

18 October 2022

Dr Brenda O'Neill
Senior Lecturer in Physiotherapy
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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-01

Amendment date: 22 September 2022

IRAS project ID: 310777

The above amendment was reviewed at the meeting of the Sub-Committee held on 20 October 2022 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 [iRehab_SA01_Amendment_Tool_v1_6_22Sep22]	N/A	22 September 2022
Covering letter on headed paper [iRehab SA01 Cover Letter 28Sep2022]	N/A	28 September 2022
Instructions for use of medical device [iRehab Physical Activity Monitor Instructions V1.0 16.09.2022]	1.0	16 September 2022
Instructions for use of medical device [iRehab Pulse Oximeter Instructions V1.0 09Sep2022]	1.0	09 September 2022

Non-validated questionnaire [iRehab_TFAQ iRehab Group v1.0_21Sep2022]	1.0	21 September 2022
Non-validated questionnaire [iRehab_TFAQ Standard care Group_v1.0_21Sep2022]	1.0	21 September 2022
Non-validated questionnaire [iRehab_TFAQ_HCP_v1.0_21Sep2022]	1.0	21 September 2022
Non-validated questionnaire [iRehab Baseline Questionnaire v2.0 09Sep2022]	2.0	09 September 2022
Non-validated questionnaire [iRehab Questionnaire Reference Pack v1.0 09Sep2022]	1.0	09 September 2022
Other [iRehab Cover Letter_Intervention_Physical Activity Monitor V2.0_09.09.2022_clean]	2.0	09 September 2022
Other [iRehab Cover Letter_Intervention_Physical Activity Monitor V2.0_09.09.2022_tracked changes]	2.0	09 September 2022
Other [iRehab Sit to Stand Instructions V2.0 30.08.2022]	2.0	30 August 2022
Other [iRehab Trial Website&Twitter v1.0 09Sep2022]	1.0	09 September 2022
Participant information sheet (PIS) [iRehab_PILinterview-participant V2.0_20Sep2022]	2.0	20 September 2022
Participant information sheet (PIS) [iRehab_PIL_V3.0_20Sep2022]	3.0	20 September 2022
Research protocol or project proposal [iRehab_Protocol_v3.0_28.09.2022 TCs]	3.0	28 September 2022
Schedule of Events or SoECAT [iRehab_RehabICU SoECAT SITES APPROVED_14Aug22]	N/A	14 August 2022
Schedule of Events or SoECAT [iRehab_RehabICU SoECAT Tool A REVISED APPROVED_14Aug22]	N/A	14 August 2022
Validated questionnaire [iRehab 6-month Questionnaire v2.0 09Sep2022]	2.0	09 September 2022
Validated questionnaire [iRehab 8-week Questionnaire v2.0 09Sep2022]	2.0	09 September 2022

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

Yours sincerely

A handwritten signature in black ink, appearing to read 'Gareth Tudor-Williams', followed by a horizontal line.

Chair – Professor Gareth Tudor-Williams

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

London - Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 20 October 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Nayema Tahmin	Registered Pharmacy Technician	Yes	
Emeritus Professor Gareth Tudor-Williams	Paediatric Infectious Diseases (Imperial College, London)	Yes	Chair