

# TMR Programme Timelines

## Guidance for Study Staff

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This document presents the TMR programme timeline using **three linked layers**:

1. Programme milestones (stable spine)
2. Rolling operational timeline (near-term detail)
3. Standing monitoring activities (ongoing work)

The aim is to retain operational truth while keeping the document readable, updateable, and extensible across the full study lifecycle.

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## Layer 1: Programme Milestones (Study Spine)

These milestones define the critical path of the programme. They change rarely and should remain short and readable.

| Milestone   | Target date | Dependencies / notes                                |
|---|-------------|---|
| Information gathering from Counterweight complete | 05/01/26    | Medical review, screening scope, app role clarified |
| Screening tools and scheduler live                | 19/01/26    | REDCap build and testing complete                   |
| Ethics approval or waiver                         | 09/02/26    | Submission to SHG ethics + Leeds                    |
| Screening period complete                         | Feb 2026    | Recruitment targets reached                         |
| Baseline data collection complete                 | 24/04/26    | Includes intervention + control                     |
| First TMR cohort completes 12 weeks               | May 2026    | Supply chain stable                                 |
| 6-month follow-up complete                        | Aug 2026    | Retention maintained                                |
| 12-month follow-up complete                       | Feb 2027    | Primary outcomes                                    |
| 24-month follow-up complete                       | Feb 2028    | Long-term outcomes                                  |

## Layer 2: Rolling Operational Timeline (Jan–Mar 2026)

This section contains **detailed, time-bound tasks**. It should only extend 8–12 weeks ahead. Older completed sections can be archived below.

### Status legend

- **Complete** – task finished
- **In progress** – task actively underway
- **Planned** – scheduled but not yet started
- **Critical / risk** – blocking issue or hard dependency
- **Ongoing** – repeated or continuous activity

### Week of 05 Jan 2026

| Task   | Output                                     | Responsible | Status      |
|--|--|-------------|-------------|
| Information gathering from Counterweight         | Clarified screening, app use, expectations | SJ / IH     | In progress |
| Identify potential participants from clinic list | Randomised list for screening              | IH          | In progress |
| Advert in local paper + Facebook                 | Advert responses list                      | SI          | Planned     |

### Week of 12 Jan 2026

| Task                            | Output                         | Responsible     | Status      |
|---------------------------------|--------------------------------|-----------------|-------------|
| Develop screening tool          | Screening REDCap database live | JC / IH / SJ    | In progress |
| Develop screening scheduler     | Screening scheduler in REDCap  | JC / IH / SJ    | In progress |
| Initial contact (list + advert) | Screening visits scheduled     | SI / AM /<br>GE | In progress |
| Complete patient flows          | XMind flows finalised          | SJ              | In progress |

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### Week of 19 Jan 2026

| Task                                  | Output                | Responsible               | Status  |
|---------------------------------------|-----------------------|---------------------------|---------|
| Test screening tool                   | QA complete           | JJ / JP / SI / AM /<br>GE | Planned |
| Develop screening data export process | Import paths defined  | JC                        | Planned |
| Screening form training               | Staff trained         | JC                        | Planned |
| Submit ethics application             | Application submitted | SI / SJ / IH              | Planned |

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### Weeks of 26 Jan 2026

| Task                         | Output                    | Responsible     | Status          |
|------------------------------|---------------------------|-----------------|-----------------|
| Screening begins             | Screening underway        | SI / AM /<br>GE | Planned         |
| Develop main REDCap database | Main database built       | JC              | Planned         |
| Monitor screening            | Screening tracker updated | IH              | Ongoing         |
| Clearing shipment            | Supplies cleared          | RJames          | Critical / risk |
| FibroScan training           | Operators trained         | —               | Planned         |

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### Week of 02 Feb 2026

| Task                   | Output                     | Responsible            | Status  |
|------------------------|----------------------------|------------------------|---------|
| Screening Continues    | Screening underway         | SI / AM / GE           | Planned |
| Test main database     | QA complete                | JJ / JP / SI / AM / GE | Planned |
| Database training      | Trained database operators | IH / SJ / JC           | Planned |
| Build initial web page | Document repository live   | IH                     | Planned |

