CARE-T2D: STATISTICAL ANALYSIS PLAN

Study name: Continuous Glucose Monitoring-Assisted Remote E-health dietetics for people with Type 2 Diabetes

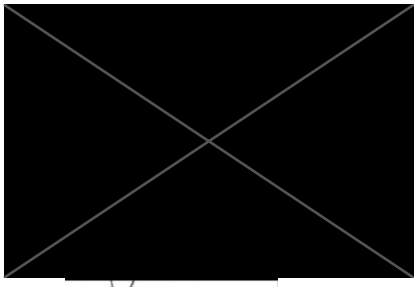
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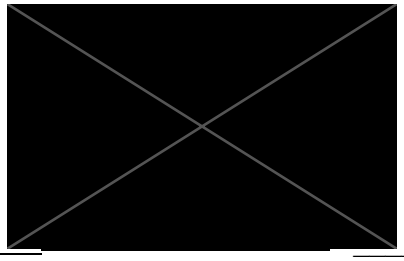
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Abbreviations

ACU	Australian Catholic University
APD	Accredited Practising Dietitian
AUC	Area under the curve
CGM	Continuous glucose monitoring
CGM-DIET	Continuous glucose monitoring plus dietetic support (intervention group)
CONSORT	Consolidated Standards of Reporting Trials
DAWN2	Diabetes Attitudes, Wishes and Needs 2
DIDP-7	DAWN2 Impact of Diabetes Profile
DIET	Dietetic support (active comparator group)
DSMQ-R	Diabetes Self-Management Questionnaire-Revised
DTSQ	Diabetes Treatment Satisfaction Questionnaire
EDE-Q	Eating Disorder Examination Questionnaire 6.0
EQ-5D-5L	EuroQol 5-Dimension 5-Level
FSL Pro iQ	FreeStyle Libre Pro iQ
FSL 2Plus	FreeStyle Libre 2 Plus
GP	General practitioner
HbA1c	Glycated haemoglobin
HDL	High-density lipoprotein
HEIFA	Healthy Eating Index for Australian Adults
HLQ	Health Literacy Questionnaire
HREC	Human Research Ethics Committee
hsCRP	High-sensitivity C-reactive protein
ICER	Incremental cost-effectiveness ratio
IDF	International Diabetes Federation
IPAQ	International Physical Activity Questionnaire
ITT	Intention to treat
LDL	Low-density lipoprotein
LibreView	Abbott LibreView software platform
MES	Medication effect score
MICE	Multiple imputation by chained equations
MMM	Modified Monash Model
PP	Per protocol

PSQI	Pittsburgh Sleep Quality Index
QALY	Quality-adjusted life year
REDCap	Research Electronic Data Capture
SAP	Statistical analysis plan
T2D	Type 2 diabetes
T2DDAS	Type 2 Diabetes Distress Assessment System
TAR	Time above range
TBR	Time below range
TIR	Time in range
TITR	Time in tight range
WHO	World Health Organization
WHO-5	WHO-5 Well-Being Index

Preface

This statistical analysis plan (SAP) describes the planned analyses and reporting for the CARE-T2D study to compare the impact of continuous glucose monitoring plus dietetic support (CGM-DIET) with dietetic support alone (DIET) in adults with type 2 diabetes. The purpose of the SAP is to outline the considerations and the pre-specified analyses for the CARE-T2D study.

The project is externally funded by an Investigator Initiated Scheme application to Abbott Diabetes Care (ADC-OUS-IIS-23-30) awarded to Dr Evelyn Parr.

The study has been approved by the ACU Human Research Ethics Committee (HREC) 2024-3690HC.

Study Objectives

The primary objective in this study is to determine the effect of the self-management of blood glucose with CGM sensors by comparing Continuous Glucose Monitoring with Dietetic support (CGM-DIET: Group 1 = novel intervention), to dietetic support only (DIET: Group 2 = active control) on changes in HbA1c over 6 months.

We will measure the glucose outcomes (via HbA1c from pathology, and CGM data) as well as assessing the interaction with the self-management, and the associated behavioural change (i.e. changes to self-efficacy and dietary intake). Therefore, a further aim of the study is to assess participants' engagement, motivation, and perceived quality of life and self-care following the adoption of the CGM.

