ISRCTN74088209 https://doi.org/10.1186/ISRCTN74088209

ReMEdi - Randomised controlled trial of the safety and efficacy of PHOE-01 in ME/CFS with digital monitoring

Submission date	Recruitment status	[ ] Prospectively registered
23/05/2025	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/05/2025	Deferred	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/11/2025	Nervous System Diseases	[X] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Contact information

Type(s)
Principal investigator

Contact name
Dr Beata Godlewska

Contact details
Department of Psychiatry,
Warneford Hospital
Oxford
United Kingdom
OX3 7JX
+44 (0)1865 618309
beata.godlewska.ext@lindushealth.com

Type(s)
Public, Scientific

Contact name
Ms Trial Lead

Contact details

Lindus Health, 2nd Floor, 90 Union Street
London
United Kingdom
SE1 0NW
+44 800 086 8449
remedi@lindushealth.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1010633

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PHOE2024-01

Study information

Scientific Title
ReMEdi - Randomised controlled trial of the safety and efficacy of PHOE-01 in ME/CFS with digital monitoring

Acronym
ReMEdi

Study objectives
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 22/01/2025, South Central - Oxford B Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8134; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0409

2. approved 24/01/2025, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 20 3080 6000; info@mhra.gov.uk), ref: CTA 17683/0223/001-0001

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied
Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

Interventions
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Primary outcome(s)
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Key secondary outcome(s))
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Completion date
30/04/2026

Eligibility

Key inclusion criteria
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record by the end date of the deferral (24 Jan 2026)

Date of first enrolment
05/02/2025

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lindus Health
Second Floor, Harlequin Building, 65 Southwark Street
London
United Kingdom
SE1 0HR

Sponsor information

Organisation
Alfred E. Tiefenbacher (Germany)

ROR
https://ror.org/05cs0pa90

Funder(s)

Funder type
Industry

Funder Name
Alfred E. Tiefenbacher

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available because of their commercial sensitivity

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes