T1IDES: Statistical Analysis Plan V1 13/11/2025

Summary of Variables

Numerical variables will be summarised as means and standard deviations, or medians and inter-quartile ranges as appropriate. Categorical variables will be summarised as frequencies and percentages. Descriptive statistics for the 3 RGC subscales (precise, flexible and misaligned) will be described with mean and standard deviation with subscale scores and frequency distributions of each strategy.

Summary of Analysis Plan

*Table 1: A summary of the analysis plan research objective 2 *Sample justification research objective in red*

	Exposure	Outcome	Statistical Test
Construct Validity T1IDSI a. Test-retest[1]	Retesting of 50 participants within 1 month	Bland-Altman plot x-axis: mean of both scores (time 1 + time 2), y-axis: difference between the two time point sets of 15 RCG domain scores. Mean difference close to zero = no systematic drift in scores over time. Standard Deviation (how much the differences vary across participants): smaller SD=better consistency; LoA (limits of agreement with lower and upper limits).	Bland-Altman plot, mean difference, SD of differences, 95% LoA with confidence intervals.
Hypothesis Testing/Research Questions (See in detail 20.3.5.3)			Before and after adjusted for demographics
1. What is the frequency distribution across the 5 domains, 15 RGC domain scores and 3 RGC scores?			Frequency distributions and descriptive statistics
2. What is the association	3 RCG scores continuous	HbA1c (self-reported)	Individual linear regression for each continuous outcome

	Exposure	Outcome	Statistical Test
between 3 RCG scores and self-reported HbA1c			
3. What is the association between the 15 RCG domain scores and HbA1c (i.e. Does this impact all domains of T1IDSI behaviours ?)	15 RCG scores	Self-reported HbA1c	Individual linear regression for each continuous outcome
4. What is the strength of association between the 3 RCG scores (for precise, misaligned and flexible strategies) and disordered eating behaviours ?	3 RCG scores continuous	DEB (1. DEB 2. no DEB) dichotomous	Individual logistic regression and mutually adjusted logistic regression to test for independence of associations
5. What is the association between recent diagnosis and 3 RCG scores?	New variable DiagnosisDuration (diagnosis =<1 year and > I year) (Computed from age of diagnosis Survey item 1 and DOB/Age Survey item 2)	3 RCG Scores for subscales Precise, Flexible and Misaligned Subscales.	Individual linear regression for each continuous outcome
6. What is the association between diagnosis	Diagnosis Age	RCG Scores for Precise, Misaligned and Flexible Subscales.	Individual linear regression for each continuous outcome

	Exposure	Outcome	Statistical Test
age and 3 RCG scores?			
7. What is the association between the age people take responsibility for diabetes self-care and 15 RCG scores?	Qu 27. How old were you when you took responsibility for CC responsibility age	15 RCG domain scores for strategy Scores across each domain.	Individual linear regression for each continuous outcome
8. What is the association between experience of severe hypoglycaemia and 3 RCG Scores? (i.e. Does this experience influence the strategies chosen?)	Qu 14. Binary Yes or No	3 RCG Scores for Precise, Misaligned and Flexible Subscales.	Individual linear regression for each continuous outcome
9. What is the association between experience of severe hyperglycaemia and 3 RCG Scores? (i.e. Does this experience influence the strategies chosen?	Qu 15. Binary Yes or No	RCG Scores for Precise, Misaligned and Flexible Subscales.	Individual linear regression for each continuous outcome
10. What is the association between	Qu. 19 Diabetes Management	RCG Scores for Precise, Misaligned and Flexible Subscales.	Individual linear regression for each continuous outcome

	Exposure	Outcome	Statistical Test
diabetes management and 3 RCG scores?	scale (-1 0 or 1)		
11. What is the association between diabetes management and 15 RCG domain scores (i.e. Does this impact all domains of T1IDSI behaviours ?)	Qu. 19 Diabètes Management scale (-1 0 or 1)	15 RCG Domain Scores	Individual linear regression for each continuous outcome

Hypothesis Testing for T1CCC TOOL	Exposure	Outcome	Statistical
1. What is the association between diagnosis duration and T1CCC capability scores?	Diagnosis duration	T1CCC capability score	Individual linear regression
2. What is the association between diagnosis duration <1 year and diagnosis >1 year and T1CCC capability scores?	Binary variable diagnosis <1 year and diagnosed >1 year	T1CCC capability score	Individual linear regression
3. What is the association between diagnosis age and T1CCC capability scores?	Diagnosis Age	T1CCC capability score	Individual linear regression
4. What is the association between strategy use and T1CCC capability scores?	3 RCG scores	T1CCC capability score	Individual linear regression
5. What is the association between diabetes management and	Diabetes Management Qu 19 (-1, 0, 1)	T1CCC capability score	Individual linear regression

	T1CCC capability scores?			
6.	What is the association between T1CCC capability scores and DEB?	T1CCC capability score	DEB	Linear regression

