

London - Central Research Ethics Committee

3rd Floor 3 Piccadilly Place London Road Manchester M1 3BN

<u>Please note: This is the</u> <u>favourable opinion of the REC</u> <u>only and does not allow</u> the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

11 March 2024

Dr Brenda O'Neill Senior Lecturer in Physiotherapy Ulster University Shore Road Newtownabbey County Antrim BT37 OQB

Dear Dr O'Neill

REC reference:

Protocol number: Amendment number:

Amendment date: IRAS project ID:

Study title:

Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge: a randomised controlled assessor-blind clinical and cost-effectiveness trial with internal pilot (iRehab). 22/LO/0314 22/0029 SA-04 14 February 2024 310777

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Completed Amendment Tool [310777_SA-04_14.02.2024 locked toolkit]	N/A	14 February 2024
Interview schedules or topic guides for participants [iRehab_Rest and sleep after critical illness - V1 16.01.2024]	1.0	16 January 2024
Interview schedules or topic guides for participants [iRehab_ReturnToWork_SelfEmpl V1 16.01.2024]	1.0	16 January 2024
Interview schedules or topic guides for participants [iRehab_Hair loss and Skin Changes - V1 16.01.2024]	1.0	16 January 2024
Interview schedules or topic guides for participants [iRehab_Managing Pain V1 16.01.2024]	1.0	16 January 2024

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <u>https://www.hra.nhs.uk/planning-and-improving-research/learning/</u>

IRAS Project ID - 310777: Please quote this number on all correspondence

Yours sincerely

Pp Ali Hussain

Dr Susan Grieve Chair E-mail: londoncentral.rec@hra.nhs.uk

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Attendance at Sub-Committee of the REC meeting on 29 February 2024

Committee Members:

Name	Profession	Present	Notes
Dr Louise Abrams	Consultant Physician and Clinical Pharmacologist	Yes	
Dr Susan Grieve	Pharma & Biotech Consultant	Yes	Chair
Emeritus Professor Gareth Tudor-Williams	Paediatric Infectious Diseases (Imperial College, London)	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mr Ali Hussain	Approvals Administrator