

FOI 23/038

31st January 2023

Dear

Thank you for your email.

Please find below answers to the questions you have raised in blue below:

- All reports / preliminary reports related to this study

The final publication of the study is available at <https://www.sciencedirect.com/science/article/pii/S0264410X22007575?via%3Dihub>.

- All versions of the protocol, as the link given in the study is broken and there the document seems to be unavailable

All versions of the protocol can be found on GitHub at <https://github.com/opensafely/Published-Protocols>. Two protocol versions are available V1.0 and V3.0.

If you have a query about the information provided, please reply to this email

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

If you remain dissatisfied following any internal review, you may ask the Information Commissioner (ICO) to decide on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review.

The ICO's address is:
The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Service Centre