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Using an AI-assisted tool to predict the behavior of children with type 1 diabetes for optimal use of sensor technology in Oman

Submission date
03/04/2025

Recruitment status
Not yet recruiting

Registration date
22/04/2025

Overall study status
Ongoing

Last Edited
22/04/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This pilot study investigates the effectiveness of the OMNIdiasense, an AI-assisted assessment tool, designed to predict and enhance adherence to continuous glucose monitor (CGM) use among children (under 18 years of age) with type 1 diabetes mellitus (T1DM) in Oman. Building on prior research highlighting AI's role in improving self-management and glycemic control, the study aims to develop and evaluate predictive models that generate personalized behavioral insights and adherence strategies to optimize diabetes care.

Who can participate?
Children diagnosed with T1DM in Oman, including CGM sub-users identified from previous formative studies and newly recruited participants.

What does the study involve?
Two groups of participants will be recruited. The first group (Questi-experimental study) will involve existing children with T1DM identified as CGMs sub-optimizers from formative cross-sectional studies who will be assigned to use the OMNIdiasense tool before reintroducing CGMs, with tailored motivational interviewing (MI)-based consultations provided at baseline, 3, and 6 months. The second group involves new prospective participants who will be randomly allocated to either the intervention or control groups. The intervention group will use the OMNIdiasense tool before applying the CGMs with MI-based consultations provided at baseline, 3, and 6 months. The control group will continue standard CGM use without the OMNIdiasense tool. All participants from both studies will be monitored over one year with follow-ups at 6 and 12 months. The study also involves predictive model development using machine learning, training sessions for healthcare teams, and real-time feedback mechanisms.

What are the possible benefits and risks of participating?
Benefits include improved adherence to CGMs, personalized diabetes management, and potential enhancement in glycemic control and quality of life. Risks are minimal and primarily pertain to data privacy and standard risks associated with CGM use.

Where is the study run from?
The study is coordinated from Muscat, Oman, involving regional polyclinics and diabetes care providers.

When is the study starting and how long will it run?
February 2025 to May 2027

Who is funding the study?
Ministry of Higher Education, Research and Innovation, Oman

Who is the main contact?
Dr Thamra Said Al Ghafri, t.alghafri@squ.edu.om

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

Utilizing an AI-assisted tool to predict the behavior of children with type 1 diabetes for optimal use of sensor technology in Oman: a multi-phase translational research project

Effectiveness of an AI-assisted assessment tool (the OMNIdiasense) to predict the behavior of adherence to CGMs use in children with T1DM in Oman: A pilot study

Study objectives
A newly developed AI-assisted tool is effective in predicting the behavior of children with type 1 diabetes in adhering to the use of the continuous glucose monitors

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/02/2025, Health Studies and Research Approval Committee (HSRAC) Ministry of Health, Sultanate of Oman (P O Box 393, Muscat, PC 100, Oman; +968-22357280; admin@mohcsr.gov.om), ref: MoH/CSR/25/29506

Study design
Quasi-experimental single-arm pilot followed by a randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Hospital, Medical and other records

Study type(s)
Prevention, Screening

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Improve the glycemic control and quality of life for children with type 1 diabetes

Interventions
The phases/sub-studies associated with this project as background are:
Sub-study 1: The characteristics of children with T1DM who received the CGMs in Oman (data from the Al Shifa system). All children who received CGMS from July 2024 to February 2025 will be included (n=1500). Data on their glycemic control will be compared at least 3 months from baseline.
Sub-study 2: Correlates of adherence to Continuous Use of CGMs in Children with T1DM in Oman: A Mixed-Design Study Based on face-to-face interviews with randomly selected children of T1DM (10-18 years of age from Sub-study 1). Demographic, psycho-social, dietary and physical activity factors influencing their CGMs use will be identified. Results from this study will inform the development of a smart AI tool that can predict the behaviour/adherence to CGMs.

This study relates to the pilot and randomised controlled trial below:
Sub-study 3: Effectiveness of an AI-assisted assessment tool in predicting adherence to CGMs in children with T1DM in Muscat. Two approaches will be used to test the effectiveness of the AI-predictive tool. First, a quasi-experimental (single-arm) study will be conducted on 100 children with T1DM from Phase 2, identified as CGM sub-users. These children will be randomly selected using random number generation in SPSS to ensure unbiased allocation of participants, and the OMNIdiasense will be used prior to the reintroduction of CGMs. Simultaneously, another group of 50 children will be recruited across the regions of Oman. Of these, 25 will be randomized to undergo the OMNIdiasense assessment to predict their adherence to CGMs, while the remaining 25 (control group) will receive CGMs as usual care without exposure to the assessment tool. Scores from the AI tool will determine the accompanied intervention (face-to-face consultations guided by motivational interviewing methods at baseline, 3 months and 6 months) to improve compliance with the use of CGMs. Scores will be reassessed at 6 and 12 months and compared to the baseline scores. All recruited children (both intervention and control groups) will be followed for one year and assessed at 6-month and 12-month follow-ups.

Intervention Type
Behavioural

Primary outcome measure
Effectiveness of the AI-assisted tool to predict the optimal use of CGMs in children with T1DM measured using
1. (OMNIdiasense) scores at baseline, 3, 6, and 12 months
2. Recordings from the CGMs at baseline, 3, 6, and 12 months
3. Motivational interviewing-guided behavior change consultations at baseline, 6 and 12 months

Secondary outcome measures
The following variables were assessed using data collected from a study questionnaire at baseline:
1. Demographic characteristics
2. Medical history of the disease
3. Family history of DM and type
4. History of co-morbidities

The following variables were assessed using data collected from patient health information records at baseline, 6 and 12 months follow-up:
1. Drug/treatment history
2. Anthropometric measures: Weight, BMI
3. Blood pressure
4. Cholesterol testing, liver function tests (LFT), and renal function tests (RFT)
5. HbA1c

Overall study start date
12/02/2025

Completion date
01/05/2027

Eligibility

Key inclusion criteria
All children with type 1 diabetes willing to participate

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
1500

Key exclusion criteria
Refusal to participate

Date of first enrolment
01/12/2025

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
Oman

Study participating centre
Oman Ministry of Health
P O box
Muscat
Oman
113

Sponsor information

Organisation

Ministry of Health Sultanate of Oman

Sponsor details
P O box
Muscat
Oman
113

Sponsor type
Government

Website
https://www.mohcsr.gov.om/

Funder(s)

Funder type
Government

Funder Name
Ministry of Higher Education, Research and Innovation

Alternative Name(s)
Ministry of Higher Education - Oman, Oman Ministry of Higher Education, Research and Innovation, Oman, Ministry of Higher Education, Research and Innovation, Minister for Higher Education, Research and Innovation, Ministry of Higher Education, Research and Innovation of the Sultanate of Oman, , MoHERI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Oman

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
15/12/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request to the PI, Dr Thamra Alghafri, thamra74@yahoo.com, t.alghafri@squ.edu.om, and official approval from the Ministry of Health, Oman.

• The type of data that will be shared: The Type of data will include characteristics of participants and measures of adherence to CGMs.
• Timing for availability: December 2027
• Whether consent from participants was required and obtained: Consent is required from the participants and is included in the consent form
• Comments on data anonymization: All data will be anonymized, which means personal details like name or contact information will not be included, instead, participant will be coded according to their regions and health institutes.
• Any ethical or legal restrictions: Ethical approval was obtained. This is a low risk study with no major ethical or legal restrictions expected.
• Any additional comments: None

IPD sharing plan summary

Available on request