the routine investigations that will be done.

For further queries/questions or help in emergency please contact.
1. **Dr. Parul Gupta 9654288685**
2. **Dr. Ravindra Shukla**

रोगी की जानकारी

आपको स्वेच्छा से अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है:

टाइप 1 मधुमेह के रोगियों में ग्लूकोज नियंत्रण ,ज्ञान,जीवन की गुणवत्ता और सामना करने की शक्ति पर व्हाट्सएप आधारित शिक्षा और निर्देश का प्रभाव

अनुसंधान का उद्देश्य:

आप टाइप 1 मधुमेह के रोगी हैं और शिक्षा आप के प्रबंधन में महत्व पूर्ण भूमिका निभाती है । यदि आप कई दैनिक इंसुलिनइंजेक्शन, रक्त शर्करा की निगरानी, हाइपोग्लाइसीमिया और केटोएसिडोसिस तीव्र जटिलताओं की रोकथाम और प्रबंधन, और आहार के महत्व के बारे में सीखते हैं, तो आप अपने मधुमेह का प्रबंधन अपने दम पर कर सकते हैं। हम आप को जानकारी प्रदान करना चाहते हैं ताकि आप अपने मधुमेह का प्रबंधन करना सीखें और मधुमेह के साथ समायोजित करना सीखें।

फोन और व्हाट्सएप का उपयोग भारत में बहुत आम होगया है ।हमें लगता है कि व्हाट्सएप आपकी मदद करेगा ताकि आप अलग-थलग महसूस नकरें और हमारे साथ अपने डर और अनुभवों पर चर्चा कर सकें और अन्य रोगियों से सीख सकें ।इस प्रकार हम आशा करते हैं कि व्हाट्सएप के माध्यम से मधुमेह की शिक्षा प्रदान करने से न केवल ग्लूकोज नियंत्रण में सुधार होगा , बल्कि आत्म प्रभाव कारिता और सामना करने की शक्ति और जीवन की गुणवत्ता में सुधार करने में भी मदद मिलेगी।

अध्ययन योजना

जिन रोगियों के पास इंटरनेट और व्हाट्सएप के साथ मोबाइल फोन है,उन्हें 2 समूहों में विभाजित किया जाएगा और व्हाट्सएप संदेशों के माध्यम से चर्चा दोनों समूहों में साप्ताहिक रूप से की जाएगी। आपको चर्चा के शुरू होने का समय एक दिन पहले और चर्चा से 4 घंटे पहले याद दिलाया जाएगा। आपसे अनुरोध है कि चर्चाओं में सक्रिय रूप से भाग लें। हम आपके 3 महीने के औसत ग्लूकोज मूल्यों (HbA1c)ज्ञान का परीक्षण करेंगे,और व्हाट्सएप चर्चा के 16 और 28 सप्ताह बाद में आपसे आपके जीवन के बारे में सवाल पूछेंगे। हम उन रोगियों से तुलना करेंगे जिनके पास मोबाइल फोन और व्हाट्सएप नहीं है। इस शोध से व्हाट्सएप के महत्व का पता लगाने में मदद मिलेगी और क्या इसका उपयोग बड़े पैमाने पर मधुमेह शिक्षा के लिए किया जा सकता है।

गोपनीयता

आपके मेडिकल रिकॉर्ड और पहचान को गोपनीय दस्तावेजों के रूप में माना जाएगा। यदि आवश्यक हो तो वे केवल अध्ययन के अन्य डॉक्टरों / वैज्ञानिकों / मॉनिटर / ऑडिटर्स के सामने आएंगे। अध्ययन के परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकते हैं लेकिन आपको नाम से नहीं पहचाना जाएगा।अध्ययन के लिए आचार समिति की मंजूरी मिल गई है।

आपकी भागीदारी और अधिकार

अध्ययन में आपकी भागीदारी पूरी तरह से स्वैच्छिक है और आप बिना कारण बताए कभी भी अध्ययन से हट सकते हैं। किसी भी मामले में,आप अपनी स्थिति के लिए उपयुक्त उपचार प्राप्त करेंगे। अध्ययन में भाग लेने के लिए आपको कोई राशि नहीं दी जाएगी। आपको नियमित जांच के लिए भुगतान करना होगा।

आगे के प्रश्नों / प्रश्नों के लिए या आपात स्थिति में मदद के लिए संपर्क करें।

1. डॉ पारुल गुप्ता 9654288685
2. डॉ रवींद्र शुक्ल।

ANNEXURE 4

CASE RECORD FORM

Final group of enrollment	Control	Intervention WhatsApp	Sham WhatsApp

DATE OF ENROLLMENT:	
NAME	
AGE	
AIIMS ID NUMBER	
MOBILE NUMBER	
ADDRESS	
DURATION OF DIABETES	

INCLUSION CRITERIA   **YES/NO**

Provides Written informed consent (Parental consent & assent if age <18)	
Has attended at least 2 sessions of diabetes education in our center	
Agrees for offline follow up	
Has a personal mobile phone with internet access	
Knows how to read messages on a mobile phone (Hindi or Hindi with English alphabets or English)	
Patient who gives willingness to receive WhatsApp messages for 28 weeks.	

