RCTs in follow-up: A remote intervention to maintain site engagement and improve data quality during the Covid-19 pandemic

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* By-Band-Sleeve - Gastric Bypass, adjustable gastric Banding or Sleeve gastrectomy surgery to treat severe and complex obesity: a multi-centre randomised controlled trial. NIHR HTA programme 09/127/53

+ MARS 2 - Mesothelioma and Radical Surgery 2: a multicentre randomised trial comparing (extended) pleurectomy decortication versus no (extended) pleurectomy decortication for patients with malignant pleural mesothelioma. NIHR HTA programme 15/188/31

Introduction

Maintaining patient engagement, ensuring follow ups are completed and data queries are resolved relies on effective communication with the research team. In normal circumstances, site visits would be carried out. However, with the emergence of the Covid-19 pandemic these became impossible.

We developed a **standardised site-specific remote intervention**, designed to maintain site engagement, improve data quality and prevent researcher led attrition. The intervention was implemented in 2 large, surgical multi-centre RCTs managed by the Bristol Trials Centre (**MARS 2** and **By-Band-Sleeve**) and its impact was monitored by measuring data quality.

MARS 2 TRIAL — MESOTHELIOMA AND RADICAL SURGERY

335 participants **23 sites**

Trial - surgical RCT for patients with a diagnosis of mesothelioma. Participants were randomised to treatment with surgery and chemotherapy or chemotherapy only.

Primary outcome - survival

Follow up - minimum of 2 years, maximum of 6 years.

Data collection - minimum of 650 core data items with an additional 70 items for patients in surgical arm.

Criteria used to trigger intervention - less than 80% CRF completion and more than 100 data queries.

18 MARS 2 sites received intervention

By-Band-Sleeve — BUILDING EVIDENCE TOGETHER

1351 participants **12 sites**

Trial - surgical RCT for patients living with complex obesity. Participants were randomised to receive gastric bypass, gastric band or sleeve gastrectomy surgery.

Co-primary outcomes - weight and quality of life (EQ5D) at 3 years.

Follow up - minimum of 3 years, maximum of 8 years.

Data collection - minimum of 900 core data items at six time points over 3 years.

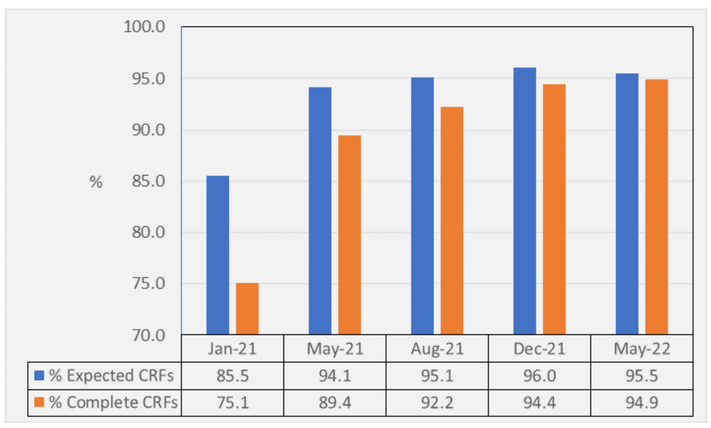
Criteria used to trigger intervention - less than 85% completion of the primary and secondary outcomes.

12 By-Band-Sleeve sites received intervention

Intervention

1. Data collection targets relating to key outcomes and safety matters relevant to each trial decided by CI, Trial Statistician and Trial Manager.
2. Standardised site-specific data extracts and reports prepared by Trial Statistician and Trial Manager.
3. Priority of sites chosen to receive intervention based on specific pre-defined criteria.
4. Standardised, site-specific data reports and structured agendas sent to sites ahead of remote intervention.
5. Intervention delivered by videoconference and required the mandatory attendance of the local PI and Site Investigators.
6. Repeat meetings organised if sites had not met data targets within a pre-defined timescale.

Results - MARS 2

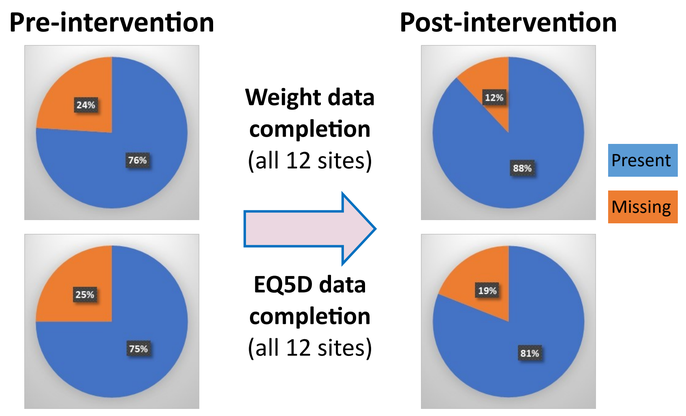


	Jan-21	May-21	Aug-21	Dec-21	May-22
% Expected CRFs	85.5	94.1	95.1	96.0	95.5
% Complete CRFs	75.1	89.4	92.2	94.4	94.9

Overall, CRF completion improved by **19.8%** and the percentage of expected CRFs improved by **10.0%**.

Even the site with the lowest data quality showed a **64.4%** improvement in data completion (from 25.0% to 89.4%) and CRF completion increased by **31.1%** (from 58.3% to 89.4%) because of the intervention.

Results—By-Band-Sleeve



In addition to the primary outcome improvements above, higher rates of query resolution was observed at all sites. Overall, the intervention reduced open data queries by at least **60%** and at two follow up time points an **85%** reduction was seen.

Once sites had the capacity to resume non-Covid research they were resolving up to 1000 data queries a month.

Summary

- Across the 2 studies, 58 interventions were conducted between July 2020 and September 2022.
- All sites who received the intervention showed improvements in the pre-defined criteria of each study.
- The intervention's standardised, site-specific data reports reminded site staff and PIs which data collection points to prioritise for each study.
- In the absence of face-to-face meetings, this remote intervention offered a way to communicate and support site staff during the pandemic.
- In both studies, sites who fall below the pre-defined primary criteria will continue to receive the intervention on a regular basis.

Discussion

This detailed, site-specific remote intervention improved data quality and query resolution. Improvements in communication with our sites and Covid-related capacity issues were flagged. The mandatory attendance of the PI ensured that site-specific problems were addressed and resolved. We recommend that similar studies prepare regular, remote monitoring meetings to achieve these benefits as a standardised practice.

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