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Effectiveness of “Rule of Seven” intervention in improving control status in diabetes mellitus protocol of a randomized controlled trial

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Abstract:

BACKGROUND: We developed the “rule of seven” intervention because different targets related to diabetes control can somehow be calculated by multiplication of seven. This study aimed to evaluate the effectiveness of the “rule of seven” in improving glycemic control in patients diagnosed with diabetes by measuring fasting plasma glucose and 2 hours postprandial plasma glucose.

MATERIALS AND METHODS: This two-arm randomized controlled trial will compare the effectiveness of the “rule of seven” intervention in achieving glycemic control in diabetes mellitus patients. The patients in the control arm will receive routine patient counseling related to diabetes mellitus. Patients registered with the noncommunicable disease (NCD) clinics of All India Institute of Medical Sciences (AIIMS), Bhubaneswar, Community Health Center (CHC) Tangi, and CHC Mendhasala will be recruited consecutively during clinic hours after fulfilling eligibility criteria and obtaining written informed consent. The sample size was estimated as 426 in each group. The ethical permission was obtained from the Institutional Ethics Committee (IEC) and prospectively registered in the Clinical Trial Registry of India (CTRI/2023/07/055522).

DISCUSSION: After the intervention, we will find out the change in knowledge regarding parameters related to glycemic status; discover the change in biochemical parameters after 1, 3, and 6 months; and conclude whether those changes are statistically significant or not.

Keywords:

Health education, patient education, rule of seven, type 2 diabetes mellitus

Introduction

Diabetes mellitus is one of the major noncommunicable diseases (NCDs), and India has the dubious distinction of being the diabetes capital of the world. Although it is a disease that can be controlled well with oral antidiabetic agents, insulin, and other non-pharmacological interventions, in countries, such as India, patients frequently end up with complications, such as diabetic nephropathy, retinopathy, and cardiovascular diseases.^[1-4] These

complications occur due to inadequate glycemic control. Achievement of reasonable glycemic control is of utmost importance to prevent complications and mortality among diabetics. Patients’ understanding and ability to remember their values and monitor themselves are indispensable in diabetes management. Studies have shown a high level of unawareness (20%–80%) among diabetes patients regarding fasting and 2 hours postprandial glucose targets.^[5-7] It is well known that a favorable outcome will be possible only with the help of ongoing patient education, which plays

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a crucial role in encouraging and supporting their treatment.^[8-10] Adequate and correct knowledge of patients about the disease and the target levels related to control status leads to their empowerment, which is vital in disease management.

However, patient education is not easy in countries, such as India, where the dual problem exists due to a lack of glycemic control. One is that the uneducated or less educated population has a misconception about real control, and the other is their inability to comprehend or remember the target values to be achieved. Many patients' perception of having reasonable control of diabetes is having good adherence and compliance to medical management, dietary management, and physical activity, their glycemic levels notwithstanding.^[11] During the treatment, even though the correct target levels of fasting plasma glucose, 2 hours postprandial plasma glucose, glycosylated hemoglobin (HbA1C), and other diabetic care information are provided by the physicians, nurses, or dieticians, the patients find it difficult to grasp or remember. Here comes the role of theories of learning, which explain how individuals obtain, comprehend, retain, and recall knowledge or information during learning. External stimuli in the form of information, along with environmental, emotional, and cognitive influences and prior experiences, shape the learning process. The five widely accepted learning theories include behaviorism, cognitivism, constructivism, connectivism, and humanism. Although each theory can be approached to facilitate patient education about diabetes, one theory of particular interest is the cognitive load theory, which falls under cognitivism. Cognitivism involves the synchronized working of external stimuli with the inner workings of the mind.^[12] Given the two types of memory, that is, working memory and long-term memory, the former has a limited capacity and duration. This theory explains how information should be presented to balance the working memory's intrinsic and extraneous cognitive load to optimize learning.^[13] "Rule of seven" is proposed to be a concise yet comprehensive way of balancing the two cognitive loads to enable patients to learn about their disease and appropriately log it into their long-term memory. Instead of an unorganized array of information about diabetes, this intervention will provide streamlined information about it, which will resonate with the concept of 7 days in a week, seven colors in a rainbow, or seven notes of music from long-term memory and help cement relevant information. Eventually, this education of patients about the disease and the various target levels for control will lead to their empowerment, which is vital in disease management and preventing complications. However, no clinical trial with a large sample size is available in India examining the effectiveness of a structured health education intervention based on specific learning theories.