We hypothesise that while both groups will improve their HbA1c (primary outcome) and glucose TIR (secondary outcome) over the duration of the study, the use of CGMs in an intermittent, self-managed setting, with support from a dietitian (CGM-DIET: Group 1) will lead to the greatest improvements in glycaemic outcomes (via HbA1c, and TIR) compared to dietetic consultations only with no glucose monitoring feedback (DIET: Group 2).

Study Outcomes

Note: all outcomes are described as continuous variables unless specified otherwise.

Primary objective: 0 to 6 months

Primary efficacy outcome: what is the effect of assignment to CGM-DIET vs. DIET on glycated haemoglobin (HbA1c) change from baseline to 6 months in all randomised participants (ITT), irrespective of adherence, medication changes or protocol deviations.

Secondary efficacy outcomes:

- Change in blinded CGM (i.e. from FSL Pro iQ) metrics from baseline to 6-months (using (1)) which will be explored in a hierarchical testing approach to reduce the type 1 error rate, testing for superiority unless stated otherwise, with at least 3 days (72 hours) of data available:
    - Proportion of time in range (TIR; >3.9-<10 mmol/L (>70-<180 mg/dL))
    - Mean glucose concentrations (mmol/L)
    - Proportion of time above range (TAR Level 1; >10 mmol/L (>180 mg/dL))
    - Proportion of time below range (TBR Level 2; <3.0 mmol/L (<54 mg/dL); non-inferiority, margin 0.5%)
    - Proportion of time below range (TBR Level 1; <3.9 mmol/L (<70 mg/dL); non-inferiority, margin 2.0%)
    - Proportion of time in tight range (TITR; >3.9-<7.8 mmol/L (>70-<140 mg/dL))
    - Proportion of time above range (TAR Level 2; >13.9 mmol/L (>250 mg/dL))
    - Nocturnal (0000 – 0400 h) glucose profiles (AUC and mean mmol/L)
    - 24-h glucose area under the curve (AUC; mmol/L x h)
- *CGM-DIET group only:* CGM application / use as per protocol (using brief monthly REDCap questionnaire)
- Change in antihyperglycaemic medication use (using Medication Effect Score (MES) (2))
- Change in self-reported body mass (kg)
- *Adverse events:* frequency and percentages of adverse events reported, and related to the intervention

Secondary objective: 0 to 3 months

- Change over time in HbA1c
- Change in CGM (i.e. from FSL Pro iQ for DIET, FSL 2Plus for CGM-DIET) metrics from baseline to 3-months (using (1)), which will be explored in a hierarchical testing

approach to reduce the type 1 error rate, testing for superiority unless stated otherwise with at least 3 days (72 hours) of data available:

  - Proportion of time in range (TIR; >3.9-<10 mmol/L (>70-<180 mg/dL))
  - Mean glucose concentrations (mmol/L)
  - Proportion of time above range (TAR Level 1; >10 mmol/L (>180 mg/dL))
  - Proportion of time below range (TBR Level 2; <3.0 mmol/L (<54 mg/dL); non-inferiority, margin 0.5%)
  - Proportion of time below range (TBR Level 1; <3.9 mmol/L (<70 mg/dL); non-inferiority, margin 2.0%)
  - Proportion of time in tight range (TITR; >3.9-<7.8 mmol/L (>70-<140 mg/dL))
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- *CGM-DIET group only:* CGM application / use as per protocol (per brief monthly REDCap questionnaire)
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- Change in self-reported body mass (kg)
- *Adverse events:* frequency and percentages of adverse events reported, and related to the intervention

Exploratory objective: blood profiles

- Change in fasting blood profiles of glucose (mmol/L), lipids (triglycerides, total cholesterol, HDL cholesterol and LDL cholesterol, all mmol/L) and inflammation (hsCRP, mg/L) across all timepoints (0, 3, 6 months)

Exploratory objective: Dietary intake and behaviours

- Change in energy intake (kJ/d) and diet composition (carbohydrate (total, added sugar), fat (total, saturated), protein, fibre, alcohol (all g/d; absolute units and relative to total energy intake), and sodium (mg/day)) using Intake24
- Change in dietary quality (HEIFA total and subscales (3)) using Intake24)
- Change in self-reported dietary behaviours (using REDCap (4,5))

