

TMR Programme Timelines

Guidance for Study Staff

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Table of contents

Layer 1: Programme Milestones (Study Spine)	1
Layer 2: Rolling Operational Timeline (Jan–Mar 2026)	2
Status legend	2
Week of 05 Jan 2026	2
Week of 12 Jan 2026	2
Week of 19 Jan 2026	3
Weeks of 26 Jan 2026	3
Week of 02 Feb 2026	3
Week of 09 Feb 2026	4
Week of 16 Feb 2026	4
Weeks of 23 Feb – 24 Apr 2026 (Staggered recruitment and baseline)	4
Week of 16 Mar 2026 (Ascension Trip)	4
Forward Plan: Broad Phases for Remainder of 2026	5
Late Apr – Jun 2026: Intervention Ramp-Up	5
Jul – Sep 2026: Mid-Programme Delivery and Early Follow-Up	5
Oct – Dec 2026: Follow-Up, Consolidation, and Learning	5
Notes on Staggered Delivery	6
Layer 3: Standing Monitoring and Coordination Activities	6
Notes on Use and Maintenance	6

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.

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
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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 / GE	In progress
Complete patient flows	XMind flows finalised	SJ	In progress

Week of 19 Jan 2026

Task	Output	Responsible	Status
Test screening tool	QA complete	JJ / JP / SI / AM / 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

Weeks of 26 Jan 2026

Task	Output	Responsible	Status
Screening begins	Screening underway	SI / AM / 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

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 / 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 / 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

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