

London - Central Research Ethics Committee

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

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

06 July 2023

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

Dear Dr O'Neill

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).

REC reference: 22/LO/0314

Protocol number: 22/0029

Amendment number: 22.0029 SA-02

Amendment date: 12 May 2023

IRAS project ID: 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [22.0029 IRAS 310777 SA02]	N/A	12 May 2023
Interview schedules or topic guides for participants [iRehab_Interview script_Staff_V2.0 02.05.2023_tracked]	2.0	02 May 2023
Other [iRehab 8-week Questionnaire Reminder Letter_V3.0_12.05.2023_tracked]	3.0	12 May 2023
Other [iRehab 8-week Questionnaire Initial Letter_V3.0_12.05.2023_tracked]	3.0	12 May 2023
Other [iRehab Pulse Oximeter Instructions V2.0 02.05.2023_tracked]	2.0	02 May 2023
Participant consent form [iRehab_ConsentForm_V2.0_09.05.2023_tracked]	2.0	09 May 2023
Participant consent form [iRehabConsentInterview-participantOrTeamV2.0_17.05.2022_tracked]	2.0	17 May 2023
Participant information sheet (PIS) [iRehab_PIL_V5.0_16.05.2023_tracked]	5.0	16 May 2023
Participant information sheet (PIS) [iRehab_PIL HCP interviews V2.0 16.05.2023_tracked]	2.0	16 May 2023
Research protocol or project proposal [iRehab_Protocol_v5.0_16.05.2023_tracked]	5.0	16 May 2023

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: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

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

Pp Ali Hussain

Mrs Dorcas Cumming
Vice Chair

E-mail: londoncentral.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Mr Nick Curry

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Attendance at Sub-Committee of the REC meeting on 15 June 2023

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Monica Bloch	Company Chair	Yes	
Mrs Dorcas Cumming	Solicitor	Yes	Vice Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Ali Hussain	Approvals Administrator