Objectives

This study aimed to evaluate the effectiveness of the "rule of seven" in improving glycemic control in patients diagnosed with diabetes by measuring fasting plasma glucose, 2 hours postprandial plasma glucose, and HbA1c. This study will also evaluate the effectiveness of the "rule of seven" in improving knowledge about diabetes in patients diagnosed with diabetes. Simultaneously, it will evaluate the "rule of seven" effectiveness in improving dietary practices and physical activity in patients diagnosed with diabetes mellitus.

Materials and Methods

Study design and setting

This will be a two-arm randomized control trial that will compare the "rule of seven" intervention with routine patient counseling in patients with diabetes. Outcomes will be assessed at baseline (T0), 4 weeks (T1), 3 months (T2), and 6 months (T3). The flow of the trial is depicted in Figure 1.

This trial will be conducted in the noncommunicable disease (NCD) clinic of the Community Health Centre, Tangi, and the NCD clinic of the Community Health Centre (CHC), Mendhasala, Khordha District. The NCD clinic in Tangi is conducted every Monday and Thursday at the CHC from 8 a.m. to 12 p.m. and caters to hypertensive and diabetic patients. In Mendhasala, the NCD clinic is conducted from 8 a.m. to 12 p.m. from Monday to Friday. This clinic offers anthropometry, blood pressure, glucose measurement, treatment, registration in the National Program for Control and Prevention of Non-Communicable Diseases (NP-NCD), and breast, oral, and cervical cancer screening. Furthermore, counseling for diet, physical exercise, tobacco or alcohol use, and medication adherence is also provided.

Study participants and sampling

Participants will be patients diagnosed with type 2 diabetes mellitus. The inclusion criteria will be patients diagnosed with type 2 diabetes mellitus for at least the past six months and patients having an NCD clinic booklet. Exclusion criteria will include patients with any diabetic complications (diabetic foot, diabetic retinopathy, cardiovascular disease, cardiovascular accident, chronic kidney disease, acute kidney injury, etc.) and illiterate patients.

The sample size for the two groups was calculated using nMaster version 2.0 software. The sample size, with an expected mean difference of 0.9 mmol/L in fasting plasma glucose between the intervention and control groups, an effect size of 0.62, 5% alpha error, and 80%

