

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

Submission date 23/05/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/05/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/11/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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Type(s)

Public, Scientific

Contact name

Ms Trial Lead

Contact details

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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

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Ethics approval required

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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

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Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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Completion date

30/04/2026

Eligibility**Key inclusion criteria**

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Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

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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