Study Protocol

Analogies As A Possible Effective Consultation Tool In Type II Diabetes Mellitus Patients on Insulin: A Retrospective Cohort Study

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List of Abbreviations

T2DM	Type 2 Diabetes Mellitus
SMBG	Self-monitoring blood glucose
HbA1c	Hemoglobin A1C / Glycated Haemoglobin
FBS	Fasting blood sugar
EMR	Electronic Medical Record

Research Synopsis

Study title	Analogies As A Possible Effective Consultation Tool In Type II Diabetes Mellitus Patients on Insulin: A Retrospective Cohort Study
Objective	To determine the effectiveness of a novel consultation tool & method based on analogies in improving glycemic control among type 2 diabetes patients on insulin
Study Design	This design will be a retrospective cohort study. We have clinical data of 107 T2DM patients registered in a newly established SMBG clinic in Klinik Kesihatan Senawang from 1 January 2023 to 1 July 2023. These clinic sessions are conducted once a week, and use a new structured consultation tool based on an analogy to explain and consult these patients. Patients are followed up every 2 months. Their HbA1c will be measured after 3 sessions of consultations (6 months). Patients who defaulted the follow up will be excluded. We will prepare a medical record abstraction form and collect demographics and clinical data from the EMR. Demographic

	data included are patients' age and gender. Clinical data collected will be baseline HbA1c and FBS at first visit and third visit (after six months). Data will be analyzed to compare the following: (1) the percentage of patients achieving reduction of HbA1c and Fasting Blood Glucose (2) Average reduction of HbA1c and Fasting Blood Glucose
Study endpoints/outcomes	Reduction of HbA1c and Fasting Blood Glucose levels after six months, after a minimum of 3 SMBG clinic visits.
Study Population	All patients enrolled and registered at the SMBG clinic in Klinik Kesihatan Senawang from 1 January 2023 to 1 July 2023.
Inclusion/Exclusion Criteria	Inclusion criteria 1. Established T2DM patients, already on insulin therapy regardless of the type of insulin or regime or duration of treatment 2. HbA1c at referral more than 8.5% 3. Already seen by diabetic educator or dietician prior to referral 4. Completed a minimum of 3 follow-ups under the SMBG Clinic 5. Has repeated HbA1c recorded at 3 follow-ups Exclusion Criteria 1. Pregnant, or found to be pregnant during follow up
Sample Size	106 Subjects (universal sampling)
Study Duration	15 March 2024 - 15 June 2024 (3 Months)

1. Background and Significance

1.1. Diabetes prevalence in Malaysia has been steadily increasing. According to data from the National Health and Morbidity Survey (NHMS), conducted by the Ministry of Health Malaysia, the rate of diabetes among adults aged 18 and above rose from 8.4% in 2011 to a concerning 13.4% in 2019. This significant increase in diabetes rates is a matter of great concern that requires immediate attention. As diabetes progresses over time, oral hypoglycemic agents (OHAs) may become less effective. Therefore, insulin therapy becomes necessary to maintain proper blood sugar control. The use of insulin therapy among Type 2 diabetes patients in Malaysia has been increasing to align with recent local and international diabetes guidelines.

1.2. Despite the growing use of insulin therapy, a significant number of patients fail to achieve long-term blood sugar control. Audits revealed that only a small percentage of patients on insulin therapy achieve the desired HbA1c level below 6.5%. Approximately 10-15% of patients successfully reach the recommended blood sugar targets. Research also indicates that insulin is often prescribed with less intensive regimens and insufficient dosage optimization.