Exploratory objective: Self-reported measures

- Change in self-reported measures between 0, 3 and 6 months, assessed via questionnaires:
    - Physical activity (IPAQ-long form (6))
    - Diabetes treatment satisfaction questionnaire (DTSQ status (0, 3 months) (7) and DTSQ change (6 months) (8))
    - Diabetes self-management questionnaire-revised (DSMQ-R (9))
    - The Type 2 Diabetes Distress Assessment System (T2-DDAS (10))
    - Diabetes-specific quality of life (DAWN2 Impact of Diabetes Profile (DIDP-7 (11,12))
    - Sleep quality and quantity (Pittsburgh Sleep Quality Index (13))
    - Eating disorders examination questionnaire (EDE-Q 6.0 (14))
    - Health literacy questionnaire (HLQ (15))
    - Quality of life (overall: WHO-5 (16), health related: EQ-5D-5L (17))

Exploratory objective: Protocol engagement

- Overall protocol engagement: self-reported via REDCap questionnaire (Assessed: 1, 2, 3, 4, 5, 6 months; discrete variable)
- CGM sensor use (i.e. number of complete days available, number of monitor checks, mean daily glucose; via data uploaded to Abbott's LibreView software) in the CGM-DIET group (Assessed: all data available within first 6 months of study enrolment, 0-3 months (continuous use), 4-6 months (intermittent))
- Self-monitoring of blood glucose via self-report in the DIET group (Assessed: via self-report at the dietitian consultations)

Exploratory objective: Participant experience

- Qualitative semi-structured interviews (Assessed: 6 months), in a subset of participants

Exploratory objective: Pre-consult CGM-related behaviour change [CGM-DIET group only]

- Novel questionnaire to assess impacts of unblinded CGM after 7 days on dietary and physical activity behaviours

Exploratory objective: Location-based outcomes

- Proportion of expressions of interest compared to randomised participants enrolled by state
- Proportion of expressions of interest compared to randomised participants enrolled by Modified Monash Model (MMM) area
- Proportion of expressions of interest compared to randomised participants enrolled by socioeconomic status based on location (postcode)
- Retention of participants enrolled by state

Exploratory objective: Diabetes status

- proportion of participants who have HbA1c <6.5% at 6 months
- proportion of participants who have HbA1c <7.0% at 6 months
- proportion of participants who have HbA1c <7.5% at 6 months
- proportion of participants who have HbA1c <8.0% at 6 months
- proportion of participants who have HbA1c >9.0% at 6 months
- HbA1c absolute improvement from baseline to 6 months ≥0.5%
- HbA1c absolute improvement from baseline to 6 months ≥1.0%
- HbA1c relative improvement from baseline to 6 months ≥10%
- HbA1c improvement from baseline to 6 months ≥1.0% or HbA1c <7.0% at 6 months
- proportions of participants who have increased or added, remained stable, or reduced or removed antihyperglycaemic medication, including those who have commenced insulin relative to those who used antihyperglycemic medication at baseline

Exploratory objective: Healthcare utilisation

- Magnitude (i.e. change in number, type, dose) of medication changes throughout the intervention period (Assessed: 1, 2, 3, 4, 5, 6 months)
- Other healthcare support accessed throughout the intervention (i.e. number of visits, number of other healthcare professionals)

Exploratory objective: Cost-effectiveness

- Quality Adjusted Life Years will be calculated using a standard conversion from the EQ-5D-5L scores (18) including discounting, baseline differences in utility scores, and

accounting for missing data. These will then be used to model Incremental Cost-Effectiveness Ratios (ICERs) using a Monte Carlo simulation to estimate the incremental benefit in QALYs of applying the intervention to this patient cohort.

- Cost of delivery (staff, resources, equipment etc)
- ICERs to assess the associated cost of reducing HbA1c by a total of 1% (using follow-up data from the trial and supported by additional data from published sources)
- Cost estimates of long term CGM use, and subsequent expected long-term cost benefit in terms of reduced incidence of diabetes-related complications and related outcomes such as heart attacks and kidney disease.
- Costs of recruitment per participant enquired, enrolled and per method used for recruitment.

