

Tailored 24-hour physical behaviours for people living with multiple cardiorenal metabolic conditions and frailty

Submission date 24/09/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/03/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The study focuses on understanding and improving 24-hour physical behaviours, which include sleep, sitting, walking, moderate to vigorous physical activity, and resistance exercise. The PERSONAL-AGILITY intervention helps people track their health and physical behaviours with support from healthcare professionals. It aims to improve the health and wellbeing of people with multiple long-term conditions by focusing on the physical behaviours that matter most to them.

Who can participate?

Participants must be over 18 years old, living with multiple long-term conditions (including Type 2 Diabetes Mellitus), and experiencing frailty. Carers who provide unpaid support to someone with these conditions can also participate.

What does the study involve? (for participants)

Participants will be randomly assigned to either continue with their usual care or receive the PERSONAL-AGILITY intervention. The study will measure various health and wellbeing indicators at 12 and 26 weeks, including body composition, blood pressure, grip strength, physical function, physical activity, and sitting time. Participants will also complete questionnaires on quality of life, social activities, symptoms, goal attainment, and carer burden. Interviews will be conducted to gather feedback on the intervention.

What are the possible benefits and risks of participating?

Participants will receive health and wellbeing assessments, with results reviewed upon completion. The PERSONAL-AGILITY intervention aims to improve independence, physical health, and mental wellbeing. However, participants may face additional time commitments and potential discomfort from functional tests and activity monitors. Travel and caring expenses will be refunded, and participants will receive a £20 voucher for interviews.

Where is the study run from?

The study is being run by the University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2024 to April 2028

Who is funding the study?
The study is funded by the National Institute of Health and Care Research (UK)

Who is the main contact?
Dr Hannah Young (Hannah.young@uhl-tr.nhs.uk)

Study website
<https://www.leicesterdiabetescentre.org.uk/research-blog/personal-agility>

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Hannah Young

ORCID ID
<https://orcid.org/0000-0002-4249-9060>

Contact details
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW
+44 1162584346
hannah.young@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
347586

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR302926, CPMS 65146

Study information

Scientific Title

Maintaining function and participation through tailored 24-hour physical behaviours for people living multiple cardiorenal metabolic conditions and frailty

Acronym

PERSONAL-AGILITY

Study objectives

Study rationale:

The prevalence of multiple long-term conditions (MLTCs) is expected to increase by 86% by 2035, placing significant strain on healthcare systems and increasing the burden on individuals living with these conditions. Cardiorenal metabolic disorders are particularly common among MLTC clusters, leading to higher rates of hospital admissions, prolonged stays, premature mortality, and increased treatment costs. Furthermore, people with MLTCs are more likely to experience frailty—a multidimensional syndrome of reduced physiological reserve—which worsens outcomes such as physical function, independence, and social participation. This frailty elevates the burden of care by increasing hospitalisations and institutionalisation, costing the NHS £5.8 billion annually.

Physical inactivity and sarcopenia are hallmark features of both MLTCs and frailty, making them critical targets for intervention. However, current rehabilitation programs are often disease-specific, facility-based, and not tailored to people with multiple conditions or frailty, leading to limited effectiveness and variable adherence. Moreover, symptom burden, such as chronic pain and fatigue, further complicates adherence to existing physical activity recommendations.

To address these challenges, a more holistic, flexible approach that integrates all aspects of 24-hour physical behaviours—such as stepping, sitting, and sleeping—is needed. Incorporating shared decision-making (SDM) is essential for personalising care to individual needs, preferences, and circumstances. The involvement of carers, whose own health and wellbeing are closely intertwined with those of care recipients, is also critical. Informal carers play a key role in supporting physical activity and rehabilitation but face increased risks of developing MLTCs themselves, particularly due to the caregiving burden. Digital tools and videos, which allow for personalised interventions and real-time monitoring, offer a cost-effective means of improving adherence and supporting both patients and carers. Recognising this, the "PERSONAL-AGILITY" intervention was developed to integrate SDM, carer involvement, and community support through social prescribing.