EXCLUSION CRITERIA   **YES/NO**

Patient with other chronic illness that may interfere with study results e.g. mental illness	
Patient with conditions that may alter HbA1c values e.g. Sickle cell	

INVESTIGATIONS

	Baseline	16 weeks	28 weeks
Fasting glucose			
PP glucose			
HbA1c			
Creatinine			
LDL			
ECG			
Fundus			
Urine micro albumin			
Urine ketones			

DETAILS OF COMPLICATIONS: ACUTE

No. Of hypoglycemia in last 2 months	
No. Of admissions in last 6 months	

DETAILS OF COMPLICATIONS: CHRONIC

	Yes/no		Yes/no
Hypertension		Neuropathy	
Retinopathy		Nephropathy	
Diabetic ulcer		Infection	
OTHERS			

TREATMENT DETAILS: INSULIN DOSES: basal bolus:

Date/visit	Dose of basal insulin	Dose of bolus insulin	Total unit/kg

INSULIN DOSES: PREMIX

Date/visit	Dose of premix insulin	Total unit/kg

ACUTE COMPLICATIONS: IF ANY DURING 28 WEEK STUDY PERIOD

HYPOGLYCEMIA:	DIABETIC KETOACIDOSIS

ANY OTHER VISIT IN 28 WEEK STUDY PERIOD:

DIABETES KNOWLEDGE TEST: 34 questions

Question topic	No.of questions	Quest. No.	Maximum marks	Baseline score	16 weeks score	28 weeks score
Insulin (types, administration & t/t)	5	1-4, 19	15			
Nutrition	7	5-11	20			
Hypoglycemia	7	12-18	19			
SMBG	3	21,22,27	9			
Exercise	5	20,23-26	11			
Sick day management	3	28,29,33	12			
Complication	1	30	4			
Travel	2	31,32	6			
Dose adjustment	1	34	4			

CODI QUESTIONNAIRE

	Baseline	16 weeks	28 weeks
Acceptance			
Avoidance			
Cognitive palliative			
Distance			
Emotional reaction			
Wishful thinking			
Overall score			

DQOL QUESTIONNAIRE

	Baseline	16 weeks	28 weeks
Satisfaction			
Impact			
Worry : social/vocational			
Worry : diabetes related			

HbA1c baseline	HbA1c at 16 weeks	HbA1c at 28 weeks

ANNEXURE 5

MODULES FOR DIABETES EDUCATION

<u>ग्लाइसेमिक इंडेक्स:</u>

कम ग्लाइसेमिक इंडेक्स वाले खाद्य पदार्थ हैं जो रक्त शर्करा को धीरे-धीरे बढ़ाते हैं। इस प्रकार उच्च ग्लाइसेमिक इंडेक्स वाले खाद्य पदार्थों से बचना चाहिए।

<u>कम ग्लाइसेमिक इंडेक्स</u>	<u>मध्यम</u>	<u>उच्च ग्लाइसेमिक इंडेक्स</u>
अनाज: मिस्सी रोटी,एटा रोटी	अनाज: चावल,पोहा	कॉर्नफ्लेक्स,मैदा,व्हाइट ब्रेड,केक
दाल: चना,सभी दाल	वेज: आलू,मटर	चीनी,शहद,कोल्ड ड्रिंक
हरी सब्जी	फल: आम,कम पके केले,पपीता	
फल: सेब अमरूद,नारंगी,आडू		पानी तरबूज,पका हुआ केला,खजूर

सेरेअल लिस्ट:

नीचे की प्रत्येक वस्तु में 15 ग्राम कार्बोहाइड्रेट, 2 ग्राम प्रोटीन, 70 किलो कैलोरी होती है

1रोटी 20 ग्राम गेहूं ∗

2 ब्रेड 3 "की चौड़ाई

½कप पके हुए चावल (20 ग्राम बिना पका हुआ)

½कप मैगी नूडल्स (20 ग्राम बिना पका हुआ)

1 बड़ा मक्का

¾कप कॉर्नफ्लेक्स 20 ग्राम

¾कप दलिया (20 ग्राम बिना पका हुआ)

¾कप ओट्स (20 ग्राम बिना पका हुआ)

¾कप उपमा (20 ग्राम सूजी)

1 मध्यम इडली

3 मोनाको / मैरीगोल्ड बिस्किट

¾कप आलू (80 ग्राम कच्चा)

¾कप अरवी ^

¾कप हरी मटर ^

1 रोटी में 17 ग्राम कार्बोहाइड्रेट, 3 ग्राम प्रोटीन, 85 किलोकलरीज होती हैं

^इन सब्जियों में उच्च कार्बोहाइड्रेट सामग्री के कारण अनाज शामिल है

मिल्क सूची

नीचे दी गई प्रत्येक वस्तु में 9 ग्राम कार्बोहाइड्रेट, 6.5 ग्राम प्रोटीन, 8 ग्राम वसा और 130 किलो कैलोरी होती है।

1 गिलास गाय का दूध बिना मलाई का
1 गिलास टोंड दूध
1 गिलास दही
4 ग्लास बटर मिल्क ∗ 1 ग्लास -200 मिली

दाल सूची

सभी दालें (राजमा,लोबिया,मटर,चना) प्रत्येक भाग (25 ग्राम, 1 कप पका हुआ) 15 ग्राम कार्बोहाइड्रेट, 6 ग्राम प्रोटीन, 80 किलो कैलोरी प्रदान करता है

सबजी सूची

प्रत्येक भाग (1 कप = 150 मिलीलीटर) 5 ग्राम कार्बोहाइड्रेट, 2 ग्राम प्रोटीन, 30 किलोकलरीज प्रदान करता है

¾कप गोभी
½कप कद्दू
¾कप गाजर
½कप लउकी

1 कप फूलगोभी
1 मध्यम टमाटर
¾कप शिमला मिर्च
½कप भिंडी

फ्रूटलिस्ट

प्रत्येक भाग10 ग्राम कार्बोहाइड्रेट और 40 किलोकलरीज प्रदान करता है

1 छोटासेब	1 मध्यमनारंगी
1 मध्यममौसमी	1/3मध्यमपपीता
1 कपतरबूज	1 मध्यमअमरूद
2 छोटेआड़ू	4-5 बेर
¼मध्यमतरबूज	1 छोटाआम
1 कपअनानास	1/2केला (कमपकाहुआ)

