



Hello MONARCH Teams across the UK!



Thank-you for all your hard work, we recognise MONARCH is proving a bit of a bumpy road but we appreciate your determination and enthusiasm to keep up with recruitment. It's great to have a new site - Welcome Gloucester!

Dr Ruth Hogg, Co-Chief Investigator

News From The MONARCH Study Team

We're opening a new site!

Gloucester is in the process of becoming the 6th MONARCH study site. They had their SIV on 16th May; we aim to green-light them in early June. Welcome to the study, Gloucester!

Amendment update (see overleaf for more details)

- Substantial Amendment 003 will be implemented on 30th May and includes:
 - Lowering the visual acuity eligibility criteria threshold from 53 to 33 letters,
 - Interviews with healthcare professionals at all site for the qualitative study,
 - Addition of a Patient Newsletter.
- Non-substantial Amendment 2 was submitted to retrospectively obtain approval for the letter recently posted to participants regarding guidance for charging devices.

MONARCH recruitment table*

*Based on data in MONARCH database 13/05/2019

Site	Months open	Consented (mean/month)
James Paget	9	48 (5.3)
Belfast	9	40 (4.4)
Southampton	9	25 (2.8)
Moorfields	8	10 (1.3)
Liverpool	7	7 (1.0)

Progress update



5 out of 6 sites are open



497 people have been approached



143 people have attended a training session



130 people have consented



14 people have been interviewed

24 KSJs returned
>2500 mVT tests received



>2400 MBT tests received



Recruitment Target: **400**

DEVICE CHARGERS

Following a reported charger fault, participants have been provided with the following guidance on charging devices:

- **Only plug in and charge the iPod and MiFi devices for up to 3 hours per week**
- **Only charge the devices during the daytime and when they are at home.**
- **When they have charged their iPod and MiFi devices, unplug the charger**

PAT-tested chargers have been provided to sites to replace participants' chargers at clinic visits. Chargers in new equipment packs will be PAT-tested.

ELIGIBILITY CHANGE

As part of SA003, the visual acuity eligibility threshold has been lowered from
Snellen score 6/24, LogMar 0.64 or 53 letters
to

Snellen score 6/60, LogMar 1.04 or 33 letters

New SL1 screening logs and CRFs will be provided prior to implementation of the amendment

MONTHLY MONITORING REPORTS

The study team will email out monthly **CARF reports**, listing all retinal images recorded in the database that have not been received by CARF.

Please send all retinal images that are used to inform patient management decisions to CARF*
*(*providing the participant has consented)*

The study team will also email out monthly **follow-up visit reports** to prompt teams to check for any participants that may be due/have recently had a clinic review to check if any data collection/entry is outstanding.

Participants will be in the report if **1)** 12 weeks post-consent no follow-up data has been entered or **2)** if 2 weeks have elapsed since the intended review schedule recorded on the previous F2 form and no further follow-up visit data has been entered.

INTERVIEWS WITH HEALTHCARE PROFESSIONALS

As part of SA003, healthcare professionals may be invited for an interview for the qualitative study to explore the acceptability of home monitoring and why some patients decline participation. The interview is voluntary and consent will be sought.

CRF CHANGES - V6.0 to V7.0

SL1 & SL5 – lowering of visual acuity eligibility criteria to *Snellen score 6/60, LogMar 1.04 or 33 letters*

E1 – Addition of a question to record if participants were not contactable to collect patient-reported data for a management decision visit.

CONTACT DETAILS

Study management team:

Abby Willcox (Study manager) &

Robin Wickens (Assistant coordinator)

✉ MONARCH-study@bristol.ac.uk

☎ 0117 342 2987

Qualitative team & equipment :

Dr Charlene Treanor

✉ monarch-qualitative@qub.ac.uk

☎ 02890 971606

Patients can contact the study team for help with equipment on weekdays between 9-5 on **07530 370171**.



Monarch Butterfly Fun Fact

Monarch caterpillars feed almost exclusively on milkweed, a toxic plant. The toxin is stored in the Monarch butterfly, making them poisonous to predators!