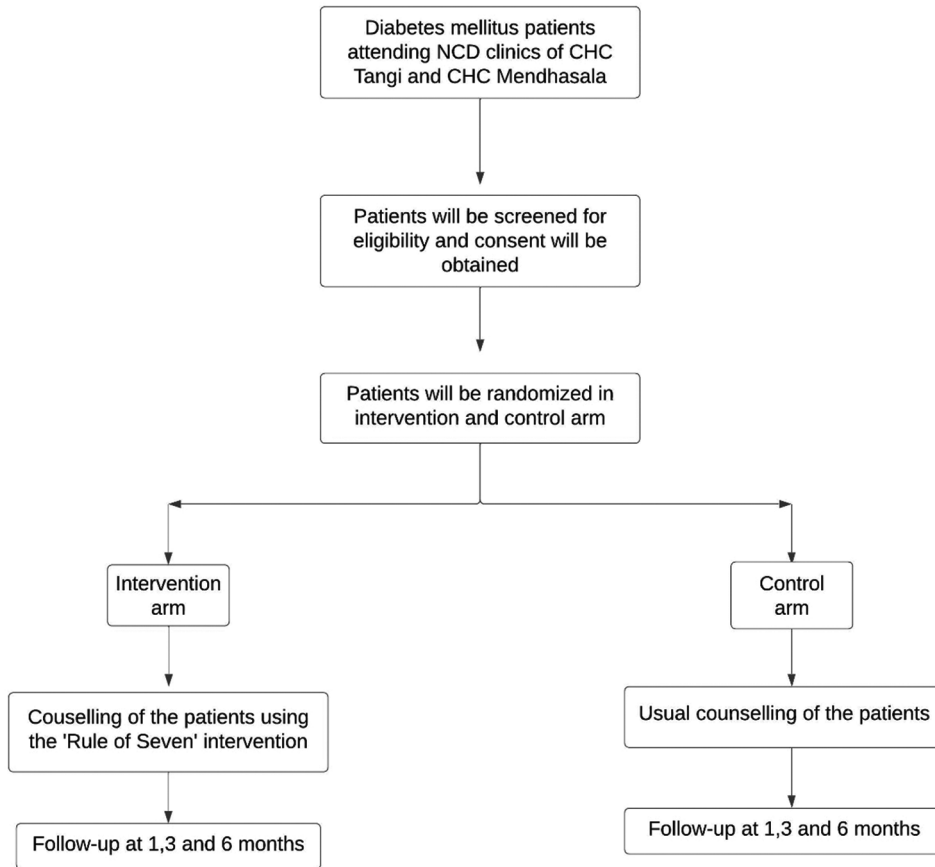


Figure 1: CONSORT flow diagram showing study flow. CHC = Community Health Center, NCD = noncommunicable disease

power, was 341 in each group.^[14] Attrition is expected to be around 20%. Hence, the sample size will be 426 in each group.

Recruitment

Patients registered with the NCD clinic at all three sites will be recruited from the registration counter during clinic hours. The participants will be recruited consecutively after screening for the eligibility criteria. The participant information sheet will be provided, followed by a consent form. A baseline assessment of outcomes will be performed, followed by the intervention procedure.

Intervention: 'Rule of Seven'

"Rule of seven" has been devised for patient education to enable them to monitor and take better control of their diabetes. It can be used by physicians as well and help them to direct the trajectory of the disease in a patient. The first step for the "rule of seven" includes asking the patient their lucky number in a single digit from 1 to 9. If the patient says his/her lucky number is 7, then the next step, such as information related to the parameters of diabetes mellitus, will be provided to the patient. If a patient says a number other than 7 or denies any number,

one of the following questions are asked: How many days are there in the week? Or how many colors are there in a rainbow? Or how many "notes" are in music? Or how many "pheras" are in a wedding? Once the number 7 enters the conversation, the values for 7 parameters related to diabetes will be explained in terms of multiples of 7 or the number 7 itself. Table 1 depicts the information that will be conveyed to the patients [Table 1].

Control arm

Patients in the control group will receive routine counseling as a part of the NCD clinic. It involves information about medication; physical activity; a diet high in fruits and vegetables and low in salt, sugar and oil with cessation of tobacco and alcohol consumption.

Randomization, allocation concealment, and blindness

One medical social worker will screen the participants for inclusion and exclusion criteria and give the participant an information sheet. After due consent, the outcome will be assessed at baseline, following which they will be given sequentially numbered opaque envelopes that will allocate patients to either the intervention group or control group with an allocation ratio of 1:1. The

Table 1: “Rule of seven” for diabetes patients: Description of parameters with respect to “7.”

Parameters	Rule of seven	Description (Patient education)
HbA1C	7×1=7	Keep it below 7%
FPG	7×1×10=70	FPG should not be below 70 mg/dl
	7×2×9=126	FPG should be below 126 mg/dl
2-hr PPG	7×2×10=140	PPG should be kept below 140 mg/dl and should be cautious
Diet	5–7	Three minor and three major meals 5–7 servings of fruits, vegetables, and salad
Exercise	5–7 days	Moderate intensity of physical activity for 30 minutes in five days among seven days
Investigations	7	FPG, PPG, HbA1c, lipid profile, kidney function test, urine microalbumin, etc.
Protect body parts	7	Brain, eyes, heart, kidney, foot, liver, pancreas

FPG=Fasting plasma glucose, HbA1C=Glycosylated hemoglobin, 2-hr PPG=Postprandial blood glucose after 2 h of meal

randomization sequence will be computer generated and saved in the above mentioned envelopes. As the intervention is a form of health education, blinding of participants will not be possible, but the outcome assessor will be blinded.

Outcome measures

Primary outcome

Knowledge about diabetes is the primary outcome of this trial, which will be calculated as a knowledge score at baseline, T1, T2, and T3. The responses will be collected as “yes,” “no,” and “I don’t know” and scored as 1 for yes and 0 for the rest.

