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Multicentre study on coaching and point-of-care technologies for patients with myalgic encephalomyelitis/chronic fatigue syndrome

Submission date
19/03/2026

Recruitment status
Not yet recruiting

Registration date
27/03/2026

Overall study status
Ongoing

Last Edited
10/04/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

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Additional identifiers

EU Horizon Europe Research and Innovation Programme
GA N° 101095654

Latvian Council of Science (Latvijas Zinātnes Padome)
THCS2025-404

Study information

Scientific Title
Multicentre study of the effectiveness of multimodal coaching interventions and the feasibility of point-of-care test device for improving the quality of life, functional capacity, and self-management in patients with myalgic encephalomyelitis/chronic fatigue syndrome

Study objectives
To evaluate the effectiveness and feasibility of multi-modal coaching interventions and point-of-care test (PoCT) device use in improving the quality of life, functional capacity, and self-management in patients with ME/CFS.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design

Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Health services research, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Improving the quality of life of patients with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS)

Interventions
Study Methodology and Interventions
This is a multicentre, mixed-design interventional study consisting of three study arms evaluating multimodal coaching interventions and the feasibility of a point-of-care testing (PoCT) device in patients with ME/CFS.

Randomisation
A stratified randomisation approach will be applied in Arm 1 to ensure balanced allocation by country and relevant baseline characteristics (e.g., disease severity). Participants will be randomly assigned in a 1:1 ratio to intervention or control groups within each stratum.
Arms 2 and 3 are designed as non-randomised interventional and feasibility studies, due to their exploratory and pilot nature.

Arm 1: Individual Coaching Intervention (Randomised Controlled Study)
Design: Stratified randomised controlled study (1:1 allocation)
Sites: Latvia (LV), France (FR)
Intervention groups:
• Latvia (n=30): Individual health coaching for 12 weeks
• France (n=30): Individual occupational coaching for 12 weeks
Control groups:
• Latvia (n=30): Usual care
• France (n=30): Usual care
Intervention description:
Participants in the intervention groups will receive structured, individual coaching sessions focusing on health management (LV) or occupational functioning (FR). Sessions will be delivered weekly or bi-weekly using standardized protocols.

Duration per participant:
• Intervention: 12 weeks
• Follow-up: 3 months post-intervention

Arm 2: Group Coaching and Education (Pilot + Multicentre Implementation)
Design: Non-randomised pilot followed by multicentre implementation
Sites: Canada (pilot), Latvia, France
Pilot phase:
• Canada (n=40): Group-based coaching and education programme (15 months total duration, including development and testing phase)
Implementation phase:
• Latvia (n=20) and France (n=20): Group coaching and education programme
Intervention description:
Participants will engage in structured group sessions focusing on patient education, self-management strategies, and peer support.
Duration per participant:
• Intervention: 3 months
• Follow-up: 3 months post-intervention

Arm 3: PoCT Device Feasibility and Usability Study
Design: Non-randomised feasibility study
Sites: Italy (development and initial testing), Latvia
Development phase:
• Italy: PoCT device development and pre-clinical validation (12 months)
Clinical testing phase:
• Italy (n=30): PoCT testing (5 months)
• Latvia (n=30): PoCT testing (5 months)
Intervention description:
Participants will undergo testing with a point-of-care device measuring inflammatory cytokines and lactate in peripheral blood. Results will be compared with standard laboratory methods and correlated with clinical outcomes.
Duration per participant:
• Active testing: up to 5 months
• Follow-up: included within study assessments

Overall Study Duration
The total study duration across all arms is 22 months, including intervention and follow-up phases.

Intervention Type
Mixed

Primary outcome(s)
1. Health-related quality of life (HRQoL) measured using SF-36, ED-5D-5L and EQ-VAS at baseline and post-intervention (12 weeks), with a follow-up at 3-6 months post-trial

Key secondary outcome(s)

Completion date
31/08/2028

Eligibility

Key inclusion criteria
1. Age 18-75 years
2. Diagnosis of ME/CFS according to International Consensus Criteria (ICC), or Canadian Consensus Criteria (CCC), or Institute of Medicine/National Academy of Medicine (IOM/NAM) criteria, or National Institute for Health and Care Excellence (NICE) criteria
3. Mild, moderate or severe functional impairment (e.g., ≥ 4 Bell Disability Scale ≤ 70)
4. Capacity to provide Informed Consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Primary psychiatric disorders (e.g., schizophrenia, bipolar disorder)
2. Severe comorbidities that interfere with participation
3. Current participation in another interventional trial

Date of first enrolment
01/09/2026

Date of final enrolment
29/02/2028

Locations

Countries of recruitment
Canada

France

Italy

Latvia

Sponsor information

Organisation
Université Paris-Est Créteil

ROR
https://ror.org/05ggc9x40

Organisation
University of British Columbia

ROR
https://ror.org/03rmrcq20

Organisation
Institute for Microelectronics and Microsystems

ROR
https://ror.org/05vk2g845

Organisation
Riga Stradiņš University

ROR
https://ror.org/03nadks56

Funder(s)

Funder type

Funder Name
Agence Nationale de la Recherche

Alternative Name(s)
French National Research Agency, French National Agency for Research, AgenceRecherche, ANR (Agence nationale de la recherche), L'Agence nationale de la recherche, National Agency for Research, L'Agence nationale de la recherche (ANR), ANR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
France

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Ministero dell'Università e della Ricerca

Alternative Name(s)
Ministry for Universities and Research, Italy, MUR Ministero dell'Università e della Ricerca, Ministry for Universities and Research, Ministero Università e Ricerca, Italian Ministero Università e Ricerca, MUR, M.U.R.

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Funder Name
Latvijas Zinātnes Padome

Alternative Name(s)
Latvian Council of Science

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Latvia

Funder Name
HORIZON EUROPE Reforming and enhancing the European Research and Innovation system

Alternative Name(s)
Reforming and enhancing the European Research and Innovation system, Reforming and Enhancing the European R&I System, Reforming and enhancing the EU research and innovation system, Reform and Enhance the EU R&I system, Reform und Verbesserung des europäischen Forschungs- und Innovationssystems, Reformar y mejorar el sistema europeo de investigación e innovación, Reforma a posílení evropského systému výzkumu a inovací, Réformer et renforcer le système européen de recherche et d'innovation, REERIS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available