### Week of 09 Feb 2026

| Task                               | Output              | Responsible     | Status          |
|------------------------------------|---------------------|-----------------|-----------------|
| Ethics approval / waiver confirmed | Go / no-go decision | —               | Critical / risk |
| Baseline data collection (part 1)  | First 6 baselines   | JJ / JP         | Planned         |
| Baseline coaching                  | Coaching delivered  | SI / AM /<br>GE | Planned         |
| Monitor baseline                   | Baseline tracker    | IH              | Ongoing         |

### Week of 16 Feb 2026

| Task               | Output             | Responsible | Status  |
|--------------------|--------------------|-------------|---------|
| TMR process review | Adjustments agreed | ALL         | Planned |

### Weeks of 23 Feb – 24 Apr 2026 (Staggered recruitment and baseline)

**Note:** Recruitment and baseline assessments are **staggered** across this period. As a result, all downstream activities (intervention start, follow-up, monitoring) will also occur on a rolling, overlapping basis rather than as single fixed dates.

| Task                              | Output                       | Responsible     | Status  |
|-----------------------------------|------------------------------|-----------------|---------|
| Baseline data collection (part 2) | Remaining baselines complete | JJ / JP         | Planned |
| Recruit control participants      | Controls recruited           | JJ / JP         | Planned |
| Baseline coaching                 | Coaching delivered (rolling) | SI / AM /<br>GE | Planned |
| Monitor baseline                  | Baseline tracker             | IH              | Ongoing |

### Week of 16 Mar 2026 (Ascension Trip)

| Task                         | Output                    | Responsible | Status  |
|------------------------------|---------------------------|-------------|---------|
| Ascension setup and training | Site operational          | —           | Planned |
| REDCap training              | Staff trained             | IH / JC     | Planned |
| Meal replacement delivery    | Supplies delivered        | —           | Planned |
| Week 1 operations            | First participants active | —           | Planned |
| Review of week 1             | Lessons documented        | ALL         | Planned |

## Forward Plan: Broad Phases for Remainder of 2026

The following blocks outline the **expected flow of activity for the remainder of 2026**, recognising that recruitment, intervention delivery, and follow-up are staggered and overlapping. These blocks are indicative and will be refined as operational experience accumulates.

### Late Apr – Jun 2026: Intervention Ramp-Up

Focus:

- Participants entering TMR at different start points
- Intensive early-phase monitoring

Key activities:

- Rolling starts of TMR intervention
  - Medication review and adjustment
  - Ongoing coaching and support
  - Close safety monitoring (particularly insulin-treated participants)
  - Data completeness and fidelity checks
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### Jul – Sep 2026: Mid-Programme Delivery and Early Follow-Up

Focus:

- Participants completing initial TMR phases
- Transition to food reintroduction and maintenance

Key activities:

- Completion of 12-week TMR phase (rolling)
  - Structured food reintroduction
  - Early follow-up measurements (3–6 months, staggered)
  - Review of retention and engagement patterns
  - Interim process review
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### Oct – Dec 2026: Follow-Up, Consolidation, and Learning

Focus:

- Medium-term outcomes
- Programme refinement

Key activities:

- Rolling 6–9 month follow-up visits
- Continued safety and medication oversight
- Qualitative data collection (participants and staff)

- Preliminary outcome summaries
  - Planning for 2027 follow-up and sustainability decisions
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## Notes on Staggered Delivery

- Most activities after baseline will occur on a **rolling cohort basis**
  - Monitoring and reporting should use **windows** rather than fixed dates
  - This structure supports flexibility while preserving governance and oversight
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## Layer 3: Standing Monitoring and Coordination Activities

These activities run throughout the programme and should not be duplicated in date-specific tables.

| Activity   | Frequency           | Responsible  |
|--|---------------------|--------------|
| Monitor screening rates                                  | Weekly              | IH           |
| Monitor baseline completeness                            | Weekly              | IH           |
| Monitor follow-up visit attendance and data completeness | Weekly              | IH           |
| Project team meeting                                     | Fortnightly         | ALL          |
| Review missed appointments                               | Fortnightly         | Project team |
| Data Monitoring Group meeting                            | Monthly / quarterly | DMG          |

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## Notes on Use and Maintenance

- Only Layer 2 should be edited frequently
- Completed operational weeks may be archived below
- Layer 1 milestones should be updated only if scope or timing changes
- This document is the authoritative timeline; visual views may be derived from it