

London - Bromley Research Ethics Committee 2 Redman Place

Stratford E20 1JQ

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.

18 August 2023

Dr Jacqueline Benfield Clinical Lecturer Derbyshire Community Health Services NHS Trust Royal Derby Hospital Uttoxeter Road Derbv **DE22 3NE**

Dear Dr Benfield

Study title:

SWALLOW STRENGTH AND SKILL TRAINING WITH **BIOFEEDBACK IN ACUTE POST STROKE DYSPHAGIA REC reference:** 23/LO/0131 Protocol number: 22043 Amendment number: 22043 SA01 Amendment date: 17 July 2023 **IRAS** project ID: 319969

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 [319969_22043 SA01]	1	17 July 2023
Interview schedules or topic guides for participants [Interview Topic Guide Final Version 1.0 02 June 2023]	1.0	02 June 2023
Participant consent form [CONSENT FORM Particpant Interview Pt experiences dysphagia mgt after stroke Final Version 1.0 6 June	1.0	06 June 2023

A Research Ethics Committee established by the Health Research Authority

2023]		
Participant information sheet (PIS) [PARTICIPANT INTERVIEW PARTICIPANT INFORMATION SHEET Pt experiences dysphagia mgt after stroke Final Version 1.0 6 June 2023]	1.0	06 June 2023
Research protocol or project proposal [PROTOCOL ssSIP FINAL version 2.0 (+VFS) 11 July 2023]	2.0	11 July 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: <u>https://www.hra.nhs.uk/planning-and-improving-research/learning/</u>

IRAS Project ID - 319969: Please quote this number on all correspondence

Yours sincerely

pp. Mar

Professor Jo Brooke Alternate Vice Chair

E-mail: <u>bromley.rec@hra.nhs.uk</u>

Enclosures:

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

Copy to: Ms Angela Shone

London - Bromley Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 08 August 2023

Committee Members:

Name	Profession	Present	Notes
Professor Jo Brooke	Professor of Nursing	Yes	Chair of meeting
Dr Ben Ward	Underwriter	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mrs Amanda Carr	Approvals Administrator