

The ROMIO Study

END OF FOLLOW-UP: 31st Aug 2021

MESSAGE FROM COORDINATION TEAM

End of an Era: Quite unbelievably the 24-month follow-up period for the ROMIO study will end on 31st August 2021.

If a participant's 36 month follow-up would fall after 31st August 2021- this will not need to be completed.

Thank you all for all your hard work. It has been such a challenging year. Following up participants does become more difficult as participants are seen in peripheral centres, or the community. We really appreciate your efforts.

NO. OF F-UPS & DATA COMPLETENESS

A big thank you to all for being so responsive to our data chases. We're really pleased with our data quality, and this is all down to your hard work. Well done especially to Southampton, Bristol, Edinburgh and Salford for such low open query numbers. Let's work together to get these even lower next check. We can't quite believe Bath have no more follow-ups!

Site	No. of patients randomised	No. of follow-ups left	Open Queries (12 th May 2021)
Bristol	55	8	2
Plymouth	88	6	218
Southampton	37	8	1
Edinburgh	19	4	2
Leicester	46	5	11
Preston	24	5	19
Salford	14	2	7
Nottingham	63	9	180
Bath	15	0 (!)	16

NEWSLETTER

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606

Participants randomised in ROMIO study (main and pilot)

4270

Questionnaire packs have been returned during follow-up completed



47

24 and 36m Follow-ups left

31 Aug 2021

End of ROMIO follow-up



MESSAGE FROM CI Prof. Metcalfe



Thanks to all of those who managed to join us on Zoom for our Investigators' Meeting. It was fantastic to see so many of you online. Many thanks for your contributions to the interpretation, this will directly inform the write up.

We will be submitting the publication in September. We have published our group authorship list here V1.0: https://osf.io/9txmy/?view_only=90cbc052d7f145628a2a91a3488c9c26

Please let us know if you notice anything that needs correction. It's important to us that everyone is properly credited for their hard work on this study. We'll be applying to present at NCRI in Nov 2021 and AUGIS in Oct 2021 so watch this space!

DATABASE & DATA CLEANING



We appreciate that your work capacity may still be affected by COVID. Please continue to do your best to answer queries and missing data. We aim to have all study data entered and free from queries for 1st Nov 2021. We will start sending out more frequent data chases as this approaches. It's critical the data are as complete as possible.



VITAL STATUS CHECK

In September we will ask for your help with another vital status check to help ensure our survival analyses data are accurate. We will provide a list of participants for you to check at the time. Only deaths occurring on or before 31st August 2021 will require reporting to us (as SAEs).

OTHER NOTIFICATIONS

END OF STUDY

See protocol (section 5.9) the point that:

1. Pathology slides returned- DONE
2. All queries in database resolved- TO DO
3. Database locked- TO DO FOR 6-24month
4. Analysis completed and paper accepted for publication- TO DO

MESSAGE FROM JO NICKLIN [Our BTC Research Nurse]

It has been a pleasure for me to follow up patients from some sites whilst you have been busy meeting the needs of the pandemic. As I work from home, I have no access to hospital records, which sometimes means that I am unable to fully complete the CRF, particularly H5. I am grateful for your help with supplying this data. Together we can obtain full data sets and contribute to the success of ROMIO.

STUDY MANAGEMENT TEAM

Elizbeth Ward (Study manager)
Stephen Palmer (Assistant coordinator)



ROMIO-study@bristol.ac.uk

**STILL WORKING FROM HOME WITH
OCCASIONAL DAYS IN THE OFFICE**

MOST COMMON MISSING DATA

The most common missing data at present are details on progression/recurrence (H5) these are really important for our secondary outcomes so please do continue to contact GP/nurses/consultants/wards in peripheral sites to get as much information as you can.



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ROMIO Study

Bristol Trials Centre (CTEU)
Bristol Royal Infirmary,
Bristol, BS2 8HW

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BRISTOL

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