This study aims to evaluate the feasibility and acceptability of this innovative approach, directly responding to pressing research priorities, including optimising exercise for MLTCs and supporting carer wellbeing.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/12/2024, South Central - Oxford B REC (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8134, +44 (0)207 104 8019; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0367

Study design

Feasibility randomized controlled trial with a mixed-methods process evaluation

Primary study design

Interventional

Secondary study design

Mixed methods feasibility study

Study setting(s)

GP practice, Home, Hospital, Medical and other records

Study type(s)

Other, Quality of life, Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Multiple long-term conditions and frailty

Interventions

Intervention arm: The PERSONAL-AGILITY intervention is designed to support individuals with multiple long-term conditions (MLTCs) and frailty through personalised approaches, incorporating both digital tools and shared decision-making. The intervention incorporates wearable devices (Fitbits, Apple Watches), interactive digital platforms, and web applications like MyHealthMapp and Steps4Health, to collect, monitor, and deliver healthcare information. These tools aim to improve physical activity, and sleep, and reduce sedentary behavior by providing personalised insights, feedback, and support to users and healthcare professionals (HCPs).

- MyHealthMapp tracks and logs health, fitness, and physical activity data, helping individuals and HCPs monitor and compare results using personalised benchmarks.
- Steps4Health offers personalised physical activity programs and support, promoting gradual increases in activity and healthy behaviors.
- Personalised videos summarize individual health data to facilitate better communication and shared decision-making between participants and HCPs.

The intervention emphasises shared decision-making (SDM), a collaborative approach where participants work with HCPs to make personalized healthcare decisions. It also includes face-to-face interactions, linking individuals to community activities, and considering individual preferences to ensure inclusivity beyond digital methods.

Duration of treatment: 26 weeks

Usual care arm: Ongoing standard care delivered by participants' usual NHS service providers in primary and secondary care. Participants in the control group will receive generic information on the 24-hour physical behaviours. Duration of treatment 26 weeks

Eligible participants (and their carer if included) in a 2:1 ratio to one of two arms:

- Intervention group: the PERSONAL-AGILITY intervention

OR

- Control group: usual care

The increased ratio of participants within the intervention group will give increased opportunity and exposure to the delivery of the intervention, which will be beneficial to refining and improving it for a future definitive trial.

Stratification will be based on one factor, frailty status, creating two strata (very mild and mild/

moderate and severe). Randomisation and treatment allocation will be performed using a third-party service using variable block sizes of 6 and 9.

Intervention Type

Behavioural

Primary outcome measure

The primary outcome measures will assess the feasibility of a future RCT of the PERSONAL-AGILITY intervention.

Qualitative data will be gathered from the process evaluation to also contextualise and enhance our understanding of these feasibility outcomes.

1. Eligibility rates are recorded as the number of eligible participants from screening logs
2. Recruitment rates recorded as the number of eligible participants who consented, separated by carer and patient groups from recruitment logs
3. Withdrawal rates recorded as rates of attrition at each stage of the study (screening, consent, randomisation by patient and carer participant group from recruitment logs
4. Outcome measure completion recorded as the number of completed measures for all secondary measures from CRF measured at baseline, 12 and 26 weeks
5. Rates of uptake and engagement with each component of the PERSONAL-AGILITY intervention and of adherence recorded using a bespoke diary measured at 12 and 26 weeks.
6. Burden associated with the intervention captured using the 24-hour Physical Behaviour Burden Questionnaire measured at 12 and 26 weeks.
7. The participants' perception of the shared decision-making process using a shared decision-making questionnaire measured at 12 and 26 weeks

Secondary outcome measures

Semi-structured interviews will be used to explore:

1. The acceptability of key trial procedures, outcome measures and exploration of any unintended harms and consequences
2. The acceptability of the intervention including, where applicable:
 - 2.1. The exploration of the influence of interaction between participants who took part as a 'dyad'
 - 2.2. The inclusion of social prescription and engagement with community groups
 - 2.3. Barriers and facilitators to engagement
3. Potential mechanisms of intervention impact
4. How contextual factors influenced intervention impact, including any unintended consequences
6. Their perceptions of PERSONAL-AGILITY, including its delivery and the need for any adaptations
7. How contextual influences hindered or facilitated implementation.

Quantitative analysis will be undertaken using descriptive statistics. Qualitative analysis will be undertaken using a reflexive thematic approach.

Overall study start date

24/09/2024

Completion date

30/04/2028

Eligibility

Key inclusion criteria

All patient and carer participants must be:

1. Adults ≥ 18 years
2. Mobile (able to walk 5m including with the use of any walking aids)
3. Able and willing to provide informed consent
4. Able and willing to use digital and online tools with support as part of the intervention. Access to digital devices and internet is not an inclusion criterion as these resources can be provided if required to support participation.

