



MONARCH STUDY

MONITORING AMD AT HOME

END OF RECRUITMENT

Recruitment to the MONARCH study ended on 31st March 2020 with a final total of **297 participants**.

Whilst the study team and steering committee agreed not to pursue a funded extension to reach the full target of 400 participants, the data being collected is very important in determining the accuracy of the diagnostic tests being investigated. In addition, some of the most important findings from this study will be about the practical and technological obstacles in home monitoring, of which we have had many!

Thank you all for screening, training and consenting participants. We know it has been a challenging study to recruit to and we appreciate your efforts.

FOLLOW-UP PHASE

The study follow-up period has *not* changed and will finish at the end of **September 2020**. Until then, participants should continue testing once a week and sites should continue to collect data from participant management decisions.

Qualitative interviews will continue to take place throughout the follow-up period.

COVID-19 UPDATES OVERLEAF



SITE RECRUITMENT

Site	Months open to rec	Recruitment	
		Total	/month
Belfast	19.5	82	4.2
James Paget	19	80	4.2
Liverpool	17	45	2.6
Southampton	15	34	1.8
Moorfields	18	32	1.8
Gloucester	8	24	3.0

NEWSLETTER

ISSUE:6 Spring 2020

6
participating
hospitals



975
people
approached

308
attended a
training session



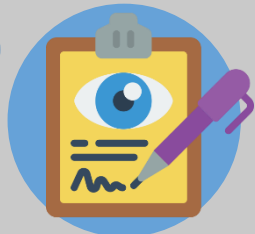
297
have
consented



61
people
interviewed



950
participant
monitoring
visits



13,579
electronic
tests received



273
KSJs returned





OTHER NOTIFICATIONS

COVID-19 is having a direct impact on the MONARCH study. It has prevented recruitment in the final weeks of the recruitment phase and is affecting the rate and protocol of patient clinics, in which management decisions are made.

CHANGES TO CLINICS

Management decisions made at clinics with regards to nAMD lesions are *key data* for this study and will be used to determine the accuracy of the diagnostic tests.

Therefore, it is important that the study team are made aware of changes to local protocol regarding patient clinics due to COVID-19.



FOLLOW-UP DATA

We appreciate that your work capacity may be affected by COVID-19. As this study does not involve any additional participant visits, we hope that you will be able to continue with follow-up data entry (F forms) and pre-visit participant questions (E forms) as much as possible.



STUDY DATABASE

The study team cannot access the study database whilst working from home, affecting several processes:

- Study team can't access participant contact details.
- Data queries excluded by sites cannot be reviewed and accepted/denied.
- Study team cannot directly review CRFs.
- New user approval may take longer than usual as this will need to be done by our database team.

NO-DATA PARTICIPANTS



As the study team cannot access participant details, we can't call patients for whom data hasn't been received in >3 weeks. Therefore, we will occasionally ask sites to contact such participants and ask them to call the helpline to help resolve issues with devices and connectivity.

MOST COMMON TECHNICAL ISSUE

The most common reason for test data not being received when participants are testing is because the MiFi router is not being turned on properly. Whilst a green light will flash when the router is charging, *that does not mean it is turned on*. The button needs to be pressed so at least 2 lights appear. A connection with the router can be confirmed by checking the WiFi symbol in the top left corner of the iPod home screen.



DATA COMPLETENESS

With recruitment finished, **we aim to have all baseline forms (SL1 to B3) completed and all data queries resolved by the end of May.** Guidance on excluding data queries can be found in the study manual (p55).

END OF STUDY – EQUIPMENT

When the follow-up phase ends, participants will be allowed to keep their study equipment, though the tests will no longer be available and the MiFi device will require a new mobile SIM card to work. The iPod will also need to be restored to factory settings, which we are working on doing remotely. We will be collecting any equipment not kept by the participants.

STUDY MANAGEMENT TEAM

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