रक्त शर्करा की स्व निगरानी

1.जटिलताओं से बचने के लिए रक्त शर्करा को नियंत्रण में रखना महत्वपूर्ण है

2. भोजन से पहले रक्त शर्करा आदर्श रूप से 80 से 130 मिलीग्राम% और भोजन के 2 घंटे बाद 90 से 180 मिलीग्राम% होना चाहिए।

3. इंसुलिन पर मरीजों को आदर्श रूप से प्रति दिन कम से कम 4 बार ग्लूकोज (नाश्ते से पहले, दोपहर और रात के खाने से पहले और रात के खाने के 2 घंटे बाद) और ससाह में एक बार रात 3 बजे मापना चाहिए इसके अलावा यदि आपको कम रक्त शर्करा के लक्षण दिखाई दे रहे हैं, तो आपको तुरंत परीक्षण करना चाहिए।

4. रक्त शर्करा के परिणामों को एक डायरी में लिखा जाना चाहिए क्योंकि रक्त शर्करा के पैटर्न में परिवर्तन खुराक समायोजन में मदद करता है।

5. एक ग्लूकोमीटर खरीदते समय सुनिश्चित करें कि स्ट्रिप्स आसानी से शहर में उपलब्ध हैं और मीटर के बजाय स्ट्रिप्स की लागत को देखते हैं।

6. मूत्र या रक्त में कीटोन्स की जाँच करें यदि रक्त शर्करा लगातार 250 mg% से अधिक या बुखार या किसी अन्य बीमारी के दौरान होता है।

7. सीजीएमएस: निरंतर ग्लूकोज मॉनिटरिंग सिस्टम: जिसके द्वारा त्वचा के नीचे तरल पदार्थ में ग्लूकोज को हर 24 घंटे की अवधि में लगातार 5 से 20 मिनट तक मापा जाता है । इस प्रकार आप दिन भर में अपने ग्लूकोज रीडिंग का विचार प्राप्त कर सकते हैं।

8. एचबीए 1 सी: पिछले 3 महीनों में बनाए औसत रक्त शर्करा को इंगित करने के लिए अस्पताल में किया गया एक परीक्षण है।इसे 7% से कम रखने का आपका प्रयास होना चाहिए

हाइपोग्लाइसीमिया

1. आपका रक्त शर्करा गिर सकता है यदि इंसुलिन इंजेक्शन,व्यायाम और भोजन के बीच एक बेमेल है (भोजन की मात्रा कम हो जाती है या इंसुलिन या अत्यधिक व्यायाम की खुराक बढ़ जाती है)

2. 70 मिलीग्राम / डीएल (हाइपोग्लाइसीमिया) से कम रक्त शर्करा भूख,कमजोरी,कंपकंपी,पसीना,चिड़चिड़ापन और चिंता के शुरुआती लक्षण हो सकता है । बाद में यह आंखों के सामने दोहरी दृष्टि या अंधेरे का कारण बन सकता है,लगातार चलने में असमर्थता, सिरदर्द और अगर तुरंत इलाज नहीं किया जाता है,तो बेहोशी या फिट हो सकता है।

3. हाइपोग्लाइसीमिया का तुरंत इलाज किया जाना चाहिए,ग्लूकोज पाउडर या चीनी 3 चम्मच या 3-4 कैंडी लें और 10 मिनट के लिए आराम करें और फिर से ग्लूकोज की जांच करें।यदि रक्त ग्लूकोज > 70 है और यह आपके भोजन का समय है,तो अपनी सामान्य इंसुलिन की खुराक लें और तुरंत अपना भोजन करें।

4. यदि आप बेहोश हो जाते हैं या फिट होते हैं ,तो एक परिवार के सदस्य को ग्लूकागन इंजेक्शन देना चाहिए और तुरंत नजदीकी डॉक्टर से परामर्श करना चाहिए।

5. यात्रा करते समय हमेशा एक हाइपो किट (ग्लूकोमीटर और ग्लूकोज और कैंडी के साथ) अपने साथ रखें। नाम और पते के साथ अपने साथ एक मधुमेह पहचान पत्र भी रखें

इन्सुलिन समायोजन

1) उच्च पूर्व भोजन चीनी के लिए इंसुलिन समायोजन: भोजनसेपहलेलक्ष्य 80-130 होना चाहिए।नियमित इंसुलिन के लिए, 1500/ कुल दैनिक इंसुलिन खुराक की गणना करें।

2) उदाहरण के लिए यदि दैनिक खुराक 50 यूनिट है,तो 1500/50 = 30 है। इसलिए प्रत्येक 30 मिलीग्राम% रक्त शर्करा के उन्नयन के लिए इंसुलिन की 1 यूनिट बढ़ाई जानी चाहिए।

2) इंसुलिन कार्बोहाइड्रेट अनुपातः 500 /इंसुलिन की कुल दैनिक इंसुलिन खुराक से विभाजित। यह आपको प्रत्येक ग्राम के लिए कितने ग्राम अतिरिक्त कार्बोहाइड्रेट का उपभोग करने की आवश्यकता है,जिससे आपको खुराक को 1 यूनिट बढ़ाने की आवश्यकता होती है

3) भोजन के लिए इंसुलिन समायोजन:

सामान्य भोजन पूर्व खुराक	भारी या हल्के भोजन के लिए,सामान्य खुराक में वृद्धि या कमी
1-3 u	0.5 u
4-9 u	1 u
>10	2 u

लंबी अवधि के निर्देश

1) यदि आपका रक्तशर्करा का मूल्य लगातार 3-4 दिनों के लिए लक्ष्य से ऊपर है, तो लंबे समय तक अभिनय करने वाले इंसुलिन (एनपीएच / ग्लार्जिनकी खुराक बढ़ सकती है।