Exploratory objective: Longevity of primary and secondary outcomes

- Longevity of outcomes (pathology, medication changes, questionnaires) via assessments at 12 months and 24 months post randomisation

Study Details

Study Design: CARE-T2D is a parallel, single-blinded, remotely conducted randomised controlled clinical trial. Participants, dietitians and study staff who are conducting randomisation, supporting dietitians and providing participants with support throughout the trial will be unblinded. Investigators who are not involved in the participant-related tasks and conducting statistical analyses will be blinded.

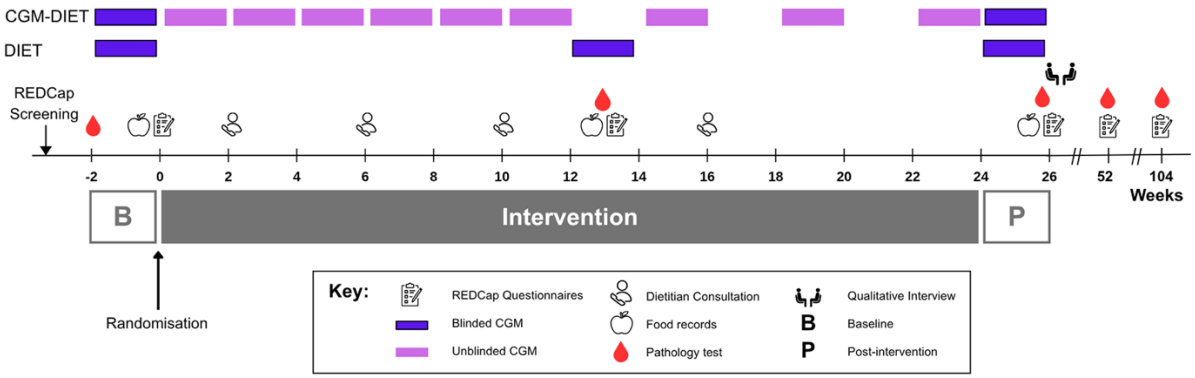


Figure 1: Study design of measurements, telehealth consultations and interventions (Group 1: CGM-DIET; Group 2: DIET) over the 26-week intervention. Two additional follow-up measures at 12 and 24 months post-randomisation will also be conducted to collect pathology and REDCap questionnaire data.

Study Population

Inclusion criteria

Study participants will be Australian adults (18+ y) with T2D (diagnosis by a GP or endocrinologist) and an HbA1c of 7.0% or greater at baseline, with a postal address and a smartphone that they can independently use.

Exclusion criteria:

- Under the age of 18 years
- Use of insulin therapy (within the previous three months) or medications which interfere with blood glucose levels (i.e. steroids)
- Use of CGM within the previous six months
- Eating Disorder Examination Questionnaire (EDE-Q 6.0) global score >2.8 OR global score ≥1.52 with sum of Q14-18 of ≥4

- Currently having ongoing consultations with an APD or have had a consult with an APD (within previous three months)
- Not weight stable (>5 kg change over the previous three months)
- Severe hypoglycaemic event (i.e. requiring assistance) within the previous six months
- Change of antihyperglycaemic or lipid-lowering medications within the previous three months
- Women who are pregnant or breastfeeding (within 24 weeks)
- History of psychotic disorder, or current diagnosis of other major psychiatric illness (e.g. mood disorder, eating disorder, substance use disorder)
- History of blood disorders (including, but not limited to, anemia and thalassemia) that impact the primary outcome (HbA1c)
- Participation in another intervention study

Medication(s) that the research team are unsure of (or unsure of the combination of), in terms of effects on the primary or secondary outcomes, will be checked by Dr Linda Watson prior to enrolment.

Sample size considerations

Based on a -0.3% superiority margin at 6-months (primary outcome) with unblinded CGM use in a non-insulin dependent T2D cohort (19), with a 0.7 percentage points SD, two-sided α=0.05, power=0.80 and a correlation of 0.60 between baseline and 6-month HbA1c, a minimum of 60 participants per group will be required. Therefore, a minimum of n=78 participants per group (total minimum sample 156 participants) will be recruited, accounting for at least 22.5% dropout.