People living with MLTCs and frailty:

1. Living with ≥ 2 long-term non-communicable conditions, one of which should be Type 2 Diabetes Mellitus (confirmed by medical history or HbA1c $\geq 6.0\%$ ($\geq 42\text{mmol/mol}$) within 3 months of trial enrolment).
2. Living with frailty, defined as a Clinical Frailty Scale (CFS) score of 4-7 (very mildly frail to severely frail)

Carers:

1. Providing regular informal care to someone living with frailty and MLTCs as defined above for ≥ 3 months

Informal care includes (but is not limited to) emotional support, prompting with taking medications, getting prescriptions, managing, and organising appointments and care tasks, encouraging participation in social events and physical activity, helping with household tasks, or providing physical care.

Healthcare professionals:

1. Clinical and non-clinical staff delivering the PERSONAL-AGILITY study
2. Aged ≥ 18 years
3. Able to provide written informed consent

Participant type(s)

Patient, Health professional, Carer

Age group

Adult

Lower age limit

18 Years

Upper age limit

110 Years

Sex

Both

Target number of participants

50 people with MLTCs and frailty

Key exclusion criteria

For all participants:

1. Unable to provide informed consent
2. Unable to communicate in English
3. Known contraindications to exercise (as defined by the American College of Sports Medicine) to include:
 - 3.1. Unstable cardiac disease (Uncontrolled arrhythmias; unstable angina or heart attack within the last 3 months; persistent uncontrolled hypertension (systolic blood pressure >180 mm Hg or diastolic blood pressure >110 mm Hg); stroke or transient ischaemic attack within the last 3 months)
 - 3.2. Active infection
 - 3.3. Significant aortic aneurysm (more than 5.5 cm)
 - 3.4. Any other condition in which the investigator feel exercise may be contraindicated.
4. Current participation in competing clinical trial (as determined by study investigator of this trial).
5. Significant cognitive impairment (Mini mental state examination score of less than 24) or unstable psychiatric disorder that limits active participation in the intervention.
6. Serious illness or event with life-expectancy <1year, active malignancy (on chemotherapy /radiotherapy) or other significant illness which, in the opinion of a study clinician, precludes involvement.
7. Self-reportedly already regularly engaging in at least 150 minutes of moderate-to-vigorous physical activity per week.

People with MLTCs and frailty:

1. Not frail as defined by:
 - 1.1. eFI: 0 - 0.12, or
 - 1.2. A CFS score of 1 - 3 (very fit to managing well).

Carers:

1. Providing paid/professional care.

Date of first enrolment

30/04/2025

Date of final enrolment

30/06/2027

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary

Infirmary Square

Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust

Sponsor details

Research Office
Trust Headquarters
Level 3 Balmoral Building
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW
+44 116 258 4109
uhlsponsor@uhl-tr.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.uhl-tr.nhs.uk/>

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The PI will be responsible for ensuring the results of the study are disseminated through peer reviewed journals, conference presentations and other local mechanisms. Dissemination will be supported by researchers involved in the study, local, and national infrastructure (including NIHR Leicester and Newcastle BRCs, East Midlands Applied Research Collaborative (EM-ARC), and the CEHR) and NIHR dissemination support structures (including NIHR INVOLVE). Communications will be supported by the communications leads for the University Hospitals of Leicester NHS Trust and the local NIHR Regional network, and their research partnerships.

Results will be disseminated to community groups, charities and EM-ARC PPI/E channels and social media via a range of different formats, including brief written reports, infographics, and short animated videos with translated subtitles. Ongoing review and revision of our dissemination strategy will be undertaken throughout the study, in partnership with PPI/E partners, to maximise impact and ensure relevance and accessibility to a wide range of people. Where possible, materials will be available in languages reflective of the local community to reach a diverse audience, inclusive of those with cognitive, sensory and communication impairments. The public will be informed through public lectures, radio, and podcasts.

All participants will receive a written report and will have access to the range of dissemination activities outlined above.

Intention to publish date

30/04/2029

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available on request from Dr Hannah Young (hannah.young@uhl-tr.nhs.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	22/08/2024	03/02/2025	No	Yes