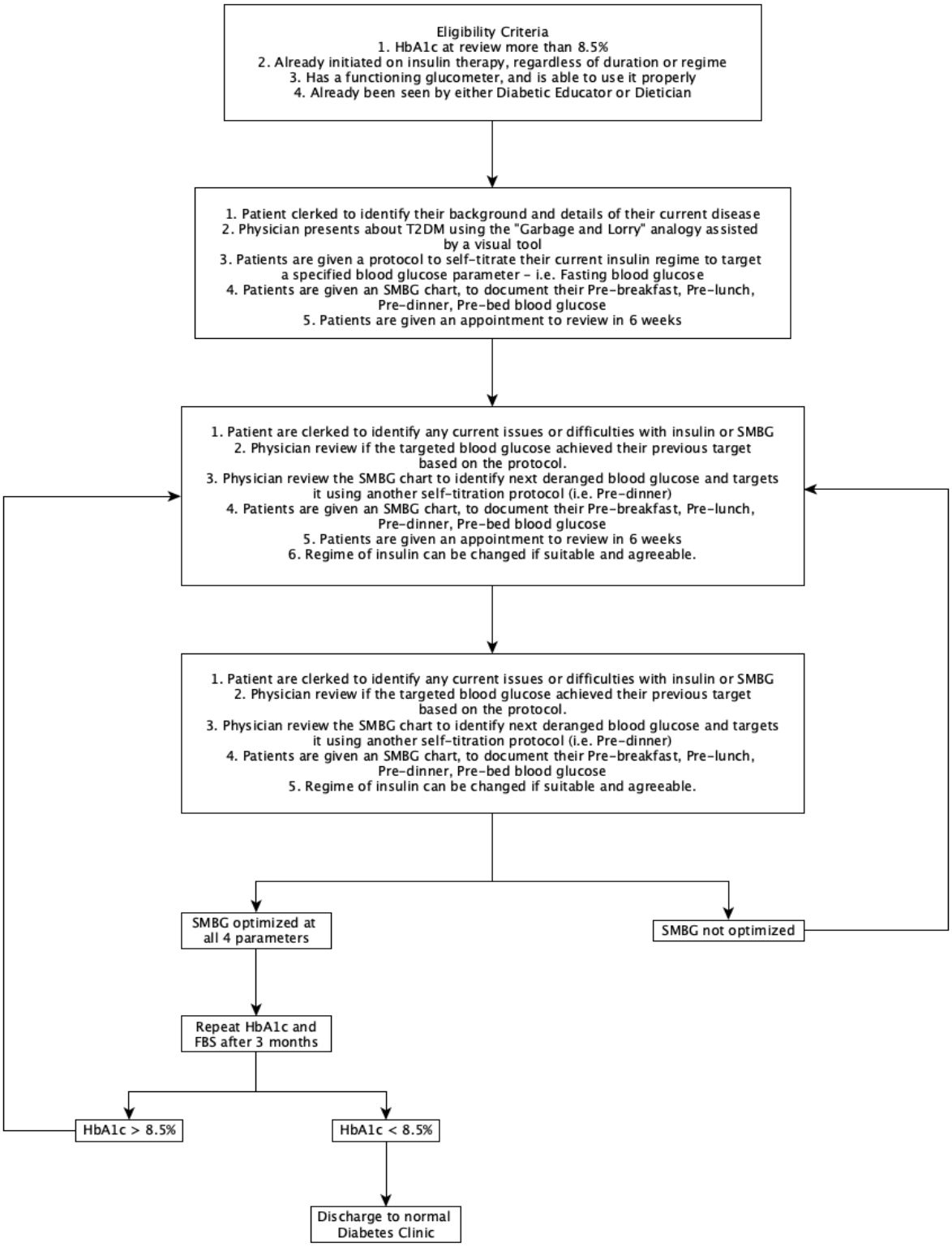
1.3. Multiple obstacles hinder optimal blood sugar control, including poor medication adherence, hypoglycemia, inadequate insulin dosage adjustments, reluctance to escalate insulin regimens (especially those requiring more frequent injections), and the underutilization of mealtime and basal insulin within basal-bolus regimens. One of the most under-addressed reasons is the patient's insight and understanding of diabetes itself. Multiple studies have shown that knowledge has direct correlation with improved glycaemic control. Healthcare workers, particularly physicians are the ones who will provide information regarding diabetes. While there are local Clinical Practice Guidelines for T2DM, there is currently no standardized guide on how to actually communicate and disseminate this information.