ANNEXURE 6: CODI QUESTIONNAIRE

स्थितियों के बारे में सोचो जब आप अपनी बीमारी के कारण परेशान या तनावग्रस्त हैं। नीचे आपको उन तरीकों की सूची मिलेगी जिनमें बच्चे हैं इन स्थितियों में अपनी भावनाओं से निपट सकते हैं। कृप्या हमें बताएं कि आप कितनी बार आमतौर पर चीजें करते हैं या आपकी बीमारी से संबंधित विचार यह हैं

	Never	Seldom	Some Times	Often	Always
ACCEPTANCE	कभी नहीं	कभी कभी	कई बार	अक्सर	हमेशा
मैं अपनी बीमारी का प्रबंधन करने में सक्षम हूं।					
मुझे अपनी बीमारी की आदत हो गई है।					
मैं अपनी बीमारी से अच्छी तरह जूझता हूं।					
मैं अपनी बीमारी को स्वीकार करता हूं।					
मैं अपनी बीमारी को आसान लेता हूं।					
मैं हास्य के साथ अपनी स्थिति का सामना करता हूं					
AVOIDANCE	कभी नहीं	कभी कभी	कई बार	अक्सर	हमेशा
मैं अपनी बीमारी को नजरअंदाज करने की कोशिश करता हूं					
मैं सब ठीक होने का दिखावा करता हूं।					
मैं अपनी बीमारी कोभूलने की कोशिश करता हूं।					
मैं अपनी बीमारी के बारे में सोचता हूं					

COGNITIVE PALLIATIVE	कभी नहीं	कभी कभी	कई बार	अक्सर	हमेशा
मेरा मानना है कि भगवान में विश्वास मेरी मदद करता है।					
मैं प्रार्थना करता हूं कि मेरी बीमारी दूर हो जाए।					
मैं अपनी बीमारी के बारे में ज्यादा से ज्यादा सीखता हूं।					
मैं खुद से कहता हूं कि प्रसिद्ध लोगों को भी बीमारी है।					
मैं बदतर स्थितियों के बारे में सोचता हूं।					
DISTANCE	कभी नहीं	कभी कभी	कई बार	अक्सर	हमेशा
मैं अपनी बीमारी की परवाह नहीं करता।					
मुझे लगता है कि मेरी बीमारी कोई बड़ी बात नहीं है।					
मुझे लगता है कि मेरी बीमारी इतनी गंभीर नहीं है।					
मैं अपनी बीमारी के बारे में भूल जाता हूं।					

EMOTIONAL REACTION	कभी नहीं	कभी कभी	कई बार	अक्सर	हमेशा
मैं रोता हूँ					
मैं परेशान हो गया हूं।					
मुझे गुस्सा है ।					
मैं रात में जागता हूं और भयानक चीजों के बारे में सोचता हूं।					
मुझे बीमार होने पर शर्म आती है। ।					
मुझे लगता है कि यह अनुचित है कि मैं बीमार हूं					
WISHFUL THINKING	कभी नहीं	कभी कभी	कई बार	अक्सर	हमेशा
मैं अपनी बीमारी को रोकना चाहता हूं।					
मुझे उम्मीद है कि बीमारी गायब हो जाएगी।					
काश मैं स्वस्थ होता।					

ANNEXURE 7: DIABETES QUALITY OF LIFE QUESTIONAIRRE
जीवन की गुणवत्ता प्रश्नावली
Satisfaction/ संतुष्टि

		Completely Satisfied	Very Satisfied	Satisfied	Less Satisfied	Dis-satisfied
		पूरी तरह से संतुष्ट	बहुत संतुष्ट	संतुष्ट	थोड़ा असंतुष्ट	असंतुष्ट
1.	अपने मधुमेह को प्रबंधित करने में कितना समय लगता है, इससे आप कितने संतुष्ट हैं?					
2.	चेकअप करवाते समय आप कितने संतुष्ट हैं?					
3	आप अपने मधुमेह की जांच में लगने वाले समय से कितने संतुष्ट हैं?					
4.	आप अपने वर्तमान उपचार से कितने संतुष्ट हैं?					
5.	आप अपने आहार से कितने संतुष्ट हैं?					
6.	आप अपने परिवार पर कितना ☐☐☐☐ लगा रहे हैं उससे आप कितने संतुष्ट हैं?					
7.	आप अपने मधुमेह के बारे में अपने ज्ञान से कितने संतुष्ट हैं?					
8.	आप अपनी नींद से कितने संतुष्ट हैं?					
9.	आप अपने सामाजिक रिश्तों और दोस्ती से कितने संतुष्ट हैं?					
10.	आप अपनी सेक्स लाइफ से कितने संतुष्ट हैं?					
11.	आप अपने काम, स्कूल और घर की गतिविधियों से कितने संतुष्ट हैं?					
12.	आप अपने शरीर की बनावट से कितने संतुष्ट हैं?					
13.	जब आप एक्सरसाइज करने में समय बिताते हैं तो आप कितने संतुष्ट होते हैं					
14.	आप अपने खाली समय से कितने संतुष्ट हैं?					
15.	आप सामान्य रूप से जीवन से कितने संतुष्ट हैं?					

completely satisfied	very satisfied	satisfied	less satisfied	dissatisfied
1	2	3	4	5

