

The Recruitment Process

Standard Operating Procedure (SOP) - guidance for study staff

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Purpose

This SOP describes the recruitment process for inviting eligible individuals to attend a screening visit for the TMR Diabetes Remission Programme.

Documentation

All recruitment contacts and outcomes (contacted, agreed, declined, no response) are recorded in the designated study database in accordance with data governance procedures.

Document	Link / Download
Recruitment telephone script	download
Participant information sheet	download
Participant flow diagrams	Participant flow diagrams

Scope

This SOP covers activities from identification of potentially eligible individuals through to the scheduling of a screening visit. All screening procedures are covered in the Screening SOP. Baseline enrolment is covered in the Baseline SOP.

Roles and responsibilities

Data handling staff. Extract potentially eligible participants from the diabetes registry and prepare recruitment lists within the REDCap Total Meal Replacement (TMR) database.

Community Health Workers (CHWs). Review the REDCap recruitment report to identify potential eligible participants. Select the person at the top of the list and make contact for potential recruitment.

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

Study clinician. Provides clinical oversight and advice where required.

Study manager. Oversees recruitment progress, coordination, and escalation of issues.

Recruitment overview

Recruitment is a structured, auditable process designed to ensure that individuals are approached consistently, respectfully, and without coercion. Participation is voluntary, and declining does not affect routine care.

Step 1: Identification of potentially eligible participants

Data handling staff use the diabetes registry to identify potentially eligible individuals based on:

- Confirmed diabetes diagnosis
- Duration of diabetes
- At least one clinic visit in the previous 12 months

For all individuals meeting these criteria, registry information is used to pre-populate the REDCap screening form in the TMR database.

Step 2: Creation of recruitment list in the REDCap TMR database

Using the pre-populated screening forms, a REDCap report is generated listing potentially eligible participants. This report functions as the active recruitment list. The *community health workers* contact individuals in the order presented in the REDCap report, starting from the top of the list.

Step 3: Recruitment contact

The *community health workers* contact individuals listed in the REDCap recruitment report by telephone or in person.

During recruitment contact:

- The approved recruitment script must be followed closely
- The purpose of the programme is explained briefly
- The individual is invited to attend a screening visit to learn more
- It is made clear that participation is optional and declining will not affect usual care

The recruitment script is provided as a downloadable document at the top of this SOP and must be used for all recruitment contacts. No screening assessments or consent are undertaken at this stage.

Step 4: Updating recruitment outcomes in REDCap

During or immediately after recruitment contact, the REDCap screening form is updated to record the outcome, including:

- Individual declined participation
- Individual agreed to attend a screening visit

This information is recorded directly in the REDCap database to maintain a real-time recruitment record.

Step 5: Scheduling the screening visit

For individuals who agree to attend a screening visit, the REDCap scheduling functionality in the TMR database is used to book the screening appointment. Once a screening visit is scheduled, the recruitment process for that individual is complete.

Step 6: Handover to screening

Screening visits are conducted by the Community Health Worker team, with support from:

- The study data manager
- The study clinician
- The study manager

From this point onward, procedures are governed by the Screening SOP.

Documentation and audit trail

All recruitment activity—including eligibility identification, contact attempts, outcomes, and scheduling—is recorded within REDCap. This provides a complete audit trail of recruitment decisions and supports monitoring of recruitment progress and equity.