Service Evaluation Protocol

Total Meal Replacement (TMR) Diabetes Remission Programme

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Executive summary

St Helena has a high burden of type 2 diabetes and obesity, placing sustained pressure on a small, integrated health system. Evidence from high-quality trials shows that Total Meal Replacement (TMR) programmes can produce substantial weight loss and improved blood glucose control, and that some people can achieve diabetes remission when weight loss is maintained.

This protocol describes a **service evaluation** of a TMR Diabetes Remission Programme delivered within routine St Helena diabetes services (with learning intended to inform delivery in other small or remote settings, including Ascension Island where relevant). The purpose is not to re-test biological efficacy, but to understand whether the programme can be delivered *safely, acceptably, and effectively* in local routine care, and what implementation learning is needed for potential continuation or scale-up.

The evaluation focuses on:

- clinical outcomes (weight, HbA1c, diabetes remission, medication changes);
- safety (including medication adjustment and adverse events);
- feasibility and acceptability for participants and staff;
- delivery and retention across programme phases.

The programme is delivered in three phases: a time-limited total meal replacement phase (approximately 12 weeks), stepped food reintroduction, and longer-term weight maintenance support. Clinical monitoring and medication adjustment are embedded throughout.

The evaluation primarily uses routinely collected clinical and registry data, supplemented by light-touch participant and staff feedback and a small number of qualitative interviews. Analysis follows an implementation-focused approach, with detailed methods set out in the linked Statistical Analysis Plan.

Associated documents:

- The implementation evidence brief
- Statistical analysis plan (sap)
- Data dictionary
- Data management plan (dmp)

Background and rationale

Type 2 diabetes and obesity represent a major and growing health burden on Saint Helena. A high proportion of adults are living with type 2 diabetes, many with poor glycaemic control and long-term complications. In a small and remote health system, this creates significant clinical, financial, and workforce pressures.

International evidence shows that structured Total Meal Replacement (TMR) programmes can lead to substantial weight loss, improved metabolic health, and—among some people—remission of type 2 diabetes. These effects are most consistently seen in people with relatively recent diagnoses, but

benefits also extend to medication reduction, improved quality of life, and reduced long-term service demand.

Randomised controlled trials, including DiRECT, have already demonstrated that TMR can be effective and safe when delivered with appropriate clinical oversight. The key remaining question for Saint Helena is not whether TMR works in principle, but whether it can be delivered safely, acceptably, and effectively within a small-island health system, and whether the benefits observed elsewhere can be realised locally.

This programme therefore adopts an implementation and service-evaluation perspective. The focus is on real-world delivery, system fit, patient experience, and clinical outcomes, rather than on re-examining efficacy under tightly controlled trial conditions.

Programme aims and evaluation objectives

Programme aim

The overall aim of the TMR programme is to support adults with type 2 diabetes on Saint Helena to achieve substantial weight loss, improved glycaemic control, and—where possible—diabetes remission, while ensuring patient safety and maintaining high-quality routine clinical care.

Evaluation objectives

The evaluation has four primary objectives:

1. **Clinical outcomes** To assess changes in weight, HbA1c, medication use, and related cardiometabolic markers over follow-up, including the proportion of participants achieving diabetes remission.
2. **Medication de-intensification and safety** To describe changes in diabetes medication burden, including insulin reduction or cessation, and to monitor adverse events and safety outcomes during and after the TMR phase.
3. **Acceptability and feasibility** To assess how acceptable the programme is to participants and staff, and how feasible it is to deliver within existing services, workflows, and workforce constraints.
4. **Implementation learning** To generate practical learning on delivery, monitoring, data capture, and follow-up that can inform future service planning on Saint Helena and in other small or remote settings.

The evaluation explicitly recognises that not all benefits will take the form of diabetes remission. Improvements short of remission—such as meaningful weight loss, better glycaemic control, reduced medication use, and improved wellbeing—are considered important and clinically relevant outcomes.