IMPACT/प्रभाव

		Never impacted	Seldom impacted	Some Times impacted	Often impacted	Always impacted
		कभी नहीं प्रभावित	कभी कभी प्रभावित	कई बार प्रभावित	अक्सर प्रभावित	हमेशा प्रभावित
1.	कितनी बार आप अपने मधुमेह के उपचार से जुड़े दर्द को महसूस करते हैं?					
2.	आप सार्वजनिक रूप से अपने मधुमेह से निपटने के लिए कितनी बार शर्मिंदा महसूस करते हैं?					
3.	आपको कितनी बार ब्लड शुगर लो होता है?					
4.	आप कितनी बार शारीरिक रूप से बीमार महसूस करते हैं?					
5.	आपका मधुमेह आपके पारिवारिक जीवन में कितनी बार हस्तक्षेप करता है?					
6.	आपको कितनी बार रात की नींद खराब होती है?					
7.	आपको कितनी बार लगता है कि आपका मधुमेह आपके सामाजिक संबंधों और मित्रता को सीमित करता है?					
8.	आप अपने बारे में कितनी बार अच्छा महसूस करते हैं?					
9.	आप अपने आहार से कितनी बार प्रतिबंधित महसूस करते हैं?					
10.	आपका मधुमेह आपके यौन जीवन में कितनी बार हस्तक्षेप करता है?					
11.	आपकी डायबिटीज आपको कितनी बार कार या मशीन (जैसे, एक टाइपराइटर) का उपयोग करने से रोकती है?					
12.	आपकी डायबिटीज आपके व्यायाम में कितनी बार हस्तक्षेप करती है?					
13.	आप अपनी डायबिटीज के कारण कितनी बार काम, स्कूल या घर के कामों में चूक जाते हैं?					
14.	आप कितनी बार खुद को समझाते हैं कि मधुमेह होने का क्या मतलब है?					
15.	आप कितनी बार पाते हैं कि आपका डायबिटीज आपके अवकाश के समय की गतिविधियों को बाधित करता है?					
16.	आप अपने मधुमेह के बारे में कितनी बार दूसरों को बताते हैं?					
17.	मधुमेह के कारण आपको कितनी बार छेड़ा जाता है?					
18.	आप कितनी बार महसूस करते हैं कि आपके मधुमेह के कारण आप दूसरों की तुलना में अधिक बाथरूम जाते हैं?					
19.	आप कितनी बार पाते हैं कि आप कुछ खाते हैं जो आपको किसी को यह नहीं बताना चाहिए कि आपको मधुमेह है?					
20.	आप कितनी बार दूसरों से इस तथ्य को छिपाते हैं कि आपको इंसुलिन से प्रतिक्रिया हो रही है?					

Worry: Social/vocational चिंता: सामाजिक/ व्यावसायिक

		Never worried	Seldom worried	Some Times worried	Often worried	Always worried
		कभी नहीं चिंतित	कभी कभी चिंतित	कई बार चिंतित	अक्सर चिंतित	हमेशा चिंतित
1.	आप कितनी बार इस बारे में चिंता करते हैं कि आपकी शादी होगी या नहीं:					
2.	आप कितनी बार इस बारे में चिंता करते हैं कि आपके बच्चे होंगे या नहीं:					
3.	आप इस बात की कितनी बार चिंता करते हैं कि आपको मनचाही नौकरी मिलेगी या नहीं:					
4.	आप कितनी बार इस बारे में चिंता करते हैं कि आपको बीमा मिलेगा या नहीं:					
5.	आप इस बात की कितनी बार चिंता करते हैं कि आप अपनी शिक्षा पूरी कर पाएंगे:					
6.	आप कितनी बार इस बारे में चिंता करते हैं कि आपको काम छोड़ना पड़ेगा:					
7.	आप कितनी बार इस बारे में चिंता करते हैं कि आप छुट्टी या यात्रा कर पाएंगे:					

Worry: Diabetes related चिंता: मधुमेह संबंधी

		कभी नहीं चिंतित	कभी कभी चिंतित	कई बार चिंतित	अक्सर चिंतित	हमेशा चिंतित
1.	आप कितनी बार इस बारे में चिंता करते हैं कि आप मर जाएंगे:					
2.	आप कितनी बार चिंता करते हैं कि आपका शरीर अलग दिखता है क्योंकि आपको मधुमेह है:					
3.	आप कितनी बार चिंता करते हैं कि आपको अपने मधुमेह से जटिलताएं / समस्याएं होंगी:					
4.	आप कितनी बार इस बारे में चिंता करते हैं कि कोई आपके साथ बाहर नहीं जाएगा क्योंकि आपको मधुमेह है:					

मधुमेह शिक्षा संबंधित प्रश्नावली

Total: 100 marks

निर्देश: यह प्रश्नावली आपके मधुमेह संबंधित जानकारी के आंकलन के लिए तैयार की गई है। इसका प्राथमिक उद्देश्य यह परखना है कि मधुमेह शिक्षा के किन क्षेत्रों में आप की जानकारी को और बेहतर बनाने के लिए हमें ज्यादा प्रयास करने की आवश्यकता है। आप हिंदी या अंग्रेजी में उत्तर लिख सकते हैं।

(जिस भी वाक्य में "आपको" संबोधित किया गया है इसका तात्पर्य आपसे या आपके बच्चे से है जिन के लिए आप मधुमेह देखभालकर्ता हैं।)

1. भोजन से बढ़ने वाले शुगर को ठीक रखने के लिए **भोजन से पहले** आपका बच्चा/ आप कौन सी इंसुलिन लेते हैं?   (4)

   (a) **नाम** बताइए।
   (b) यह भोजन के **कितनी देर पहले** लेना चाहिए?
   (c) इसका **अधिकतम प्रभाव** कितनी देर बाद होता है?
   (d) इसका असर कितनी देर बाद **खत्म** हो जाता है?

2. (a) शरीर के किन अंगों पर इंसुलिन इंजेक्शन लगाया जाता है? ऐसे <u>चार भाग/ अंगों</u> का नाम बताइए।
   i. …………………………………..   (4)
   ii. …………………………………..
   iii. …………………………………..
   iv. …………………………………..

