

ISPAD-JDRF FELLOWSHIP AWARD PROGRESS REPORT

Title: The glycaemic impact of blood glucose monitoring and diabetes education program in youth (aged 0-25 yr) with type 1 diabetes in a resource-limited center

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BACKGROUND

Optimal management for T1D involves intensive insulin management, where blood glucose levels are maintained in the normal range by multiple daily injections of insulin. A large, long term international study has shown that over a 30 year follow up period, intensive insulin management reduced diabetes related complications by 30-49% and lowered mortality by 33%.¹ Worldwide, T1D related outcomes are improving², related to development of insulin analogues, access to home glucose monitoring and continuous glucose monitors and access to specialty diabetes teams.³ Unfortunately, in resource poor areas and in certain vulnerable populations, diabetes related mortality and morbidity is increasingly disproportionate.⁴

People with T1D from regions with lower socio-economic status typically have a higher HbA1c, earlier mortality and higher rates of diabetes related complications. India is home to many young people with type 1 diabetes, but the true incidence and burden of T1D in India is unknown. In 2006, Registry of Youth Onset Diabetes in India (YDR) was established by the Indian Council of Medical Research.⁵ From this database, an incidence of 4.9 cases per 100,000 has been reported.⁶ The average HbA1c was 11.0% in

comparison to a North American register where the average HbA1c was 7.8%.⁷ In India, 23.5% of young people with diabetes used multiple daily injection regime compared to 65.1% in the North American register.⁸

Sher-I-Kashmir Institute of Medical Sciences

The Sher-I-Kashmir Institute of Medical Sciences (SKIMS) in Srinagar, India services 400 children with type 1 diabetes. The average HbA1c is 10.5% and the average life expectancy is 29 years. Access to blood glucose monitoring and diabetes education is limited. Patients attending SKIMS see an endocrinologist regularly. They do not have access to diabetes nurse educators, dietitians or social workers.

SWIIM

Success With Intensive Insulin Management (SWIIM) is a pediatric diabetes management program developed by the John Hunter Children's Hospital Pediatric Diabetes team over the past 20 years. The average HbA1c at this center is 7.0%. The program received the New South Wales Health Research and Innovation Award in 2019. Outcomes of the program have been published⁹ and the center has consistently achieved among the best diabetes outcomes in Australia.¹⁰

The SWIIM program centers on multidisciplinary care including endocrinologists, diabetes nurse educators, dietitians, social workers and general practitioners. A flexible insulin regime is used where individualized dosing cards (ezyBICC cards) calculate insulin doses based on pre-meal BGL and the amount of carbohydrate in the meal. A target HbA1c of 6.5% consistent with international guidelines is adopted across the clinic. BGL targets are 3.5-8.0mmol/L and families are empowered to adjust their insulin doses if the BGLs are not in target. Patients with newly diagnosed T1D receive a standardized inpatient education program. The cornerstone of education is the "10 Essential Habits" that guide families with managing T1D at home.

Implementing the SWIIM Program

While diabetes management principals do not change with geographical location, differences in language, culture and daily routines mean that diabetes management must be adapted to suit the local population. There are a number of differences in the population attending SKIMS to that attending JHCH including: non-English speaking, non-Australian population; lower socioeconomic status; limited access to subsidized insulin, BGL monitoring and diabetes technology; lack of access to a multidisciplinary diabetes

team; use of different units for BGL monitoring (mg/dL compared to mmol/L). For these reasons the SWIIM program needs to be adapted to suit this population.

AIMS

The primary aim of the study is to determine if the implementation of the JHCH SWIIM program improves outcomes for young people with diabetes in a developing population. The primary outcome measured will be a reduction in clinic HbA1c by 1.0%.

Secondary outcomes will include the rates of diabetes related complications, hospital admissions, rates of DKA and severe hypoglycemia.

Methodology

Prior to the study, A SKIMS clinician attended the JHCH for a 6-week educational visit. Resources on carbohydrate counting, insulin dosing and adjustments, insulin calculation sheets and patient educational materials were provided. In collaboration with SKIMS clinicians, the JHCH SWIIM resources have been adapted to be culturally appropriate and to reflect common mealtimes and food choices for the region. Weekly meetings with SKIMS clinicians will be continued over the study visit to discuss clinician and patient experiences and allow for further adaptation of the provided resources. Through the Life for A Child, the clinic was provided with glucometers and glucose testing strips to distribute to patients in the clinic. Patients will have access to 3 glucose testing strips per day.

Baseline data collection will occur when participants attend to collect their glucometer. This data will reflect management and outcomes prior to the intervention. If the participant is on a fixed dosing regime, the opportunity to switch to a flexible insulin regime will be provided if it is felt appropriate by the SKIMS clinician. Education and written resources will be provided to the patient on insulin administration, carbohydrate counting and insulin dose calculations. Participants will be reviewed at 3 monthly intervals and data collection will be repeated.

Data collection will include:

1. Patient demographics – Age, sex, duration of diabetes, HbA1c
2. Insulin administration type/Number of injections per day
3. Number of blood glucose measurements per day
4. Presence of diabetes related complications
5. Number of episodes of DKA, severe hypoglycemia and hospital admissions for diabetes related complications.

Current Status of first 3 months (January 2023 to March 2023)

The ethical clearance for the study was obtained from the Institutional Ethics Committee (IEC) at SKIMS with the Protocol No# RP 209/2021. Additionally, the study was registered on the Clinical Trials Registry India (CTRI) with the registration number CTRI/2023/01/049112, dated 19th January 2023.

Recruitment of subjects for the study started on 20th January 2023, and so far, 115 subjects with type 1 diabetes have been recruited after their baseline data was collected. These recruited subjects were then shifted to the SWIIM program, and a follow-up was conducted for the first 3 months. Blood samples were collected to gather HbA1C data during this follow-up period.

The 6th month follow-up is scheduled to be completed in June 2023. After the data from the first 6 months of the study is analyzed, the interim results will be presented as an abstract at the 49th Annual Conference of the International Society for Pediatric and Adolescent Diabetes (ISPAD). This indicates that the study is progressing according to the planned timeline, and the interim results will be shared with the scientific community at the conference in October 2023.

Next Steps

The study will be continued for 1 year and the follow up with HbA1c will be collected at 9th and 12th month.

The significant contribution of ISPAD-JDRF to this research will be included in all presentations and will be noted in any publication

Timetable

Key milestone of the Study	Est. completion date
SKIMS Clinician visit to JHCH	March-April 2022
Ethics approval	April 2022
Trial registered on CTRI	January 2023
Baseline data collection complete	April 2023
Presentation of study protocol and 6 months study results at ISPAD conference	October 2023
12 months of follow up data collected	December 2023
Data analysis complete	Feb 2024
Manuscript complete	August 2024
Submission to international journal	September 2024

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