Study design overview

This is a prospective, non-randomised service evaluation of a Total Meal Replacement programme delivered within routine diabetes services on Saint Helena and Ascension Island.

Up to 50 eligible and willing participants are offered the TMR programme. Outcomes among participants are evaluated longitudinally and, for selected analyses, compared with a matched group of individuals with type 2 diabetes drawn from the island's diabetes registry who do not take part in the programme.

The study is designed as an implementation evaluation rather than a conventional randomised controlled trial. This approach reflects:

- the strong existing evidence base for TMR effectiveness;
- the small size of the eligible population;
- ethical considerations around withholding an intervention with known benefits; and
- the primary interest in real-world delivery, system integration, and sustainability.

Two analytic populations are defined:

- **Primary cohort**: adults with type 2 diabetes not using insulin at baseline.
- **Exploratory cohort**: adults with type 2 diabetes using insulin at baseline, included with enhanced clinical monitoring and more exploratory analysis.

Participant eligibility and recruitment

Target population

The programme is offered to adults with type 2 diabetes living on St Helena or Ascension Island who are overweight or obese and for whom meaningful weight loss is clinically appropriate.

The primary target group comprises adults with relatively recent diagnoses of type 2 diabetes who are not using insulin at baseline, reflecting the population in which diabetes remission is most plausible based on existing evidence. Adults using insulin are also eligible to participate but are treated as a secondary, exploratory group with enhanced clinical oversight.

Inclusion criteria

Participants must meet all of the following criteria at screening:

- Diagnosis of type 2 diabetes.
- Age 18–65 years.
- Body mass index (BMI) 25 kg/m².
- Engagement with routine diabetes care - assessment as at least 1 clinic visit in the past 12 months.
- Willingness and ability to participate in the programme and attend follow-up visits.

Participants using insulin are eligible, provided they are assessed as suitable by the clinical team and agree to closer monitoring and medication adjustment during the TMR phase.

Exclusion criteria

Individuals will not be referred to or enrolled in the programme if they have:

- Pregnancy, breastfeeding, or plans to become pregnant during the early phases of the programme.
- Severe or unstable medical conditions that would make rapid weight loss unsafe (e.g. recent myocardial infarction or stroke, severe heart failure, advanced renal disease).

- Active eating disorders, substance use disorders, or conditions that would impair safe participation (assessed at screening).
- Prior bariatric surgery.
- Any other clinical or practical factors judged by the care team to make participation unsafe or inappropriate.

A full operational list of inclusion and exclusion criteria is available on the website eligibility page

Identification and recruitment

Potential participants are identified through the island's diabetes registry, local adverts, and clinic lists. Eligible individuals are contacted and invited to attend a screening visit, during which eligibility is confirmed, the programme is explained, and interest in participation is assessed.

Recruitment is intentionally pragmatic. All eligible and willing individuals are offered the programme until capacity is reached. Individuals who decline participation are not excluded from routine care, and—with appropriate consent—their registry data may be used to support comparative analyses.

Recruitment, screening outcomes, and baseline scheduling are tracked using REDCap-based tools to ensure transparency, auditability, and linkage to subsequent clinical and evaluation data.

Consent

Written informed consent is obtained prior to baseline assessment. Consent covers participation in the programme, collection and use of clinical data for evaluation purposes, and—where applicable—participation in qualitative components such as interviews or surveys.

Participants may withdraw from the programme or from evaluation activities at any time without affecting their access to routine clinical care.

Description of the intervention

The Total Meal Replacement (TMR) programme is a structured, time-limited dietary intervention followed by phased food reintroduction and longer-term weight maintenance support. It is delivered within routine diabetes services, with regular clinical monitoring and medication adjustment to ensure safety.

The programme is organised into three main phases. While the overall structure is standardised, delivery allows limited flexibility to accommodate individual needs, preferences, and clinical circumstances.

Phase 1: Total Meal Replacement (weeks 0–12)

Participants replace all usual meals with nutritionally complete meal-replacement products for approximately 12 weeks. Daily energy intake is substantially reduced, with the aim of achieving rapid and clinically meaningful weight loss.

