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

Submission date
24/09/2024

Recruitment status
Recruiting

Registration date
25/11/2024

Overall study status
Ongoing

Last Edited
27/10/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 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 24 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, uhl-tr.personalagility@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
347586

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR302926, CPMS 65146

Study information

Scientific Title
Maintaining function and participation through tailored 24-hour physical behaviours for people living with multiple conditions and frailty

Acronym
PERSONAL-AGILITY

Study objectives
Current study objectives as of 27/10/2025:
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. 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.

Previous study objectives:
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.

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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

Study type(s)
Quality of life, Treatment, Other

Health condition(s) or problem(s) studied
Multiple long-term conditions and frailty

Interventions
Current interventions as of 27/10/2025:
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: 24 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 24 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.

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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(s)
Current primary outcome measures as of 27/10/2025:
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 24 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 24 weeks.
6. Burden associated with the intervention captured using the 24-hour Physical Behaviour Burden Questionnaire measured at 12 and 24 weeks.
7. The participants' perception of the shared decision-making process using a shared decision-making questionnaire measured at 12 and 24 weeks

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The primary outcome measures will assess the feasibility of a future RCT of the PERSONAL-AGILITY intervention.
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7. The participants' perception of the shared decision-making process using a shared decision-making questionnaire measured at 12 and 26 weeks

Key secondary outcome(s))
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.

Added 27/10/2025:
1. Body composition is measured using bioimpedance analysis at baseline, 12 and 24 weeks
2. Blood pressure is measured using an automated sphygmomanometer at baseline, 12 and 24 weeks
3. Handgrip strength is measured using hand-held dynamometry at baseline, 12 and 24 weeks
4. Physical function is measured using the Short Physical Performance Battery at baseline, 12 and 24 weeks
5. Balance is measured using the Berg Balance Scale at baseline, 12 and 24 weeks
6. 24-hour physical behaviours (stepping, sweating, strengthening, sitting and sleep) are measured using accelerometery and inclinometry at baseline, 12 and 24 weeks
7. Quality of life is measured using the EQ-5D-5L and the Short Form-36 at baseline, 12 and 24 weeks
8. Life participation is measured using the Late Life Function and Disability Instrument at baseline, 12 and 24 weeks
9. Symptoms are measured using The Patient Outcome Scale at baseline, 12 and 24 weeks
10. Goal attainment is measured using the Goal Attainment Scale at baseline, 12 and 24 weeks
11. Care burden is measured using the Zarit Burden Interview (carers only) at baseline, 12 and 24 weeks

Completion date
30/04/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/10/2025:
All patient and carer participants must be:
1. Adults ≥18 years
2. Mobile (able to walk 5 m 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
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

Previous inclusion criteria:
All patient and carer participants must be:
1. Adults ≥18 years
2. Mobile (able to walk 5 m 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 ≥6.0% (≥42 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)

Carer, Health professional, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
110 years

Sex
All

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
United Kingdom

England

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

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

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.young44@nhs.net)

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
Participant information sheet	version 2.0	05/08/2025	27/10/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes