

Eligibility

Guidance for Study Staff

Ian Hambleton, Selvi Jeyaseelan

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Purpose of eligibility assessment

Eligibility criteria are used to:

- Ensure participant safety
- Identify those most likely to benefit from TMR
- Apply inclusion rules consistently and fairly

Eligibility is assessed in **two stages**:

1. Registry-based pre-screening
2. In-person screening confirmation

Eligibility is only final once **both stages** are complete.

Stage 1: Registry-based eligibility (pre-screening)

Stage 1 eligibility is assessed using *existing Diabetes Registry data only*.

An individual may proceed to screening if all of the following apply:

- Age *65 years*
- Diagnosed with *type 2 diabetes*
- Diabetes duration *6 years*
 - This may be extended to *10 years* if recruitment numbers are low
- At least *one diabetes-related visit in the past 12 months*

- Likely *BMI* ≥ 25 (confirmed at screening)

Individuals meeting these criteria are flagged as *potentially eligible* and may be invited to screening.

No consent is obtained at this stage.

Stage 2: Screening visit eligibility

Eligibility is confirmed at an *in-person screening visit*.

To remain eligible, the individual must:

- Have *BMI* ≥ 25 confirmed by measured height and weight
- Have no exclusion criteria (see below)
- Be willing and able to attend scheduled study visits
- Be willing to consider participation in the full programme

Eligibility status is recorded in the screening instrument.

At this screening visit each person also takes part in an *eating habits / eating disorders* review. This may exclude a small number of people, but more likely, it will identify participants that will benefit from additional support.

Exclusion criteria (apply at any stage)

An individual is *not eligible* if any of the following apply:

- Pregnant, breastfeeding, or planning pregnancy
- Severe renal impairment (e.g. eGFR <30 mL/min/1.73m²)
- Active cancer
- Myocardial infarction or stroke within the past 6 months
- Severe heart failure (NYHA class III or IV)
- Active eating disorder
- Active substance use disorder
- Prior bariatric surgery
- Any condition where the clinical team judges TMR to be unsafe or inappropriate

These criteria will ideally be identified through a clinical review of a person's notes. Clinical judgement should be documented where exclusions are discretionary. The absence of information in the clinical notes may require an in-person clinical review.

Participants using insulin

Insulin use is *not an automatic exclusion*.

However:

- Insulin-treated participants require enhanced clinical oversight
- Medication adjustment protocols must be followed

- Insulin status should be clearly flagged at screening and baseline

Insulin-treated participants may be analysed separately.

If eligibility is not met

If an individual does not meet eligibility criteria:

- This should be recorded in the screening log
- The reason for ineligibility should be documented
- Routine diabetes care continues as normal

Ineligibility does *not* affect access to services.

Systems and documentation

Eligibility assessment uses:

- Diabetes Registry (Stage 1)
- Eligibility screening REDCap instrument (Stage 2)
- Recruitment and screening logs

Eligibility decisions must be auditable.

Key documents and links

- [Project protocol](#)
- [Participant flow diagrams](#)

Key principle

Eligibility assessment is a *safety and consistency function*, not a recruitment tool.

When in doubt, pause, document, and escalate.