

The Screening Visit

Standard Operating Procedure (SOP) - guidance for study staff

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Purpose

This SOP describes the standard process for screening potential participants for the Total Meal Replacement (TMR) Diabetes Remission Programme.

The screening visit is designed to:

- Confirm eligibility and safety
- Provide clear, neutral information about the programme
- Support informed choice
- Identify next steps (baseline visit, control group, or no further contact)

Screening is *not* consent to participate and does not commit the individual to the programme.

Documentation

The following documents are used directly as part of the screening visit process.

Document	Link / Download
Screening visit information sheet	download
Screening visit checklist	download
Participant flow diagrams	participant flow diagrams

Scope

This SOP applies to all staff involved in:

- Identifying potential participants
- Conducting screening visits (always in-person)
- Recording screening data in the REDCap TMR database

Roles and Responsibilities

Community Health Workers. conduct screening, record data, explain next steps

Study data manager. Provides REDCap and data system support throughout recruitment.

Study clinician. available for clinical queries or borderline cases

Study manager. scheduling and follow-up

Overview of the Screening Process

1. Identify potential participant
2. Initial contact and explanation
3. Screening assessment (eligibility and safety)
4. Confirm interest
5. Agree next step
6. Record outcome

Detailed Procedure

1. Identification of Potential Participants

Potential participants may be identified through:

- Diabetes registry listing (using a report in the REDCap TMR database)
- Clinic lists
- Referrals from clinical staff
- Self-referral following publicity

2. Initial Contact

Explain:

- This is a diabetes remission *service*, not a research trial
- Participation is voluntary
- Screening is to see if the programme is suitable and safe

Provide a brief description of:

- Total diet replacement phase
- Follow-on food reintroduction and maintenance
- Time commitment

3. Screening Assessment

Confirm or collect the following:

Core eligibility

- Age within programme limits
- Type 2 diabetes diagnosis
- Duration of diabetes
- Recent clinic attendance
- Body Mass Index (measured or recent)

Safety exclusions

This medical check will likely occur before the screening visit takes place. The reviewer (study clinician or specialist diabetes nurse) will review patient notes, looking for any pre-existing exclusion factors - such as. This will be recorded by the study clinician or specialist diabetes nurse in the REDCap TMR database screening form:

- Pregnancy or breastfeeding
- Recent major cardiovascular events
- Severe renal impairment
- Active eating disorder
- Other significant clinical exclusions

4. Explain Programme Expectations

Cover clearly:

- The intensity of the first 12 weeks
- Medication changes may occur under supervision
- Regular follow-up visits are required
- Participants can stop at any time

Check understanding and allow questions.

5. Confirm Interest

Ask neutrally:

- Whether the individual wishes to proceed to a baseline visit

If **yes**:

- Schedule a baseline visit

If **no**:

- Thank the individual
- Ask permission to use routine data as part of the control group (where applicable)

6. Record Outcome

In REDCap, record:

- Eligibility outcome
- Interest outcome
- Baseline visit scheduled (yes/no)
- Any notes relevant to safety or follow-up

Handling Special Situations

- *Borderline eligibility.* escalate to clinical lead
- *Insulin-treated participants.* flag for enhanced clinical oversight

- *Safeguarding concerns.* follow standard clinical procedures

Documentation

- Screening data is recorded in the screening REDCap database
- No consent forms are signed at screening