2. (b) इंसुलिन इंजेक्शन एक ही जगह पर बार-बार लेने के क्या परिणाम हो सकते हैं? <u>कोई एक परिणाम</u> बताइए।   (1)

3. इंसुलिन सिरिंज / पैन की सुई (needle) को ज्यादा से ज्यादा **कितनी बार** इस्तेमाल करने के बाद बदलना चाहिए?   (2)

4. *इस प्रश्न के तीन भाग हैं, (a) भाग का उत्तर केवल वे लोग दें जो **इंसुलिन सिरिंज** से दूधिया (एनपीएच-NPH) इंसुलिन लगाते हैं, (b)भाग का उत्तर केवल वे लोग दें जो **इंसुलिन सिरिंज** से बेसलॉग (Basalog) इंसुलिन लगाते हैं, और (c)भाग का उत्तर केवल वे लोग दें जो पैन से इंसुलिन लगाते हैं।* (2)

(a) **जो इंसुलिन सिरिंज से इंसुलिन लगाते हैं,** उन्हें दूधिया+ रेगुलर (Regular)मिश्रित (मिलाहुआ) टीका लगाते वक्त सिरिंज में कौन सा इंसुलिन **पहले** खींचना चाहिए?

(b) जो **इंसुलिन सिरिंज से बेसलॉग (Basalog) इंसुलिन लगाते हैं,** उन्हें रेगुलर इंसुलिन **कितने यूनिट** का इस्तेमाल करनाचाहिए?

(c) **जो पैन से इंसुलिन लगाते हैं,** अगर कभी आपका पैन खराब हो जाए और आपको कार्ट्रिज (cartridge/refill) से सिरिंज में लेकर इंसुलिन लगाने की जरूरत पड़े, तो आप **कितने यूनिटकी सिरिंज** का प्रयोग करेंगे?

5. नीचे दिए फलों में से कौन से **दो (2) फलों** का सेवन ज्यादा उचित है? (2)
   (a) सेब   (b) तरबूज   (c) संतरा

6. आपको/आप के बच्चे को अगर कभी ऐसे वक्त पर भूख लग रही हो जब भोजन लेने का निर्धारित समय नहीं है, तो ऐसे **पांच खाद्य पदार्थों/ पदार्थ समूह** के नाम पर गोला ⭘ लगाइए जिनके इस्तेमाल से ब्लड शुगर बढ़ता नहीं है, (इनको **कैलोरी फ्री या कैलरी विहीन प्रदार्थ** कहा जाता है) और इन्हें ऐसे समय पर इस्तेमाल किया जा सकता है। (5)

   (a) सब्जियों का सूप   (b) फल   (c) मुरमुरा/लाई (लहिया) /मुड़ी
   (d) खीरा-ककड़ी   (e) टमाटर-मूली का सलाद   (f) बिना शक्कर का नींबूपानी
   (g) दूध की चाय   (h) पतला मट्ठा   (i) बादाम   (j) बिस्किट

7. निम्नलिखित पदार्थों / भोजन समूह में से ऐसे **दो पदार्थों के** नाम पर गोला ⭘ लगाइए, जो मध्यरात्रि में हमारा शुगर कम (हाइपोग्लाइसीमिया) होने से बचाव के लिए हम रात को सोते समय ले सकते हैं? (2)

   (a) दूध या दूध से बने पदार्थ   (b) फलों का जूस
   (c) फल्लीयां (beans) और दालें   (d) हरी सब्जियां

8. खाना पकाने में कौनसे **तीन (3) प्रकार** के तेल/ घी का इस्तेमाल नहीं करना चाहिए?   (3)

   a) …………………………………

   b) …………………………………

   c) …………………………………

9. ऐसे **पांच** खाद्य पदार्थों के नाम बताएं जो शुगर को तेजी से बढ़ने नहीं देते; इन्हें **लो ग्लाइसेमिक इंडेक्स (low glycemic index)** प्रदार्थ कहा जाता है एवं इनका सेवन अपने भोजन में करना ज्यादा उचित है?

                                                                                      (5)

   (a) …………………………………

   (b) …………………………………

   (c) …………………………………

   (d) …………………………………

   (e) …………………………………

10. निम्नलिखित खाद्य पदार्थों में से कौनसे दो पदार्थों में **300 किलोकैलोरी (kcal)** ऊर्जा/ एनर्जी (energy) है? उन पदार्थों पर गोला ◯ लगाइए।   (2)

   (a) 2 कप पकी हुई Maggi (मैंगी)   (b) एक मध्यम आकार का आम

   (c) 4 मध्यम आकार की रोटियां/चपाती   (d) 10 बादाम

   (e) एक गिलास (200 ml) गाय का दूध   (f) एक कप (150 ml) पकी हुई राजमा दाल

11. खाद्य समूह कार्बोहाइड्रेट विनिमय तालिका (Carbohydrate exchange table) के अनुसार **एक मध्यम आकार की रोटी** के बदले आप कौन सा खाद्य प्रदार्थ ले सकते हैं, **एक** सही जवाब है, उस पर ◯ गोला लगाइए।   (1)

   (a) पोना (3/4th) कटोरी पका हुआ चावल   (b) एक छोटा सेब   (c) 5 बादाम

12. अगर आपकी/ आपके बच्चे की शुगर डायरी (mg/dL में) इस प्रकार है, तो इसमें से जितनी भी रीडिंग हाइपोग्लाइसीमिया (कम शुगर) है, उस पर **गोला** ⭕ लगाइए :- (3)

सुबह	नाश्ते के 2 घंटे बाद	दोपहर खाने से पहले	खाने के 2 घंटे बाद	रात खाने से पहले	खाने के 2 घंटे बाद	रात के 2:00 बजे
40	-	206	-	130	122	-
146	172	90	154	170	50	116
64	-	226	-	82	140	-

13. हाइपोग्लाइसीमिया (शुगर की कमी) के **पांच लक्षण** बताइए । (5)

 (a) ………………………………….

