Author’s response to reviews

Title: Remote Assessment of Disease and Relapse in Major Depressive Disorder (RADAR-MDD): A multi-centre prospective cohort study protocol

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Author’s response to reviews:

Many thanks for taking the time to review the protocol. As per the revisions requested by the editor, we are pleased to submit a revised version which includes the following changes:

1) Please reformat the Abstracts (both on the online submission system and manuscript) such that they are divided into a Background, Methods, and Discussion subsections.

   We have made this amendment on both the manuscript and the online submission system,

2) Please expand and provide further details in the Methods to justify the estimated sample size, including a power analysis if appropriate.

   We have included the following in the methods section, page 5:

   “An estimated 100 relapses are required in order to provide sufficient power on which to test the predictive utility of RMT, if 10 variables were entered into the predictive model (32). With an approximated annual relapse rate of 33% (a lower estimate than that provided in the Star*D trial; (33)), 300 participants would be required, followed-up for one year. Although there is evidence to suggest promising uptake to RMT protocols, the attrition rate in this length of follow-up is unknown, there are likely to be missing data, data are inherently “noisy”, and the relapse rate in our population may be lower than anticipated. We therefore aim to recruit a total of 600 individuals with a history of MDD across three research sites.”

3) Please reference, where appropriate in the main text, the supplementary material attached to your manuscript, for enhanced clarity.

   We only have one piece of supplementary material, which has been referenced to on page 7:

   “The aRMT app will also deliver an ESM schedule (see online supplementary material), which has been designed to collect brief, in-the-moment assessments relating to several of our domains of interest: mood, stress, sociability, activity and sleep.”

4) Please provide the approval numbers obtained from the Camberwell St Giles and the CEIC Fundacio Sant Joan de Deu Ethics Committees, and append these to the ‘Ethics
approval and consent to participate’ section of the Declarations. In addition, please provide details (committee name, approval number) of the ethics approval obtained for the study in the Netherlands in this same section.

These have been added to the declarations section on page 13:

“RADAR-MDD will be conducted per the Declaration of Helsinki and Good Clinical Practice, adhering to principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). Ethical approval has been obtained in London from the Camberwell St Giles Research Ethics Committee (REC reference: 17/LO/1154), in London from the CEIC Fundacio Sant Joan de Deu (CI: PIC-128-17) and in The Netherlands from the Medische Ethische Toetsingscommissie VUms (METc VUmc registratienummer: 2018.012 – NL63557.029.17).”

5) Please state the procedure (i.e. verbal/written) for obtaining informed consent from the participants in the ‘Ethics approval and consent to participate’ section of the Declarations.

We have added this to the declarations section on page 13:

“Interested individuals will be sent the study materials, including information sheet and consent form to review. If, after reading, they wish to participate, they will have their eligibility to participate confirmed and be invited to an enrolment session which will involve the collection of written consent before the administration of any study procedures.”

6) Please state the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript. This should be declared in the funding section of the Declarations.

We have added this to the declarations section on page 14:

“The funding body have not been involved in the design of the study, the collection or analysis of data, or the interpretation of data.”

7) Please ensure that tables are free of shading and formatted according to BMC Psychiatry guidelines (https://emea01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fbmcpshyiatry.biomedcentral.com%2Fsubmission-guidelines%2Fpreparing-your-manuscript%23preparing%2Btables&amp;data=01%7C01%7Cfaith.matcham%40kcl.ac.uk%7C77e62e6a4bf440f1586008d681ea47d4%7C8370cf11416f34c1683c724071654356%7C0&amp;sdata=ANOHvRubQ%2Bi58IKVrSak5cBIdBVg9bp7cEBiEZslRA%3D&amp;reserved=0).
We have ensured that our tables meet these guidelines.