Justification of sample size

The sample size calculation will be based on the following research question:-

4.	What is the strength of association between the 3 RCG scores (for precise, misaligned and flexible strategies) and disordered eating behaviours ?	Exposure: 3 RCG scores continuous	Outcome: DEB (1. DEB 2. no DEB) dichotomous	Statistical Analysis: Individual logistic regression and mutually adjusted logistic regression to test for independence of associations

As the T1IDSI questionnaire is unique there is no precedent for this exposure. However, we do have some data on the outcome prevalence from previous literature. A search for 'type 1 diabetes and DEPS-R on PubMed revealed 18 studies over the past 5 years across the world which used DEPS-R, and the average percentage of people scoring above the cutoff on DEPS-R for DEB was also 35%. The expected odds ratio will need to be estimated, and it is considered that an odds ratio of moderate effect OR=2.0 would be clinically meaningful. At 80% power using multiple predictors (3 RGC scores) and + 5 possible confounders (age, age of diagnosis, diabetes duration, gender, CC responsibility age). Looking at the events per variable (EPV) rule, it is considered appropriate to have 10 events per predictor variable. For 8 predictors (3 RGC scores plus 5 confounders) a sample size of 80 events are required (80/0.35) so a sample of 229 people would be required. A sample size of 229 will allow up to 8 variables to be included in a single logistic regression model to assess associations between precise, flexible and/or misaligned strategies plus confounders on the primary hypothesis testing outcome (DEB). This is based on the recommendation of 10 or more events (DEB) per variable[2] and also an outcome prevalence (DEPS-R) of 35% has been thoroughly investigated[3].

Construct Validity of Domains and Subscales

Summary of baseline data and flow of patients

Objective 1: Scale Development (refinement of measurement tools) outcome analysis

The primary outcome of the pilot study is to develop a reliable validated scale for measuring insulin dosing strategies, determine the appropriate set of items in each domain and test the usability and reliability of the T1CCC tool.

The inventory will be revised based on the data analysis from the cognitive interviews, and the PPIE Lived Experience and Clinical Advisory Groups will be asked to comment on any revisions. Data collected from the final online survey combining the T1IDSI with the other study questionnaires will be analysed to confirm the final items to be included in the inventory (as described in the data analysis summary table). Structural validity is not required for formative measurement models according to Cosmin guidelines COSMIN checklist with 4-point scale and the T1IDSI is underpinned by rigorous content validity.

Objective 2: Construct Validity of T1IDSI

Frequency distributions for the 15 RCG domain scores will be summarised. T1IDSI behaviours will be summarised according to RCG domain scores (precise, flexible, misaligned). Mean scores for each of the 3 RCG strategies within each domain will be summarised where appropriate, as well as overall mean scores for each RCG strategy. Please see Table 25.

Table 1: 15 RCG Domain Scores

Domains/subscales					
	Calculating Carbohydrate	Considering SMBG Levels in Calculations	Adapting insulin	Adapting Physical Activity	Adapting Carbohydrate Consumption
Precise	✓	✓	✓	✓	✓
Flexible	✓	✓	✓	✓	✓
misaligned	✓	✓	✓	✓	✓

Defining T1IDSI as an observable inventory rather than a questionnaire

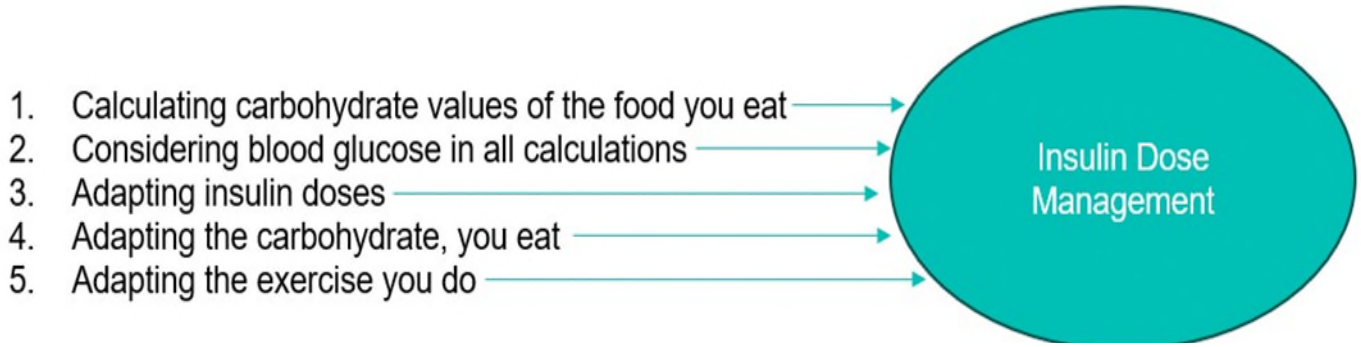

Figure 1: Conceptual Framework of T1IDSI

T1IDSI measures observable behaviours used by young people to achieve adequate blood glucose control based on assessment of social, psychological and biological risk. It is very much a patient-

centred approach. The domains/ indicators have been validated using content validity and are not in question as they are not theoretical concepts used to explain behaviours, in terms of collection instrument tools, T1IDSI is a checklist or an inventory rather than a questionnaire[4].