Secondary outcomes

1. Glycemic control will be assessed as fasting plasma glucose and postprandial glucose at baseline, T1, T2, and T3.
2. Improvement or continuation of diabetic diet, including low sugar, salt, or oil and high fruits and vegetables, will be assessed using a 24-hour dietary recall. Low sugar will be defined as consumption of less than 5–9 teaspoons of sugar per day; low salt will be defined as less than 5 grams of salt per day; and low oil will be defined as less than five teaspoons per day. High fruits and vegetables will be defined as consuming more than five servings daily. One serving of fruit is defined as 80 gm of fruit or medium-sized or two small-sized fruits. One serving of vegetables is 80 gm or one cup (250 ml) of raw vegetables or 125 ml of cooked vegetables.^[14-16]
3. Initiation or continuation of physical activity will be assessed through self-report and defined as a moderate-intensity activity for 150 minutes per week. Moderate intensity is defined as an activity that makes you breathe somewhat harder.^[17]

Data and statistical analysis

All data will be collected using Epicollect forms at baseline and T1, T2, and T3. Excel sheets for the data will be generated automatically and cleaned and analyzed using IBM Statistical Package for the Social Sciences (SPSS) version 26. Continuous variables will be expressed as mean, median, standard deviation,

interquartile range, frequency, and percentage and analyzed using appropriate parametric tests. Categorical data will be analyzed using appropriate nonparametric tests. Intention-to-treat analysis will be performed with interim analysis at T1, T2, and T3 [Figure 1]. The Chi-square and Fisher’s exact tests will be used to examine the two groups for any differences in sociodemographic characteristics at baseline. Outcome variables, such as knowledge score and blood glucose, will be compared for pre- and post-intervention groups using paired-sample t-tests. In contrast, self-reported diet and physical activity will be compared using the Wilcoxon signed-rank test. The Consolidated Standards of Reporting Trials (CONSORT) 10 standards will be used in reporting the study results.

Ethical statement

We obtained ethical permission from the Institutional Ethics Committee (IEC) of All India Institute of Medical Sciences (AIIMS), Bhubaneswar (IEC no.: T/IM-NF/CM and FM/22/157). A detailed participant information sheet will be given, followed by written informed consent for interested participants. There are no invasive procedures involved in the trial. Participant data will be kept in password-protected computers or laptops. Personal identifiers will be removed during the analysis and reporting of data. Adverse events, such as any unfavorable and unintended symptoms or diseases related to this study, will be recorded and reported. Required care related to the adverse events will be provided following ethical guidelines. Results will be published in peer-reviewed journals and presented at conferences according to the CONSORT recommendations.

Discussion

The theme for 2022’s World Diabetes Day, observed on November 14, was “Educate to protect tomorrow.”^[18] With India witnessing a shift from infectious to NCDs, this theme becomes all the more relevant. The Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) study estimated the prevalence of diabetes mellitus as 7.3% in India.^[19] Odisha has a high burden of diabetes,

with an overall prevalence of 6.8% in adults and 22.2% in the elderly.^[20] The NP-NCD program takes care of the diagnosis and treatment part of the disease. Still, a significant program component is health promotion through health education. There is a lack of proper guidelines and standard operating procedures. Hence, various patient education techniques have been experimented with to improve knowledge about diabetes. These techniques have always aimed to impart health literacy and lead to better disease control. Physicians often end up using traditional methods of teaching, which fall short of adequate or comprehensible information about diabetes.^[21] The authors have devised the “rule of seven” taking learnings from the cognitive load theory, a theory of learning. Working memory and long-term memory are two parts of our memory system. The working memory first processes any information presented and then is finally stored in the long-term memory. Working memory has a limited capacity and duration; hence, the stimuli or “cognitive load” provided must be carefully titrated to ensure optimum learning and retrieval. The two types of cognitive load, that is, extraneous cognitive load, how the information is presented, and intrinsic load, that is, intrinsic content, will determine how the memory will be processed. “Rule of seven” aims to work its way through the extraneous load by providing organized information and at the same time, tapping into concepts from long-term memory to provide better loading of information.^[13]

Conclusion

Focused education programs and monitoring during follow-up visits will improve self-care in the less adhered-to aspects. Those who are adherent to dietary modifications and drugs have better glycemic control. Structured health education intervention (“rule of seven”) can be considered an appropriate strategy for helping in achieving reasonable glycemic control among patients of NCDs, specifically type 2 diabetes mellitus. The NP-NCD program warrants the role of information, education, and communication at all levels of healthcare facilities. The program document mentioned health education’s role in managing different NCDs. The underlying learning theories emphasize that using numbers in communication can increase effectiveness. We will assess the effectiveness of the health education strategy built upon the number “7.” This study will open up a new horizon for numerical inpatient education for many diseases.

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Conflicts of interest

There are no conflicts of interest.

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