 (b) ………………………………….

 (c) ………………………………….

 (d) ………………………………….

 (e) ………………………………….

14. हाइपोग्लाइसीमिया (शुगर की कमी) होने के **चार कारण** बताइए । (4)

 (a) ………………………………….

 (b) ………………………………….

 (c) ………………………………….

 (d) ………………………………….

15. शुरुआती अवस्था में हाइपोग्लाइसीमिया (शुगर की कमी) को ठीक करने के लिए कदम नहीं उठाने पर क्या **गंभीर परिणाम** हो सकते हैं? **दो परिणाम** बताइए । (2)

 a) ………………………………….

 b) ………………………………….

16. हाइपोग्लाइसीमिया (शुगर की कमी) की वजह से अगर आपका बच्चा पूरी तरह जागृत (जागी हुई) अवस्था में नहीं है और मुंह से कुछ खा पी नहीं सकता, तो ब्लड शुगर बढ़ाने के लिए आप क्या करेंगे? **दो बातें या तरीके** बताइए। (2)

a) …………………………………………

b) …………………………………………

17. ग्लूकोमीटर में कम शुगर दिखने पर भी यह संभव है कि आपको / आपके बच्चे को हाइपोग्लाइसीमिया (शुगर की कमी) के लक्षण **ना** दिखें। (ऊपर दिए कथन के लिए उपयुक्त उत्तर के डब्बे पर '√ 'चिन्ह लगाएं) (1)

(a) सही 　☐

(b) गलत 　☐

18. आपके बच्चे को घर पर हाइपोग्लाइसीमिया (शुगर की कमी) से बेहोशी या दौरा पड़ने पर आपको तुरंत कौन सा **इंजेक्शन** देना चाहिए? (2)

19. आप अपना/ आपके बच्चे का इंसुलिन दुकान से खरीदते समय किन बातों का ध्यान रखेंगे? कोई **दो बातें** बताइए। (2)

(a) …………………………………………

(b) …………………………………………

20. मधुमेह के बच्चों को खेल-कूद की **प्रतियोगिताओं** में भाग लेना _____ है। (1)

(ऊपर दिए कथन के लिए उपयुक्त उत्तर के डब्बे पर '√ 'चिन्ह लगाएं)

(a) उचित 　☐

(b) अनुचित 　☐

21. आपकी/ आपके बच्चे की शुगर नीचे बताए गए समय पर किस रेंज/ सीमा के बीच होनी चाहिए? रेखाओं (↘↦↗) की मदद से **जोड़ी मिलाइए**। (4)

(a) भोजन से पहले 　　　　　　　i) 80-162 mg/dL

(b) रात के 2:00 बजे 　　　　　　ii) 70-145 mg/dL

(c) रात सोते समय 　　　　　　　iii) 90-180 mg/dL

(d) भोजन के 2 घंटे बाद 　　　　iv) 120-180 mg/dL

22. शुगर का नियंत्रण जानने के लिए हर 3 महीने पर **खून** की कौनसी जांच की जाती है? (2)

23. यदि आपका/ आपके बच्चे का भाग-दौड़ वाला खेल (उदाहरण:फुटबॉल) **1 घंटे से ज्यादा समय तक चलता हो या चलने वाला हो तो**

    (a) आपको/आपके बच्चे कोअल्पाहार कब-कब लेना चाहिए? **एक सही** जवाब चुनिए। (2)

        i. हर 15 मिनट में

        ii. हर आधे घंटे में

        iii. खेल के बाद

    (b) आप/आपका बच्चा अल्पाहार में क्या-क्या ले सकते हैं? **एक सही** जवाब चुनिए। (2)

        i. पाँच बादाम   ii. एक टॉफी

        iii. तीन ग्लूकोस बिस्किट   iv. दो पकौड़े

24. खेल-कूद/ व्यायाम से संबंधित नीचे दिए वाक्यों के लिए उपयुक्त उत्तर के डब्बे पर '√' चिन्ह लगाएं। (4)

    (a) जब आपका / आपके बच्चे का शुगर 260 mg/dL से ऊपर है या पेशाब में कीटोन आ रहे हैं तो व्यायाम अवश्य करना चाहिए।

        i. उचित ☐   ii.अनुचित ☐

    (b) खेल-कूद करने के _____घंटे बाद तक शुगर कम होने (हाइपोग्लाइसीमिया होने) की संभावना रहती है।

        i. 4 घंटे   ii. 12 घंटे   iii. 24 घंटे

    (c) लंबे खेल-कूद के बाद की लंबे दौरान तक काम करने वाली इंसुलिन [दूधिया (NPH) / बेसलॉग / लेंटस] की मात्रा (डोज़) को10 से 20% तक कम करना चाहिए।

        i. सही ☐   ii. गलत ☐

    (d) लंबे खेल-कूद के बाद रात सोते समय प्रोटीन-वसायुक्त अल्पाहार (snacks) लेना चाहिए।

        i. सही ☐   ii. गलत ☐

25.दौड़-भाग वाले खेल/ व्यायाम के पहले भोजन के समय का इंसुलिन आप शरीर के **किस भाग** में लेंगे? (1)

26.सभी को प्रतिदिन **कम से कम** कितने मिनट व्यायाम करना या दौड-भागवाला खेल खेलना चाहिए। **एक सही** जवाब चुनिए।   (1)

   (a) 15 मिनट   (b) 30 मिनट   (c) 90 मिनट

27. सामान्यतः शुगर की जांच दिन में तीन बार भोजन के पहले तो करते ही हैं, लेकिन और भी अच्छे नियंत्रण के लिए और कौनसे **तीन (3)वक्त** शुगर की जांच करनी चाहिए?   (3)