While observable characteristics do not require measurement theories[5], using measurement theory is helpful to understand the inventory and what it measures. The inventory can be viewed as a formative model of 64 items (minus 14 for non-pump users) assessing 3 constructs, 20 items measuring precise strategy use (minus 3 for non-pump users), 15 items measuring flexible strategy use (minus 1 for non-pump users) and 32 items measuring misaligned strategy use (minus 10 for non-pump users). See T1IDSI items by strategy 28.3.3. The T1IDSI can be described as formative, because the 5 domains are distinct non-interchangeable components that together form comprehensive insulin management. If there is an improvement in one of the domains, you would expect to see improvement in overall insulin dose management[5].

Validity

Criterion Validity

Criterion validity cannot be assessed for this measure as there is no comparable existing 'gold standard' for insulin dose management practices of this detail. Previous self-management questionnaires have focused on adherence (do patients calculate carbohydrate, consider blood glucose in calculations, adapt insulin accordingly) rather than patient-centred blood glucose control strategies (how do patients calculate and modify carbohydrate, insulin and exercise) [6-8] with the exception of two study specific unvalidated questions which cover some specific carbohydrate-counting behaviours [9 10]. In the case where no gold standard is available COSMIN guidelines state that construct validity can be testing using hypothesis testing to test expected associations and expected differences between relevant groups[11]. See Objective 2 Hypothesis Testing 20.3.9.

Construct Validity

What we are most interested in is whether using particular strategies (illustrated by the inventory

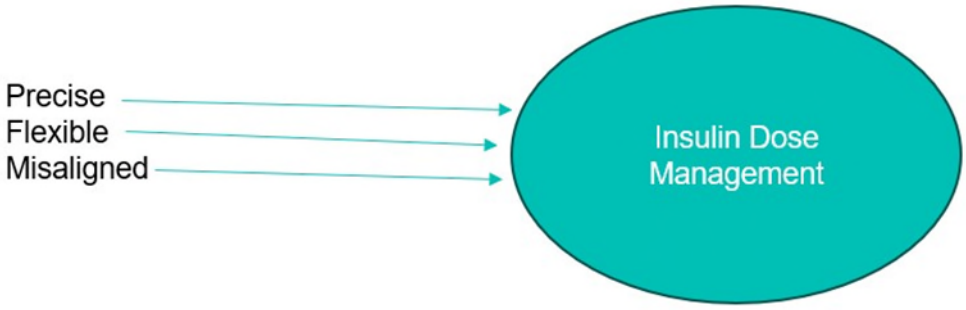

Figure 2: T1IDSI Strategy Scales

items) that are clinically recommended could have an impact, particularly in disordered eating and whether this inventory could be more useful than adherence measures, which do not consider patient-centred strategy choice. These 3 strategies, precise, flexible and misaligned are not latent variables either, but rather they have been determined by their relationship to clinical guidance by an expert of clinical health care professionals who work with young people with type 1 diabetes (See 13.3.1.1.4). Content validity is paramount for observable constructs. Practises that can be scored in relation to clinically recommended guidance are self-validating to an extent but are considered valid if supported by rigorous content analysis[4]. Structural validity and internal consistency are not relevant to formative models according to COSMIN guidelines [11].

Reliability

Reliability can be tested using Limits of Agreement (LoA) to ascertain test-retest reliability. Test-retest will be assessed by retesting 50 participants within 1 month to assess the repeatability of a participant's responses by estimating the strength of the relationship between scale items over two time points[12] calculating the mean difference and the Standard deviation of difference in the scores at each of the two time points and using a Bland-Altman plot to illustrate the limits of agreement (LoA).

Objective 2: Hypothesis Testing

Convergent Validity

As there is no gold standard for what we are measuring, we can only look at construct validity by comparing results with other studies i.e. by comparable correlations with convergent criteria as expected to support validity.

Poorer treatment adherence has previously been associated with higher DEB[13] scores and higher self-management scores have been associated with improved HbA1c [14 15] . While T1IDSI is not an adherence scale, we would assume that strategies misaligned to recommended clinical guidance would also be associated with higher DEB scores and that precise strategies would be associated with better HbA1c scores. COSMIN guidelines state construct validity can be tested for formative measurement models by hypothesis testing of expected associations and expected differences between relevant groups[11] so we will be investigating the association with DEB and the 3 RGC strategies. as well as HbA1c and the 3 RGC strategies. As per hypothesis 1 and 2 in the statistical summary table. See table 23 for a summary of the analysis plan by research objectives for all hypotheses.

Sensitivity analyses will be conducted to compare young people who use insulin pumps as opposed to people using multiple daily injections.

Filter variables denoting exposure variables (named in the statistical analysis plan) without missing data will be computed. Analyses will only select cases if the filtered condition is satisfied (variables with no missing data).

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