1.4. In clinical practice, analogies are recognized as valuable tools for facilitating communication while enhancing doctor-patient interactions, particularly in elucidating complex medical concepts. It is widely used in oncology to communicate with patients about their current condition. When presented in vignette form, analogies have demonstrated a potential for increasing objective comprehension among patients. They offer a means for simplifying intricate medical concepts, thus improving patient comprehension and engagement, ultimately leading to better health outcomes. This represents a promising approach to enhancing doctor-patient communication in a very complex disease like T2DM. However, the effectiveness of analogies may vary depending on the complexity of the medical issue and the numeracy level of the individual, highlighting the importance of tailoring analogies to suit the needs and cultural context of the patient.

1.5. Hence, we developed a consultation tool based on the “Garbage, lorry, factory” analogy. In this analogy, the garbage represents glucose, the lorry represents insulin, and the factory represents the muscle. We tested this method through a

specialized clinic in Klinik Kesihatan Senawang, Negeri Sembilan from January 2023, where patients are referred to a 2-monthly consultation with primary care doctors. On the very first visit, patients are clerked to provide baseline background information. Then, they will be presented with the “Garbage and Lorry” analogy, assisted by a visual tool (Appendix 1), to explain the pathophysiology of T2DM. The presentation includes detailed lifestyle modification advice like diet, exercise, sleep. It ends with an explanation of the pharmacology of the common T2DM drugs and insulin, all guided by the same analogy. At the end of the consultation, patients would be given an insulin intensification protocol built based on Malaysia’s local guidelines that they would have to follow, and was given a follow up after 2 months, with a 4-point SMBG chart to be monitored a week before. The follow up would be reviewing the SMBG, and optimizing their insulin regime based on the blood glucose profile. Once their SMBG is optimized, their HbA1c is repeated. Figure 1 shows a flowchart of how the SMBG clinic runs.

1.6. If proven efficacious and viable, this innovative approach holds potential as a cost-effective strategy to enhance glycemic control among T2DM patients, potentially revolutionizing diabetes management in Malaysia.



(Figure 1 - SMBG Clinic KK Senawang Flow Chart)

First visit to SMBG clerking and consultation contents:

1. Building Rapport
2. Social History
3. Co-morbidities History
4. The Diabetes History
5.The Diet History
6. The Activities & Exercise History
7. The Insulin History
8. The Blood Glucose Monitoring History
9. Summarizing
10. Improving Insight With Analogies
- Presentation of the garbage & lorry analogy using a visual tool
11. Insulin Intensification
- Education regarding how to titrate insulin based on the protocols
12. Given appointment in 6 weeks to review

(Figure 2 - SMBG Clerking and consultation content)

(Figure 3 - SMBG Clinic KK Senawang Insulin Intensification Protocol)

2. Objective

To determine the effectiveness of a novel consultation tool based on analogies in improving glycemic control among type 2 diabetes patients on insulin with HbA1c and FBS as primary outcomes.

3. Methodology

3.1 Study Design

This design will be a retrospective cohort study. Clinical data of 107 T2DM patients enrolled in the SMBG clinic in Klinik Kesihatan Senawang from 1 January 2023 to 1 July 2023 (6 months) will be extracted from the electrical medical record (EMR). Patients who defaulted the follow up intervals will be excluded, as well as those without a repeated HbA1c. We will prepare a medical record abstraction form and collect demographics and clinical data. Demographic data included are patients' age and gender.

Clinical data collected will be baseline HbA1c and FBS at first visit and fourth visit (after six months). Data will be analyzed to compare the following: (1) the percentage of patients achieving reduction of HbA1c and FBS from baseline (2) Average reduction of HbA1c and FBS from baseline.