   (a) ……………………………………

   (b) ……………………………………

   (c) ……………………………………

28. इंसुलिन इंजेक्शन लेते हुए भी ब्लड शुगर लगातार ज्यादा आने के **पांच कारण** बताइए।   (5)

   (a) ……………………………………

   (b) ……………………………………

   (c) ……………………………………

   (d) ……………………………………

   (e) ……………………………………

29.अगर मधुमेह की अवस्था में बीमारी/ बुखार हो जाए और शुगर बढ़ी हुई हो (उदाहरण: 400 mg/dL), तो ऐसी अवस्था में आप कौन-सी **चार बातों** का ध्यान रखेंगे?   (4)

   (a) ……………………………………

   (b) ……………………………………

   (c) ……………………………………

   (d) ……………………………………

30.शुगर का उचित नियंत्रण ना होने पर लंबे दौरान में शरीर के किन **चार (4) अंगों** पर बुरा प्रभाव पड़ सकता है?   (4)

   (a) ……………………………………

   (b) ……………………………………

   (c) ……………………………………

   (d) ……………………………………

31. यात्रा के दौरान आपके पास hypo- kit (शुगर की कमी के इलाज का सामान) हमेशा होना चाहिए, इस किट की **तीन सामग्रियों** के नाम बताइए ।   (3)

   (a) ………………………………
   (b) ………………………………
   (c) ………………………………

32. यात्रा के दौरान हाइपो संबंधित सामग्री के अलावा डायबिटीज संबंधित और कौनसी वस्तुऐं आपके पास होनी चाहिए? **तीन चीजों का नाम बताइए** ।   (3)

   (a) ………………………………
   (b) ………………………………
   (c) ………………………………

33. पेशाब/ रक्त में कीटोन (ketones) आने पर आप किन **तीन (3) बातों** का ध्यान रखेंगे?   (3)

   (a) ………………………………
   (b) ………………………………
   (c) ………………………………

34. यदि आपका बच्चा 7:00 बजे सुबह का इंसुलिन लेकर स्कूल जाता है, 11:00 बजे स्कूल में टिफिन खाने का समय (ब्रेक) होता है और 1:00 बजे आकर इंसुलिन लेकर दोपहर का भोजन करता है तो नीचे दिए गए सवालों का जवाब दीजिए ।

   (ध्यान रहे आपको दोनों प्रश्नों में जो गलत जवाब है उस पर '√ 'चिन्ह लगाना है।)

   (a) उसका सुबह के नाश्ते के 2 घंटे के बाद वाला शुगर 100 mg/dL से 180 mg/dL के बीच आता है, परंतु पाठशाला से घर आने पर उसका दोपहर के भोजन से पहले का शुगर यदि लगातार बढ़ा हुआ आ रहा है, तो आप क्या बदलाव करेंगे? निम्नलिखित में से एक **गलत उत्तर** चुनिए ।   (2)

   i.   स्कूल जाने से पहले का नाश्ता कम मात्रा में देंगे ।
   ii.   दोपहर के भोजन से पहले की तुरंत प्रभावी (रेगुलर) इंसुलिन का डोज बढ़ाएंगे ।
   iii. स्कूल केखाने के डिब्बे (टिफिन) में तेल से बना हुआ भोजन पदार्थ नहीं देंगे ।

(b) उसका सुबह के नाश्ते के 2 घंटे के बाद वाला शुगर 200 mg/dL से 300 mg/dL के बीच आ रहा है और पाठशाला से घर आने पर उसका दोपहरके भोजन से पहले का शुगर भी लगातार बढ़ा हुआ आ रहा है, तो आप क्या बदलाव करेंगे? निम्नलिखित में से एक **गलत उत्तर** चुनिए।   (2)

i.   दोपहर के भोजन से पहले की तुरंत प्रभावी (रेगुलर) इंसुलिन का डोज बढ़ाएंगे ।

ii.   स्कूल के खाने के डिब्बे(टिफिन) में तेल से बना हुआ भोजन पदार्थ नहीं देंगे ।

iii. सुबह नाश्ते के पहले का तुरंत प्रभावी (रेगुलर) इंसुलिन का डोज बढ़ाएंगे ।

iv.   स्कूल जाने से पहले का नाश्ता नहीं देंगे ।

------------   0   -------   X   -------   0   -------------

WHATSAPP FOR DIABETES SELF MANAGEMENT EDUCATION (DSME) IN TYPE 1 DIABETES MELLITUS:

A RANDOMIZED CONTROLLED TRIAL

ABSTRACT

BACKGROUND: WhatsApp can be used for Diabetes Self-Management Education (DSME) in Type 1 diabetes mellitus.

OBJECTIVES: A randomized controlled trial to study the effect of WhatsApp based DSME on glycemic status, knowledge, quality of life and coping skills.

RESULTS: Type 1 diabetes patients (15-40 years) with WhatsApp were randomized into "Intervention" (n=28) who received weekly educational WhatsApp messages and "Sham" (n=28) who received weekly greeting messages. In addition, patients without access to WhatsApp formed "Control" group (n=10). The mean baseline HbA1c was 10.69 ± 2.74. The primary objective was change in HbA1c from baseline at 16 week and 28 weeks in all 3 groups. The difference was significant between WhatsApp group and control group (P 0.003, mean square 1.453) but not significant between Intervention and Sham group. Knowledge improved significantly in the intervention group (p value 0.001) but there was no significant difference in the coping skills or quality of life score or hypoglycemia among 3 groups.

CONCLUSION: Use of WhatsApp for DSME improves the HbA1c as compared to those who don't use WhatsApp. Active WhatsApp intervention improved the knowledge but did not translate into improvement in glycemic control, coping skills or quality of life.