During this phase:

- Diabetes and blood pressure medications are reviewed and adjusted according to agreed clinical protocols.

- Participants are seen regularly for weight checks, symptom review, and clinical monitoring.
- Blood glucose and blood pressure are monitored closely, particularly in the early weeks.
- Participants receive behavioural support and practical guidance to support adherence and wellbeing.

This phase carries the greatest potential for rapid metabolic improvement and therefore also requires the most intensive clinical oversight.

Phase 2: Food reintroduction (approximately weeks 12–18)

Following completion of the TMR phase, participants transition gradually back to food-based meals. Meal-replacement products are reduced in a stepwise manner while balanced meals are reintroduced.

The focus during this phase is on:

- Maintaining weight loss achieved during TMR.
- Establishing sustainable eating patterns.
- Supporting participants to understand portion sizes, food choices, and meal timing.

Clinical monitoring continues during food reintroduction, with medication adjusted as required.

Phase 3: Weight maintenance and follow-up (weeks 19+)

After food reintroduction, participants enter a longer-term weight maintenance phase. The aim is to stabilise weight, prevent regain, and support sustained improvements in glycaemic control.

Follow-up during this phase includes:

- Periodic clinical review and weight monitoring.
- Ongoing support for diet, physical activity, and behaviour change.
- Continued review of diabetes medications, including opportunities for further de-intensification.

Where weight regain or deterioration in glycaemic control occurs, additional support or temporary return to meal replacement may be offered, guided by clinical judgement.

Clinical monitoring, safety, and governance

Participant safety is a central component of programme delivery. The TMR intervention is embedded within routine clinical care, with clear escalation pathways and governance arrangements.

Clinical monitoring

Across all phases, participants are monitored for:

- Weight change and symptoms.
- Blood pressure and blood glucose.
- Changes in diabetes and cardiovascular medication.
- Adverse events or clinical deterioration.

Monitoring intensity is highest during the TMR phase and is adjusted thereafter based on clinical stability and individual risk.

Medication adjustment

Structured protocols guide the reduction, withdrawal, and reintroduction of diabetes and blood pressure medications. These protocols are designed to minimise the risk of hypoglycaemia, symptomatic hyperglycaemia, hypotension, and other adverse effects.

Medication decisions remain the responsibility of qualified clinicians, with protocols providing guidance rather than rigid rules.

Adverse events and escalation

Adverse events are identified through routine clinical contact and participant self-report. Serious or unexpected events are documented, reviewed, and escalated according to agreed governance pathways.

A Data Monitoring Group oversees safety during the programme, reviewing emerging issues and recommending modifications if required.

Governance and quality assurance

The programme operates under established clinical, information governance, and data protection frameworks. Documentation, data flows, and decision-making processes are designed to be auditable and proportionate to the scale of the programme.

Data collection and outcome measures

Data collection for the evaluation is designed to align closely with routine clinical care, minimising additional burden on participants and staff while ensuring that outcomes of interest can be assessed robustly.

Data sources

Data are drawn from three main sources:

- The St Helena diabetes registry.
- Structured participant questionnaires, collected directly into an online REDCap database.
- Qualitative interviews with a subset of participants and staff.

Primary outcomes

The primary clinical outcomes for the evaluation are:

- Change in body weight between baseline and 12-month follow-up.
- Change in HbA1c between baseline and 12-month follow-up.
- Diabetes remission, defined as sustained HbA1c below the diagnostic threshold without glucose-lowering medication, assessed according to pre-specified criteria.

These outcomes reflect both international definitions and what is clinically meaningful in routine practice.

Secondary outcomes

Secondary outcomes include:

- Changes in diabetes medication use, including insulin dose reduction or cessation.
- Blood pressure and lipid profile changes.
- Measures of wellbeing, quality of life, and diabetes-related distress.
- Programme retention and completion.

For participants using insulin at baseline, outcomes are interpreted cautiously and reported separately.