3.2 Study Population

All patients registered and enrolled to the SMBG clinic in Klinik Kesihatan Senawang during the period of 1 January 2023 to 1 July 2023

3.3 Inclusion Criteria

1. Established T2DM patients, already on insulin therapy regardless of the type of insulin or regime or duration of treatment
2. HbA1c at referral more than 8.5%
3. Already seen by diabetic educator or dietician prior to referral
4. Completed a minimum of 3 follow-ups under the SMBG Clinic
5. Has HbA1c recorded at 6 months

3.4 Exclusion Criteria

1. Pregnant or found to be pregnant during follow-up

3.5 Withdrawal Criteria

Not applicable

3.6 Sample Size

106 patients. This study will use a universal sampling method. 106 patients were enrolled in the SMBG Clinic of Klinik Kesihatan Senawang from 1 January 2023 to 1 July 2023.

3.7 Study Duration and Timeline

- Start date: 20 March 2024
- End date: 20 September 2024
- Stage 1, review of medical records - 2 months
- Stage 2, data collection and data analysis - 2 months
- Stage 3, presentation and publication - 2 months

Gantt Chart

Year	2024										
Month	02	03	04	05	06	07	08	09	10	11	12
Proposal development											
Ethical approval											
Data collection											
Data analysis											
Report writing											
Dissemination											

3.8 Study Visits and Procedures

Not applicable

3.9 Statistical Analysis Plan

The data analysis will be done using the SPSS version 29. Descriptive data will be expressed as mean ± standard deviation (SD) unless otherwise stated. Paired T-Test will be used for analysis of normally distributed variables. Wilcoxon signed-rank test will be used for non-normally distributed data. A value of $P < 0.05$ is considered statistically significant.

3.10 Risk and benefit to participants

As stated in the literature above, there are no serious side effects known to be caused by the investigational product. The study procedures are all routine procedures for the disease/condition studied. There is thus minimal risk for subjects. This study does not present any direct benefit to the participants. However the study does provide a better understanding of the disease/condition studied.

3.11 Risk Benefit Assessment

As stated above, there is minimal risk from the investigational product and study procedures. Study findings shall potentially greatly improve treatment outcomes. The expected benefit outweighs the minimal risk to subjects and thus this study should be supported. If any injuries do occur as a direct result of participating in the study, treatment for such injuries shall be provided or paid for by the sponsor

3.12 Ethics of Study

Study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline

3.13 Informed Consent/Assent Process

This study involved a retrospective review of existing clinical records of patients who had already received standard care under the Self-Monitoring of Blood Glucose (SMBG) clinic. No additional procedures, interventions, or patient contact were conducted for research purposes.

The consultation framework and tool was implemented as part of routine clinical service improvement, not as an experimental intervention at the time of delivery. Data analysed were anonymized prior to extraction, and no identifiable patient information was used.

As this was a retrospective analysis of de-identified records with minimal risk to participants, the requirement for individual informed consent was waived by the institutional ethics review committee in accordance with the Declaration of Helsinki (2013) and Malaysian Good Clinical Practice guidelines.

3.14 Privacy and Confidentiality

Subject's data will be kept on a password-protected database and will be linked only with a study identification number for this research. The identification number instead of patient identifiers will be used on subject data sheets. All data will be entered into a computer that is password protected. On completion of study, data in the computer will be copied to CDs and the data in the computer erased. CDs and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study. The CDs and data will be destroyed after that period of storage. Subjects will not be allowed to view their personal study data, as the data will be consolidated into a database. Subjects can write to the investigators to request access to study findings

3.15 Conflict of Interest

The investigators declare they have no conflict of interest

3.16 Publication Policy

No personal information will be disclosed and subjects will not be identified when the findings of the survey are published. The permission from the Director General of Health, Malaysia will be obtained prior to publication

3.17 Termination of Study

The sponsor may decide to terminate the study at any time.