Randomisation details

Stratified blocked (block size = 4) randomisation by sex (female, male) and baseline HbA1c (7.0 – 7.9%, 8.0 – 8.9%, 9.0 – 9.9%, ≥10%) (i.e. 8 stratifications).

Estimand Considerations

Population

- Australian adults (18+ y) with T2D with an HbA1c of 7.0% or greater at baseline (see inclusion/exclusion criteria above)

Variable

- Pre to post change in glycated haemoglobin (HbA1c) over 6 months

Treatments

- Dietetic support only (DIET)
- CGM plus dietetic support (CGM-DIET)

Population level summary

- 6-month difference in mean change in HbA1c between treatment groups

Intercurrent events

- Discontinuation of intervention for any reason (including: lifestyle, dislike of intervention and non-related medical adverse events).
- Unable to attend 6-month pathology assessment (for HbA1c) within 10 days of pre-specified time due to reasons unrelated to diet and/or CGM use (including, but not limited to, travel or moving overseas).
- Drop-out of study with reason unspecified (including being unable to contact).

Intercurrent event strategies

The primary estimand will use a treatment-policy strategy. Participants will be analysed according to their randomised group regardless of intervention adherence, CGM use, dietetic consultation attendance, medication changes, protocol deviations, or discontinuation of the assigned intervention. Where 6-month HbA1c is observed, the observed value will be used in the primary ITT analysis irrespective of any intercurrent event.

For participants with missing 6-month HbA1c, the missing value will be imputed for the primary ITT analysis using the multiple-imputation approach specified in the Analysis sets section. The 3-month HbA1c value and other observed baseline and follow-up covariates will inform the imputation model but will not replace the 6-month primary endpoint.

The per-protocol analysis will be conducted as a complete-case analysis among participants who meet the prespecified adherence criteria and have observed baseline and 6-month HbA1c values. Missing 6-month HbA1c values will not be imputed for the per-protocol analysis. Sensitivity analyses will assess the robustness of the primary result to alternative assumptions about missing 6-month HbA1c and intervention discontinuation, including complete-case and conservative/worst-case assumptions, where appropriate.

Sensitivity analysis: Worst case

The most *conservative* approach to manage the individuals who discontinued the study with no reason provided:

- All individuals in the CGM-DIET group with drop-out reason unknown will be assumed they had discontinued the dietary advice and use of CGM.
- All individuals in the DIET group with drop-out reason unknown will be imputed as if they had continued the diet (providing they had completed at least one consultation).

Sensitivity analysis: Complete case

- *Per protocol (PP):* No imputation and will only be performed if >5% of participants will be excluded. The analysis will only include individuals who attended at least three dietetic consultations (±10 days) and attended at least two measurements of HbA1c (baseline and 6 months; ±10 days). This analysis conditions on post-randomisation adherence and outcome availability.
- *All consultations:* No imputation and will only be performed if >5% of participants will be excluded. The analysis will only include individuals who attended all four dietetic consults. This analysis conditions on post-randomisation adherence and outcome availability; it will be interpreted as a sensitivity analysis rather than as an unbiased estimate of the randomised treatment effect.

Sensitivity analysis: Medication changes

- Medication changes are likely to occur at a greater rate/occurrence in the CGM-DIET group due to greater awareness. This will be managed by a sensitivity analysis of only individuals who had no medication changes (i.e. MES = 0).

Statistical Considerations

Error control: The primary comparison of CGM-DIET with DIET will be assessed using a two-sided 95% confidence interval, corresponding to a two-sided 5% type I error rate. No multiplicity adjustment will be made for secondary or exploratory outcomes; their results will therefore be interpreted as supportive or exploratory.