Qualitative outcomes

Qualitative data are collected to understand participant and staff experiences, including:

- Acceptability of the programme.
- Barriers and facilitators to engagement and adherence.
- Perceived impacts on daily life and self-management.

These data provide essential context for interpreting quantitative findings and for informing future service development.

Analysis approach

The analysis approach is designed to support a rigorous, implementation-focused service evaluation of the TMR Diabetes Remission Programme in *St Helena and Ascension Island*. The aim is to generate credible, decision-relevant evidence on outcomes and delivery in routine care, recognising that statistical inference is one component of a broader evaluation that also considers feasibility, safety, and acceptability.

Analyses will be conducted in accordance with the Statistical analysis plan (sap), which provides full technical detail. The summary below describes the overall analytic strategy and interpretive principles.

Overall analytic strategy

The evaluation uses a non-randomised, observational design appropriate to service delivery. Analyses combine:

- registry-based matched cohort comparisons; and
- longitudinal modelling of outcome trajectories over time.

These complementary approaches are used to contextualise outcomes observed among programme participants and to strengthen causal interpretation where feasible, while recognising the limitations inherent in routine-care data.

Analytic populations

Analyses are stratified by baseline insulin use, reflecting clinically meaningful differences in complexity and expected outcomes. A primary analytic population (participants not using insulin at baseline) and

an exploratory analytic population (participants using insulin at baseline) are defined, as set out in the *Statistical Analysis Plan*.

Primary analyses follow intention-to-treat principles, with additional analyses used to explore the impact of programme exposure and adherence.

Outcomes and estimation

Clinical, process, safety, and acceptability outcomes are analysed using appropriate statistical models for repeated measures / longitudinal data. Emphasis is placed on estimation and uncertainty (effect sizes and confidence intervals), with formal hypothesis testing used selectively and interpreted cautiously in light of sample size and service-evaluation context.

Primary and secondary endpoints, including definitions of diabetes remission, weight loss thresholds, and medication outcomes, are pre-specified in the *Statistical Analysis Plan*.

Interpretation and robustness

Findings are interpreted by triangulating results across analytic approaches and outcome domains, rather than relying on single tests or thresholds. Sensitivity analyses are undertaken to assess robustness to key assumptions, including confounding control and missing data, as described in the *Statistical Analysis Plan*.

Overall interpretation explicitly integrates quantitative findings with implementation-relevant considerations, recognising that decisions about service continuation or adaptation depend on more than statistical significance alone.

Qualitative analysis

Qualitative data (including free-text survey responses and semi-structured interviews) are analysed thematically using inductive coding, supported by simple software tools where appropriate. Interviews are conducted in English, digitally recorded, and transcribed verbatim with participant consent. Qualitative findings are used to explain and contextualise quantitative results, particularly around acceptability, feasibility, and barriers and facilitators to engagement.

Ethics, information governance, and consent

This work is a service evaluation of a pilot clinical programme rather than a research study. Nevertheless, ethical principles relating to consent, confidentiality, and data protection are applied throughout.

Ethics and approvals

The evaluation protocol is reviewed through appropriate governance and ethics processes, including UKHSA REGG and local approval routes where required.

Consent and confidentiality

Informed consent is obtained for participation in evaluation activities beyond routine care, including surveys and interviews. Participation in evaluation components is voluntary and does not affect access to clinical care.

All evaluation data are handled in accordance with UK GDPR and local information governance requirements. Identifiable data are restricted to those involved in care delivery, and evaluation outputs use anonymised and aggregated data.

Small numbers and disclosure control

Given the small population size, particular care is taken to prevent disclosure. Suppression, aggregation, and careful reporting practices are applied consistently.

Reporting and dissemination

Findings from the evaluation will be reported in a form suitable for clinical teams, health system leaders, and external stakeholders.

Reporting will focus on:

- Clinical outcomes and safety.
- Programme acceptability and feasibility.
- Practical lessons for future service delivery.

Outputs may include internal reports, summaries for participants, and contributions to the wider evidence base on diabetes remission programmes in small or remote settings.