Analysis sets: The primary ITT analysis of efficacy outcomes at 6 months will include all randomised individuals in their assigned groups. For participants missing the 6-month HbA1c outcome, the 6-month HbA1c value will be imputed under a missing at random assumption using multiple imputation by chained equations (MICE) within treatment group. Variables included in the imputation model will be age, sex, diabetes duration, body mass change, baseline HbA1c and/or 3 month HbA1c (where available), MM regionality, baseline fasting glucose concentration, baseline time in range, medication class(es), and medication effect score (MES). Assuming moderate missingness, 50 imputations will be performed using predictive mean matching for continuous variables. Imputed values will be checked against observed values using graphical and numerical diagnostics, and model estimates will be pooled using Rubin's rules. Exploratory outcomes will be analysed using complete cases where relevant, unless otherwise specified.

Covariate adjustment: All comparisons of treatment effect will include adjustment for stratification factors (sex and baseline HbA1c as a continuous variable). Adjustment for baseline HbA1c and sex will be included as these variables were used in the randomisation scheme and are expected to be prognostic of HbA1c outcomes.

Descriptive statistics: A CONSORT flow diagram will present the number of individuals who participated in online REDCap screening and data collection (timepoints 0, 3 and 6 months, Figure 1). Descriptive summary statistics will be reported for baseline characteristics of all individuals who were randomised.

Statistical methods

Primary Outcome

Statistical evaluation of the primary outcome will use a linear model with between-group differences in HbA1c as the outcome at 6 months. Fixed effects will include treatment group,

baseline HbA1c and sex. The primary contrast will be the adjusted between-group difference in HbA1c change at 6 months, conditional on baseline HbA1c. Models will be built using the R programming language and the *lm* function with significance set at $p<0.05$.

Statistical superiority will be concluded if the upper bound of the two-sided 95% confidence interval for the adjusted between-group difference in HbA1c change at 6 months (CGM-DIET minus DIET) is less than or equal to -0.30 percentage points. The primary treatment effect will be reported as the adjusted between-group difference in HbA1c change (baseline to 6 months) with its 2 sided confidence interval. Mean changes in HbA1c from baseline to 3 months and 6 months will also be reported descriptively.

As we expect there to be an even inclusion of HbA1c (due to stratification) between the groups, we will conduct exploratory sub-analysis of the primary outcome of change in HbA1c and the secondary outcome of TIR within these 1% range of HbA1c subgroups (i.e. 7-7.9%, 8-8.9%, 9-9.9%, ≥10%). The assumptions of each model will be assessed using the performance:check_model function. The main effects and any interactions will be extracted from each model (stats:anova). Tukey adjustment will be applied to exploratory post hoc tests (emmeans:emmeans) among multiple group comparisons. The primary outcome variable will be assessed based on ITT and PP. Secondary outcomes will be analysed using observed data among participants with available outcome data for each measure unless otherwise specified. Exploratory outcomes will be analysed using either observed data and/or complete cases (where relevant dependent on outcome) for each outcome and interpreted descriptively. Secondary and exploratory outcomes will use the same general modelling approach as the primary outcome where appropriate, but will not be subject to formal multiplicity adjustment. Secondary efficacy blinded CGM outcomes will be explored in a hierarchical testing approach to reduce the type 1 error rate, testing for superiority unless stated otherwise.

Inclusion in per-protocol (PP) analysis will be defined by:

- Attendance at ≥3 dietetic consults, within ±10 days of the designated 2-, 6-, 10- and 16-week time points
- Completion of the baseline and 6-month (±10 days at each timepoint) HbA1c blood samples

Protocol violations are considered (but not limited to):

Major (i.e. excluded in the PP analysis):

- Use of insulin
- Prolonged (>1 week) illness and/or hospitalisation
- Diagnosis of medical condition which requires medication/treatment which interacts with the primary outcome

Minor (i.e. included in PP analysis):

- Change of pathology site
- Deviation from prescribed CGM use (i.e. non-continuous use in weeks 0-12 and/or non-intermittent use in weeks 14-24, or self-initiated CGM use in DIET group (where known))
- Prior use of CGM within 6-month period of baseline (from LibreView data; possible to identify in CGM-DIET only)

Analysis of adverse events will be conducted when there are at least four individuals who experience an adverse event, a Fisher exact test will be conducted comparing the rates of occurrence (irrespective of grade) between the two intervention groups. No adjustments for multiple testing will be performed, with the exception of hierarchical analysis of CGM-related outcomes.

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